Adopted: 31 May 2024

DOI: 10.2903/j.efsa.2024.8841

SCIENTIFIC REPORT

efsa JOURNAL

Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR)

EFSA (European Food Safety Authority)

Correspondence:
pesticides.mrl@efsa.europa.eu

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 55th Session of the Codex Committee on Pesticide Residues (CCPR). In the current report, EFSA provided comments and recommendations on the Codex maximum residue level (MRL) proposals 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

55th CCPR meeting, consumer risk assessment, MRL setting, residue definitions, toxicological evaluation

CONTENTS

Abstract 1
Summary 8
1. Introduction 9
1.1. Background 9
1.2. Terms of Reference 9
2. Assessment 10
3. General consideration items/comments on Chapter 'General considerations' of JMPR reports 12
3.1. Developments in dietary exposure methodology for pesticide residues in foods 12
3.2. Development of guidance on the assessment and interpretation of nonlinear toxicokinetics 12
3.3. The need for sponsors to provide accurate chemical structures and related information on metabolites 13
3.4. Resolving inconsistent assessment of common metabolites 13
3.5. On the rolling submission of data 13
3.6. Why is a residue definition sometimes not agreed when there is an ADI/ARfD? 13
3.7. Enhancement of process 14
3.8. Strategy and timing for JMPR re-evaluation of dithiocarbamates 14
4. Responses to specific concerns raised by the Codex Committee on Pesticide Residues (ccpr) 14
4.1. Indoxacarb (216) 14
4.2. Mefentrifluconazole (320) 15
4.3. Metalaxyl (138) 16
4.4. Phosmet (103) 16
5. Comments on JMPR report Chapter 5 (individual substances assessed) 17
5.1. Pyrethrins (63) R 17
5.1.1. Background information 17
5.1.2. Toxicological reference values 17
5.1.3. Residue definitions 18
5.1.4. Analytical methods 18
5.1.5. Codex MRL proposals 18
5.1.6. Consumer risk assessment 18
5.1.7. Conclusions 19
5.2. Carbendazim (72) R/T 19
5.2.1. Background information 19
5.2.3. Residue definitions 20
5.2.4. Analytical methods 20
5.2.5. Codex MRL proposals 20
5.2.6. Consumer risk assessment 20
5.2.7. Conclusions 21
5.3. Thiophanate-methyl (77) R/T 21
5.3.1. Background information 21
5.3.2. Toxicological reference values 22
5.3.3. Residue definitions 22
5.3.4. Analytical methods 23
5.3.5. Codex MRL proposals 24
5.3.6. Consumer risk assessment 26
5.3.7. Conclusions 26
5.4. Carbofuran (96) R/T 27
5.4.1. Background information 27
5.4.2. Toxicological reference values 27

5.4.3. Residue definitions 28
5.4.4. Analytical methods 28
5.4.5. Codex MRL proposals 29
5.4.6. Consumer risk assessment 29
5.4.7. Conclusions 30
5.5. Iprodione (111) R/T 30
5.5.1. Background information 30
5.5.2. Toxicological reference values 31
5.5.3. Residue definitions 32
5.5.4. Analytical methods 32
5.5.5. Codex MRL proposals 33
5.5.6. Consumer risk assessment 35
5.5.7. Conclusions 36
5.6. Zeta-cypermethrin (118) R 36
5.6.1. Background information 36
5.6.2. Toxicological reference values 37
5.6.3. Residue definitions 37
5.6.4. Analytical methods 38
5.6.5. Codex MRL proposals 39
5.6.6. Consumer risk assessment 39
5.6.7. Conclusions 40
5.7. Permethrin (120) R/T 41
5.7.1. Background information 41
5.7.2. Toxicological reference values 41
5.7.3. Residue definitions 42
5.7.4. Analytical methods 42
5.7.5. Codex MRL proposals 42
5.7.6. Consumer risk assessment 42
5.7.7. Conclusions 43
5.8. Diflubenzuron (130) R 43
5.8.1. Background information 43
5.8.2. Toxicological reference values 43
5.8.3. Residue definitions 44
5.8.4. Analytical methods 45
5.8.5. Codex MRL proposals 45
5.8.6. Consumer risk assessment 46
5.8.7. Conclusions 46
5.9. Deltamethrin (135) R 46
5.9.1. Background information 46
5.9.2. Toxicological reference values 47
5.9.3. Residue definitions 47
5.9.4. Analytical methods 48
5.9.5. Codex MRL proposals 49
5.9.6. Consumer risk assessment 49
5.9.7. Conclusions 50
5.10. Prochloraz (142) R/T 50
5.10.1. Background information 50
5.10.2. Toxicological reference values 51
5.10.3. Residue definitions 51

5.10.4. Analytical methods 52
5.10.5. Codex MRL proposals 52
5.10.6. Consumer risk assessment 52
5.10.7. Conclusions 52
5.11. Carbosulfan (145) R/T 53
5.11.1. Background information 53
5.11.2. Toxicological reference values 53
5.11.3. Residue definitions 55
5.11.4. Analytical methods 56
5.11.5. Codex MRL proposals 56
5.11.6. Consumer risk assessment 57
5.11.7. Conclusions 58
5.12. Propiconazole (160) R 58
5.12.1. Background information 58
5.12.2. Toxicological reference values 59
5.12.3. Residue definitions 60
5.12.4. Analytical methods 61
5.12.5. Codex MRL proposals 61
5.12.6. Consumer risk assessment 63
5.12.7. Conclusions 64
5.13. Boscalid (221) R 64
5.13.1. Background information 64
5.13.2. Toxicological reference values 64
5.13.3. Residue definitions 65
5.13.4. Analytical methods 65
5.13.5. Codex MRL proposals 66
5.13.6. Consumer risk assessment 66
5.13.7. Conclusions 66
5.14. Difenoconazole (224) R 67
5.14.1. Background information 67
5.14.2. Toxicological reference values 67
5.14.3. Residue definitions 68
5.14.4. Analytical methods 68
5.14.5. Codex MRL proposals 69
5.14.6. Consumer risk assessment 71
5.14.7. Conclusions 72
5.15. Clothianidin (238) R 72
5.15.1. Background information 72
5.15.2. Toxicological reference values 73
5.15.3. Residue definitions 73
5.15.4. Analytical methods 74
5.15.5. Codex MRL proposals 74
5.15.6. Consumer risk assessment 76
5.15.7. Conclusions 76
5.16. Fluopyram (243) R 77
5.16.1. Background information 77
5.16.2. Toxicological reference values 77
5.16.3. Residue definitions 78
5.16.4. Analytical methods 78

5.16.5. Codex MRL proposals 79
5.16.6. Consumer risk assessment 82
5.16.7. Conclusions 83
5.17. Thiamethoxam (245) R 84
5.17.1. Background information 84
5.17.2. Toxicological reference values 84
5.17.3. Residue definitions 85
5.17.4. Analytical methods 85
5.17.5. Codex MRL proposals 86
5.17.6. Consumer risk assessment 87
5.17.7. Conclusions 88
5.18. Acetamiprid (246) R 88
5.18.1. Background information 88
5.18.2. Toxicological reference values 89
5.18.3. Residue definitions 89
5.18.4. Analytical methods 90
5.18.5. Codex MRL proposals 90
5.18.6. Consumer risk assessment 90
5.18.7. Conclusions 91
5.19. Emamectin (247) T 91
5.19.1. Background information 91
5.19.2. Toxicological reference values 92
5.19.3. Residue definitions 92
5.19.4. Analytical methods 93
5.19.5. Codex MRL proposals 93
5.19.6. Consumer risk assessment 93
5.19.7. Conclusions 93
5.20. Dinotefuran (255) R 94
5.20.1. Background information 94
5.20.2. Toxicological reference values 94
5.20.3. Residue definitions 95
5.20.4. Analytical methods 95
5.20.5. Codex MRL proposals 95
5.20.6. Consumer risk assessment 96
5.20.7. Conclusions 97
5.21.1. Background information 97
5.21.2. Toxicological reference values 97
5.21.3. Residue definitions 98
5.21.4. Analytical methods 99
5.21.5. Codex MRL proposals 99
5.21.6. Consumer risk assessment 102
5.21.7. Conclusions 102
5.22. Imazapyr (267) R 102
5.22.1. Background information 102
5.22.2. Toxicological reference values 103
5.22.3. Residue definitions 103
5.22.4. Analytical methods 104
5.22.5. Codex MRL proposals 104
5.22.6. Consumer risk assessment 105

5.22.7. Conclusions....105
5.23. Cyflumetofen (273) R....106
5.23.1. Background information....106
5.23.2. Toxicological reference values....106
5.23.3. Residue definitions....107
5.23.4. Analytical methods....108
5.23.5. Codex MRL proposals....108
5.23.6. Consumer risk assessment....109
5.23.7. Conclusions....109
5.24. Oxathiapiprolin (291) R....110
5.24.1. Background information....110
5.24.2. Toxicological reference values....110
5.24.3. Residue definitions....111
5.24.4. Analytical methods....111
5.24.5. Codex MRL proposals....112
5.24.6. Consumer risk assessment....113
5.24.7. Conclusions....114
5.25. Tetraniliprole (324) R....114
5.25.1. Background information....114
5.25.2. Toxicological reference values....115
5.25.3. Residue definitions....115
5.25.4. Analytical methods....115
5.25.5. Codex MRL proposals....116
5.25.7. Conclusions....116
5.26. Isoflucypram (330) R/T....117
5.26.1. Background information....117
5.26.2. Toxicological reference values....117
5.26.3. Residue definitions....118
5.26.4. Analytical methods....119
5.26.5. Codex MRL proposals....120
5.26.6. Consumer risk assessment....121
5.26.7. Conclusions....122
5.27. 1,4-Dimethylnaphthalene (331) R/T....122
5.27.1. Background information....122
5.27.2. Toxicological reference values....123
5.27.3. Residue definitions....123
5.27.4. Analytical methods....125
5.27.5. Codex MRL proposals....125
5.27.7. Conclusions....128
5.28. Florylpicoxamid (332) R/T....128
5.28.1. Background information....128
5.28.2. Toxicological reference values....129
5.28.3. Residue definitions....129
5.28.4. Analytical methods....129
5.28.5. Codex MRL proposals....130
5.28.6. Consumer risk assessment....134
5.28.7. Conclusions....134
5.29. Fluazinam (333) R/T....134
5.29.1. Background information....134

5.29.2. Toxicological reference values 135
5.29.3. Residue definitions 136
5.29.4. Analytical methods 136
5.29.5. Codex MRL proposals 136
5.29.6. Consumer risk assessment 136
5.29.7. Conclusions 136
5.30. Isocycloseram (334) R/T 137
5.30.1. Background information 137
5.30.2. Toxicological reference values 137
5.30.3. Residue definitions 138
5.30.5. Codex MRL proposals 139
5.30.6. Consumer risk assessment 144
5.30.7. Conclusions 144
5.31. Isotianil (335) R/T 145
5.31.1. Background information 145
5.31.2. Toxicological reference values 145
5.31.3. Residue definitions 145
5.31.4. Analytical methods 146
5.31.5. Codex MRL proposals 146
5.31.6. Consumer risk assessment 149
5.31.7. Conclusions 149
5.32. Mepiquat-chloride (336) R/T 150
5.32.1. Background information 150
5.32.2. Toxicological reference values 150
5.32.3. Residue definitions 150
5.32.4. Analytical methods 151
5.32.5. Codex MRL proposals 151
5.32.6. Consumer risk assessment 154
5.32.7. Conclusions 154
5.33. Tricyclazole (337) R/T 155
5.33.1. Background information 155
5.33.2. Toxicological reference values 155
5.33.3. Residue definitions 156
5.33.4. Analytical methods 156
5.33.5. Codex MRL proposals 157
5.33.6. Consumer risk assessment 158
5.33.7. Conclusions 159
Abbreviations 159
Conflict of interest 160
Requestor 160
Question number 160
Copyright for non-EFSA content 160
References 161
Appendix A 168

SUMMARY

For the preparation of the 55th session of the Codex Committee on Pesticide Residues (CCPR meeting), the European Commission asked EFSA to provide comments on the individual active substances (a.s.) assessed in the 2023 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), in particular on the recommended toxicological reference values and the proposed maximum residue levels (MRLs) at steps 3 and 6 of the Codex procedure.

In 2023, JMPR assessed 33 a.s.: 7 of them were assessed in the framework of the periodic review, 7 a.s. were assessed for the first time by JMPR; and the remaining a.s. were assessed in view of setting new Codex maximum residue limits (CXLs) for new uses or other new information. For additional three a.s. (indoxacarb, mefentrifluconazole and phosmet), 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.

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 reports. Since EFSA does not have access to the original studies and more detailed information on the JMPR evaluations, the EFSA comments are restricted to the specific questions specified in the Terms of Reference and the concise information provided in the 2023 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 2023 JMPR Report. In total, JMPR assessed 33 a.s.: 7 of them were assessed in the framework of the periodic review, 7 a.s. were assessed for the first time by JMPR; and the remaining a.s. were assessed in view of setting new CXLs for new uses or other new information. For additional three a.s. (indoxacarb, mefentrifluconazole and phosmet), JMPR replied to specific concerns raised by the delegations, which were submitted by means of concern forms.[2] 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 13 December 2023, the European Commission requested EFSA to give advice and comments on the recommendations of the 2023 Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and on the proposed Codex maximum residue levels (MRLs) in order to support the Commission in its preparation of the EU coordinated positions for the 55th session of the Codex Committee on Pesticide Residues (CCPR55) in 2024. This should cover the substances evaluated in the 2023 JMPR report except piperonyl butoxide[3] 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 2023 JMPR reports but by (an) earlier JMPR report(s).

Additionally, the European Commission requested EFSA to give its comments to the general chapters of the 2023 JMPR report, where relevant for risk assessment, as well as comments on the other relevant documents for discussion in CCPR55, e.g. as regards the JMPR priority list.

EFSA has created one question EFSA-Q-2023-00897 that will cover the following a.s. requested by the mandate: 1,4-dimethylnaphthalene, acetamiprid, boscalid, carbendazim, carbofuran, carbosulfan, clothianidin, cyantraniliprole, cyflumetofen, deltamethrin, difenoconazole, diflubenzuron, dinotefuran, emamectin, florylpicoxamid, fluazinam, fluopyram, imazapyr, iprodione, isocycloseram, isoflucypram, isotianil, mepiquat-chloride, oxathiapiprolin, permethrin, prochloraz, propiconazole, pyrethrins, tetraniliprole, thiamethoxam, thiophanate-methyl, tricyclazole, zeta-cypermethrin, indoxacarb, mefentrifluconazole and phosmet.

The draft scientific report of EFSA was submitted for commenting to the EU Member State (MS) experts and European Commission on 19 March 2024. All the comments received were addressed either directly in the final EFSA scientific report or though discussion during the Council Working Party meetings for the preparation of the 55th Session of the Codex Committee on Pesticide Residues. The Member States consultation report (EFSA, 2024f) 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 report sheet of the PRIMo is presented in Appendix A.

1.2 | Terms of Reference

The requested advice and comments on the recommendations of the 2023 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 (see Annex), should contain the following information:

1. Background information on all active substances under discussion regarding the status of the active substance at EU level (approval status of the active substance, availability of EFSA conclusions and availability of EFSA reasoned opinions on MRL applications or MRL review).
2. In case new toxicological reference values are proposed by JMPR, a comparison of the proposed reference values with agreed EU reference values and an evaluation of the reasons for possible differences.

[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]For metalaxyl, the concern form submitted by the Republic of Korea has been withdrawn.

[3]Since piperonyl butoxide is not an active substance according to the EU definitions, it is not covered by Regulation (EC) No 396/2005.

3. As regards the proposed draft Codex MRLs for discussion in CCPR55, 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 analytical methods are available to enforce the proposed draft Codex MRLs; to this end EFSA can consider consulting the European Reference Laboratories (EURLs), when necessary;
   c. Whether the proposed draft Codex MRLs are comparable with the existing EU MRLs;
   d. Whether the proposed draft Codex MRLs are sufficiently supported by data;
   e. 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;
   f. Whether the proposed draft Codex MRLs are safe for European consumers with regard to chronic and, where relevant, acute exposure.

4. For existing CXLs that were previously implemented in EU legislation and that were revoked in CCPR55, EFSA should identify fall-back MRLs, unless a new Codex MRL proposal was derived for the respective pesticide/crop combination, provided that the new proposal is sufficiently supported by data and does not pose a risk to European consumers. If no fall-back MRL can be identified, this should be taken into account in the EFSA recommendations.

The EFSA draft scientific report addressing point 1 to 3 of the Terms of Reference (ToR) should be delivered by 18th of March 2024. The EFSA report addressing point 4 (assessment of fall-back MRLs for revoked CXLs) may be presented in form of a separate output, which should be published by the 31st of January 2025.

The requested comments to the general chapters of the 2023 JMPR report relevant for risk assessment as well as comments on the JMPR priority list can be provided as contribution to the EU coordinated positions when these are discussed with the Member States and do not need to be covered by the scientific report.

2 | ASSESSMENT

EFSA agreed with the European Commission to respond to this request with a scientific report. On 19 March 2024, EFSA submitted the compilation of the comments on the substances covering the ToRs 1 to 3 for commenting to MSs and European Commission.

A second draft report addressing the MS comments was completed on 25 April 2024; this document was then further discussed in the second Council Working Party held on 16 May 2024.

The comments provided by MSs during the commenting period were addressed either directly in the final EFSA scientific report or through discussion during the Council Working Party meetings for the preparation of the 55th Session of the CCPR.

ToR 4 will be addressed in a separate report.

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

In Chapter 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 point 1 to 3 of the ToR. Background information on the a.s. assessed by JMPR (point 1 of the ToR) was retrieved from the database on pesticides.[4] 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.[5]

In order to address the second point of the ToRs on the toxicological reference values (TRVs), 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[6] or in other relevant EU assessments (e.g. MRL applications). The following sources of information were used: EFSA conclusions available for the a.s. 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(f):

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

[5] Reference date for background information and other EU information (e.g. toxicological reference values, residue definitions, EU MRLs, etc): 31 March 2024.

[6] 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.

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)[7] 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 a.s. or MS evaluations in Draft Assessment Reports.

Ad 3(b): EFSA, supported by experts of the EU reference laboratories (EURLs) checked information reported on the analytical methods that could be used for MRL enforcement for the commodities for which Codex MRL proposals were derived by 2023 JMPR. The source of information was the most recent JMPR report, but for a.s. that were already assessed in previous years, EURLs/EFSA looked up information in previous JMPR reports. As the level of detail on validation data is rather limited in the JMPR report, a detailed evaluation of the method validation data as usually performed in EU assessments (e.g. MRL applications) could not be performed.

Ad 3(c): 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.

Ad 3(d): 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 acceptable'. Details on independence of residue trials, storage stability, analytical method validation and other details, which would be assessed in detail in the framework of EU MRL applications, are not reported in the JMPR reports. Hence, comments on these aspects of the dossier are not within the scope of the current assessment.

For 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 and 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(e): 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/appropriate, 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(f): 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 2018e, 2019f). 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 a.s. 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.

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 TRVs, 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.

Finally, it should be mentioned 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.

[7]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.

It is noted that comments were derived on the basis of the JMPR reports summarising the recommendations of the 2023 JMPR meeting, which was published on 28 February 2024 and republished on 8 March 2024, adding information that was missing in the first version of the report. 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.

It is highlighted that 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 a.s. under consideration reflect information available in JMPR reports, EFSA conclusions/Reasoned opinions and other sources referenced approved until March 2024. 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 | GENERAL CONSIDERATION ITEMS/COMMENTS ON CHAPTER 'GENERAL CONSIDERATIONS' OF JMPR REPORTS

3.1 | Developments in dietary exposure methodology for pesticide residues in foods

In Chapter 2.1 of the JMPR report, JMPR reported that the meeting agreed on the transition from international estimated daily intake (IEDI; mean food consumption data derived from food balance sheets) to global estimate of chronic dietary exposure (GECDE)-mean, which, according to JMPR, reasonably reflects the mean estimated dietary exposure of the general population and the mean dietary exposure of specific population groups that may have a higher exposure than the general population (JMPR 2023).

The consumption data used in GECDE are derived from food surveys, for which data are available for the country-cohort combinations (i.e. general population, all adults, female adults, children, adolescents, infants and toddlers).

JMPR also agreed to investigate the implementation and modification options for the GECDE-high for the assessment of dietary exposure for chronic and shorter-than-lifetime assessment with the aim of a transition to adoption. In addition, JMPR committed to investigate the degree of conservatism of IEDI and GECDE (mean and high).

EFSA noted that for the comparison presented in the 2022 report, the results obtained with IEDI and GECDE differed significantly. Also, within a cohort the results differed significantly (e.g. difenoconazole) which could give an indication that the surveys do not contain all the relevant food commodities that contribute to the dietary exposure.

EFSA recommends informing the CCPR meeting that work has been initiated at EU level on the modification of the methodology used for long-term exposure. In the new revision of EFSA PRIMo (rev. 4), calculations are performed using mean consumption of the food commodities included in the diet, averaging the consumption for the duration of the food survey. With this type of calculation, for each relevant population subgroup (country/cohort) the distribution of the exposure estimates is derived. For risk management decisions, PRIMo 4 calculations will present the mean exposure of the relevant subgroups (country/cohort) and higher percentiles (e.g. P95). A decision has not yet been taken, which percentile will be the basis for risk management decisions.

An impact assessment, comparing the level of conservatism of calculations with the current PRIMo methodology (using the point estimate of the mean consumption of the pertinent food commodity of the relevant subgroup of the population, normalised by body weight (bw)) and the new PRIMo version is ongoing.

In future, further modifications of the chronic risk assessment methodology are expected at EU level, since an alignment of the methodology across different food domains is envisaged. Recommendations of the alignment were elaborated in a report of EMA/EFSA.[8]

3.2 | Development of guidance on the assessment and interpretation of nonlinear toxicokinetics

In Chapter 2.2 of the JMPR report, JMPR informed that an electronic working group (EWG) started with the development of a guidance document on the assessment and interpretation on nonlinear toxicokinetics. The guidance document should be completed by the next JMPR meeting held in September 2024. Stakeholders were invited to submit relevant studies illustrating reasons for nonlinear toxicokinetics.

EFSA welcomes the development of the guidance document on the assessment and interpretation of nonlinear toxicokinetics, as being prepared by the dedicated EWG of JMPR.

EFSA is of the opinion that toxicokinetic data is helpful in the interpretation of available toxicity studies and that it can support in the design of toxicity studies. EFSA notes that at EU level, hazard classification is an important element to decide on the approval of an a.s. According to ECHA – the EU agency responsible for classification and labelling – the kinetically

[8] https://www.ema.europa.eu/en/documents/report/ema-efsa-report-development-harmonised-approach-human-dietary-exposure_en.pdf.

derived maximum dose (KMD) approach is not suitable/not appropriate to fulfil the legislative needs for classification and labelling; instead, the maximum tolerated dose (MTD approach; with inclusion of the non-linear kinetics as complementary information) would be the most appropriate methodology to derive selection of the high dose level for toxicological studies.

More detailed information on the content of the guidance would be desirable, including information whether the (draft) guidance will be open for commenting.

3.3 | The need for sponsors to provide accurate chemical structures and related information on metabolites

In Chapter 2.3 of the JMPR report, JMPR stressed the importance of submission of correct chemical structures of metabolites, as this information is used to perform in silico analysis to predict genotoxicity.

EFSA supports the views of JMPR: for a reliable hazard assessment, the knowledge of the identity of the compound is an indispensable pre-requisite.

3.4 | Resolving inconsistent assessment of common metabolites

In Chapter 2.4 of the JMPR report, JMPR informed on the difficulties to identify common metabolites identified in the assessment of different pyrazole-based pesticides, and the consequences for the assessment by JMPR, leading to inconsistencies.

For overcoming the problems, EFSA recommends that sponsors/manufacturer of pesticides are requested to consult metabolism databases, such as the MetaPath,[9] for identification of metabolites that could be also derived from other a.s.

JMPR is also invited to consult the MetaPath database to identify common metabolites for a.s. assessed by JMPR. The powerful search functions are expected to support JMPR's assessment and help increasing the overall efficiency of the assessment process.

In addition, sponsors/manufacturers should be encouraged by JMPR to update the MetaPath database with information related to metabolism studies for the a.s. assessed by JMPR.

3.5 | On the rolling submission of data

In Chapter 2.5 of the JMPR report, JMPR noted that submission of incomplete dossiers and multiple updates of submissions (rolling submission of data) causes confusion, disruption and delay in the evaluation of JMPR.

EFSA supports the view of JMPR that a comprehensive, state-of-knowledge assessment requires the timely submission of all relevant information. Incomplete dossiers are leading to inefficiencies, which should be avoided, considering the high workload of JMPR.

In 2023, two a.s. were concerned for the rolling submission of dossiers: i.e. permethrin being assessed under the periodic review programme, and fluazinam.

It is highlighted that for permethrin, the last periodic review took place in 1987. Most of the MRLs have been established more than 30 years ago. On 2 April 2022, the manufacturer confirmed preparedness for periodic review of permethrin in 2023.

For a.s. scheduled for periodic reviews, sponsors should have sufficient time to generate the necessary studies. An incomplete dossier, or late submission of key studies should not be a possibility to extend the validity of outdated CXLs.

Fluazinam was evaluated by JMPR in 2018; however, the toxicological assessment could not be completed because of missing critical information and therefore no Codex MRLs could be established so far.

Overall, in the interest of efficiency of use of JMPR resources, it needs to be avoided that the submission of incomplete dossiers leads to delays in the review of CXLs and/or the process of setting new CXLs. It is therefore suggested to develop an efficient procedure for cases where sponsors of substances scheduled for the periodic review programme do not submit incomplete dossiers, precluding that existing CXLs are maintained in the Codex system and avoiding that the compounds are scheduled at each Meeting, which is binding capacities at JMPR level.

3.6 | Why is a residue definition sometimes not agreed when there is an ADI/ARfD?

In Chapter 2.6 of the JMPR report, JMPR explained in which cases residue definitions cannot be finalised, although the information is sufficient to derive TRVs for the parent compound; in particular, JMPR noted plant and/or livestock metabolites not identified in animals used in toxicity studies or metabolites occurring in significant amounts, which are not identified.

The clarifications are supported and no further comments are required from EFSA's view.

[9]Information on MetaPath can be found under the following link: https://oasis-lmc.org/products/software/metapath.aspx.

3.7 | Enhancement of process

JMPR discussed with the chair of the EWG on the Enhancement of CCPR and JMPR Operational Procedures proposals prepared for the CCPR54 and presented in Appendix XVI of the 2023 CCPR report.

Based on the feedback of JMPR, the EWG will present its recommendations for discussion in the CCPR meeting (CCPR55) under agenda item 11.

3.8 | Strategy and timing for JMPR re-evaluation of dithiocarbamates

In view of the upcoming periodic review of a.s. belonging to the class of dithiocarbamates, JMPR listed a number of questions which should be answered by the sponsors in advance, to allow a better planning of the task.

EFSA proposes to inform JMPR on the recent MRL review of dithiocarbamates at EU level (EFSA, 2023c).

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

4.1 | Indoxacarb (216)

JMPR assessed the information provided by the EU in the concern form submitted at the CCPR54: The EU requested a prioritisation of the re-evaluation of toxicology and residues of indoxacarb and all its CXLs and TRVs derived by JMPR, in view of the acute and chronic risks identified by the EU, taking into account that the latest JMPR assessment was performed 18 years ago.

JMPR, however, did not see a reason to propose a re-prioritisation of the periodic review of indoxacarb. The EU was invited to explain in more detail the basis for the conclusion that lead to a lower acceptable daily intake (ADI)/acute reference dose (ARfD).

In the following, EFSA presents the rationale behind the EU decision taken in 2018 to lower the ADI and the ARfD:

During the peer review by EFSA (2018c), the EU replaced the previous ADI of 0.006 mg/kg bw per day by a **new ADI of 0.005 mg/kg bw per day**, based on the no observed adverse effect level (NOAEL) of 0.5 mg/kg bw per day for maternal toxicity in a developmental toxicity study in rats, and applying an uncertainty factor (UF) of 100. The ADI at Codex level is set at 0.01 mg/kg bw per day.

The previous EU ARfD of 0.125 mg/kg bw (based on an acute rat neurotoxicity study) was replaced by a **new ARfD of 0.005 mg/kg bw**, based on the same point of departure as the ADI and applying an UF of 100. The JMPR ARfD is set at the level of 0.1 mg/kg bw.

The MS experts discussed indoxacarb during the pesticides peer review meeting 162 in September 2017 and derived an overall NOAEL for maternal toxicity at 0.5 mg/kg bw per day from a developmental toxicity study in rats (study from 2004, the same study was reported in both the JMPR and the EU revised RAR (France, 2017, p. 235)). It is acknowledged that in the EU peer review reports, two pilot studies and three main studies in rats, the latest one dated 2005, presented a higher maternal NOAEL at 2 mg/kg bw per day.

The 2004 study was performed according to Good Laboratory Practice (GLP) and followed the OECD TG 414 (1981) without deviations. Indoxacarb was administered by oral gavage to female rats on gestation days (GD) 6 to 20 (22 rats/dose group) at dose levels of 0, 0.5, 1.0, 2.0 and 3.5 mg/kg bw/day. In this study, maternal body weight gains were statistically significantly reduced during GD 6–8 at the dose levels of 1 mg/kg bw per day and above by more than 60% compared to control animals (France, 2017, Table B.6.6.2–14 of the RAR: −62%, −67% and −67% of control animals at 1, 2 and 3.5 mg/kg bw per day, respectively). The animals recovered during the study period, and the body weight gain during GD 6–21 (corrected for gravid uterine weight) was reduced by more than 10% at 1 and 2 mg/kg bw per day, and statistically significantly reduced at 3.5 mg/kg bw per day by 27.7% compared to control animals. These findings were considered as acute adverse effects, relevant to derive the ARfD and ADI (since this represents the lowest NOAEL of the data set).

The JMPR monograph mentions maternal toxicity based on the same adverse effects, but concluded that the maternal NOAEL is 2 mg/kg bw per day.

The EU also highlighted in the concern form that the JMPR residue definition for animal products (risk assessment) covers a metabolite IN-JT333 for which it is unclear whether the TRV derived for the parent can be applied. According to JMPR, it is not genotoxic and based on the available information, it seems to be more toxic than the parent.

In its response to the concern form, JMPR acknowledged that the toxicity could not be addressed. In order to demonstrate that the metabolite is unlikely to lead to an intake concern, a conservative intake calculation was performed which should demonstrate that the exposure will not exceed the threshold of toxicological concern (TTC) for non-genotoxic compounds (Cramer class III). To underpin its argumentation that the metabolite IN-JT333 is of no concern, JMPR also referred to the EFSA conclusion (EFSA, 2018c) where it was stated that residues of IN-JT333 are 'unlikely to be above the limit of quantitation [...]'. However, it should be clarified that the sentence was taken out of the context: this conclusion was derived for the limited number of representative uses evaluated in the renewal process. EFSA also highlighted that 'for any future use leading to an increase of the dietary burden calculation, the validity of these feeding studies should be reconsidered

and additional data might be needed to address the toxicity and the magnitude of all compounds included in the residue definitions for risk assessment set for poultry and ruminants matrices'.

EFSA notes that the use of TTC approach is normally not accepted in the EU, but acknowledges that at JMPR level, it became a tool that is regularly applied to address metabolites for which insufficient toxicological data are available to perform a full hazard characterisation. Following the explanations of JMPR, formally, it would be appropriate to revise the JMPR residue definition, excluding the metabolite IN-JT333, since the TRVs derived for the parent substance is not applicable. Overall, EFSA recommends to submit further clarifications to JMPR, as the EU concerns were not addressed by JMPR.

4.2 | Mefentrifluconazole (320)

In 2022, the JMPR proposed maximum residue levels for mefentrifluconazole in various commodities, including leafy greens (subgroup) at 30 mg/kg. However, the acute dietary exposure assessment showed that residues in 'Leafy greens, Subgroup of' exceeded the ARfD of 0.3 mg/kg bw.

JMPR received a concern from the Delegation of the United States, requesting that head lettuce is evaluated separately from the other leafy vegetables, as the residue data available for head lettuce was considerably lower than that for other types of leafy greens. The JMPR Secretariat agreed to review the USA concern form at the 2023 JMPR meeting and CCPR agreed to retain Codex MRL proposal of 30 mg/kg for leafy greens (subgroup) at step 4.

In 2023, JMPR withdrew its previous recommendation of 30 mg/kg for leafy greens (subgroup), and derived new proposals for head lettuce, leaf lettuce and spinach, noting that for leaf lettuce and spinach the ARfD was exceeded; the new MRL proposals of JMPR are presented in Table 1.

TABLE 1 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL/voted	Comment
Leafy greens, Subgroup of[a]	30 (W)	0.01* (chard, chervil, lettuce, lamb's lettuce, purslane, endives, spinach)	The previous Codex MRL proposal for the whole group is replaced by individual MRL proposals for lettuce head, leaf lettuce and spinach In CCPR 2023, the EU expressed opposition to the proposed Codex MRL for leafy greens, subgroup, due to short-term intake concerns
Head lettuce	**5**	0.01*	cGAP: USA, 3 × 0.146 kg a.s./ha, 7-day RTI, 0-day PHI Number of trials: 8 trials on head lettuce (with wrapper leaves), the highest residue (HR) is 2.2 mg/kg Sufficiently supported by data: Yes Specific comments: At EU level, head forming lettuce varieties and leafy lettuces are covered by one MRL (set for code 251020). As the proposed Codex MRL for leaf lettuce poses a risk to EU consumers (see below), the MRL proposal for head lettuce could be a fall-back option **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Leaf lettuce[a]	**15**	0.01*	cGAP: USA, 3 × 0.146 kg a.s./ha, 7-day RTI, 0-day PHI Number of trials: 7 (leaf lettuce, HR is 8.3 mg/kg) Sufficiently supported by data: Yes Specific comments: At EU level, head forming lettuce varieties and leafy lettuces are covered by one MRL (set for code 251020). The proposed Codex MRL poses a short-term risk for the consumer (identified in JMPR and EFSA calculation, see section consumer risk assessment) **Conclusion:** The proposed Codex MRL is not acceptable because a potentially risk to the consumers was identified Follow-up action: None
Spinach[a]	**30**	0.01*/**7**	cGAP: USA, 3 × 0.146 kg a.s./ha, 7-day RTI, 0-day PHI Number of trials: 8, HR is 18 mg/kg Sufficiently supported by data: Yes Specific comments: The proposed Codex MRL poses a short-term risk for the consumer (identified in JMPR and EFSA calculation, see section consumer risk assessment) **Conclusion:** The proposed Codex MRL is not acceptable because a potentially risk to the consumers was identified Follow-up action: None
General comments	General comment: In the JMPR report, no information is provided on the magnitude of TDMs (triazole derivative metabolites). Hence, the EU risk assessment for the TDMs could not be updated for the uses assessed by JMPR		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval; 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]On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure.

In Table 2, the updated risk assessment is presented.

TABLE 2 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 An indicative short-term dietary risk assessment (PRIMo rev. 3.1) was performed for lettuce and spinach The risk assessment is indicative, because information on the residue concentrations related to the TDMs is not available The calculations are therefore affected by additional, non-standard uncertainties	**RA assumptions:** The risk assessment was performed with the EU ADI An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1 (normal mode calculation). The input values of the most recent long-term risk assessment (EFSA, 2023j) were updated, including the STMR values derived by JMPR for the crops under consideration. In addition, the recently derived Codex MRLs (CCPR, 2023) not yet implemented in the EU legislation were included in the exposure calculations The calculations are affected by additional, non-standard uncertainties, since the risk assessment could be performed only for parent mefentrifluconazole, but not for TDMs	**Specific comments:** –
Results: The calculated short-term exposure exceeded the ARfD for: Spinaches: 271% of ARfD Lettuce: 211% of ARfD (calculation with the HR of 8.3 mg/kg derived for leafy lettuces); 56% of ARfD (calculation with HR of 2.2 mg/kg derived for head lettuce) Processed products: Spinach, frozen, boiled: 167% of ARfD (no refinements with PF)	**Results:** **No long-term consumer health risk was identified** The overall chronic exposure accounted for 33% of the ADI Among the crops under consideration, spinach was identified as the main contributor, accounting for up to 17% of the ADI	**Results:** Long-term exposure: Max 20% of the JMPR ADI Short-term exposure exceedances of the ARfD were indicated by JMPR also for: leafy lettuce: 170% of ARfD Spinach: 140% of ARfD No exceedance of the ARfD for head lettuce (result was not reported) JMPR did not report the results of the GECDE calculations

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; HR, highest residue; MRL, maximum residue level; PF, processing factor; RA, risk assessment; STMR, supervised trials median residue; TDM, triazole derivative metabolite.

In Table 3, the assessment of mefentrifluconazole is summarised, considering the assessment of the a.s. in the context of the CCPR54 meeting (EFSA, 2023f).

TABLE 3 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 TRV available
Residue definitions	EU and Codex RD for enforcement are identical for plant commodities; for RA, in the EU additional RDs are set for the triazole derivative metabolites (TDMs)
Analytical methods	Sufficiently validated analytical methods are available for the commodities under assessment
Codex MRL proposals	The Codex MRL proposals are sufficiently supported by data
Dietary risk assessment	An acute intake concern was identified by EFSA and by JMPR for leafy lettuce and for spinach. The proposed Codex MRL for head lettuce did not lead to an intake concern. No chronic intake concerns identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; RA, risk assessment; TRV, toxicological reference value.

4.3 | Metalaxyl (138)

The concern form submitted by the Republic of Korea was withdrawn. No further comments required.

4.4 | Phosmet (103)

Following the submission of a concern form by the EU, JMPR concluded that phosmet needs to be scheduled for periodic review, as the last review took place more than 20 years ago. This conclusion is highly supported.

5 | COMMENTS ON JMPR REPORT CHAPTER 5 (INDIVIDUAL SUBSTANCES ASSESSED)

In the following sections, the a.s. assessed by JMPR in the most recent assessment are presented (FAO and WHO, 2024). The terms in brackets after the name of the a.s. in the header of the sections refer to the code number used by JMPR; the second parenthesis provides information whether the substance was assessed for toxicological properties (T) and/or for residues (R). The substances are sorted according to the codex number (Tables 4–213).

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.[10]

5.1 | Pyrethrins (63) R

5.1.1 | Background information

TABLE 4 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	IT	
Approval status	Approved. Renewal process ongoing	Commission Directive 2008/127/EC[11] Renewal Assessment Report (RAR) submitted, EFSA peer review on ED clock-stop
EFSA conclusion available	Yes, see comments	EFSA (2013a) EFSA (2015j) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for pyrethrins in light of confirmatory data) EFSA (2017f) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for pyrethrins in light of confirmatory data) EFSA peer review ongoing (additional data requested)
MRL review performed	No, see comments	MRL review on hold, awaiting the outcome of the renewal process
EU MRL applications or other EU assessments	No	
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.	Assessment ongoing	Deadline for completion: March 2026
Other relevant information	Until 2020, pyrethrins were approved as biocide[12] In 2013, the approval conditions for pyrethrins were modified, requesting national authorities to pay particular attention on the risk to operators and workers and the risk to non-target organisms. The applicant were requested to submit confirmatory information among others as regards the residue definition	

5.1.2 | Toxicological reference values

TABLE 5 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.04 mg/kg bw per day	JMPR (1999, 2005)	0.04 mg/kg bw per day	EFSA (2013) (study and UF)	Yes
ARfD	0.2 mg/kg bw	JMPR (1999)	0.2 mg/kg bw	EFSA (2013) (study and UF)	Yes
Conclusion/comments a.s.	At EU level, the renewal process of the approval is ongoing. The TRV might therefore change				

(Continues)

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

[11] Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances. OJ L 344, 20.12.2008, p. 89–111.

[12] Commission Implementing Decision (EU) 2020/1036 of 15 July 2020 on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 227, 16.7.2020, p. 68–71.

TABLE 5 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Comments on metabolites	Compounds included in JMPR RD for RA: – pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2 Compounds included in EU RD for RA: – pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2 In the framework of the approval in 2013 (EFSA, 2013a), data requirements were identified on pyrethrolone metabolites and on toxicological relevance of hydroxychrysanthemic acid metabolites As the renewal process is ongoing, a change of the residue definition for risk assessment may be decided				

Abbreviations: bw, body weight; UF, uncertainty factor.

5.1.3 | Residue definitions

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	Total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract	Reg. 396/2005: Pyrethrins Peer review (EFSA, 2013a): Pyrethrins (sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2) (provisional)	Yes
	Animal products	Total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract The residue is fat soluble	Reg. 396/2005: Pyrethrins Peer review (EFSA, 2013a): Pyrethrins (sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2) (provisional, pending finalisation of plant residue definitions) The residue is not fat soluble	Yes
RD-RA	Plant products	Total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract	Peer review (EFSA, 2013a): Pyrethrins (sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2) (provisional)	Yes
	Animal products	Total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract	Peer review (EFSA, 2013a): Pyrethrins (sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2) (provisional, pending finalisation of plant residue definitions)	Yes
Conclusion, comments	–			

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

5.1.4 | Analytical methods

Not relevant, no Codex MRL proposals derived by JMPR.

5.1.5 | Codex MRL proposals

JMPR assessed uses in citrus, blackberries, strawberries, cabbage, leafy vegetables, tomatoes, tree nuts, coffee, herbs and spices (seeds). However, as the residue trials were insufficient and/or did not match the critical GAP, no CXL proposals were derived by JMPR.

5.1.6 | Consumer risk assessment

Not relevant, no CXL proposals were derived by JMPR.

EFSA noted an error in the JMPR report, in the section dietary risk assessment for pyrethrins, JMPR reported erroneously that the assessment was performed for 'permethrins'. JMPR should be invited to reflect on a corrigendum.

5.1.7 | Conclusions

TABLE 7 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 (EFSA peer review currently on clock-stop)
Toxicological assessment	EU TRV available. As the renewal process is ongoing, the TRV might change in the EU
Residue definitions	EU and Codex RDs are identical. However, the EU RD might change following the renewal process
Analytical methods	Not relevant, no residue evaluation was performed
Codex MRL proposals	No new Codex MRL proposals under discussion
Dietary risk assessment	Not relevant, no residue evaluation was performed
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.2 | Carbendazim (72) R/T

5.2.1 | Background information

TABLE 8 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	JMPR noted that insufficient toxicological information was submitted to allow a re-evaluation of the a.s. MRL proposals derived in the assessment of carbendazim
RMS	DE	
Approval status	Not approved	Commission Directive 2011/58/EU[13] No application to renew the approval was submitted
EFSA conclusion available	Yes, see comments	EFSA (2010b)
MRL review performed	Yes, see comments	EFSA (2014i)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2024d) Assessment of reliability of the studies used to derive the TRVs EFSA (2024b) (Art. 43 assessment on the toxicological properties and maximum residue levels) EFSA (2021d) (Art. 43 assessment)
Classification of a.s. (cut-off criteria)	Yes, see comments	Mutagen cat. 1B; Toxic for reproduction cat. 1B ATP17[14] ECHA (2019c)
Endocrine effects of a.s.	No, see comments	Carbendazim is not an endocrine disruptor in humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009,[15] as amended by Commission Regulation (EU) 2018/605[16] (EFSA, 2024b)
Other relevant information	Carbendazim is used as a biocide Carbendazim is a metabolite of thiophanate-methyl and of benomyl, both compounds are also used as pesticides, but are not approved in the EU. A.s. is also listed in PIC Regulation[17]	

Abbreviations: a.s., active substance; MRL, maximum residue level.

[13]Commission Directive 2011/58/EU of 10 May 2011 amending Council Directive 91/414/EEC to renew the inclusion of carbendazim as active substance.

[14]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.

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

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

[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.

5.2.2 | Toxicological reference values

TABLE 9 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**TRV comparable**
ADI	See comments	JMPR (2023)	0.02 mg/kg bw per day	Commission Directive 2006/135/EC, confirmed in 2021	Not applicable
ARfD	See comments	JMPR (2023)	0.02 mg/kg bw	Commission Directive 2006/135/EC, confirmed in 2021	Not applicable
Conclusion/comments a.s.	JMPR (2023) concluded that insufficient toxicological information was submitted to allow a re-evaluation of this substance to confirm or amend the reference values established in 1995 (ADI) and 2005 (ARfD). On this basis, the WHO Core Assessment Group withdraws the current ADI and ARfD values. For assessing the carbendazim (metabolite of thiophanate-methyl), TTC (Cramer class III) was considered applicable (see also thiophanate-methyl) The EU ADI and ARfD of 0.02 mg/kg bw per day were based on the developmental data in rats and rabbits (NOAEL of 10 mg/kg bw per day), and applying a safety factor of 500. There is a margin of safety of 2500 between the reference values and the NOEL for the induction of aneuploidy in vivo. These TRVs have been confirmed by (EFSA, 2021d) In 2024, it was agreed to maintain previous ADI and ARfD of carbendazim (EFSA, 2024b, 2024d)				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Not relevant, as JMPR did not confirm the previous Codex residue definitions Metabolites included in EU RD for RA: see section thiophanate-methyl				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; NOEL, no observed effect level; RA, risk assessment; RD, residue definition; TTC, threshold of toxicological concern.

5.2.3 | Residue definitions

TABLE 10 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	See comments below	See section thiophanate-methyl	Not applicable
	Animal products	See comments below	See section thiophanate-methyl	Not applicable
RD-RA	Plant products	See comments below	See section thiophanate-methyl	Not applicable
	Animal products	See comments below	See section thiophanate-methyl	Not applicable
Conclusion, comments	The previous residue definitions (i.e. sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim) were not confirmed by JMPR For the use of thiophanate-methyl, JMPR proposed residue definitions which are reported in the chapter on thiophanate-methyl			

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

5.2.4 | Analytical methods

Not relevant, no Codex MRL proposals derived by JMPR for carbendazim.

5.2.5 | Codex MRL proposals

Recommendations for Codex MRLs are reported in Section 5.3 on thiophanate-methyl.

5.2.6 | Consumer risk assessment

See Section 5.3 on thiophanate-methyl.

5.2.7 | Conclusions

TABLE 11 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 on 30 November 2014, as an application for renewal was not submitted). Carbendazim is a metabolite of thiophanate-methyl (see thiophanate-methyl)
Toxicological assessment	JMPR could not re-evaluate the toxicological profile of carbendazim, due to insufficient information submitted. EU TRV have been confirmed recently
Residue definitions	JMPR did not derive residue definitions; the previous Codex residue definitions were revoked
Analytical methods	No information available in JMPR report
Codex MRL proposals	See thiophanate-methyl
Dietary risk assessment	See thiophanate-methyl
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; TRV, toxicological reference value.

5.3 | Thiophanate-methyl (77) R/T

5.3.1 | Background information

TABLE 12 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Not approved	Commission Implementing Regulation (EU) 2020/149[18] Expiration of approval: 19/10/2020. The application for renewal was withdrawn
EFSA conclusion available	Yes, see comments	EFSA (2018b)
MRL review performed	Yes, see comments	EFSA (2014i)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2024b) (Art. 43 assessment on the toxicological properties and maximum residue levels) EFSA (2021d) (Art. 43 assessment) EFSA (2009b) (Art. 43 assessment)
Classification of a.s. (cut-off criteria)	No, see comments	Thiophanate-methyl does not fall under cut-off criteria. ATP17[19] ECHA (2019a)
Endocrine effects of a.s.	Yes, see comments	Thiophanate-methyl meets the criteria for endocrine disrupting properties for the thyroid (T)-modality in humans, as laid down in point 3.6.5 of Annex II to Regulation (EC) No 1107/200,[20] as amended by Commission Regulation (EU) 2018/605[21] (EFSA, 2024b)
Other relevant information	Thiophanate-methyl is subject to PIC regulation Carbendazim is a metabolite of thiophanate-methyl, which is also used as an a.s.; details on carbendazim are reported in the chapter on carbendazim	

Abbreviations: a.s., active substance; MRL, maximum residue level.

[18]Commission Implementing Regulation (EU) 2020/149 of 15 October 2020 concerning the non-renewal of approval of the active substance thiophanate-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 342, 16.10.2020, p. 5–7.

[19]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.

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

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

5.3.2 | Toxicological reference values

TABLE 13 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.09 mg/kg bw per day	JMPR (2023)	0.02 mg/kg bw per day	EFSA (2021)	No
ARfD	1 mg/kg bw	JMPR (2023)	0.02 mg/kg bw	EFSA (2021)	No
Conclusion/comments a.s.	In 2017, **JMPR** derived the ADI based on a NOAEL of 8.8 mg/kg bw per day based on reduction in body weight gain and clinical chemistry, urine analysis and histopathological changes in the kidney, thyroid, liver and adrenals in a 2-year study in rats, using a safety factor of 100 The ARfD was based on a NOAEL of 125 mg/kg bw for transient reductions in body weight gains (including body weight losses) and feed consumption in an acute neurotoxicity study in rats, using a safety factor of 100. The ADI and ARfD were confirmed by JMPR (2023) The **EU** ADI and ARfD are based on a NOAEL of 2 mg/kg bw per day for maternal and developmental toxicity in the rabbit and applying an uncertainty factor of 100. These TRVs were confirmed in the recent assessments, taking into consideration the endocrine disrupting properties of the a.s. through the T-modality. Uncertainties remained with regard to the androgen (A) and steroidogenesis (S)-modalities (further data to be generated to allow a conclusion), however no additional UF was considered necessary to cover these uncertainties based on the lack of adversity in the available data set for the in vivo endpoints that are expected to be sensitive to perturbations of these modalities (EFSA, 2021d, 2024b)				
Comments on metabolites	Metabolites included in JMPR RD for RA: – sodium 2-(methoxycarbonylamino)-1*H*-benzimidazol-5-yl (5-OH-carbendazim (MBC)) (free and conjugated) In 2017, JMPR concluded that the toxicities of 5-OH-MBC and 5-OH-MBC-S are covered by that of thiophanate-methyl, as they were major rat metabolites of the parent: 5-OH-MBC-S was found in rats at more than 40% of the absorbed dose in a toxicokinetic study with thiophanate-methyl and at 21–43% of the absorbed dose in a toxicokinetic study with carbendazim. 5-OH-MBC is an intermediate in the metabolic pathway leading to the formation of 5-OH-MBC-S Metabolites included in EU RD for RA: – Carbendazim (MBC) See section on carbendazim (ADI 0.02 mg/kg bw per day, ARfD: 0.02 mg/kg bw) – 2-AB – FH-432 No toxicological data available on either of the two metabolites – DX-105 Oral LD_{50} > 5000 mg/kg bw, insufficient information to conclude on consumer exposure risk assessment for the metabolite The toxicological assessment of the metabolites is still pending				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LD_{50}, lethal dose, median; NOAEL, no observed adverse effect level; TRV, toxicological reference value.

5.3.3 | Residue definitions

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	Sum of thiophanate-methyl and carbendazim, expressed as sum of thiophanate-methyl	Reg. 396/2005: RD 1: Thiophanate-methyl RD 2: Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) In April 2024, vote in PAFF to implement the RD derived in an Art. 43 assessment (EFSA, 2024b), Art. 43 assessment (EFSA, 2021d) and Peer review (EFSA, 2018b): RD 1: Thiophanate-methyl RD 2: Carbendazim RD 3: Benomyl	No
	Animal products	Sum of thiophanate-methyl, carbendazim and sodium 2-(methoxycarbonyl amino)-1*H*-benzimidazol-5-yl (5-OH-MBC) (free and conjugated), expressed as thiophanate-methyl The residue is not fat soluble	Reg. 396/2005: Carbendazim and thiophanate-methyl, expressed as carbendazim In April 2024, vote in PAFF to implement the RD derived in Art. 43 assessment (EFSA, 2024b), Art. 43 assessment (EFSA, 2021d): RD 1: Thiophanate-methyl RD 2: Sum of carbendazim and 5-hydroxy-carbendazim, expressed as carbendazim and (separate RDs)	No

TABLE 14 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			RD 3: Benomyl Peer Review (EFSA, 2018b): could not be established (data gap) MRL review (EFSA, 2014i): Thiophanate-methyl The residue is not fat soluble	
RD-RA	Plant products	Thiophanate-methyl	Art. 43 assessment (EFSA, 2024b), 1. Thiophanate-methyl 2. Carbendazim 3. 2-AB, FH-432, DX-105, final expression of the RD pending tox assessment of the metabolites Art. 43 assessment (EFSA, 2021d), Peer review (EFSA, 2018b) and MRL review (EFSA, 2014i): Thiophanate-methyl	No
	Animal products	Thiophanate-methyl	Art. 43 assessment (EFSA, 2024b), Art. 43 assessment (EFSA, 2021d): RD 1: Thiophanate-methyl (Cattle and swine tissues, milk) RD 2: Sum of carbendazim and 5-hydroxy carbendazim, expressed as carbendazim (Cattle and swine tissues) RD 3: Sum of carbendazim, 5-hydroxy carbendazim and 4-hydroxy-carbendazim, expressed as carbendazim (milk) Peer review (EFSA, 2018b) and MRL review (EFSA, 2014i): Thiophanate-methyl	No
Conclusion, comments	The reside definition for enforcement and risk assessment in the EU and JMPR are different, because the JMPR combined thiophanate-methyl and carbendazim (and 5-OH-MBC for animal commodities) whereas in the EU a separate residue definition is derived for thiophanate-methyl only for plants and as carbendazim and thiophanate-methyl, expressed as carbendazim for animal commodities In the latest EFSA assessment (EFSA, 2024b), three different RD for RA were proposed for plant commodities: – RD-RA 1: thiophanate-methyl; – RD-RA 2: carbendazim; – RD-RA 3 (tentative): 2-AB, FH-432, DX-105, final expression of the RD pending tox assessment of the metabolites RD-RA 3 was found not relevant fruit crops (EFSA, 2024b) where the main components of the total radioactive residues (TRRs) were identified as thiophanate-methyl and its metabolite carbendazim. In PAFF meeting in April 2024, new residue definitions and new MRLs were agreed, establishing separate MRLs (most of them at the LOQ) for thiophanate methyl and carbendazim			

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

5.3.4 | Analytical methods

TABLE 15 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Thiophanate-methyl			
Plant commodities: High oil content	Yes	0.05	Extraction with acidic methanol, clean-up by liquid–liquid partition, LC-UV (soybean seed, peanut nutmeat) EURL data show successful validation of thiophanate-methyl in high oil content commodities of plant origin (peanut and almond) with an LOQ of 0.01 mg/kg (peanut) and 0.002 mg/kg (almond) using QuOil and LC–MS/MS
Carbendazim			
Plant commodities: High oil content	Yes	0.05	Extraction with acidic methanol, clean-up by liquid–liquid partition, LC-UV (soybean seed, peanut nutmeat) EURL data shows successful validation of carbendazim in high oil content commodities of plant origin (plant oil) with an LOQ of 0.001 mg/kg using QuOil and LC–MS/MS
Conclusion	The EU residue definitions for MRL enforcement for the relevant matrix group are not fully comparable with the JMPR residue definition The current EU MRL for the commodity under discussion (i.e. almonds) is higher than the Codex MRL proposal Sufficiently analytical methods for the enforcement of the EU MRL for high oil content matrices for the JMPR residue definition and the EU residue definition are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LC-UV, liquid chromatography with ultraviolet detection; LOQ, limit of quantification; MRL, maximum residue level.

5.3.5 | Codex MRL proposals

TABLE 16 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal[a]	Existing EU MRL/new MRLs[b]	Comment
Almond	**0.15***	0.2*/0.01*	cGAP: USA, per-application of 1.18 kg a.s./ha (2.35 kg a.s./ha per year) with application between pink bud and petal fall Number of trials: 5 Sufficiently supported by data: Yes Specific comments: The carbendazim (MBC) residue values in almond were ($n = 5$): < 0.05 (5) mg/kg. The total residue values in almond were ($n = 5$, as thiophanate-methyl (TM)): < 0.14 (5) mg/kg TM eq The JMPR agreed that the applications were close to harvest and that no residue (below LOQ) in the trials was expected. Therefore, the JMPR decided to estimate a maximum residue level for almond at the LOQ of 0.15* mg/kg **Conclusion:** It is recommended to discuss with Member States (MS) whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs Follow-up action: None
Apricot	2 (B)(W)	2/0.01*	The existing CXL is proposed for withdrawal
Asparagus	0.2 (C) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Banana	0.2 (B) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Barley	0.5 (C) (W)	0.3/0.01*	The existing CXL is proposed for withdrawal
Barley, hay and/or straw	2 (C) (W)	–	The existing CXL is proposed for withdrawal
Beans (dry)	0.5 (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Berries and other small fruits, except grapes	1 (B, T) (W)	3 (wine grapes); 0.1* (table grapes and other small fruits)/0.01* (all)	The existing CXL is proposed for withdrawal
Brussels sprouts	0.5 (B) (W)	1/0.01*	The existing CXL is proposed for withdrawal
Carrot	0.2 (B) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Cattle meat	0.05* (B) (W)	– Muscle: 0.05*/0.01*	The existing CXL is proposed for withdrawal
Cherries (subgroup)	10 (T) (W)	0.3/0.01*	The existing CXL is proposed for withdrawal
Chicken fat	0.05 (B) (W)	0.05*/0.01*	The existing CXL is proposed for withdrawal
Coffee beans	0.1 (C) (W)	0.1*/0.05*	The existing CXL is proposed for withdrawal
Common bean (pods and/or immature seeds)	0.5 (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Cucumber	0.05* (B, C) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Edible offal (mammalian)	0.05* (B) (W)	0.05*/0.01*	The existing CXL is proposed for withdrawal
Eggs	0.05* (B) (W)	0.05*/0.01*	The existing CXL is proposed for withdrawal
Garden pea, shelled (succulent seeds)	0.02 (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Gherkin	0.05* (B, C) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Grapes	3 (B, T) (W)	0.1* (table grapes) 3 (wine grapes)/0.01*	The existing CXL is proposed for withdrawal
Lettuce, head	5 (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Mango	5 (C) (W)	1/0.01*	The existing CXL is proposed for withdrawal
Milks	0.05* (B) (W)	0.05*/0.01*	The existing CXL is proposed for withdrawal
Nectarine	2 (B) (W)	2/0.01*	The existing CXL is proposed for withdrawal
Oranges, sweet, sour (including orange-like hybrids)(subgroup)	1 (B) (W)	6/0.01*	The existing CXL is proposed for withdrawal

TABLE 16 (Continued)

Commodity	Codex MRL proposal[a]	Existing EU MRL/new MRLs[b]	Comment
Peach	2 (B) (W)	2/0.01*	The existing CXL is proposed for withdrawal
Peanut	0.1* (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Peanut fodder	3 (T) (W)	–	The existing CXL is proposed for withdrawal
Peppers chilli	2 (T) (W)	0.1*	The existing CXL is proposed for withdrawal
Peppers chilli, dried	20 (C) (W)	–	The existing CXL is proposed for withdrawal
Pineapple	5 (B) (W)	0.1*	The existing CXL is proposed for withdrawal
Plums (including fresh prunes) (subgroup)	0.5 (B) (W)	0.3	The existing CXL is proposed for withdrawal
Pome fruits (group)	3 (B, C, T) (W)	0.5 (apples, pears and quinces) 2 (medlars and loquats/Japanese medlars) 0.1* (azaroles/ Mediterranean medlars and Kaki/Japanese persimmons)/0.01*	The existing CXL is proposed for withdrawal
Poultry meat	0.05* (B) (W)	– Muscle: 0.05*/0.01*	The existing CXL is proposed for withdrawal
Rape seed	0.05* (C) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Rice, hay and/or straw	15 (C) (W)	–	The existing CXL is proposed for withdrawal
Rice, husked	2* (B) (W)	–	The existing CXL is proposed for withdrawal
Rye	0.1 (C, T) (W)	0.05/0.01*	The existing CXL is proposed for withdrawal
Soya bean (dry)	0.5 (T) (W)	0.3/0.01*	The existing CXL is proposed for withdrawal
Soya bean, hay and/or straw	0.1 (C) (W)	–	The existing CXL is proposed for withdrawal
Spices, fruits and berries	0.1(W)	0.1*/0.05*	The existing CXL is proposed for withdrawal
Spices, roots and rhizomes	0.1(W)	0.1*/0.05*	The existing CXL is proposed for withdrawal
Spices, seeds	5 (W)	0.1*/0.05*	The existing CXL is proposed for withdrawal
Squash, summer	0.5 (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Sugar beet	0.1* (T) (W)	0.1*/0.01*	The existing CXL is proposed for withdrawal
Tomato	0.5 (B, C) (W)	1/0.01*	The existing CXL is proposed for withdrawal
Tree nuts (group)	0.1* (B) (W)	0.2*/0.01*	The existing CXL is proposed for withdrawal
Wheat	0.05* (B, T) (W)	0.05/0.01*	The existing CXL is proposed for withdrawal
'Wheat, hay and/or straw'	1 (Risk a) (W)	–	The existing CXL is proposed for withdrawal
General comments	To estimate a maximum residue level, JMPR considered the sum of TM (thiophanate-methyl) and MBC (total residue), expressed as TM, calculated by adjustment of molecular weight (a factor of 1.79 for MBC to TM; a factor of 0.558 for TM to MBC) The proposed Codex MRL for almonds is lower than the current EU MRL, but is higher than the new MRL recently agreed at EU level. All the other CXLs are proposed for withdrawal		

Abbreviations: cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; LOQ, limit of quantification; MRL, maximum residue level; 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]Letters in upper case indicate the source(s) of the data on which the MRL is based (B: benomyl; C: carbendazim; T: thiophanate-methyl).

[b]New MRLs for thiophanate-methyl voted in PAFF meeting of April 2024.

5.3.6 | Consumer risk assessment

TABLE 17 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 short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the Codex MRL proposal for almonds Since carbendazim and thiophanate methyl share a similar toxicological effect, EFSA proposed to perform the risk assessment of carbendazim and thiophanate methyl separately and then to sum the results from the two single assessments to obtain their combined exposures. This approach allows to evaluate the overall toxicological burden taking into account the combined exposure to carbendazim and thiophanate-methyl The calculations are indicative, because the RD for RA derived by JMPR is different from the EU RD for RA 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. The input values of the most recent long-term risk assessment (EFSA, 2024b) were used, taking into account the STMR for almonds derived by JMPR and the recently lowered EU MRLs (voted in PAFF meeting held in April 2024) Since carbendazim and thiophanate methyl share a similar toxicological effect, EFSA proposed to perform the risk assessment of carbendazim and thiophanate methyl separately and then to sum the results from the two single assessments to obtain their combined exposures. This approach allows to evaluate the overall toxicological burden taking into account the combined exposure to carbendazim and thiophanate-methyl The calculations are indicative, because the RD for RA derived by JMPR is different from the EU RD for RA Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** The JMPR agreed that the following compounds could be individually assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 μg/kg bw per day, applying the threshold for both the chronic and acute exposure estimates: carbendazim, 5-OH-MBC (free and conjugated), 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB and 4-OH-FH-432 Based on the relative amounts of those metabolites in food and feed commodities, the JMPR noted that assessments for carbendazim and 5-OH-MBC (free and conjugated) will address exposures for the remaining metabolites listed above The estimated long-term and acute exposures of carbendazim were 0.00167 μg/kg bw per day and 0.2 μg/kg bw per day, respectively. 5-OH-MBC (free and conjugated) is only present in animal commodities. Since the JMPR estimated a livestock dietary burden of 0 ppm, no dietary exposure to 5-OH-MBC (free and conjugated) is expected The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The JMPR concluded that based on the exposures to carbendazim and 5-OH-MBC (free and conjugated), exposures to carbendazim, 5-OH-MBC (free and conjugated), 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB and 4-OH-FH-432 are unlikely to present a dietary exposure concern from the use evaluated by the current JMPR The JMPR also noted that should further uses be considered in the future, this conclusion may need to be re-evaluated
Results: No short-term consumer health risk was identified **Thiophanate-methyl:** Almonds: 2% of ARfD **Carbendazim:** 0.7% of ARfD **Combined:** 2.7% of ARfD	**Results:** No long-term consumer health risk was identified **Thiophanate-methyl:** 0.1% ADI (IE adult) **Carbendazim:** 1% ADI (NL toddler) **Combined:** 1% ADI (NL toddler)	**Results:** Long-term exposure: Max 0% of the JMPR ADI (all diets) GECDE mean: 0% (all diets) GECDE max: Max. 0% (all diets) Short-term exposure: Result for almonds: 0% of ARfD (all diets)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; MRL, maximum residue level; RA: risk assessment.

5.3.7 | Conclusions

TABLE 18 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 19/10/2020, as application for renewal was withdrawn)
Toxicological assessment	EU TRV available for thiophanate-methyl. The toxicological assessment of carbendazim, a metabolite of thiophanate, is currently ongoing
Residue definitions	EU and Codex RDs are not fully compatible
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. However, further risk management discussions required
Dietary risk assessment	No acute and no chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.4 | Carbofuran (96) R/T

5.4.1 | Background information

TABLE 19 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	JMPR was informed that carbofuran was no longer supported. Therefore, JMPR recommended withdrawal of all CXLs for carbofuran. Revised/new Codex MRL proposals resulting from the use of carbosulfan are presented/discussed under carbosulfan (Section 5.11)
RMS	BE	
Approval status	Not approved	Commission Decision 2007/416/EC[22]
EFSA conclusion available	Yes, see comments	EFSA (2009c) (peer review on carbofuran) EFSA (2009f) (peer review on carbosulfan)
MRL review performed	Yes, see comments	EFSA (2014a) (combined MRL review for carbofuran, carbosulfan, benfuracarb and furathiocarb under Art. 43)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2014a) (Art. 43 assessment)
Classification of a.s. (cut-off criteria)	No, see comments	Carbofuran does not fall under cut-off criteria CLP00[23] (not assessed by ECHA)
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Carbofuran is subject to PIC Regulation and is listed in the Rotterdam convention.[24] Carbofuran is also a metabolite of carbosulfan (see also carbosulfan, Section 5.11)	

Abbreviations: CXL, Codex maximum residue limit; MRL, maximum residue level.

5.4.2 | Toxicological reference values

TABLE 20 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.001 mg/kg bw per day	JMPR (2023)	0.00015 mg/kg bw per day	EFSA (2009)	No
ARfD	0.001 mg/kg bw	JMPR (2023)	0.00015 mg/kg bw	EFSA (2009)	No
Conclusion/comments a.s.	JMPR: The ADI and ARfD of 0.001 mg/kg bw are based on the overall NOAEL of 0.03 mg/kg bw per day for inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) from acute neurotoxicity studies in rats and using a safety factor of 25. A safety factor of 25 was applied by the JMPR because the acute toxic effects of carbofuran are dependent on C_{max} rather than area under the curve of concentration–time (AUC) and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity by carbofuran are similar. The TRV only apply to sources of carbofuran that have a purity of 99.8% or greater EU: The ADI and ARfD are based on the LOAEL of 0.03 mg/kg bw for a significant inhibition of the brain AChE (of 20%) in pups from the acute neurotoxicity studies, and applying an uncertainty factor of 200 The use of a supplementary assessment factor of 2 was supported by a benchmark dose approach for a 10% decrease of brain AChE, resulting in an overall uncertainty factor of 200 According to the assessment of the RMS, carbofuran itself could be considered a weak mutagen in some, but not all, strains of *Salmonella Typhimurium*, with indications of chromosomal aberrations and micronucleus formation in exposed mice, according to some published papers. However, guideline studies on these endpoints conducted with TGAI relevant for the EU-dossier showed negative outcomes for in vivo clastogenicity. The possibility of in vivo gene mutation activity cannot be excluded, although the outdated in vivo germ cell mutation activity in *Drosophila* was negative. Therefore, there are still some data gaps regarding this endpoint, although it is noted that the TGAI carbofuran lacks carcinogenicity, on the basis of data of 4 guideline studies (2 on rats, 2 on mouse)				

(Continues)

[22]2007/416/EC: Commission Decision of 13 June 2007 concerning the non-inclusion of carbofuran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 156, 16.6.2007, p. 30–31.

[23]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.

[24]https://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx.

TABLE 20 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
	The EU-dossier, supported by some open public literature, indicates a positive in vitro genotoxicity of 3-hydroxy carbofuran, showing thus some similarity with carbofuran itself. No in vivo studies were available for this metabolite. Since 3-OH-carbofuran is the main metabolite of carbofuran in mammalian cells, a similar toxicological profile as the parent seems plausible, and is it considered toxicologically relevant				
Comments on metabolites	See comments on carbosulfan (Section 5.11.2)				

Abbeviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LOAEL, lowest observed adverse effect level; NOAEL, no observed adverse effect level; RD, residue definition; RA: risk assessment.

5.4.3 | Residue definitions

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	The previous RD for carbofuran will be replaced by the new residue definitions reported in Section 5.11.3 for carbosulfan	Reg. 396/2005: Carbofuran (sum of carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb) and 3-OH carbofuran expressed as carbofuran	See Section 5.11.3
			Peer review (EFSA, 2009f): (1) Carbosulfan to be monitored separately from (2) carbamate structured metabolites; however, no precise definition can currently be proposed due to outstanding data and information (preferably the same as for risk assessment pending information on the efficiency of the analytical method and the establishment of a conversion factor for 3-keto-carbofuran)	
	Animal products		Reg. 396/2005: 3-OH-carbofuran (free and conjugated) expressed as carbofuran	See Section 5.11.3
			Peer review (EFSA, 2009f): No precise definition can currently be proposed due to outstanding data and information (preferably the same as for risk assessment pending information on the efficiency of the analytical method and the establishment of a conversion factor for 3-keto-carbofuran)	
			The residue is not fat soluble	
RD-RA	Plant products		Peer review (EFSA, 2009f): Carbofuran plus 3-hydroxy carbofuran plus 3 keto carbofuran and their conjugates expressed as carbofuran (uses with soil application)	See Section 5.11.3
	Animal products		Peer review (EFSA, 2009f): 3-hydroxy carbofuran and 3-keto carbofuran, free and conjugated expressed as carbofuran	See Section 5.11.3
Conclusion, comments	See the assessment on carbosulfan for more details.			

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

5.4.4 | Analytical methods

See analytical methods in Section 5.11.4 (carbosulfan).

5.4.5 | Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Oranges, Sweet, Sour (subgroup)	0.5 (W)	0.01*	The existing CXL is proposed for withdrawal
Alfalfa fodder	10 (W)	–	The existing CXL is proposed for withdrawal
Alfalfa forage (green)	10 (W)	–	The existing CXL is proposed for withdrawal
Banana	0.01* (W)	0.01*	The existing CXL is proposed for withdrawal
Cantaloupe	0.2 (W)	0.01*	The existing CXL is proposed for withdrawal
Cattle fat	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Citrus pulp, Dry[a]	2 (W)	–	The existing CXL is proposed for withdrawal
Coffee beans	1 (W)	0.05*	The existing CXL is proposed for withdrawal
Cotton seed	0.1 (W)	0.1	The existing CXL is proposed for withdrawal
Cucumber	0.3 (W)	0.002*	The existing CXL is proposed for withdrawal
Edible offal of cattle, goats, horses, pigs and sheep	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Goat fat	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Horse fat	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Maize forage	0.5 (W)	–	The existing CXL is proposed for withdrawal
Maize	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Mandarin	0.5 (W)	0.01*	The existing CXL is proposed for withdrawal
Meat of cattle, goats, horses, pigs and sheep	0.05* (W)	– Muscle: 0.01*	The existing CXL is proposed for withdrawal
Milks	0.05* (W)	0.001*	The existing CXL is proposed for withdrawal
Pig fat	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Potato	0.2 (W)	0.001*	The existing CXL is proposed for withdrawal
Rape seed	0.05* (W)	0.02*	The existing CXL is proposed for withdrawal
Rice straw and fodder, dry	1 (W)	–	The existing CXL is proposed for withdrawal
Rice, husked	0.1 (W)	0.01*	The existing CXL is proposed for withdrawal
Sheep fat	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Sorghum	0.1* (W)	0.01*	The existing CXL is proposed for withdrawal
Sorghum forage (green)	2 (W)	–-	The existing CXL is proposed for withdrawal
Sorghum straw and fodder, dry	0.5 (W)	–	The existing CXL is proposed for withdrawal
Spices, roots and rhizomes	0.1 (W)	0.05*	The existing CXL is proposed for withdrawal
Squash, summer	0.3 (W)	0.002*	The existing CXL is proposed for withdrawal
Sugar beet leaves or tops	0.07 (W)	–	The existing CXL is proposed for withdrawal
Sugar beet	0.2 (W)	0.01*	The existing CXL is proposed for withdrawal
Sugar cane	0.1* (W)	0.01*	The existing CXL is proposed for withdrawal
Sunflower seed	0.1* (W)	0.02*	The existing CXL is proposed for withdrawal
Sweet corn (corn-on-the-cob)	0.1 (W)	0.002*	The existing CXL is proposed for withdrawal
General comments	JMPR recommended withdrawal of all existing CXL for carbofuran as the new residue definition for MRL enforcement derived for carbosulfan will also cover carbofuran. Codex MRL proposals are reported under carbosulfan (Section 5.11.5)		

Abbreviations: CXL, Codex maximum residue limit; MRL, maximum residue level; 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]Arising from the use of carbosulfan.

5.4.6 | Consumer risk assessment

See consumer risk assessment reported under carbosulfan in Section 5.11.6.

5.4.7 | Conclusions

TABLE 23 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU, EU assessments available
Toxicological assessment	EU TRV available. Divergent conclusions on toxicological profile of parent and metabolites from EU and JMPR assessments
Residue definitions	See carbosulfan
Analytical methods	See carbosulfan
Codex MRL proposals	See carbosulfan
Dietary risk assessment	See carbosulfan
Final conclusion	See carbosulfan

Abbreviations: a.s., active substance; TRV, toxicological reference value.

5.5 | Iprodione (111) R/T

5.5.1 | Background information

TABLE 24 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	
RMS	FR	
Approval status	Not approved	Commission Implementing Regulation (EU) 2017/2091[25]
EFSA conclusion available	Yes, see comments	EFSA (2016f)
MRL review performed	Yes, see comments	EFSA (2013e)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2018q) (Art. 43 assessment)
Classification of a.s. (cut-off criteria)	No, see comments	Iprodione does not fall under cut-off criteria CLP00[26] (CLP00 not assessed by ECHA) No RAC Opinion available (application withdrawn in 2018) Note: Pesticides peer review suggested that Carc Cat 1B and Repro 2 may be appropriate for iprodione
Endocrine effects of a.s.	Yes, see comments	Iprodione was considered an endocrine disruptor in humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009[27] (interim criteria) (EFSA, 2016f) No assessment performed according to ED criteria defined in Commission Regulation (EU) 2018/605[28]
Other relevant information	Iprodione is subject to PIC Regulation In 2019, following the decision on non-renewal of the approval, the EU lowered all existing MRLs to the LOQ[29]	

Abbreviations: LOQ, limit of quantification; MRL, maximum residue level; RAC, Committee for Risk Assessment.

[25]Commission Implementing Regulation (EU) 2017/2091 of 14 November 2017 concerning the non-renewal of approval of the active substance iprodione, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 297, 15.11.2017, p. 25–27.

[26]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.

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

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

[29]Commission Regulation (EU) 2019/38 of 10 January 2019 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 iprodione in or on certain products. OJ L 9, 11.1.2019, p. 94–105.

5.5.2 | Toxicological reference values

TABLE 25 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.06 mg/kg bw per day	JMPR (2023)	0.02 mg/kg bw per day	Reg. (EU) 2017/2091	No
ARfD	0.6 mg/kg bw	JMPR (2023)	0.06 mg/kg bw	Reg. (EU) 2017/2091	No
Conclusion/comments a.s.	The ADI derived by JMPR is based on a NOAEL of 6.1 mg/kg bw per day in the two-year chronic toxicity and carcinogenicity study in rats, using an uncertainty factor of 100 The ARfD is based on a NOAEL of 60 mg/kg bw, based upon body weight loss and reduced food consumption between gestational day (GD) 6 and GD 12, at 200 mg/kg bw per day in the developmental toxicity study in rabbits, and using an uncertainty factor of 100 The EU ADI was derived from the LOAEL of 6 mg/kg bw per day for testicular histopathology and adrenal effects in the zona glomerulosa and reticularis, which is also the LOAEL for carcinogenicity (Leydig cell adenomas) in the 2-year rat study, applying an uncertainty factor (UF) of 300 The EU ARfD was based on the LOAEL of 20 mg/kg bw per day for increased incidence of umbilical hernia observed in the developmental toxicity study in rabbits, applying an UF of 300 For both (ADI and ARfD) an additional UF of 3 to the standard UF of 100 was applied, considering the use of a LOAEL (EFSA, 2016f):				
Comments on metabolites	Metabolites included in **JMPR RD for RA**: – 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP 32490) – *N*-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide (RP 36114) The TRVs of the parent also apply to RP 32490 and RP 36114, expressed as iprodione; both metabolites were considered not genotoxic as they are covered by the parent (major rat metabolites) In addition, RP 36115 (not included in the RD of JMPR) is covered by the ADI 2023 JMPR also concluded that for the following metabolites no indications of genotoxicity were identified and therefore they can be assessed against Cramer Class III TTC: • RP 30228, • RP 36112, • RP 36221, • RP 25040, • 3,5-DCA (conjugate) and • RP 31767. Metabolites included in **EU RD for RA**: – 3,5-dichloroaniline (common moiety) (RP 32596) – 3,5-dichloroaniline conjugate (M610F007) Metabolite 3,5-dichloroaniline (RP 32596) is unlikely to be genotoxic. For this metabolite, an ADI of 0.0005 mg/kg bw per day and an ARfD of 0.0075 mg/kg bw were proposed at EU level, being lower than the TRVs of the parent – RP 32490 (3-(3,5-Dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide) TRVs of parent apply for this metabolite (EFSA, 2016f) – RP 30228 (N-(3,5-Dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide, degradation product identified in standard hydrolysis studies) TRVs set for parent do not apply (EFSA, 2016f). Since there are genotoxicity concerns (positive in vitro micronucleus (MN) test and equivocal in the in vivo MN test), toxicological reference values could not be derived In addition, no conclusion could be reached on genotoxic potential or toxicological profile of additional metabolites, i.e. – RP 36112 – RP 25040 – RP 31767 According to EFSA (2016f), TRVs of parent apply also for RP 36114 (not included in EU RD) Altogether, for four metabolites (RP 30228, RP 36112, RP 25040 and RP 31767), the EU assessment differs from the JMPR assessment				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LOAEL, lowest observed adverse effect level; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition; TTC, threshold of toxicological concern.

5.5.3 | Residue definitions

TABLE 26 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Iprodione	Reg. 396/2005 (implementing MRL review): Iprodione Peer review (EFSA, 2016f): Iprodione	Yes
	Animal products	Not concluded	Reg. 396/2005 (implementing MRL review): Sum of iprodione and all metabolites containing the 3,5-dichloroaniline moiety, expressed as iprodione Peer review (EFSA, 2016f): RP32490 (Reg. No. 5079628) The residue is not fat soluble	Not applicable
RD-RA	Plant products	Iprodione	Peer review (EFSA, 2016f): 1. Sum of iprodione, RP 30228 and RP 32490 expressed as iprodione and separately (RD is provisional, pending further data on the toxicological relevance of metabolites of iprodione, in particular data on the genotoxic potential of metabolites (in particular on RP30228) and of any potential common effects of 3,5-dichloroaniline with iprodione, RP 30228 and RP 32490) 2. Sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroanilin MRL review (EFSA, 2013e): Iprodione (tentative)	No
	Animal products	Iprodione +3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP32490) + *N*-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide (RP36114), expressed as iprodione	Peer review (EFSA, 2016f): Residue definition is inconclusive (it is pending the submission of further data on toxicological relevance of metabolites, on the behaviour in livestock of 3,5-dichloroaniline and submission of new feeding studies investigating residues of iprodione in ruminants and poultry performed according to OECD guidelines). MRL review (EFSA, 2013e): Sum of iprodione and all metabolites containing the 3,5-dichloroaniline moiety, expressed as iprodione	Not applicable
Conclusion, comments	JMPR assessed plant metabolism studies in strawberries (foliar and soil use), peaches (foliar) lettuce (foliar) wheat (foliar and soil), rice (foliar use), peanuts (foliar). The plant metabolism studies revealed qualitative similarities in the crops investigated, with quantitative differences. JMPR considered iprodione being a sufficient marker for MRL enforcement, occurring between 25 and 98% of TRR in all raw and processed commodities. The inclusion of additional plant metabolites in the residue definition for risk assessment was considered not necessary EFSA noted that in carrot roots, iprodione accounted for less than 10% of TRR, and therefore for root crops, the parent would not be a good marker compound **Animal products:** JMPR concluded that iprodione and RP32490 represent suitable markers for enforcement in animal commodities. However, as suitable analytical methods are not available, a residue definition for enforcement purpose in animal commodities could not be derived. For risk assessment, considering the results of metabolism studies and of the toxicological assessment, JMPR proposed to include the two major metabolites found in all bovine and poultry tissues, milk and eggs (RP32490) and the major metabolite found in milk (RP36114) in the residue definition **Processed commodities**: In the standard hydrolysis studies to investigate the effect of processing on the nature of residues, iprodione was found to be almost stable at conditions simulating pasteurisation, but degraded notably at conditions representative of baking, brewing, boiling and sterilisation under formation of RP 30228, RP 37176 and 3,5-dichloroaniline		

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TRR, total radioactive residues.

5.5.4 | Analytical methods

TABLE 27 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content	Yes	0.02	Extraction with acetonitrile/water/hexane partition, HPLC-UV

TABLE 27 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High oil content	See remarks	0.01–0.1	In the JMPR assessments, validation data are not reported in detail: The report of 1994 speaks about a GLC-EC method that works for 'most crop and animal samples', without specifying the matrices for which sufficient validation data were available Validation data are available on a method published by the EURL-FV (Parrilla Vázquez et al., 2016)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The current EU MRLs for food commodities belonging to the three matrix groups listed above are lower than the Codex MRL proposal under discussion Validated analytical methods for the enforcement of the MRLs for the relevant matrices are partially available		

Abbreviations: GLC-EC, gas–liquid chromatography with electron-capture detection; HPLC-UV, high performance liquid chromatographic method coupled with ultraviolet detector; LOQ, limit of quantification; MRL, maximum residue level.

5.5.5 | Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Almond	**0.3**	0.01*	cGAP: USA, 4 × 0.560 kg/ha, RTI depending on the growth stage, last application up to 5 weeks after petal fall 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
Almond hulls	50 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Barley	2 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Bean, hay and/or straw (*Phaseolus* spp.)	20 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Beans (*Phaseolus* spp.)–dry	0.1 (W)	0.01*	The existing CXL is proposed for withdrawal; JMPR received 6 residue trials for the US GAP. But as the storage stability in high protein crops was not demonstrated, JMPR did not derive a new Codex MRL proposal and decided to withdraw the previous recommendation
Beans with pods (*Phaseolus* spp.)–immature pods and succulent seeds	**1.5**	0.01*	cGAP: USA, 2 × 1.1 kg/ha, 5-day RTI, last application at full bloom (BBCH 65) Number of trials: 5 trials in snap beans Sufficiently supported by data: Yes Specific comments: Considering the early application (at bloom), the high residues found in the harvested crop are surprising. Details of the trials should be checked. JMPR mentioned one additional trial in lima beans, but apparently, this trial was not considered for deriving the STMR **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: To check details in JMPR evaluation
Blackberries	30 (W)	0.01*	The existing CXL is proposed for withdrawal
Broccoli[a]	**40**	0.01*	cGAP: USA, 2 × 1.1 kg/ha, 1st application after thinning (2–4 leaf stage), 0-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: See consumer risk assessment **Conclusion:** The proposed Codex MRL is not acceptable because acute intake concerns were identified by JMPR and at EU level Follow-up action: None
Cane berries, subgroup of	**50**	0.01* Blackberries, raspberries, dewberries	cGAP: USA, 4 × 1.1 kg/ha, 14-day RTI, 0-day PHI Number of trials: 13 (9 on raspberries and 4 on blackberries) Sufficiently supported by data: Yes Specific comments: The STMRs of the two data sets differed by less than aa factor of 5, but as the Mann–Whitney test showed that they two data sets belong to a different population, JMPR used the trials on blackberries only. It is also noted that the US tolerance for cane berries is 25 mg/kg **Conclusion:** The proposed Codex MRL is not acceptable because an acute intake concern was identified in the EU risk assessment for blackberries and raspberries Follow-up action: None

(Continues)

TABLE 28 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Carrot	10 (Po) (W)	0.01*	The existing CXL is proposed for withdrawal. An insufficient number of trials was submitted for the cGAP notified to JMPR
Cherries, subgroup of	**0.3**	0.01*	cGAP: USA, 2 × 1.1 kg/ha, 1st application at full bloom, 2nd application at petal fall Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Common bean (pods and/or immature seeds)	2 (W)	0.01*	The existing CXL is proposed for withdrawal
Cucumber	2 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Grapes	10 (W)	0.01*	The existing CXL is proposed for withdrawal. An insufficient number of trials was submitted for the cGAP notified to JMPR
Kiwifruit	5 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Lettuce, head	10 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Lettuce, leaf	25 (W)	0.01*	The existing CXL is proposed for withdrawal. An insufficient number of trials was submitted for the cGAP notified to JMPR
Onion, bulb	**0.15**	0.01*	cGAP: USA, 4 × 0.842 kg/ha, 14-day RTI, 7-day PHI Number of trials: 6 (4 trials matching the US GAP +2 overdosed trials (4 × 1.1 kg/ha) with residues below the LOQ) Sufficiently supported by data: No Specific comments: The number of trials matching the GAP was insufficient. To complement the data set, overdosed trials were used (in these trials, residues were below the LOQ) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Peaches (including Nectarines and Apricots), Subgroup of	**0.05***	0.01* Peaches, apricots	cGAP: USA, 2 × 1.1 kg/ha, 1st application at full bloom, 2nd application at petal fall Number of trials: 7 Sufficiently supported by data: Yes Specific comments: The trials were performed with three instead of two applications. Considering the timing of the last application (not later than last petal fall) and residues were all below the LOQ of 0.05 mg/kg, JMPR accepted the trials **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the trials do not fully reflect the GAP Follow-up action: None
Peaches	10 (W)	0.01*	The existing CXL is proposed for withdrawal; replaced by the new MRL proposal of 0.05* mg/kg
Pome fruits (group)	5 (Po) (W)	0.01*	The existing CXL is proposed for withdrawal as for the cGAP (Chile, 2 × 67 g/hL (foliar use up to petal fall), followed by a 2-min post-harvest immersion at 100 g ai (hl with a PHI of 3 days) an insufficient number of residue trials were available
Potato	**0.05***	0.01*	cGAP: USA, 4 × 1.1 kg/ha, 14-day RTI, 0-day PHI Number of trials: 14 Sufficiently supported by data: Yes Specific comments: Residues of parent iprodione were all below the LOQ; the results for the residue definition parent plus RP32490 showed that the metabolite can occur in significant amounts: in two trials the metabolite accounted for 0.11 mg/kg and 0.26 mg/kg, which gives an indication that the parent compound is not a sufficient marker for root and tuber vegetables. See also comments residue definitions and comments on potato culls **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, in view of the substantial amount of residues of metabolite RP32490 Follow-up action: To check details in JMPR evaluation
Potato culls	0.15	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose. However, it is noted that the MRL proposal for potato culls (which are by definition whole unpeeled potato not suited for fresh market or processing and which have the same Codex code as potatoes) it is unclear why a different MRL and STMR was derived than for potatoes for human consumption
Potato flakes/ granules	0.05*	–	JMPR derived a processing factor of 0.29. Currently, no EU MRLs are established for processed products
Rape seed	0.5 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided

TABLE 28 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Raspberries, red, black	30 (W)	0.01*	The existing CXL is proposed for withdrawal
Rice, husked	10 (W)	0.01*	The existing CXL is proposed for withdrawal
Spices, roots and rhizomes	0.1 (W)	0.05*	The existing CXL is proposed for withdrawal. No GAP information provided
Spices, seeds	0.05* (W)	0.05*	The existing CXL is proposed for withdrawal. No GAP information provided
Strawberry	10 (W)	0.01*	The existing CXL is proposed for withdrawal. An insufficient number of trials was submitted for the cGAP notified to JMPR
Sugar beet	0.1* (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Sunflower seed	0.5 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Tomato	5 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Witloof chicory (sprouts)	1 (W)	0.01*	The existing CXL is proposed for withdrawal. No GAP information provided
Potato chips	–	–	JMPR derived a processing factor of 0.45. Currently, no EU MRLs are established for processed products
Bean, forage (*Phaseolus* spp.)	n.a.	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
General comments	EFSA noted that in Annex 1 of the JMPR report, the HR and STMR values were interchanged. JMPR should be informed, to consider publishing a corrigendum. The risk assessment (presented in Annex 3 and 4 to the JMPR report) was performed with the correct values It is also noted that JMPR did not calculate the dietary burden for livestock, although potatoes could serve as animal feed. JMPR highlighted that MRLs for animal products could not be estimated because no enforcement residue definition could be derived, lacking a suitable analytical methods for MRL enforcement		

Abbreviations: BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; dw, dry weight; GAP, Good Agricultural Practice; MRL, maximum residue level; n.a., not applicable; PHI, pre-harvest interval; Po, the recommendation accommodates post-harvest treatment of the commodity; RTI, re-treatment interval; STMR, supervised trials median residue; 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]On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of iprodione for the consumption of broccoli may present a public health concern.

5.5.6 | Consumer risk assessment

TABLE 29 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The indicative risk assessment for iprodione 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. almonds, apricots, cherries, peaches, blackberries, dewberries, raspberries, potatoes, onions, broccoli, beans with pods) A risk assessment for the second residue definition derived at EU level (i.e. sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline) could not be performed, as in the JMPR assessment, no data are available for this residue definition The calculations are indicative, because the EU residue definitions for risk assessment differ from the JMPR residue definition. In addition, it needs to be highlighted that based on the available information, the genotoxic potential of one metabolite could not be excluded Therefore, the calculations are affected by additional, non-standard uncertainties	**RA assumptions:** The indicative risk assessment for iprodione was performed with the EU ADI An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1. The calculations were performed with the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. almonds, apricots, cherries, peaches, blackberries, dewberries, raspberries, potatoes, onions, broccoli, beans with pods). For the remaining commodities, the existing EU MRLs were used as input values A risk assessment for the second residue definition derived at EU level (i.e. sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline) could not be performed, as in the JMPR assessment, no data are available for this residue definition The calculations are indicative, because the EU residue definitions for risk assessment differ from the JMPR residue definition. In addition, it needs to be highlighted that based on the available information, the genotoxic potential of one metabolite could not be excluded Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** –

(Continues)

TABLE 29 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: **Iprodione** The calculated short-term exposure exceeded the ARfD for several crops under assessment (indicative calculation) Broccoli: 1664% of ARfD Blackberries: 404% of ARfD Raspberries: 348% of ARfD **Sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline** Calculations could not be performed	**Results:** **Iprodione** No long-term consumer health risk was identified (indicative calculation) The overall chronic exposure accounted for 49% of the ADI Among the crops under consideration, broccoli was identified as the main contributor, accounting for up to 27% of the ADI **Sum of 3,5-dichloroaniline and its conjugates expressed as 3,5-dichloroaniline** Calculations could not be performed	**Results:** Long-term exposure: Max 3% of the JMPR ADI. GECDE mean: Max. 190% (infants and toddler) GECDE max: Max. 1000% (infants and toddler) Short-term exposure: Highest result for broccoli: 190% of ARfD For the remaining commodities, the acute exposure was found below the ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.5.7 | Conclusions

TABLE 30 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 on 5 December 2017. A.s. was not renewed)
Toxicological assessment	EU TRVs available for the parent compound. However, genotoxic potential and/or toxicological properties for some metabolites/degradation product cannot be concluded, based on available information
Residue definitions	For plant commodities, the EU and Codex RD for enforcement are identical; for RA, the EU RDs are more comprehensive for plant products. For animal products, the residue definitions are not comparable. EFSA noted that for root crops, the parent compound is not a good marker substance
Analytical methods	Sufficiently validated analytical methods are available for high water and high acid matrices; limited validation data available in JMPR assessments for high oil content matrices
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk assessment identified intake concerns of iprodione residues in broccoli, blackberries and raspberries. For the remaining commodities, the risk assessment is indicative, affected by a high level of uncertainty. In an indicative chronic risk assessment performed for iprodione, no intake concern was identified. However, the chronic risk assessment is also affected by additional, non-standard uncertainties due to numerous data gaps and lack of availability of data for the second EU residue definition for plant products
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.6 | Zeta-cypermethrin (118) R

5.6.1 | Background information

TABLE 31 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	See comments	BE and AT for first approval and renewal (application withdrawn)/ toxicological re-assessment for MRL review, respectively
Approval status	Not approved	Expiration of approval: 01/12/2020; The application for renewal was withdrawn
EFSA conclusion available	Yes, see comments	EFSA (2009a)
MRL review performed	Yes, see comments	EFSA (2023b)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2023d) (Statement on the review of residue definitions for pyrethroid common metabolites) EFSA PPR Panel (2022b) (Scientific opinion on toxicity of pyrethroid common metabolites)

TABLE 31 (Continued)

		Comments, references
Classification of a.s. (cut-off criteria)	No, see comments	Cypermethrins: A.s. does not meet cut-off criteria (independently of its stereoisomers ratio) ECHA (2019e); ATP17[30]
Endocrine effects of a.s.	No conclusion derived	EFSA (2023b)
Other relevant information	–	

5.6.2 | Toxicological reference values

TABLE 32 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.02 mg/kg bw per day	JMPR (2006)	0.0015 mg/kg bw per day	EFSA (2023)	No
ARfD	0.04 mg/kg bw	JMPR (2006)	0.0015 mg/kg bw	EFSA (2023)	No
Conclusion/comments a.s.	The JMPR derived group TRVs for cypermethrins, including alpha-cypermethrin and zeta-cypermethrin In the EU, TRVs were set of each separate a.s In the EU, in 2023, the previous ADI of 0.04 mg/kg bw per day and the previous ARfD of 0.125 mg/kg bw have been replaced by new TRV The new ADI is based on a DNT study with zeta-cypermethrin, supported by rat, 2-year (cypermethrin), applying a UF of 100 and 250, respectively. The ARfD is based on a DNT study with zeta-cypermethrin and a UF of 100 (EFSA, 2023b)				
Comments on metabolites	Metabolites included in JMPR RD for RA: not relevant Metabolites identified in the EU being relevant for risk assessment (RD for RA): – 3-phenoxybenzoic acid (3-PBA) – 3-(4′-hydroxyphenoxy)benzoic acid (4-OH-PBA) A separate residue definition for risk assessment covering the group of related metabolites bearing the 3-phenoxybenzoyl moiety, notably the major metabolites 3-PBA, 4-OH-PBA including their conjugated forms and PBAld, was proposed but is not yet implemented and is still provisional (EFSA, 2023d) Regarding the common metabolites to several pyrethroid substances, 3-phenoxybenzoic acid (3-PBA) and 3-(4′-hydroxyphenoxy)benzoic acid (4-OH-PBA), they do not raise a concern with respect to genotoxicity For the metabolite PBAld, the hazard characterisation is not yet completed pending the availability of aneugenicity data on this compound For 3-PBA and 4-OH-PBA metabolites, an ADI of 0.1 mg/kg bw per day and an ARfD of 1 mg/kg bw were derived as per the Opinion of the EFSA Scientific Panel on Plant Protection Products and their Residues (EFSA PPR Panel, 2022b)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition; UF, uncertainty factor.

5.6.3 | Residue definitions

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	Cypermethrins (sum of isomers)	Reg. 396/2005: Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) MRL review (EFSA, 2023b) and Peer review (EFSA, 2009a): Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
	Animal products	Cypermethrins (sum of isomers) The residue is fat soluble	Reg. 396/2005: Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) MRL review (EFSA, 2023b) and Peer review (EFSA, 2009a): Cypermethrin including other mixtures of constituent isomers (sum of isomers) The residue is fat soluble	Yes

(Continues)

[30]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.

TABLE 33 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD-RA	Plant products	Cypermethrins (sum of isomers)	MRL review (EFSA, 2023b): Cypermethrin including other mixtures of constituent isomers (sum of isomers) A formal decision on the establishment of a separate residue definition for common metabolites of pyrethroids is still pending (assessed in EFSA (2023d)) Peer review (EFSA, 2009a): Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
	Animal products	Cypermethrins (sum of isomers)	MRL review (EFSA, 2023b): Cypermethrin including other mixtures of constituent isomers (sum of isomers) A formal decision on the establishment of a separate residue definition for common metabolites of pyrethroids is still pending (assessed in EFSA (2023d)) Peer review (EFSA, 2009a): Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
Conclusion, comments	The EU residue definitions for MRL enforcement and for risk assessment are identical/comparable with the JMPR residue definition			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.6.4 | Analytical methods

TABLE 34 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content	Yes	0.01	Extraction by DFG S19; determination by GC-ECD or –MS. Validation data for cypermethrin and zeta-cypermethrin in high water content and high acid content commodities available but the details are not reported in the JMPR report EURL validation data show successful validation of cypermethrin in high water content and high acid content commodities (LOQ of 0.005 mg/kg). The stated LOQs for cypermethrin are supposed applicable for all the other a.s. of the 'Cypermethrin family' containing other constituent isomer ratios
High oil content	Yes	0.05	Extraction by liquid–liquid extraction using hexane and acetonitrile, followed by clean-up using SPE; determination by GC-ECD. Seeds: Extraction using hexane and acetone, followed by clean-up using solvent partitioning GPC; determination by GC-ECD EURL validation data show successful validation of cypermethrin in high oil content commodities (LOQ of 0.05 mg/kg). The stated LOQs for cypermethrin are supposed applicable for all the other a.s. of the 'Cypermethrin family' containing other constituent isomer ratios
Conclusion	The JMPR received four methods of analysis used in the supervised trials (Method P-3559, Method P-3451, Method RAN-231M and Method RAN-0193M). Additional information on a multiresidue method suitable for enforcement which had been evaluated by the 2009 JMPR (Method DFG S19) was also provided The JMPR confirmed validation of the following methods for zeta-cypermethrin: Method P-3559 (GC-ECD) in commodities with high acid content including blackberry and blueberry with an LOQ of 0.05 mg/kg; Method P-3451 (GC-ECD) in avocado with an LOQ of 0.035 mg/kg, Method RAN-0193M (GC-ECD) in commodities with high water content including bulb onion and spring onion with an LOQ of 0.05 mg/kg Sufficiently analytical methods for the enforcement of the MRLs for these matrices are available The EURLs noted that using conventional chromatographic separation techniques, it is not possible to selectively determine zeta cypermethrin. Alpha-cypermethrin may be quantified but, when GC methods are used, quantification will be biased as any thermal transformation of other isomers to any of the two alpha-cypermethrin cannot be accounted for		

Abbreviations: GC-ECD, gas chromatography with electron capture detector; GC–MS, gas chromatography with mass spectrometry; GPC, Gel Permeation Chromatography; LOQ, limit of quantification; MRL, maximum residue level; SPE, solid-phase extraction.

5.6.5 | Codex MRL proposals

TABLE 35 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	Existing EU MRL/ proposed new MRLs[a]	Comment
Avocado	**0.5**	0.05*/–	cGAP: USA, Foliar, 6 × 56 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, the proposal is not acceptable since an exceedance of the EU ARfD for this crop cannot be excluded (see risk assessment results) Follow-up action: None
Subgroup of bulb onions	0.05*	0.1/0.09 or LOQ (garlic, onion, shallots)	cGAP: USA, Foliar, 5 × 56 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: Overdosed trials performed with 5 applications at 112 g a.s./ha (2N rate). In three trials, storage periods were longer than 20 months and not considered for the Codex MRL proposal. From the valid trials ($n = 12$), the residue data were always below the LOQ: 12 × < 0.05 mg/kg. The JMPR noted that onion is the representative commodity for the Codex subgroup of bulb onions and the GAP covers all commodities in this subgroup. Therefore, the JMPR estimated an MRL for the subgroup of bulb onions. This extrapolation would be acceptable in the EU **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of bush berries	**1.5**	0.05*/– (blueberries, currants, gooseberries, rose hips)	cGAP: USA, Foliar, 5 × 56 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: Trials performed on blueberries. JMPR noted that blueberry is a representative commodity for the Codex subgroup of bush berries and the GAP covers all commodities in this subgroup. Therefore, the JMPR estimated an MRL for the subgroup of bush berries **Conclusion:** The proposed Codex MRL is not acceptable since an exceedance of the EU ARfD for these crops cannot be excluded (see risk assessment results) Follow-up action: None
General comments	In the Art 12 review of cypermethrins (EFSA, 2023b), EFSA proposed the following MRL for bulb onions (garlic, onions, shallots): 0.09 mg/kg or LOQ (risk manager consideration is needed) A risk management decision has not yet been taken Uses on avocados, blueberries, currants, gooseberries and rose hips were not reported in the Art 12		

Abbreviations: ARfD, acute reference dose; cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

[a]EFSA (2023b).

5.6.6 | Consumer risk assessment

TABLE 36 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 for zeta-cypermethrin 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/proposed new EU MRL (i.e. avocado, blueberries, gooseberries, currants and rose hips). The short-term exposure calculations were also performed for onions, shallots and garlic, using an HR of 0.05 mg/kg, considering that the EU MRLs might be lowered to the LOQ following the recent EU assessment	**RA assumptions:** The risk assessment was performed with the EU ADI for zeta-cypermethrin. Considering only the Codex MRL proposals derived by JMPR in 2023 In addition, a combined long-term dietary risk assessment was performed using PRIMo rev. 3.1. For this scenario, the input values of the most recent long-term risk assessment (EFSA, 2023b) 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. avocado, blueberries, gooseberries, currants and rose hips; for onions, shallots and garlic, the input values reflecting the proposed EU MRL of 0.09 mg/kg was used in the calculation, as the EU MRL might be lowered to the LOQ)	**Specific comments:** –

(Continues)

TABLE 36 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
	The calculation is based on the median residue levels derived for raw agricultural commodities Residues in crops that were leading to exceedance of the ARfD in the EFSA assessment of 2023 were removed from the calculation All input values refer to the residues in the raw agricultural commodities except for citrus fruits and cucurbits with inedible peel, for which residues in the pulp were considered For the combined risk assessment, the exposure is compared with the TRVs derived for alpha cypermethrin. For each commodity, the most critical input value was selected for the exposure calculation This approach is based on the assumption that the three active substances are not used together on the same crop. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation	
Results: The calculated short-term exposure exceeded the ARfD for several crops under assessment **Zeta-cypermethrin** Avocados: 806% of ARfD Currants: 279% of ARfD Blueberries: 211% of ARfD Gooseberries: 208% of ARfD Onions: 76% of ARfD Garlic: 12% of ARfD Shallots: 9% of ARfD Rose hips: 78% of ARfD Processed commodities: Currants (juice): **762% of ARfD** Rose hips/jam: 81% of ARfD Shallots/boiled: 54% of ARfD Onions/boiled: 31% of ARfD	**Results:** The calculated long-term exposure exceeded the ADI (combined risk assessment) **Zeta-cypermethrin** The chronic exposure related to the proposed Codex MRLs accounted for 16% of the ADI (NL toddler) Among the crops under consideration, currants were identified as the main contributor, accounting for up to 9% of the ADI **Combined risk assessment** The overall chronic exposure accounted for 110% of the ADI (NL toddler) Among the crops under consideration, currants were identified as the main contributor, accounting for up to 9% of the ADI	**Results:** Long-term exposure: Max 20% of the JMPR ADI (children) GECDE mean: Max. 70% (infants and toddler) GECDE max: Max. 250% (infants and toddler) Short-term exposure: Highest result for currants: 30% of ARfD (children)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; HR, highest residue; LOQ, limit of quantification; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue; TRV, toxicological reference value.

5.6.7 | Conclusions

TABLE 37 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 on 1 December 2020, as the application for renewal was withdrawn)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs are identical
Analytical methods	Sufficiently validated analytical methods are available. The details on the method validation are not reported in the JMPR report
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute intake concerns were identified for several commodities; chronic intake concerns were identified. In a refined chronic exposure assessment, the exposure was below the ADI. Details see above
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.7 | Permethrin (120) R/T

5.7.1 | Background information

TABLE 38 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	JMPR could not finalise the periodic review
RMS	No RMS assigned	
Approval status	Not approved	Commission Decision 2001/2/EC[31]
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2016e) (certain products of animal origin)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria CLP00[32] (not assessed by ECHA)
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Permethrin is authorised for use in veterinary medicine, it is used as a biocide and it is subject to PIC Regulation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.7.2 | Toxicological reference values

TABLE 39 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	–	See comments below	0.05 mg/kg bw per day	Biocide assessment (ECHA, 2014a)	Not applicable
ARfD	–	See comments below	0.5 mg/kg bw	ECHA (2014a)	Not applicable
Conclusion/comments a.s.	JMPR could not conclude on toxicological reference values for permethrin Previous ADI: 0.05 mg/kg bw per day was derived by JMPR in 1987 and was confirmed in 1999 Previous ARfD: 1.5 mg/kg bw (FAO and WHO, 2002a) In 2000, JECFA at its 54th meeting was unable to establish an ADI for the 80:20 *cis*:*trans* isomeric mixture proposed for use as a veterinary drug because of the lack of information on toxicity In the EU, in 2014, the ADI derived by JMPR has been taken over under the biocide legislation for the technical-grade permethrin with *cis*:*trans* (ratios of 25:75 to 40:60) (based on the NOAEL of 5 mg/kg bw per day derived from a chronic rat study assessed by WHO/FAO JMPR) The toxicological assessment for the use of permethrin as veterinary medicinal products could not be retrieved				
Comments on metabolites	Metabolites included in JMPR RD for RA: JMPR could not conclude on the residue definitions for risk assessment. The toxicological assessment of metabolites relevant for dietary risk assessment will be continued when the compound is next scheduled for toxicological re-evaluation Metabolites included in EU RD for RA: not relevant				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition.

[31]2001/2/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 substance (notified under document number C(2000) 4140). OJ L 332, 28.12.2000, p. 114–115.

[32]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.

5.7.3 | Residue definitions

TABLE 40 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Permethrin (sum of *cis*- and *trans*-isomers)	Reg. 396/2005: Permethrin (sum of isomers) No EU peer review and no MRL review	Yes
	Animal products	Permethrin (sum of *cis*- and *trans*-isomers)	Reg. 396/2005: Permethrin (sum of isomers)	Yes
		Fat solubility not specified	No EU peer review and no MRL review The residue is fat soluble	
RD-RA	Plant products	– (See conclusion below)	No EU peer review and no MRL review	Not applicable
	Animal products	– (See conclusion below)	No EU peer review and no MRL review	Not applicable
Conclusion, comments	JMPR did not derive residue definitions for risk assessment, since the WHO core assessment group could not conclude on toxicological reference values for permethrin. The assessment was postponed For MRL enforcement, JMPR considered that permethrin (sum of isomers) was a suitable marker for MRL compliance in plant and animal products			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.7.4 | Analytical methods

TABLE 41 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities:	No details	Not reported	QuEChERS method, extraction with acetonitrile, SPE column clean-up and LC–MS/MS analysis
Animal products	No details	Not reported	QuEChERS method, extraction with acetonitrile or acetonitrile/water, dispersive SPE clean-up and LC–MS/MS analysis
Conclusion	JMPR reported a number of analytical methods to determine permethrin (parent compound) and some metabolites (DCVA, 3-PBAlc in plant and animal matrices, as well as 3-PBA in animal matrices) For MRL enforcement, JMPR considered suitable analytical methods are available to analyse the parent compound in plant and animal matrices. However, details on validation data, such as LOQs achievable for the different matrices, are not reported		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); SPE, solid-phase extraction.

5.7.5 | Codex MRL proposals

The periodic review could not be completed, due to incomplete dossier submission.

It is acknowledged that for a comprehensive periodic review it is necessary to have a complete dossier, covering the toxicological studies on the a.s. and its relevant metabolites, to take a decision on the TRVs. In addition, the information on the supported GAPs need to be provided, accompanied by the relevant residue data such as trials.

In its assessment, JMPR did not report, for which crops GAP information and residue trials were submitted.

EFSA is of the opinion that a decision on the revocation of CXLs for commodities no longer supported could be taken before the toxicological assessment is completed. Hence, in order to avoid unnecessary delays in revocation of CXLs that are no longer supported, it would be desirable to identify the unsupported commodities at an early stage and take a decision on the revocation as soon as possible, considering that the existing CXLs have been derived mostly more than 30 years ago. The submission of incomplete dossiers submitted to JMPR for a.s. scheduled for periodic review should not be misused to maintain CXLs for commodities in the Codex system, for which supporting data are not available.

5.7.6 | Consumer risk assessment

Not relevant, no CXL proposals were derived by JMPR.

5.7.7 | Conclusions

TABLE 42 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 TRV available. JMPR could not conclude on TRV
Residue definitions	JMPR could not conclude on residue definitions for risk assessment. For MRL enforcement, the EU and the Codex RD are the comparable, covering the *cis*- and *trans*-isomers of permethrin
Analytical methods	According to JMPR assessment, validated analytical methods are available. However, details on method validation are not reported
Codex MRL proposals	Due to lack of key studies, JMPR postponed the assessment The existing CXLs (most of them derived before 1990) have not been withdrawn
Dietary risk assessment	Due to lack of key studies, JMPR postponed the assessment.
Final conclusion	EU position to be discussed/decided by risk managers. EFSA also recommends discussion whether a revocation of CXLs for commodities that are no longer supported should be considered, although the toxicological assessment is not yet completed

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.8 | Diflubenzuron (130) R

5.8.1 | Background information

TABLE 43 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	SE	
Approval status	Not approved	Commission Implementing Regulation (EU) 2022/801[33] Expiration of approval: 31/12/2020; The application for renewal was withdrawn
EFSA conclusion available	Yes, see comments	EFSA (2009d) (peer review for the approval) EFSA (2012c) (peer review of confirmatory data submitted) EFSA (2015e) (peer review of the metabolite PCA)
MRL review performed	Yes, see comments	EFSA (2020e) (Statement; no MRL review required)
EU MRL applications or other EU assessments	No	–
Classification of a.s. (cut-off criteria)	Not assessed	– Note: under the biocide assessment as PT18, the classification proposed by the RMS does not include cut-off criteria (ECHA, 2012b)
Endocrine effects of a.s.	Not assessed	– Note: under the biocide assessment at PT18, the RMS considers the a.s. not deemed to be an ED (ECHA, 2012b)
Other relevant information	Diflubenzuron is used as a biocide	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.8.2 | Toxicological reference values

TABLE 44 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.02 mg/kg bw per day	JMPR (2001)	0.1 mg/kg bw per day	Reg. (EU) 2017/855	No
ARfD	Unnecessary	JMPR (2001)	Unnecessary	Reg. (EU) 2017/855	Yes

[33]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. OJ L 143, 23.5.2022, p. 7–10.

TABLE 44 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Conclusion/comments a.s.	–				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: – 4–chlorophenylurea (CPU) CPU toxicity is covered by the TRVs of the parent – 4-chloroaniline (PCA) PCA is an in vivo genotoxic carcinogenic agent; accordingly, no TRVs can be derived since a threshold cannot be assumed. A benchmark dose (BMD) analysis was performed in view of determining a margin of exposure (MoE): – $BMDL_{10}$ = 0.56 mg/kg bw (rat adrenal gland pheochromocytomas endpoint, log-probit model) – $BMDL_5$ = 0.16 mg/kg bw (rat adrenal gland pheochromocytomas endpoint, log-probit model) EFSA (2015e) Since the BMD analysis used by the RMS is no longer supported by EFSA, the analysis was performed using the new EFSA tool (Bayesian Benchmark Dose Modelling v 0.0.0.9077) and following the latest EFSA guidance (EFSA Scientific Committee, 2022) on the adrenal gland pheochromocytomas in male rats observed in a study from the National Toxicology Program (NTP) (1989). This resulted in: – model average $BMDL_{10}$ (MA-$BMDL_{10}$) = 2.4 mg PCA/kg bw per day. – MA-BMD_5 = 1.4 mg PCA/kg bw per day. The reasons for the difference with the previous BMDL calculations is that previously the lowest BMDL was selected as a Point of Departure, whereas currently, the recommended approach is to use a model average BMDL. Furthermore, the previously selected lowest BMDLs were obtained from the 'logProbit' model, which is not supported anymore as part of the candidate models to be used for BMD analysis. Overall, the current approach is considered to provide more reliable Points of Departure compared to the previous BMDL estimates – 4-chloroacetanilide (PCAA) No conclusion could be drawn on PCAA due to insufficient information available (EFSA, 2015e)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition.

5.8.3 | Residue definitions

TABLE 45 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Diflubenzuron	Reg. 396/2005: Diflubenzuron Peer review (EFSA, 2015e): Diflubenzuron (for fruit crops after foliar application)	Yes
	Animal products	Diflubenzuron The residue is fat soluble	Reg. 396/2005: Sum of diflubenzuron and 4-chlorophenylurea expressed as diflubenzuron Peer review (EFSA, 2015e): Diflubenzuron and 4-chlorophenylurea (CPU) expressed as diflubenzuron The residue is fat soluble	No
RD-RA	Plant products	Diflubenzuron	Peer review (EFSA, 2015e): Fruit crops (foliar application): (1) Diflubenzuron (2) PCA	No
	Animal products	Diflubenzuron	Peer review (EFSA, 2015e): (1) Diflubenzuron and 4-chlorophenylurea (CPU), expressed as diflubenzuron (2) PCA and provisionally PCAA, expressed as PCA (pending full assessment of toxicological properties of PCAA)	No
Conclusion, comments	At EU level, metabolism studies were available for fruits and mushrooms; JMPR had studies available for maize, soybean, apple, cabbage, cotton, orange, mushrooms, rice, wheat and beans, which were assessed in its previous assessments (JMPR 2002, 2011). For the current assessment, no new metabolism studies were reported It would be desirable that JMPR in its assessment discusses the relevance of the metabolism studies and the appropriateness of the current residue definitions for the new uses assessed For the commodity under discussion in this CCPR meeting (i.e. tea), the EU and Codex enforcement and risk assessment residue definitions are identical. However, in the EU, an additional residue definition was established, encompassing 4-chloroaniline (PCA) a genotoxic carcinogen metabolite (EFSA). At EU level no metabolism studies are available for leafy crops to cover the Codex MRL proposal for tea			

TABLE 45 (Continued)

Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		In the EU, standard hydrolysis studies with radiolabelled diflubenzuron were available to investigate the degradation of residues under conditions simulating pasteurisation, boiling/brewing/baking and sterilisation. Significant degradation of diflubenzuron occurred under sterilisation conditions (pH of 6, temperature 120°C), leading to the formation of PCA up to 58% of the applied radioactivity (AR), and the detection of 4-chlorophenylurea (CPU) at 6%, a precursor of PCA Tea is primarily consumed as an infusion prepared from fermented/dried tea leaves with boiling water. Information on the formation of PCA during fermentation/drying is not available. The pH of tea infusions is neutral/slightly acidic; for green tea infusions. In standard hydrolysis studies, the formation of PCA was not observed under boiling conditions (pH 5, 100°C), EFSA is of the opinion that the available data do not allow to exclude the presence of PCA in tea infusion (100°C, neutral or slightly acidic pH) The transfer of diflubenzuron residues from tea leaves into tea infusions was assessed by JMPR. In this study, the possible formation of PCA was not investigated	

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

5.8.4 | Analytical methods

TABLE 46 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: Difficult matrices	Yes	0.01 mg/kg for green and black tea, 0.004 mg/kg for fresh leaves, 0.0002 mg/L for tea infusions	Extraction with acidified (1% formic acid) acetonitrile and distilled water, LC–MS/MS According to the JMPR report 2023, the analytical method was used for the following commodities: – fresh tea leaves, green and black tea and their infusions. EURL-FV has validation data in black tea, using QuEChERS with $CaCl_2$ and PSA in the dSPE step with LOQ of 0.05 mg/kg
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is identical with the JMPR residue definition The current EU MRL for the commodity under discussion (tea) is lower than the Codex MRL proposal under discussion Sufficiently validated analytical methods for the enforcement of the MRLs for tea are available		

Abbreviations: dSPE, dispersive solid-phase extraction; LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.8.5 | Codex MRL proposals

TABLE 47 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Black, green tea infusions	–	–	JMPR derived a processing factor (dilution factor) of 0.004
Tea, black, green, dried and fermented (subgroup)	**40**	0.05*	cGAP: China, 1 × 13 g a.s./hL, 5-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: In total, 8 trials (green tea and black tea) were available both, from the same data set (*Camellia sinensis*). JMPR used the highest values from each trial to estimate a maximum residue level for green and black tea. The HR of 23.5 mg/kg was derived from the data set on black tea **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, see comments on dietary risk assessment Follow-up action: None
General comments	–		

Abbreviations: ARfD, acute reference dose; cGAP, critical Good Agricultural Practice; HR, highest residue; MRL, maximum residue level; PHI, pre-harvest interval.
*Indicates that the input value is proposed at the limit of quantification.

5.8.6 | Consumer risk assessment

TABLE 48 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant for parent diflubenzuron since no ARfD was allocated	**RA assumptions:** The risk assessment was performed with the EU ADI A long-term dietary risk assessment was performed for diflubenzuron, using PRIMo rev. 3.1, including STMR values derived by JMPR for tea, black, green, dried and fermented For the remaining commodities, the exposure calculations were performed with the existing EU MRLs (all set at the LOQ) The risk assessment is therefore affected by additional, non-standard uncertainties as the formation of the genotoxic degradation product PCA under conditions representative for the preparation of tea infusion cannot be excluded	**Specific comments: –**
Results: Not relevant	**Results:** The overall chronic exposure accounted for 2% of the ADI Tea was identified as the main contributor, accounting for up to 1% of the ADI	**Results:** Long-term exposure: Max 20% of the JMPR ADI GECDE mean: Max. 60% (infants and toddler) GECDE max: Max. 120% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.8.7 | Conclusions

TABLE 49 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 on 31 December 2020, as the application for renewal was withdrawn)
Toxicological assessment	EU TRV available for the parent compound
Residue definitions	For the commodity under discussion (tea), the EU and Codex RD for enforcement are identical; for RA, EU RDs are more comprehensive
Analytical methods	Sufficiently validated analytical methods are available for MRL enforcement
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). The chronic exposure calculation for diflubenzuron was well below the ADI. However, based on the available information, the formation of the genotoxic degradation product PCA in tea infusions cannot be fully ruled out
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.9 | Deltamethrin (135) R

5.9.1 | Background information

TABLE 50 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Approved, process of renewal of the approval ongoing	Commission Directive 2003/5/EC[34] Renewal Assessment Report (RAR) submitted, EFSA peer review on ED clock-stop

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

TABLE 50 (Continued)

		Comments, references
EFSA conclusion available	No	EFSA peer review ongoing (additional data requested)
MRL review performed	Yes, see comments	EFSA (2015h)
EU MRL applications or other EU assessments	Yes, see comments	Art. 10 in cherries (additional data requested) EFSA (2022g) (maize/corn) EFSA (2022c) (import tolerance in mangoes and papayas) EFSA (2022b) (Art. 12 confirmatory data and MRLs modification in tomatoes and okra/lady's fingers) EFSA (2020d) (carobs/Saint John's breads) EFSA (2018f) (kale) EFSA (2017a) (celery, Florence fennel and rhubarb)
Classification of a.s. (cut-off criteria)	No, see comments	Deltamethrin does not fall under cut-off criteria ATP01[35]
Endocrine effects of a.s.	Assessment ongoing	–
Other relevant information	Deltamethrin is authorised for use in veterinary medicine. It is also used as a biocide	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.9.2 | Toxicological reference values

TABLE 51 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.01 mg/kg bw per day	JMPR (2000)	0.01 mg/kg bw per day	Commission Directive 2003/5/EC	Yes
ARfD	0.05 mg/kg bw	JMPR (2000)	0.01 mg/kg bw	Commission Directive 2003/5/EC	No
Conclusion/comments a.s.	The RMS highlighted that the EU TRV may be revised in the framework of the ongoing process of renewal of the approval. The discussions in an expert meeting took place in June 2023, but since the a.s. is currently on clock-stop due to ED assessment, the new TRV are not yet published/adopted				
Comments on metabolites	Metabolites included in JMPR RD for RA: – • alpha-*R*-isomer • *trans*-isomer No toxicological information available Metabolites included in EU RD for RA: • alpha-*R*-isomer • *trans*-isomer No toxicological information available				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.9.3 | Residue definitions

TABLE 52 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of the deltamethrin and its *trans*- and alpha-*R*-isomers	Reg. 396/2005: Deltamethrin (cis-deltamethrin) MRL review (EFSA, 2015h): Deltamethrin (tentative)	No
	Animal products	Sum of the deltamethrin and its *trans*- and alpha-*R*-isomers The residue is fat soluble	Reg. 396/2005: Deltamethrin (cis-deltamethrin) MRL review (EFSA, 2015h): Deltamethrin (tentative) The residue is fat soluble	No

(Continues)

[35]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 52 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD-RA	Plant products	Sum of the deltamethrin and its *trans*- and alpha-*R*-isomers	MRL review (EFSA, 2015h): Sum of deltamethrin and its alpha-*R*-isomer and *trans*-isomer (tentative)	Yes
	Animal products	Sum of the deltamethrin and its *trans*- and alpha-R-isomers	MRL review (EFSA, 2015h): Sum of deltamethrin and its alpha-*R* isomer and *trans*-isomer (tentative)	Yes
Conclusion, comments	The RMS noted that an additional residue definition for risk assessment might be established in future for all pyrethroid pesticides, which covers the common metabolites: Sum of PBA, PBA(OH) (including their conjugates) and PBAld, using the specific health-based guidance values derived for these compounds (EFSA PPR Panel, 2022b) In addition, it was noted that the alpha-*R*-isomer is most probably an artefact and therefore could be taken out of the residue definition All three mentioned isomers of deltamethrin are diastereomers and can be determined using common multi-residue methods and instruments, involving conventional chromatographic separation. Using GC techniques, the isomers in question are typically chromatographically well separated, but according to the EURL experience, thermally promoted interconversion of isomers occurs, leading to uncertainties and bias in the quantification of the individual isomers. Still, due to the similar detection responses of the isomers, the uncertainty of the summed residue is typically acceptable. In addition, with GC methods may not be sufficiently specific to distinguish between deltamethrin and tralomethrin (see also comments on analytical methods). Using LC the problems related to thermal isomerization are circumvented It should be noted that neither conventional GC nor conventional LC are capable of separating enantiomeric pairs. The current RD-wordings (of both EU and JMPR) refer to single isomers disregarding the inability of conventional methods to distinguish between the above stated isomers and their respective enantiomers (this is rather a formal aspect)			

Abbreviations: GC, gas chromatography; LC, liquid chromatography; MRL, maximum residue level; RD-RA, residue definition for risk assessment; RD enf, residue definition for enforcement practice.

5.9.4 | Analytical methods

TABLE 53 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Deltamethrin (*cis*-isomer)			
Plant commodities: High water content	Yes	0.02	Extraction with acetone followed by dichloromethane/petroleum ether mixture; clean-up by GPC; determination by GC-ECD. EURL data show successful validation in high water content commodities using GC–MS/MS (LOQ of 0.005 mg/kg) On specificity of GC methods, see conclusion below
***trans*-isomer**			
Plant commodities: High water content	Yes	0.02	Extraction with cyclohexane or hexane; clean-up by GPC; determination by GC-ECD. Based on EURL validation data and the experience gained for Deltamethrin (*cis*-isomer), an LOQ of 0.005 mg/kg is supposed achievable also for the *trans*-isomer. On specificity of GC methods, see conclusion below
α-*R*-isomer			
Plant commodities: High water content	No validation data reported	–	At JMPR level, recovery data on the alpha-*R*-isomer are available for milk, liver, beef and chicken muscle with an LOQ of 0.005 mg/kg, each, as well as for diverse food and feed products related to maize, wheat and rice, with an LOQ of 0.02 mg/kg (FAO and WHO, 2002b). The data do not meet the current criteria for validations in the EU (just two replicate experiments per level and matrix provided). Based on EURL validation data and the experience gained for deltamethrin (*cis*-isomer), an LOQ of 0.005 mg/kg is supposed achievable also for the alpha-*R*-isomer, however only in cases where the *cis*-isomer is absent or at very low levels (unlikely case). In the presence of *cis*-deltamethrin as transformation to alpha-*R*-deltamethrin takes place in the GC injector, affecting the quantification of the latter On specificity of GC methods, see conclusion below

TABLE 53 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is not fully comparable with the JMPR residue definition The current EU MRL for food commodity under discussion (i.e. papaya) is lower than the Codex MRL proposal Sufficient analytical methods for the enforcement of the MRL for papaya are not available for all components included in JMPR's RD. Validation data for the **α-*R*-isomer** are missing in the requested commodity group (high water content) For the other two components entailed in the JMPR-RD (**deltamethrin** and its ***trans*-isomer)**, adequate analytical methods for the enforcement of the MRL for papaya are available EURLs also highlighted that with GC methodologies, deltamethrin cannot be distinguished from tralomethrin, as tralomethrin quantitatively decomposes within the GC-Injector to deltamethrin via the elimination of Br_2 Using GC, there are some uncertainties created due to isomerisations taking place within the hot injector, but still, the quantification of the summed residue of all three isomers is less affected Using LC techniques, accurate analysis of the individual isomers is possible, provided that chromatographic separation is sufficient		

Abbreviations: GC-ECD, gas chromatography with electron capture detector; GC–MS/MS, gas chromatography with tandem mass spectrometry; GPC, Gel Permeation Chromatography; LC, liquid chromatography; LOQ, limit of quantification; MRL, maximum residue level.

5.9.5 | Codex MRL proposals

TABLE 54 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Papaya	**0.2**	0.01*	cGAP: Brazil, 3 × 12.5 g/ha, 14-day RTI, 1-day PHI Number of trials: 4 Sufficiently supported by data: Yes Specific comments: In the residue trials, the pulp and the peel were analysed separately. The results for the whole fruit was reconstituted from pulp and peel results **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
General comments	–		

Abbreviations: cGAP, critical Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.
*Indicates that the input value is proposed at the limit of quantification.

5.9.6 | Consumer risk assessment

TABLE 55 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 papaya only	**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 papayas. In addition, the calculations were updated, taking into account the recently voted MRLs and the corresponding STMR values (PLAN/2023/326)	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment Papayas: 4.2% of ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 96% of the ADI The contribution of papayas accounted for less than 0.01% of the ADI	**Results:** Long-term exposure: Max 100% of the JMPR ADI. GECDE mean: Max. 520% (children and adolescents) GECDE max: Max. 1100% (children and adolescents) Short-term exposure: Highest result for papaya: 1% of ARfD

Abbreviations: ARfD, acute reference dose; ADI, acceptable daily intake; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.9.7 | Conclusions

TABLE 56 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 (EFSA peer review currently on clock-stop)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RD for RA are identical; for RA, the JMPR RDs are more comprehensive
Analytical methods	Sufficient analytical methods for the enforcement of the MRL for papaya are not available for all components included in JMPR's RD. Validation data for the alpha-*R*-isomer are missing in the requested commodity group (high water content). However, the alpha-*R* isomer is most probably an artefact
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	Proposed Codex MRL is sufficiently supported by data and is unlikely to pose a risk for consumers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.10 | Prochloraz (142) R/T

5.10.1 | Background information

TABLE 57 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	Assessment of toxicology only. The residue evaluation of prochloraz was deferred to the 2024 JMPR meeting
RMS	IE	
Approval status	Not approved	Commission Implementing Regulation (EU) No 1143/2011[36] Expiration of approval: 31/12/2021; The application for renewal was withdrawn
EFSA conclusion available	Yes, see comments	EFSA (2011c) EFSA (2015i) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for prochloraz in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2018m)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2023i) (Targeted risk assessment for prochloraz following the expiry of the EU approval)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria CLP00[37] (not reviewed by ECHA)
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Prochloraz is subject to PIC Regulation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

[36]Commission Implementing Regulation (EU) No 1143/2011 of 10 November 2011 approving the active substance prochloraz, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC Text with EEA relevance. OJ L 293, 11.11.2011, p. 26–30.

[37]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.

5.10.2 | Toxicological reference values

TABLE 58 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.02 mg/kg bw per day	JMPR (2023)	0.01 mg/kg bw per day	Reg. (EU) No 1143/2011	No
ARfD	0.2 mg/kg bw	JMPR (2023)	0.025 mg/kg bw	Reg. (EU) No 1143/2011	No
Conclusion/comments a.s.	The JMPR established the ADI based on an overall NOAEL of 1.7 mg/kg bw per day for macroscopic and microscopic signs of liver toxicity in two 2-year studies in rats. The ADI is supported by an overall NOAEL of 2.5 mg/kg bw per day from 90-day and 1-year studies in dogs. The JMPR noted a margin of 1300 between the ADI and the LOAEL for hepatocellular adenomas and carcinomas in mice. The JMPR further noted that the previously set ADI of 0.01 mg/kg bw per day, now withdrawn, was based on increased alkaline phosphatase levels (ALP) and minimal histopathological effects in one 2-year dog study, these effects being currently considered as isolated changes in dogs and not adverse The ARfD of JMPR is based on a NOAEL of 20 mg/kg bw for clinical signs, effects on motor activity and rearing counts, righting reflex and approach response, and reduced body temperature observed in an acute neurotoxicity study in rats. The previously set ARfD of 0.1 mg/kg bw, now withdrawn, was based on ALP changes in dogs in a 14-day study that are now considered isolated finding and not adverse An UF of 100 was applied to both the ADI and ARfD The EU ADI is based on the NOAEL of 0.9 mg/kg bw per day for increased liver weight, biochemical changes and histopathology observed in a 2-year dog study, applying an UF of 100 The EU ARfD is based on an overall NOAEL of 2.5 mg/kg bw per day taking into consideration effects seen in the 14-day (increased in AP activity after 3 days treatment) and 90-day (emesis and salivation) studies in dogs, and multigeneration reproduction toxicity study in rats (increased gestation length in two regulatory studies and nipple retention reported in the open literature), and applying an UF of 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: The Codex residue definitions will be reviewed by 2024 JMPR The current residue definition for risk assessment at Codex level cover the parent compound prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz 2023 JMPR assessed some studies on toxicologically relevant metabolites, i.e. • BTS 44596 • BTS 9608 • BTS 45186 • BTS 3037 These metabolites are considered not genotoxic and covered by the TRV of the parent • BTS 44595 • BTS 54906 • BTS 44770 Not genotoxic or no genotoxicity alerts, JMPR recommended assessment according to TTC Cramer class III				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LOAEL, lowest observed adverse effect level; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition; TTC, threshold of toxicological concern; UF, uncertainty factor.

5.10.3 | Residue definitions

TABLE 59 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	RD will be reviewed by 2024 JMPR Current RD: Sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz	Reg. 396/2005: Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) MRL review (EFSA, 2018m): Sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz Peer review (EFSA, 2011c): Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz	No (current RD)

(Continues)

TABLE 59 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	RD will be reviewed by 2024 JMPR. Current RD: Sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz The residue is fat soluble	Reg. 396/2005: Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) MRL review (EFSA, 2018m): Sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz Peer review (EFSA, 2011c): Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz The residue is fat soluble	No (current RD)
RD-RA	Plant products	RD will be reviewed by 2024 JMPR. Current RD: Sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz	MRL review (EFSA, 2018m): prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety Peer review (EFSA, 2011c): Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz	Yes (current RD)
	Animal products	RD will be reviewed by 2024 JMPR. Current RD: Sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz	MRL review (EFSA, 2018m): Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz Peer review (EFSA, 2011c): Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz	Yes (current RD)
Conclusion, comments	The Codex residue definitions will be reviewed by 2024 JMPR			

Abbreviations: RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; MRL: maximum residue level.

5.10.4 | Analytical methods

Not relevant, no Codex MRL proposals derived by JMPR.

5.10.5 | Codex MRL proposals

No CXL proposals were derived by JMPR.

5.10.6 | Consumer risk assessment

Not relevant, no CXL proposals were derived by JMPR.

5.10.7 | Conclusions

TABLE 60 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 on 31 December 2021; application for renewal was withdrawn)
Toxicological assessment	EU TRV available
Residue definitions	Review was deferred to 2024 JMPR
Analytical methods	Review was deferred to 2024 JMPR
Codex MRL proposals	Review was deferred to 2024 JMPR

TABLE 60 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Dietary risk assessment	Review was deferred to 2024 JMPR
Final conclusion	To await outcome of assessment by 2024 JMPR

Abbreviations: a.s., active substance; TRV, toxicological reference value.

5.11 | Carbosulfan (145) R/T

5.11.1 | Background information

TABLE 61 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Periodic review	
RMS	BE	
Approval status	Not approved	Commission Decision (EC) 2007/415/EC[38]
EFSA conclusion available	Yes, see comments	EFSA (2009f)
MRL review performed	Yes, see comments	EFSA (2014a) (combined MRL review for carbofuran, carbosulfan, benfuracarb and furathiocarb under Art. 43)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2008c) (Art. 43 assessment)
Classification of a.s. (cut-off criteria)	No, see comments	Carbosulfan does not fall under cut-off criteria. ATP01[39]
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Carbosulfan is subject to PIC Regulation Carbosulfan is a precursor of carbofuran, which is also used as a.s. as such	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.11.2 | Toxicological reference values

TABLE 62 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.01 mg/kg bw per day	JMPR (2023)	0.005 mg/kg bw per day	EFSA (2009)	No
ARfD	0.02 mg/kg bw	JMPR (2023)	0.005 mg/kg bw	EFSA (2009)	No
Conclusion/comments a.s.	JMPR based the ADI on an overall point of departure of 1.3 mg/kg bw per day derived from the NOAEL values of 1.2 mg/kg bw per day in the 13-week neurotoxicity study in rats, 1 mg/kg bw per day for toxicity in the 104-week study of toxicity and carcinogenicity in rats, and 1.3 mg mg/kg bw per day for parental and offspring toxicity in the three-generation reproductive toxicity study in rats. The NOAEL of 0.38 mg/kg bw per day in the 90-day rat study was not considered appropriate to derive the ADI because of the wide dose spacing, with the lowest observed adverse effect level (LOAEL) of 9.8 mg/kg bw per day. A safety factor of 100 was used The ARfD was based on the NOAEL of 0.5 mg/kg bw in the acute neurotoxicity study in rats. A safety factor of 25 was considered appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than the area under the concentration–time curve (AUC) The EU ADI and ARfD are based on an acute neurotoxicity study with a NOAEL of 0.5 mg/kg bw for brain acetylcholinesterase inhibition, applying an uncertainty factor of 100				

(Continues)

[38]2007/415/EC: Commission Decision of 13 June 2007 concerning the non-inclusion of carbosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C(2007) 2463) (Text with EEA relevance). OJ L 156, 16.6.2007, p. 28–29.

[39]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 62 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Comments on metabolites	Metabolites included in **JMPR RD for RA**: – Carbofuran JMPR derived an ADI and an ARfD of 0.001 mg/kg bw (per day) (details see Section 5.4.2). JMPR noted that the TRV only apply to sources of carbofuran that have a purity of 99.8% or greater JMPR should be asked to specify the impurities present in the batches which gave positive results in genotoxicity tests. In addition, JMPR should be asked for clarification whether the proposed ADI/ARfD based on carbofuran with a purity of at least 99.8% can be applied to carbofuran being a metabolite of carbosulfan (as the purity of the metabolite cannot be specified) – 3-hydroxy carbofuran Information presented in JMPR 2023 for 3-hydroxycarbofuran: Acute oral LD_{50}: 8.3 to 21.9 mg/kg bw (rat), not genotoxic in in vitro assays for gene mutation in bacteria and mammalian cells and in vitro MN test (purity 99.1%) (in conflict with information assessed by EFSA in 2009); the metabolite acts as a cholinesterase inhibitor (potency similar to parent based on acute toxicity) – 3-hydroxy-7-phenol carbofuran Not genotoxic based on QSAR analysis; no evidence of clinical signs consistent with anticholinesterase effects in the acute toxicology studies in rats – 3-keto-7-phenol carbofuran Not genotoxic based on QSAR analysis; NOAEL for parental and offspring toxicity in a one-generation reproduction study was 2.5 mg/kg bw per day, the highest dose tested. There was no evidence of toxicity associated with the inhibition of AChE JMPR concluded that the ADI and ARfD of the parent apply also to 3-hydroxy-carbofuran, 3-hydroxy-7-phenol-carbofuran and 3-keto-7-phenol-carbofuran, expressed as carbofuran. As the TRVs for carbosulfan are higher than those for carbofuran and its metabolites, JMPR included relative potency factor of 10 and 20 in the residue definitions for chronic and acute risk assessment, respectively (see also Section on residue definition, 5.11.3) Metabolites included in **EU RD for RA**: – Carbofuran The EU ADI and ARfD of 0.00015 mg/kg bw are based on the LOAEL of 0.03 mg/kg bw for a significant inhibition of the brain AChE (of 20%) in pups from the acute neurotoxicity studies, and applying an uncertainty factor of 200. The use of a supplementary assessment factor of 2 was supported by a benchmark dose approach for a 10% decrease of brain AChE, resulting in an overall uncertainty factor of 200 (EFSA, 2009f), see also Section 5.4.2 on carbofuran – 3-hydroxy carbofuran This metabolite of carbofuran was addressed in the carbofuran dossier. 3-hydroxy carbofuran is genotoxic in vitro (positive results in an Ames test and in a TK locus in L5178Y mouse lymphoma cells assay) (in conflict with information in JMPR 2023); In 2009, it was concluded that the reference values of carbofuran could be applied to this metabolite (EFSA, 2009f) – 3-keto carbofuran This metabolite of carbofuran was addressed in the carbofuran dossier. In 2009, it was concluded that the reference values of carbofuran could be applied to this metabolite (EFSA, 2009f) It is noted that, based on the information available in the EU carbofuran dossier, a similar genotoxicity profile was concluded between the parent and metabolite 3-hydroxy-carbofuran, i.e., positive for gene mutation in vitro for both substances and carbofuran showing negative results in an in vivo study (sex-linked recessive lethal test in *Drosophila melanogaster*—OECD TG 477) (EFSA, 2009f) It is noted that according to current standards, the in vivo tests performed on the parent may not be sufficiently sensitive to dismiss the positive results obtained in vitro. The respective OECD test guidelines 477 have been deleted meanwhile. In view of the current approach on the assessment of genotoxicity, the RMS, BE, reviewed the information available in the EU carbofuran dossier and expressed agreement with the EFSA comments: 'While the now outdated SLRL (sex-linked recessive lethal test in *Drosophila melanogaster* – OECD TG 477) is the most sensitive assay within the *D. melanogaster* in-vivo model, it cannot be completely excluded that positive in-vitro findings in bacterial or mammalian cells should be tested in a more accurate in-vivo assay for the detection of gene mutations, e.g. the in-vivo comet or the transgenic assay. On the other hand, while some published articles indicated some genotoxicity in-vivo, the most relevant and recent guideline GLP studies in the EU-dossier did not indicate CA or MN induction' In addition, the RMS confirmed the positive results obtained with 3-OH carbofuran in bacterial (2 out of 4 runs with metabolic activation were positive, and one equivocal in the same strain TA1537; no test available in strain TA97, which is more sensitive for detecting frame-shift mutations) and mammalian cells (mutagenic in the TK mutation system with and without metabolic activation), while no in vivo test is available with the metabolite This conclusion is supported by some open public literature, showing some similarity with carbofuran itself Since 3-OH-carbofuran is the main metabolite of carbofuran in mammalian cells, the metabolite is considered likely to share a similar toxicological profile as the parent and it may be discussed whether the current database is still sufficient to conclude on the genotoxicity profile of carbofuran and its metabolite 3-OH-carbofuran				

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

5.11.3 | Residue definitions

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 carbosulfan and carbofuran (expressed as carbosulfan)	Reg. 396/2005: Carbofuran (sum of carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb) and 3-OH carbofuran expressed as carbofuran	No
	Animal products	Not established Fat solubility not specified	Reg. 396/2005: 3-OH-carbofuran (free and conjugated) expressed as carbofuran Peer review (EFSA, 2009f): No precise definition can currently be proposed due to outstanding data and information (preferably the same as for risk assessment pending information on the efficiency of the analytical method and the establishment of a conversion factor for 3-keto-carbofuran) The residue is not fat soluble	Not applicable
RD-RA	Plant products	**For long-term dietary exposure:** Carbosulfan plus 10× (sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan **For acute dietary exposure**: Carbosulfan plus 20× (sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan	Peer review (EFSA, 2009f): Carbofuran plus 3-hydroxy carbofuran plus 3-keto carbofuran and their conjugates expressed as carbofuran (uses with soil application)	No
	Animal products	Not established	Peer review (EFSA, 2009f): 3-hydroxy carbofuran and 3-keto carbofuran, free and conjugated expressed as carbofuran	Not applicable
Conclusion, comments	**Plant commodities:** JMPR investigated carbosulfan metabolism in various crops, including citrus, maize, rice, sugar beet, alfalfa and soybean. Metabolic pathways involve hydrolysis to carbofuran and dibutylamine or oxidation to carbosulfan sulfone. Carbofuran further oxidises to 7-phenol, forming 3-hydroxy-7-phenol and 3-keto-7-phenol. Alternatively, it becomes N-hydroxymethyl carbofuran or 3-hydroxy/3-keto carbofuran. Metabolites exist in conjugated/non-conjugated forms Major foliar residues are carbosulfan, carbofuran and dibutylamine; soil applications yield carbofuran and 3-hydroxy carbofuran, with phenol-derivatives increasing. Dibutylamine declines in immature plants. Residues in mature sugar beet roots, maize/rice grain are low for identification; soybeans/maize stover contain minimal 3-hydroxy carbofuran and phenol-derivatives **Rotational crops**: JMPR concluded that significant residues of carbosulfan metabolites are not expected in food commodities from rotational crops, but there is a potential for metabolite residues to be taken up in feed commodities. **Animal commodities:** Carbosulfan undergoes rapid metabolism and excretion in animals, typically detected at very low levels (< 2% TRR). Predominant metabolites include 3-hydroxy-carbofuran (found in poultry muscle, milk and kidney) and dibutylamine (found in poultry muscle and liver), with carbofuran being a minor component in all matrices. In goats, the proposed metabolic pathway involves hydrolytic cleavage of the N–S bond to form dibutylamine and carbofuran, followed by the formation of carbamate derivatives or phenolic carbofuran derivatives The EU residue definition for enforcement is more comprehensive than the one proposed by JMPR. For risk assessment the residue definitions are not compatible		

Abbreviations: RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TRR: total radioactive residues.

5.11.4 | Analytical methods

TABLE 64 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Carbosulfan			
Plant commodities: High water content High acid content	Yes	0.05	Analysis performed on 'properly stored, frozen samples in order to prevent degradation' (FAO and WHO, 2004a); extraction with hexane/2-propanol, acetonitrile or acetone, clean-up by partitioning steps and/or SPE; determination by GC- or LC techniques using different detectors EURLs have validated carbosulfan after conversion to carbofuran in high water and high acid content commodities (LOQ of 0.001 mg/kg). This methodology is however not specific to carbosulfan. This LOQ is supposed to be also achievable for the other commodities of plant origin, with exception of difficult commodities for which additional experience needs to be gained
Carbofuran and 3-hydroxy-carbofuran			
Plant commodities: High water content	Yes	0.05 (each)	Extraction with hexane/2-propanol, acetonitrile or acetone, clean-up by partitioning steps and/or SPE; determination by GC- or LC techniques using different detectors EURLs data show successful validation for both compounds in high water content commodities (LOQ of 0.001 mg/kg each)
Plant commodities: High water content (banana)	Yes	0.01 (each)	Successful validation reported but without giving details on method and validation figures (FAO and WHO, 2013). The EURLs are of the opinion that bananas may be represented by high water content commodities
Plant commodities: High acid content	Yes	0.05 (each)	Extraction with hexane/2-propanol, acetonitrile or acetone, clean-up by partitioning steps and/or SPE; determination by GC- or LC techniques using different detectors EURLs data show successful validation for both compounds in high acid content (LOQs at 0.001 mg/kg each) and in dry commodities (LOQs at 0.005 mg/kg each) EURLs data show successful validation for Carbofuran in high oil content commodities (LOQ at 0.005 mg/kg)
Conclusion	The EURLs noted that carbosulfan (as well as benfuracarb and furathiocarb) are precursor compounds of carbofuran. All three precursors tend to degrade to carbofuran at various stages after their application, including during food processing but also during analysis. In an experiment by the EURL for Single Residue Methods (EURL-SRM), it was further shown that during household processing considerable fractions of carbosulfan, benfuracarb and furathiocarb will transform to carbofuran The EU residue definition for MRL enforcement for the relevant matrix groups are not identical/not equivalent with the JMPR residue definition The current EU MRLs for food commodities belonging to the matrix groups of high water content commodities (eggplant and mango) are lower than the Codex MRL proposals under discussion Validated analytical methods for the enforcement of the MRLs for these matrices are only partially available at JMPR level		

Abbreviations: GC, gas chromatography; LC, liquid chromatography; LOQ, limit of quantification; MRL, maximum residue level; SPE, solid-phase extraction.

5.11.5 | Codex MRL proposals

TABLE 65 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus pulp, Dry	0.1 (W)	–	The existing CXL is proposed for withdrawal
Cotton seed	0.03* (W)	0.1	The existing CXL is proposed for withdrawal. In EU a higher MRL is applicable
Edible offal (mammalian)	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Eggplant	**0.15**[a]	0.002*	cGAP: Thailand: 3 × 60 g a.s./hL (use of carbosulfan), 7-day RTI, 9-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: Residue trials were analysed for carbosulfan and carbofuran

TABLE 65 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is not acceptable because there is an acute intake concern was identified in the JMPR and the EU risk assessment (see risk assessment section) Follow-up action: None
Eggs	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Maize	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Maize forage	0.05* (W)	–	The existing CXL is proposed for withdrawal
Mandarin	0.1 (W)	0.01*	The existing CXL is proposed for withdrawal
Mango	**0.1**[a]	0.01*	cGAP: Thailand 3 × 60 g a.s./hL (approx. 0.84–0.92 kg/ha of carbosulfan), 7-day RTI, 14-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: Trials were analysed for carbosulfan and carbofuran **Conclusion:** The proposed Codex MRL is not acceptable because there is an acute intake concern identified in the JMPR and the EU risk assessment (see risk assessment section) Follow-up action: None
Meat (from mammals other than marine mammals)	0.05* fat (W)	– Muscle: 0.01*	The existing CXL is proposed for withdrawal
Milks	0.03* (W)	0.001*	The existing CXL is proposed for withdrawal
Oranges, sweet, sour (subgroup)	0.1 (W)	0.01*	The existing CXL is proposed for withdrawal
Potato	0.05 (W)	0.001*	The existing CXL is proposed for withdrawal
Poultry meat	0.05* (W)	– Muscle: 0.01*	The existing CXL is proposed for withdrawal
Poultry, edible offal of	0.05* (W)	0.01*	The existing CXL is proposed for withdrawal
Rice	0.05* (W)	–	The existing CXL is proposed for withdrawal
Rice straw and fodder, dry	0.05* (W)	–	The existing CXL is proposed for withdrawal
Spices, fruits and Berries	0.07 (W)	0.05*	The existing CXL is proposed for withdrawal
Spices, roots and rhizomes	0.1 (W)	0.05*	The existing CXL is proposed for withdrawal
Sugar beet	0.3 (W)	0.01*	The existing CXL is proposed for withdrawal
Sugar beet leaves or tops	0.05* (W)	–	The existing CXL is proposed for withdrawal
General comments	–		

Abbreviations: cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval; 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]JMPR concluded that the estimated acute dietary exposure to residues of carbosulfan for the consumption of mangoes and eggplants exceeds the ARfD and therefore may present a public health concern.

5.11.6 | Consumer risk assessment

TABLE 66 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 derived for carbosulfan 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 (mangoes and eggplants), using the HR derived by JMPR The calculations are indicative, because the residue definition for RA derived by JMPR is different than EU. Hence the risk assessment is affected by a high level of uncertainty	**RA assumptions:** The risk assessment was performed with the EU ADI derived for carbosulfan A long-term dietary risk assessment was performed using PRIMo rev. 3.1, the STMR values derived by JMPR for the commodities for which Codex MRLs were derived. For the remaining commodities, the calculations were performed with the existing MRLs and default LOQ of 0.01 mg/kg The calculations are indicative, because the RA derived by JMPR is different than EU. Hence the risk assessment is affected by a high level of uncertainty	**Specific comments:** –

(Continues)

TABLE 66 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: The calculated short-term exposure exceeded the ARfD for all crops under assessment Mangoes: 2044% of ARfD Eggplants: 455% of ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 11% of the ADI Among the crops under consideration, eggplants were identified as the main contributor, accounting for up to 2% of the ADI (GEMS/Food G06)	**Results:** Long-term exposure: Max 2% of the JMPR ADI GECDE mean 70% of ADI GECDE max. 390% ADI (children and adolescents diet) Short-term exposure: Highest result for mangoes: 310% of ARfD egg plants: 210% of ARfD derived by JMPR

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.11.7 | Conclusions

TABLE 67 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU, EU assessments available
Toxicological assessment	EU TRV available. Divergent conclusions on toxicological profile of parent and metabolites from EU and JMPR Assessments
Residue definitions	EU and Codex RDs are not comparable/not fully compatible
Analytical methods	Validated analytical methods are available. EURLs reported validation data for EU RDs for MRL enforcement
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. However, see results of risk assessment
Dietary risk assessment	An acute intake concern was identified by EFSA and by JMPR
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.12 | Propiconazole (160) R

5.12.1 | Background information

TABLE 68 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	FI	
Approval status	Not approved	Commission Implementing Regulation (EU) 2018/1865[40]
EFSA conclusion available	Yes, see comments	EFSA (2017b) EFSA (2018k) (conclusion confirmatory data on TDMs)
MRL review performed	Yes, see comments	EFSA (2015a)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2021a) (Art. 12 confirmatory data)
Classification of a.s. (cut-off criteria)	Yes, see comments	Toxic for reproduction cat. 1A/1B ATP13,[41] ECHA (2016)

[40]Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 304, 29.11.2018, p. 6–9.

[41]Commission Regulation (EU) 2018/1480 of 4 October 2018 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 Commission Regulation (EU) 2017/776. OJ L 251, 5.10.2018, p. 1–12.

TABLE 68 (Continued)

		Comments, references
Endocrine effects of a.s.	Yes, see comments	EFSA (2017b) In the EU concern form submitted in 2021 to CCPR, the EU highlighted that EFSA was unable to conclude on the endocrine disrupting potential of propiconazole. In the EU evaluation, toxic effects have been observed on endocrine organs in the available data. Given the positive results observed in vitro for oestrogen and androgen receptor antagonism, AhR (aryl hydrocarbon receptor) agonism and aromatase inhibition and in the absence of a full investigation of the possibly related endpoints in the two-generation reproductive toxicity study (in particular the lack of sperm parameters), the possibility that propiconazole is an endocrine disruptor cannot be excluded. Further investigations of the endocrine disruption potential of propiconazole would be needed in particular on the male reproductive toxicity including a complete sperm analysis Under the framework of the biocide legislation, propiconazole is considered as having endocrine-disrupting properties that may cause adverse effects in humans (recital 5 of the Commission Implementing Regulation (EU) 2023/2596)[42] (ECHA, 2022)
Other relevant information	Propiconazole belongs to the class of triazole fungicides; it is authorised for use in veterinary medicine and as a biocide; in addition, this a.s. is subject to PIC regulation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.12.2 | Toxicological reference values

TABLE 69 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.07 mg/kg bw per day	JMPR (2004)	0.04 mg/kg bw per day	Reg. (EU) 2018/1865	No
ARfD	0.3 mg/kg bw	JMPR (2004)	0.1 mg/kg bw	Reg. (EU) 2018/1865	No
Conclusion/comments a.s.	JMPR (FAO and WHO, 2004b): The ADI is based on the NOAEL of 7 mg/kg bw per day in a multigeneration study of reproductive toxicity in rats and a 100-fold safety factor The ARfD is based on the NOAEL of 30 mg/kg bw per day in the study of developmental toxicity in rats and a 100-fold safety factor EU: The ADI is based on long-term NOAEL of 3.6 mg/kg bw per day in the 2-year study. An uncertainty factor of 100 was applied The ARfD is based on developmental NOAEL of 30 mg/kg bw per day in the developmental toxicity study in rats. A standard uncertainty factor of 100 was applied during the first review. The experts agreed to apply an additional uncertainty factor of 3 to the standard uncertainty factor of 100 to obtain a higher MOS with regard to the lowest observed adverse effect level (LOAEL) for the severe effects on cleft palate (EFSA, 2017b) In the EU concern form submitted in 2021 to CCPR, the EU highlighted that the ADI and ARfD values established by the EU are lower than those of the JMPR: In the EU assessment, the NOAEL of the 2-year study in rats was set at 100 ppm corresponding to 3.6 mg/kg bw per day for males and 4.6 mg/kg bw per day for females based on statistically significantly reduced bodyweight gain in females over the first year of the study and statistically significantly reduced adrenal weights in males at the end of the study in animals treated with 500 ppm. It is acknowledged that this conclusion is conservative JMPR considered the slight reduction in adrenal weights and slight reduction in bodyweight gain, in the absence of any related findings, as not adverse Regarding the setting of the ARfD, an additional UF of 3 was applied in the EU to obtain a higher MOS with regard to the LOAEL (lowest observed adverse effect level) for the severe effects on cleft palate. This conclusion was reached by consensus between the EU experts. JMPR considered that the margin between the ARfD of 0.3 mg/kg bw and the LOAEL for the severe effect of cleft palate and maternal toxicity at 300 mg/kg bw per day was adequate				
Comments on metabolites	Metabolites included in JMPR RD for RA: – all metabolites convertible to 2,4-dichlorobenzoic acid The common moiety is unspecific and covers a number of metabolites (e.g. CGA91305, SYN547889, NOA436613). See below on metabolites included in EU RD for RA				

(Continues)

[42]Commission Implementing Regulation (EU) 2023/2596 of 21 November 2023 renewing the approval of propiconazole as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L, 22.11.2023, p. 1–9.

TABLE 69 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
	Metabolites included in EU RD for RA: – CGA118244 (3,5-dideoxy-1,2-*O*-[(1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl)ethylidene]-D,L-pentitol) There is not sufficient information to conclude on the genotoxicity and general toxicity (EFSA, 2017b). The metabolite is not covered by TRVs of parent – all metabolites convertible to 2,4-dichlorobenzoic acid The common moiety is unspecific and covers a number of metabolites (CGA91305, SYN547889, NOA436613). In 2021, EFSA concluded that more detailed qualitative and quantitative comparison to parent is missing for concluding on the toxicological profile of these metabolites, even if they are considered unlikely to be genotoxic – CGA91305 ((1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl) ethanol) There is not sufficient information to conclude on the genotoxicity and general toxicity (EFSA, 2017b). The metabolite is not covered by TRVs of parent TDMs – CGA142856 (TAA) An ADI of 1 mg/kg bw per day and an ARfD of 1 mg/kg bw have been set (EFSA, 2018k). The ADI and ARfD of this metabolite are higher than those of propiconazole. Therefore, CGA142856 (TAA) is covered by the TRVs of the parent – CGA131013 (TA) An ADI of 0.3 mg/kg bw per day and an ARfD of 0.3 mg/kg bw have been set (EFSA, 2018k). The ADI of this metabolite is higher than that of propiconazole and the ARfD of this metabolite is the same as that of propiconazole. Therefore, CGA131013 (TA) is covered by the TRVs of the parent – CGA71019 (1,2,4-triazole) An ADI of 0.023 mg/kg bw per day and an ARfD of 0.1 mg/kg bw have been set (EFSA, 2018k). The ADI of this metabolite is lower than that of propiconazole. The ARfD of this metabolite is the same as that of propiconazole. Therefore, CGA71019 (1,2,4-triazole) is covered by the ARfD of the parent, but not by the ADI of the parent				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition; UF, uncertainty factor.

5.12.3 | Residue definitions

TABLE 70 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Propiconazole	Reg. 396/2005 (implementing MRL review): Propiconazole (sum of isomers) Peer review (EFSA, 2017b): Propiconazole (sum of isomers)	Yes
	Animal products	Propiconazole The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Propiconazole (sum of isomers) Peer review (EFSA, 2017b): CGA91305 (free and conjugated) The residue is fat soluble	Yes
RD-RA	Plant products	Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	Peer review (EFSA, 2017b): Primary crops: (1) Propiconazole (sum of isomers) (2) CGA 118244 (3,5-dideoxy-1,2-*O*-[(1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl)ethylidene]-D,L-pentitol) free and glucoside conjugated – whether the parent compound and CGA 118244 should be considered together or separately depends on the submission of toxicological data to address the toxicity profile of CGA 118244 (3) TDMs (EFSA, 2018k)	No
	Animal products	Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	Peer review (EFSA, 2017b): (1) propiconazole, CGA91305 (free and conjugated) and CGA118244 (The expression of the residue definition is pending the requested toxicological profile for CGA 91305 and CGA 118244); (2) CGA71019 (1,2,4-triazole)	No

TABLE 70 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	The EU residue definitions for risk assessment are currently provisional; the available metabolism studies with propiconazole which is a racemic mixture of four stereoisomers do not investigate the impact of plant and livestock metabolism on the isomer ratio of propiconazole While the JMPR residue definitions (based on common moiety) appear more comprehensive, they are not appropriate until the genotoxicity of certain metabolites (CGA118244, CGA91304 and CGA118245) is adequately addressed			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TDM, triazole derivative metabolite.

5.12.4 | Analytical methods

TABLE 71 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High oil content Dry commodities	Yes	0.01	DFG S19 method LC–MS/MS detection
Animal products Fat Liver/kidney Eggs	Yes	0.01	DFG S19 method LC–MS/MS detection
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The current EU MRLs for food commodities belonging to the matrix groups high oil content, dry commodities, liver/kidney and fat are lower than the Codex MRL proposal under discussion Sufficiently analytical methods for the enforcement of the MRLs for these matrices are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level.

5.12.5 | Codex MRL proposals

TABLE 72 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	**0.02**	0.01*	cGAP: USA, 2 × 1.26 g a.s./cm, 90-day RTI, 7-day PHI Number of trials: 6 (root infusion) Sufficiently supported by data: Yes Specific comments: Two data sets were available: one comprising 6 trials following trunk injection and 6 trials following root infusion which selected by JMPR due to the highest residue levels. The results were reported for fruits without stones, which were then recalculated to the whole fruit. It was assumed that the stone constitutes 15% of the whole fruit's weight thus the trial results were multiplied with a factor of 1.15. EFSA notes that the calculations were incorrect: the residue results referring to pulp and peel need to be divided by 1.15 (instead of multiplying it with 1.15). Hence, a lower MRL of 0.01 mg/kg would be sufficient **Conclusion:** The proposed Codex MRL is sufficiently supported by data. JMPR should be asked to re-calculate the MRL, as the residues in the whole fruit are expected to be lower than in the pulp plus peel Follow-up action: None
Edible offal (mammalian)	**0.2**	0.01*	Max. dietary burden (beef/dairy cattle): 29 ppm Max. residues in liver: 0.18 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Eggs	0.01*	0.01*	Max. dietary burden (poultry layer): 8.4 ppm Max. residues in eggs: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: Since no measurable residue levels were observed even at the highest feeding level, JMPR confirmed its previous CXL of 0.01* **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

(Continues)

TABLE 72 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	**0.05**	0.01*	Max dietary (beef/dairy cattle): 29 ppm. Max residues in fat: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	0.01*	– Muscle: 0.01*	Max. dietary burden (beef/dairy cattle): 29 ppm Max. residues in muscle: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: Since no measurable residues were observed even at the highest feeding level (75 ppm), JMPR confirmed its previous CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Milks	0.01*	0.01*	Max. dietary burden (beef/dairy cattle): 29 ppm Max. residues in milk: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR confirmed its previous CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Peanut	**0.03**	0.01*	cGAP: USA, 4 × 123 kg a.s./ha, 10-day RTI, 14-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: The trials were analysed only for propiconazole. JMPR applied a conservative default factor of 3 to convert residues of parent to total residues convertible to 2,4-DCBA based on the metabolism studies. Further details on the conversion factor to be checked in JMPR Evaluation **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, as data on the residue definition for risk assessment are not available Follow-up action: To check details in JMPR evaluation
Peanut, hay and/or straw	50 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Poultry fats	0.01*	0.01*	Max. dietary burden (poultry layers): 8.4 ppm Max. residues in fats: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: Since no measurable residues were observed even at the highest feeding level (37.5 ppm), JMPR confirmed its previous CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: To check details in JMPR evaluation
Poultry meat	0.01*	– Muscle: 0.01*	Max. dietary burden (poultry layers): 8.4 ppm Max. residues in liver: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR confirmed its previous CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry, edible offal of	0.01*	0.01*	Max. dietary burden (poultry layers): 8.4 ppm Max. residues in liver: < 0.05 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR confirmed its previous CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Rice bran, processed	80	–	JMPR derived a processing factor of 2.39 (for RD for MRL enforcement). Currently, no EU MRLs are established for processed products
Rice, grain	30	–	See husked rice. EU MRLs are set for husked rice, but not for rice grain
Rice, hulls	80	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice, husked	**4**	0.01*	cGAP: South Korea: 4 × 7 g/hL, 1600 L/ha (resulting in calculated rate of 11.2 g a.s./ha), 7-day RTI, 21-day PHI Number of trials: 10 (Thailand, India and China) Sufficiently supported by data: Yes Specific comments: The trials were conducted at 2.2–3.3 g a.s./hL (underdosed); number of applications not reported. The results were corrected by applying scaling factors ranging from 2.1 to 3.1. For rice grain, a MRL proposal of 30 mg/kg was derived. For deriving the Codex MRL proposal in husked rice, a processing factor (PF) of 0.13 was applied to the proposed Codex MRL in grain

TABLE 72 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is sufficiently supported by data Follow-up action: To check details on the residue trials in JMPR evaluation (number of applications in residue trials)
Rice, polished	10	–	JMPR derived processing factors of 0.07 and 0.12 for MRL enforcement and risk assessment, respectively. Currently, no EU MRLs are established for processed products
Peanut meal	–	–	JMPR derived a processing factor of ≤1. Currently, no EU MRLs are established for processed products
Rice bran, unprocessed	–	–	JMPR derived a processing factor of 2.9. Currently, no EU MRLs are established for processed products
General comments			

Abbreviations: cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; dw, dry weight; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

5.12.6 | Consumer risk assessment

TABLE 73 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment for propiconazole was performed with the EU ARfD The indicative 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 (avocado, peanut, rice-husked mammalian fats, edible offal). For rice, since no STMR-P for husked rice was provided the calculation was done with STMR for polished rice The risk assessment is indicative since the EU residue definitions are provisional (see comments on residue definitions) A risk assessment for TDMs and for the second EU RD could not be performed, as no input data are available reflecting these RDs The calculations are therefore indicative and affected by additional non-standard uncertainties. Moreover, by using the STMR for polished rice may underestimate the residues expected on treated rice	**RA assumptions:** The risk assessment for propiconazole was performed with the EU ADI A long-term dietary risk assessment was performed using PRIMo rev. 3.1, including the STMR values derived by JMPR for avocado, peanut, rice grain and for animal products. For the remaining commodities, the calculations were performed using the MRLs set at the LOQ. For rice, since no STMR-P for husked rice was provided the calculation was done with STMR for polished rice. The risk assessment is indicative since the EU residue definitions are provisional (see comments on residue definitions) A risk assessment for TDMs and for the second EU RD could not be performed, as no input data are available reflecting these RDs The calculations are therefore indicative and affected by additional non-standard uncertainties. Moreover, by using the STMR for polished rice may underestimate the residues on treated rice	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment Bovine edible offal: 36% ARfD Bovine liver: 36% of ARfD Rice: 25% ARfD For the rest of the commodities the acute exposure was below 20% of the ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 11% of the ADI (NL toddler) Rice identified as the main contributor, accounting for up to 8% of the ADI	**Results:** Long-term exposure: Max 20% of the JMPR ADI GECDE Mean: 100% ADI (children/adolescents) GECDE Max: 230 of ADI (infants/toddler) Short-term exposure: Highest result for rice grain: 100% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue; TDM, triazole derivative metabolite.

5.12.7 | Conclusions

TABLE 74 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. a.s. meets EU cut-off criteria
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs for MRL enforcement are identical, but for risk assessment, they are different
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. Clarifications should be requested from JMPR for avocados
Dietary risk assessment	No acute and no chronic intake concern identified. However, the risk assessment is indicative, and could not be performed for all EU residue definitions
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.13 | Boscalid (221) R

5.13.1 | Background information

TABLE 75 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	SK	
Approval status	Approved. Renewal process ongoing	Commission Directive 2008/44/EC[43] Renewal Assessment Report (RAR) submitted, EFSA peer review on clock-stop
EFSA conclusion available	No	EFSA peer review including Art. 12 assessment of confirmatory data currently ongoing (additional data requested)
MRL review performed	Yes, see comments	EFSA (2014d)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2020c) (pomegranates) EFSA (2019d) (honey) EFSA (2015c) (beans and peas with pods)
Classification of a.s. (cut-off criteria)	Not assessed	–
Endocrine effects of a.s.	Assessment ongoing	–
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.13.2 | Toxicological reference values

TABLE 76 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.04 mg/kg bw per day	JMPR (2019, 2006)	0.04 mg/kg bw per day	Commission Directive 08/44/EC	Yes
ARfD	Unnecessary	JMPR (2006)	Not necessary	Commission Directive 08/44/EC	Yes
Conclusion/comments a.s.	The JMPR ADI applies to boscalid plus metabolite M510F49, expressed as boscalid				

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

TABLE 76 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Comments on metabolites	Metabolites included in JMPR RD for RA: – 2-chloro-*N*-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide (M510F01) The metabolite M510F01 is retrieved in urine > 10% of the absorbed dose (oral absorption being around 50% of the administered dose) and is therefore considered covered by the ADI of the parent Metabolites included in EU RD for RA: – 2-chloro-*N*-(4′-chloro-5-hydroxybiphenyl-2-yl nicotinamide) (free and conjugated) (M510F01) – bound residues (measured as M510F53 (*N*-(4′-chlorobiphenyl-2-yl)acetamide) or M510F52 (*N*-(4′-chlorobiphenyl-2-yl)formamide)) A toxicological assessment of the metabolites is ongoing				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.13.3 | Residue definitions

TABLE 77 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	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 offal (except liver and kidney) milk, eggs: Boscalid Kidney, liver: Sum of boscalid and its hydroxy metabolite 2-chloro-*N*-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide (free and conjugated) expressed as boscalid The residue is fat soluble	No (for kidney and liver)
RD-RA	Plant products	Boscalid	MRL review (EFSA, 2014d): Boscalid	Yes
	Animal products	Sum of boscalid, 2-chloro-*N*-(4′-chloro-5-) hydroxybiphenyl-2-yl nicotinamide (M510F01) including its conjugate, expressed as boscalid	MRL review (EFSA, 2014d): Muscle, fat, edible offal (except liver and kidney), milk, eggs: Boscalid Kidney: Sum of boscalid and M510F01 (2-chloro-*N*-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide) (free and conjugated), expressed as boscalid Liver: Sum of boscalid and M 510F01(2-chloro-*N*-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide) (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid	No (except for kidney)
Conclusion, comments	As the renewal process is currently ongoing at EU level, a modification of the EU residue definitions might be proposed. The different residue definitions for some animal products are not of relevance for the current assessment, since no MRL proposals for animal products were derived by JMPR			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.13.4 | Analytical methods

TABLE 78 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High acid content	Yes	0.01	Extraction with QuEChERS extraction, LC–MS/MS (FAO and WHO, 2019)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is identical with the JMPR residue definition The current EU MRL for food commodity under discussion (i.e. pomegranate) is set at the same level as the Codex MRL proposal Sufficiently analytical methods for the enforcement of the MRL for this matrix are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.13.5 | Codex MRL proposals

TABLE 79 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Pomegranate	2	2	cGAP: Greece and Italy, 2 × 0.5 kg/ha, 5-day RTI, 7-day PHI Number of trials: 4 Sufficiently supported by data: Yes Specific comments: Residue concentration measured in whole fruits and in the edible part of the fruits. The GAP was also assessed in the EU **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
General comments	–		

Abbreviations: cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

5.13.6 | Consumer risk assessment

TABLE 80 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 calculations performed in the most recent long-term risk assessment (EFSA, 2020c) were refined, replacing the STMR derived from the residue trials assessed in the EU with the STMR-P (residues measured in the edible part of the crop)	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 75% of the ADI Pomegranates accounted for up to 0.02% of the ADI	**Results:** Long-term exposure: Max 60% of the JMPR ADI GECDE mean: Max. 160% (children and adolescents) GECDE max: Max. 560% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; RA, risk assessment; STMR, supervised trials median residue.

5.13.7 | Conclusions

TABLE 81 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 (EFSA peer review currently on clock-stop)
Toxicological assessment	EU TRV available. They are identical with the JMPR TRV
Residue definitions	EU and Codex RDs for enforcement and risk assessment for plant products are identical. The different residue definitions for some animal products are not of relevance for the current assessment, since no MRL proposals for animal products were derived by JMPR
Analytical methods	According to JMPR assessment, sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRL is sufficiently supported by data
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	The proposed Codex MRL is sufficiently supported by data and is unlikely to pose a risk for consumers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.14 | Difenoconazole (224) R

5.14.1 | Background information

TABLE 82 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Approved, renewal process ongoing	Commission Directive 2008/69/EC[44] Renewal Assessment Report (RAR) submitted, EFSA peer review on ED clock-stop
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 of confirmatory data) EFSA (2018k) (conclusion confirmatory data on TDMs) EFSA (2023k) (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 (additional data requested) Art. 31 peer review on confirmatory data concerning difenoconazole (ongoing)
MRL review performed	Assessment ongoing	
EU MRL applications or other EU assessments	Yes, see comments	Art. 10 import tolerance in various crops (additional data requested) EFSA (2023h) (wheat and rye) (implementation of the new MRL proposals was put on hold due to potential chronic intake concerns and additional uncertainties in relation to metabolites, which will be addressed in other ongoing assessments) EFSA (2021b) (leafy brassica) (implementation of the new MRL proposals was put on hold due to potential chronic intake concerns and additional uncertainties in relation to metabolites, which will be addressed in other ongoing assessments) EFSA (2018d) (various crops) EFSA (2017c) (various crops) EFSA (2014g) (lettuce and other salad plants including Brassicaceae and in basil (mint)) EFSA (2014b) (peppers and aubergines) EFSA (2013c) (various crops) EFSA (2012b) (raspberries, blackberries and cucurbits (edible peel)) EFSA (2011b) (beet leaves (chard), globe artichokes, broccoli, cardoons and strawberries) EFSA (2010c) (peppers and aubergines) EFSA (2010a) (swedes and turnips) EFSA (2009e) (various leafy vegetables)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2021b)
Endocrine effects of a.s.	Assessment ongoing	–
Other relevant information	Difenoconazole belongs to the class of triazole fungicides; the a.s. is listed as a candidate for substitution	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.14.2 | Toxicological reference values

TABLE 83 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.01 mg/kg bw per day	JMPR (2007)	0.01 mg/kg bw per day	European Commission (2013)	Yes
ARfD	0.3 mg/kg bw	JMPR (2007)	0.16 mg/kg bw	European Commission (2013)	No

(Continues)

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

TABLE 83 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Conclusion/comments a.s.	As the renewal process is ongoing, the TRV might change				
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) According to JMPR 2007, this metabolite was also found in rats. The LD_{50} was > 2000 mg/kg bw and the substance did not show alerts for mutagenic activity. Metabolites included in EU RD for RA: – Difenoconazole alcohol (CGA 205375) 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 – TDM Separate TRV were derived for the triazole derivative metabolites				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LD_{50}, lethal dose, median; RD, residue definition; RA, risk assessment; TRV, toxicological reference value; TDM: triazole derivative metabolite.

5.14.3 | Residue definitions

TABLE 84 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Difenoconazole	Reg. 396/2005: Difenoconazole Peer review (EFSA, 2011a): Difenoconazole	Yes
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA205375), expressed as difenoconazole The residue is fat soluble	Reg. 396/2005: Difenoconazole Peer review (EFSA, 2011a): Difenoconazole alcohol (CGA 205375) expressed as difenoconazole According to Reg. 396/2005, the residue is classified as not fat soluble	No
RD-RA	Plant products	Difenoconazole	Peer review (EFSA, 2011a): (1) Difenoconazole (2) TA and TLA, TAA and 1,2,4-triazole (based on conclusion confirmatory data on TDMs) (EFSA, 2018k)	Yes
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol) (CGA205375), expressed as difenoconazole	Peer review (EFSA, 2011a): (1) Difenoconazole alcohol (CGA-205375) expressed as difenoconazole (2) TA and TLA, TAA and 1,2,4-triazole (based on conclusion confirmatory data on TDMs) (EFSA, 2018k)	No
Conclusion, comments	The EU residue definition for MRL enforcement for the relevant matrix groups (plant products) is identical with the JMPR residue definition The enforcement and risk assessment residue definitions for animal commodities are currently not comparable. This has no impact on the current assessment since Codex MRL proposals are not made for animal commodities As the renewal process is ongoing, the residue definitions may be subject to revision The major difference between risk assessment residue definitions derived by the EU and by the JMPR in plant and animal commodities is the fact that JMPR did not consider TDMs			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TDM, triazole derivative metabolite.

5.14.4 | Analytical methods

TABLE 85 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content	Yes	0.003	Extraction with Korean Food Code Method, LC–MS/MS (FAO and WHO, 2018b)
Plant commodities: High acid content	Yes	0.01	Extraction with acetone/water mixture (2:1; v/v), LC–MS/MS (FAO and WHO, 2018b)

TABLE 85 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: Dry commodities	Yes	0.01	Refluxing with methanol/conc. ammonium hydroxide (8;2 v/v), LC–MS/MS (FAO and WHO, 2018b)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition Most of the current EU MRLs for food commodity under discussion are lower than the Codex MRL proposal The current JMPR received validation data for the method REM 147.08 in blackberries, mustard greens, radish roots, radish leaves, maize including several processed maize matrices and potato tubers Sufficiently analytical methods for the enforcement of the MRL for the relevant matrix groups are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level.

5.14.5 | Codex MRL proposals

TABLE 86 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Cane berries	**3**	1.5 (blackberries and raspberries); 0.1 (dewberries)	cGAP: USA, ground or air application, 4 × 126 g a.s./ha, 14-day RTI, 0-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Combined data set of residue trials performed with blackberries (4) and raspberries (4). The JMPR noted that median residues on blackberries and raspberries are within a fivefold difference and the Mann–Whitney U-test also determined that the data sets are not statistically different, therefore the JMPR decided to combine these data sets for a subgroup recommendation **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Maize aspirated grain fractions[a]	–	–	JMPR derived a processing factor of 49.6 (22.2; 77.18). Currently, no EU MRLs are established for processed products
Maize gluten[a]	0.05	–	JMPR derived a processing factor of 3.1 (2.82; 3.39). Currently, no EU MRLs are established for processed products
Maize oil, crude	0.02	–	JMPR derived a processing factor of 1.2 for wet milled refined oil, which was used to derive the MRL for maize crude oil. Hence, according to EFSA, the Codex MRL proposal of 0.02 mg/kg should refer to refined oil. Currently, no EU MRLs are established for processed products
Maize, bran[a]	–	–	JMPR derived a processing factor of 3.2 (2.7; 3.6). Currently, no EU MRLs are established for processed products
Maize, flour	0.015	–	JMPR derived a processing factor of 0.77 (0.68; 0.85). Currently, no EU MRLs are established for processed products
Maize, hay and/or straw[a]	15 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Mustard greens	**8**	4 (Chinese cabbage, baby leaf crops)	cGAP: USA, ground or air application, 4 × 0.128 kg a.s./ha, 7-day RTI, 7-day PHI (cGAP for brassica leafy vegetable, subgroup 13B)[b] Number of trials: 13 (8 for mustard greens, 5 radish leaves) Sufficiently supported by data: Yes Specific comments: MRL proposal for mustard greens was derived from combined data set of trials with mustard greens and radish leaves. The JMPR noted that median residues on mustard greens and radish leaves are within a fivefold difference and the Mann–Whitney U-test also determined that the data sets are not statistically different; therefore, the JMPR decided to combine these data sets. The corresponding commodity in the EU classification is Chinese cabbage (pe-tsai, code 243010). In addition, mustard greens would also be covered by baby leaf crops (including brassica species) (code 251080). The US registration covers the subgroup of brassica leafy vegetable and since mustard greens and radish leaves are representative commodities the extrapolation of the estimates to the subgroup was possible according to Codex practices/rules. However, the JMPR noted that, the international estimate of short-term intake calculation for Chinese cabbage (VL 0466) resulted in a maximum of 120% of ARfD for children, therefore decided to estimate maximum residue level and STMR for the individual commodities of mustard greens and radish leaves only. See also general comments reported below in footnote (b).

(Continues)

TABLE 86 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is not acceptable because the calculated short-term exposure exceeded the ARfD for Chinese cabbages, which is the corresponding commodity of part A of the EU food classification for mustard greens (N.B.: lacking specific consumption data for mustard greens, EFSA calculated the exposure using the consumption data for Chinese cabbages). However, risk managers may discuss options on the implementation of the Codex MRL for mustard greens in a footnote to Chinese cabbage, specifying that it would apply only for mustard greens only and for baby leaf crops Follow-up action: None
Prunes	**4**	0.5	JMPR derived a processing factor of 2.55, based on the individual processing studies (1.9; 2.7; 2.7; 2.9). Hence, according to EFSA, the processing factor should be corrected to 2.7 (which is the median PF) (instead of 2.55, which is the mean of the individual PFs). Currently, no EU MRLs are established for processed products
Radish	**0.7**	0.4	cGAP: USA, ground, or air application or chemigation, 4 × 0.128 kg a.s./ha, 7-day RTI, 7-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: Residues obtained in radish roots **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Radish leaves	**8**	2	cGAP: USA, ground, or air application or chemigation, 4 × 0.128 kg a.s./ha, 7-day RTI, 7-day PHI (cGAP for brassica leafy vegetable, subgroup 13B)[b] Number of trials: 5 Sufficiently supported by data: Yes Specific comments: See also general comments reported below in footnote a **Conclusion:** The proposed Codex MRL is not acceptable because the calculated short-term exposure exceeded the ARfD for kales, which is the corresponding commodity of part A of the EU food classification for radish leaves (N.B.: lacking specific consumption data for radish leaves, the exposure calculation was performed with the consumption data for kale). However, risk managers may discuss options on the implementation of the Codex MRL for radish leaves in a footnote to kale, specifying that it would apply only for radish leaves and not for kale Follow-up action: None
Stone fruits	**1.5**	0.7 (apricots) 0.3 (cherries) 0.5 (peaches and plums)	cGAP: USA, ground or air application, 4 × 0.128 kg a.s./ha, 7-day RTI, 0-day PHI Number of trials: 20 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed on cherries (5), peaches (9) and plums (6). The JMPR noted that median residues on cherries, peaches and plums are within a fivefold difference and Kruskal–Wallis H-test indicates that these three populations are not significantly different. The JMPR decided to combine these data sets **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of maize Cereals	0.015	0.05*	cGAP: USA, Foliar, 3 × 0.126 kg a.s./ha, 7-day RTI, 30-day PHI Number of trials: 24 Sufficiently supported by data: Yes Specific comments: Registration is for the use on maize, popcorn and teosinte **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Sweet potato	**4**	0.1	cGAP: USA, Post-harvest spray, 1 × 3.3 g a.s./tonne, 0-day PHI Number of trials: 5 trials in potatoes Sufficiently supported by data: Yes Specific comments: The residue data were already assessed by the JMPR in 2013 where an MRL of 4 mg/kg in potatoes was proposed. The current JMPR confirmed its previous recommendations on potatoes and recommends extrapolating the estimates to sweet potato. In the 2014 CCPR meeting, the EU made a reservation on the potato MRL, as an intake concern was identified **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
General comments	None of the samples were analysed for triazole derivative metabolites (TDMs) [b]The codes for subgroup 13B cover a number of commodities, which have a corresponding entry in Part A of the EU food classification, i.e. Roman rocket/rucola, kales, cresses and other sprouts and shoots, red mustards, baby leaf crops (including brassica species), land cresses		

TABLE 86 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			In addition, some crops falling under this subgroup are classified in the EU in Part B, such as • Radish leaves (0243020–008), currently classified under kales (0243020), • Mustard greens (VL 0485) corresponds in the EU to Indian mustard (243010–002) which is classified under Chinese cabbages (243010) • Indian mustards/mustard greens (251080–003) are classified under baby leaf crops (251080). The JMPR noted an exceedance of the ARfD for Chinese cabbages (VL 0466) which corresponds in the EU to Pak-choi/paksoi (243010–005) classified in the EU under Chinese cabbages/pe-tsai (243010)

Abbreviations: ARfD, acute reference dose; a.s., active substance; cGAP, critical Good Agricultural Practice; dw, dry weight; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

[a]Value not relevant for IEDI assessment calculations.

5.14.6 | Consumer risk assessment

TABLE 87 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. blackberries, raspberries, dewberries, radish leaves (listed under kales), mustard greens (covered by Chinese cabbage), baby leaf crops, radish root, apricots, cherries, plums, peaches and sweet potatoes) The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD, which also includes the triazole derivative metabolites (TDMs) Since there is no information on the residue levels of TDMs, is it not possible to assess their contribution to the dietary risk assessment Additional uncertainties are resulting from the fact the calculations were performed for the commodities kale, Chinese cabbage and baby leaf crops, instead of radish leaves and mustard greens, as in PRIMo rev. 3.1, specific consumption data are not available for these products For processed products, further refinements of the exposure calculations could be performed, if appropriate processing factors were available In addition, the exposure calculation may underestimate the toxicological burden for consumers, as an uncertainty factor for risk assessment has recently been proposed concerning the isomeric behaviour of difenoconazole in treated crops, following the Art. 31 peer review on confirmatory data for difenoconazole (ongoing) 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, 2023h) (wheat and rye) 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. blackberries, raspberries, dewberries, radish leaves (from kales), mustard greens (from Pak-choi/paksoi), baby leaf crops, radish root, apricots, cherries, plums, peaches and sweet potatoes) The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD, which also includes the triazole derivative metabolites (TDMs) Since there is no information on the residue levels of TDMS is it not possible to assess their contribution to the dietary risk assessment Additional uncertainties are resulting from the fact the calculations were performed for the commodities kale, Chinese cabbage and baby leaf crops, instead of radish leaves and mustard greens, as in PRIMo rev. 3.1, specific consumption data are not available for these products In addition, the exposure calculation may underestimate the toxicological burden for consumers, as an uncertainty factor for risk assessment has recently been proposed concerning the isomeric behaviour of difenoconazole in treated crops, following the Art. 31 peer review on confirmatory data for difenoconazole (ongoing) Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** -
Results: The calculated short-term exposure exceeded the ARfD for two crops under assessment Radish leaves (covered by kales): 168% of ARfD (children) Mustard greens (covered by Chinese cabbages/pe-tsai): 123% of ARfD (children) Sweet potatoes: 25% of the ARfD (adults) Processed commodities: Kales/boiled: 105% of ARfD (children) Sweet potatoes: 60% of the ARfD (adults) Baby leaf crops: no specific consumption data available	**Results:** No long-term consumer health risk was identified in the indicative risk assessment The overall indicative chronic exposure accounted for 97% of the ADI (NL toddler) Among the crops under consideration, sweet potatoes were identified as the main contributor, accounting for up to 43% of the ADI (IE adult)	**Results:** Long-term exposure: Max 100% of the JMPR ADI (children) GECDE mean: Max. 430% (children and adolescents) GECDE max: Max. 1400% (children and adolescents) Short-term exposure: Highest result for mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards): 100% of ARfD (children)

(Continues)

TABLE 87 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The calculated short-term exposure exceeded the ARfD for processed commodities under assessment (kales (boiled))		
In addition, the exposure for boiled witloofs (not under assessment) was found to exceed the ARfD. The exposure calculation was performed without refinement (e.g. use of processing factors)		

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; RA, risk assessment.

5.14.7 | Conclusions

TABLE 88 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 (EFSA peer review on clock-stop) and MRL review are currently ongoing
Toxicological assessment	EU TRV 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)
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk intake concerns were identified for some of the commodities assessed by JMPR. No chronic intake concern identified; however, considering the narrow safety margin to the ADI and the additional, 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	EU position to be discussed/decided by risk managers

Abbreviations: ADI, acceptable daily intake; a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.15 | Clothianidin (238) R

5.15.1 | Background information

TABLE 89 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	See comments	BE and DE, as RMSs of the first approval and renewal, respectively, kindly provided support to prepare comments on this a.s.
Approval status	Not approved	In the light of the restrictions defined by Regulation (EU) No 2018/784,[45] 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 (2018h)
MRL review performed	Yes, see comments	EFSA (2014h)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2018n) (potatoes) In addition, EFSA assessed a number of emergency authorisations granted by Member States between 2018 and 2021

[45]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.*

TABLE 89 (Continued)

		Comments, references
Classification of a.s. (cut-off criteria)	No, see comments	Clothianidin does not fall under cut-off criteria. ATP01[46] ECHA (2021c)
Endocrine effects of a.s.	Not assessed	A.s. was not peer reviewed
Other relevant information	Clothianidin belongs to the group of neonicotinoids; this a.s. is used as a biocide and is subject to the PIC regulation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.15.2 | Toxicological reference values

TABLE 90 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.1 mg/kg bw per day	JMPR (2010)	0.097 mg/kg bw per day	06/41/EC	No
ARfD	0.6 mg/kg bw	JMPR (2010)	0.1 mg/kg bw	06/41/EC	No
Conclusion/comments a.s.	According to JMPR 2010 (FAO and WHO, 2011a), 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 existing TRVs 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				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition.

5.15.3 | Residue definitions

TABLE 91 Comparison of the residue definitions derived by JMPR and at EU level.

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

Abbreviations: MRL, maximum residue level; RA: risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

[46]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.

5.15.4 | Analytical methods

TABLE 92 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content High oil content	Yes	0.01	Extraction with REM 179.06 using water/methanol mixture, clean-up by solvent partition and cartridge columns, determination with LC–MS/MS (FAO and WHO, 2015b) HPLC–MS/MS method 00552 (single residue method) Method AG-765 and method R20013B: Extraction with acetonitrile/water, (microwave extraction), clean-up by liquid–liquid partition with hexane and on cartridge columns, determination with LC–MS (FAO and WHO, 2011c)
Plant commodities: Difficult matrices (cumin seed)	Yes	0.1	Method AG-765 and method R20013B: Extraction with acetonitrile/water, (microwave extraction), clean-up by liquid–liquid partition with hexane and on cartridge columns, determination with LC–MS (FAO and WHO, 2011c)
Conclusion	The JMPR received new recovery data for the use of Method AG-765 and validation data for method R20013B, used for goji berry, and the method used for cumin seeds. Method AG-765 and R20013B were demonstrated to have adequate performance for recovery of thiamethoxam, with an LOQ of 0.01 mg/kg Sufficiently analytical methods for the enforcement of the MRLs for the relevant matrices are available		

Abbreviations: HPLC–MS/MS, high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS, liquid chromatography with tandem mass spectrometry; LC–MS, liquid chromatography with mass spectrometry; LOQ, limit of quantification.

5.15.5 | Codex MRL proposals

TABLE 93 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	Existing EU MRL[a]/new EU MRL[b]	Comment
Almond hulls	0.1 (dw) T	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Celery	0.04 T (W)	0.04/0.01*	The existing CXL is proposed for withdrawal. It will be replaced by the new Codex MRL proposal for Subgroup of stems and petioles
Cumin seed	**1**	0.05*/0.05*	cGAP: No GAP information or residue trials for the use of thiamethoxam or clothianidin on cumin seed were provided Number of trials: The JMPR received monitoring data from India and of the 1089 samples analysed, 328 samples contained quantified residues Sufficiently supported by data: Yes Specific comments: The JMPR noted that according to the current Codex procedure (FAO, 2016) sufficient data of detected residues were available to estimate a maximum residue level. The upper 95% one-tailed confidence limit of the 95th percentile of the detected residues is 0.97 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 in view of possible risks for pollinators, noting that details on the authorised uses (cGAPs) are not available Follow-up action: None
Fruiting vegetables other than cucurbits	0.05 (W)		The existing CXL is proposed for withdrawal, to be replaced by the new MRL proposal for fruiting vegetables other than cucurbits, except goji berries
Fruiting vegetables other than cucurbits except goji berry	**0.05** T	0.04/0.01* (tomatoes, sweet peppers/bell peppers, aubergines/eggplants; 0.01*/0.01* (okra/lady's fingers)	cGAP of thiamethoxam (Italian GAP in sweet peppers, 1 × 0.1 kg a.s./ha, 3-day PHI) was assessed by JMPR in 2010 Specific comments: The CXL derived by JMPR in 2010 and adopted by CCPR in 2011 was now restricted, excluding goji berries, for which a separate Codex MRL proposal was derived in 2023 The CXL derived in 2011 has not been taken over in the EU legislation, because the extrapolation approach taken by JMPR was considered not acceptable. (Trials on pepper compliant with the Italian cGAP from greenhouse treatment were used to derive Codex MRLs for the whole group of 'Fruiting vegetables other than cucurbits except goji berry'.) The previously expressed EU reservation on the Codex MRL derived in 2011 has not been withdrawn

TABLE 93 (Continued)

Commodity	Codex MRL proposal	Existing EU MRL[a]/new EU MRL[b]	Comment
			In addition, it is noted that the EU uses of thiamethoxam which are the basis of the Codex MRL are no longer authorised in the EU **Conclusion**: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs in view of the appropriate level of protection for pollinators Follow-up action: None
Goji berry	**0.06** T	0.04/0.01*	cGAP: China, 1 × 0.01 kg a.s./hL, 3-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: The cGAP is reported as 0.01 kg/hL. The exact water amount per hectare is not defined in the cGAP **Conclusion:** 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 appropriate level of protection for pollinators. Follow-up action: To check details in JMPR evaluation to verify that trials were representative for the GAP (check the water amount)
Goji berry, dried	0.3 T	–	JMPR derived a processing factor of 4.9 (4.55, 5.23; 3.85, 6.3). First 2 values from sun-dried goji berry, last 2 values from hot air-dried goji berry. Currently, no EU MRLs are established for processed products
Group of tree nuts	0.01* T	0.01*/0.01*	cGAP: USA, 2 × 70 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed with pecan (5) and almonds (5). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators Follow-up action: None
Onion, bulb	0.01* T	0.01*/0.01*	cGAP: USA, Seed treatment, 1 × 0.2 mg a.s./seed Number of trials: 7 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators Follow-up action: None
Pecan	0.01* (W)	0.01*/0.01*	The existing CXL is proposed for withdrawal and will be replaced by the new Codex MRL proposal for tree nuts
Subgroup of stems and petioles	**0.04,** T	0.01*/0.01* (cardoons, Florence fennels, rhubarbs); 0.04/0.01* (celeries)	cGAP: USA, Foliar, 2 × 96 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 4 trials in celeries Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators Follow-up action: None
General comments	–		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; PHI, pre-harvest interval; MRL, maximum residue level; RTI, re-treatment interval.

[T]Based on thiamethoxam use only; W: the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended; dw: dry weight.

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

[a]The EU MRLs currently applicable are set according to Commission Regulation (EU) 2017/671.

[b]New MRLs established by Commission Regulation (EU) 2023/334 (not yet applicable).

5.15.6 | Consumer risk assessment

TABLE 94 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. cumin seed, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, goji berry, cardoons, Florence fennels, rhubarbs and celeries) 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 (not yet applicable) where all MRLs are set at the LOQ, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. cumin seed, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, goji berry, cardoons, Florence fennels, rhubarbs and celeries) 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:** –
Results: No short-term consumer health risk was identified for the crops under assessment **Clothianidin** Highest individual results for Sweet pepper: 2% of the ARfD **Combined (thiamethoxam and clothianidin)** Highest exposure among the commodities under consideration Celeries: 3% of the ARfD	**Results:** No long-term consumer health risk was identified **Clothianidin** The overall chronic exposure accounted for 1% of the ADI (NL toddler) From the crops under consideration, tomatoes contributed up to 0.04% of the ADI (GEMS/Food G06) **Combined (thiamethoxam and clothianidin)** The overall chronic exposure accounted for 6% (NL toddler)	**Results:** Long-term exposure: Max 2% of the JMPR ADI (children). GECDE mean: 7% (children and adolescents) GECDE max: Max. 20% (infants and toddlers) Short-term exposure: Result for all crops under consideration: 0% of ARfD (children)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; LOQ, limit of quantification; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.15.7 | Conclusions

TABLE 95 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 TRV available
Residue definitions	EU and Codex RDs for plant commodities (enforcement and risk assessment) are equivalent
Analytical methods	For the commodities under discussion, sufficiently validated analytical methods are available
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 discussion with risk managers are recommended in view of the EU policy on protection of pollinators

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.16 | Fluopyram (243) R

5.16.1 | Background information

TABLE 96 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	DE	
Approval status	Approved. Renewal process ongoing	Commission Implementing Regulation (EU) No 802/2013[47] Dossier submitted by the applicant, RMS assessment ongoing
EFSA conclusion available	Yes, see comments	EFSA (2013b) EFSA (2018p) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for fluopyram in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2020a)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2023e) (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 (2014c); ATP09[48]
Endocrine effects of a.s.	Not assessed	Not assessed under the new criteria established by Regulation (EU) 2018/605 EFSA (2013b)
Other relevant information	Fluopyram meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.16.2 | Toxicological reference values

TABLE 97 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**TRV comparable**
ADI	0.01 mg/kg bw per day	JMPR (2010)	0.012 mg/kg bw per day	Reg. (EU) No 802/2013	No (minor difference due to rounding policy)
ARfD	0.5 mg/kg bw	JMPR (2010)	0.5 mg/kg bw	Reg. (EU) No 802/2013	Yes
Conclusion/comments a.s.	–				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 2-(trifluoromethyl)benzamide (M25) – *N*-(*E*)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl) benzamide (M02) – *N*-(*Z*)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl) benzamide (M03) No toxicological information reported on the three metabolites, but according to the toxicological evaluation of WHO (FAO and WHO, 2011a), the three metabolites were major rat metabolites. However, the inconsistent coding of metabolites in JMPR assessments impedes the verification of the results reported Metabolites included in EU RD for RA: – fluopyram-benzamide (M25) – fluopyram-*E*/*Z*-olefin (M02/M03) No data available on the three metabolites, M25, M02 or M03				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

[47]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 540/201. OJ L 225, 23.8.2013, p. 13–16.

[48]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.

5.16.3 | Residue definitions

TABLE 98 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, 2013b): Fluopyram	Yes
	Animal products	Sum of fluopyram and 2-(trifluoromethyl) benzamide (M25), 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, 2013b): Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram The residue is not fat soluble	Yes
RD-RA	Plant products	Fluopyram	MRL review (EFSA, 2020a): Sum of fluopyram, fluopyram-benzamide (M25), expressed as fluopyram Peer review (EFSA, 2013b): Sum of 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, 2020a): Sum of fluopyram, fluopyram-benzamide (M25) and fluopyram *E/Z*-olefin (M02/M03), expressed as fluopyram Peer review (EFSA, 2013b): Sum of fluopyram, fluopyram-benzamide (M25), fluopyram-*E/Z*-olefin (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 (M101, 2-(trifluoromehtyl)benzamide)			

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.16.4 | Analytical methods

TABLE 99 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Fluopyram			
Plant commodities: Dry commodities (wheat)	Yes	0.01	Extraction Method 00984 and GM-001-P07-01, LC–MS/MS (FAO and WHO, 2011b) An additional analytical method (GM-006-P18-01) was validated for wheat and sorghum: extraction by acetonitrile-water (4:1, v/v) and analyse using LC–MS/MS
Animal products Milk Eggs	Yes	0.01	Extraction Method 01079, LC–MS/MS (FAO and WHO, 2011b)
Animal products Muscle/meat Fat Liver/kidney	No validation data reported	–	No methods could be found in JMPR assessments
Fluopyram benzamide (M25) (only relevant for animal matrices)			
Animal products Milk Eggs	Yes	0.01 (EURL: 0.005)	Extraction Method 01079, LC–MS/MS Validation data in milk also available from the EURL-SRM at 0.005 mg/kg using CEN-QuEChERS and LC–MS/MS)

TABLE 99 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Animal products Muscle/meat Fat Liver/kidney	Partially (see remarks)	EURL: 0.005 (see remarks)	No method validation data could be found at JMPR level. Validation data in liver and milk available from the EURL-SRM at 0.005 mg/kg using CEN-QuEChERS and LC–MS/MS)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The current EU MRL for the commodities under discussion are lower than the Codex MRL proposals Sufficiently validated analytical methods for the enforcement of the MRLs for the relevant matrices are available, except for muscle/meat, fat and liver/kidney		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.16.5 | Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	**0.4**	0.2	cGAP: USA, 2 × 0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 16 Sufficiently supported by data: Yes Specific comments: For a very similar EU cGAP assessed in the MRL review (EFSA, 2020a) with a lightly longer PHI slightly than in US GAP (i.e. 35 days), lower MRLs have been derived from the NEU and SEU residue trials (0.07 and 0.2 mg/kg, respectively) **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified. See also follow-up action Follow-up action: To investigate why for a similar GAP the Codex MRL proposal is significantly higher than the EU MRL proposal
Buckwheat	**0.4**	0.02	cGAP: USA, 2 × 0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 16 trials on barley, extrapolated to buckwheat Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Edible offal (mammalian)	**8**	Liver from – swine: 0.5; sheep, goat and equine: 0.8 Kidney from – swine: 0.08; – bovine, sheep, goat and equine: 0.15 Edible offal (other than liver and kidney) from – swine: 0.5; – bovine, sheep, goat and equine: 0.8	Max. dietary burden (beef): Australia, 65 ppm Max. residues in liver: 7.2 mg/kg Sufficiently supported by data: Yes Specific comments: The calculations of the DB are not reported in Annex 6 of the JMPR report 2023, the information cannot be verified **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Eggs	**2**	0.15	Max. dietary burden (layer): Europe, 9.1 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. Based on the current dietary burden calculation, a slightly lower value of 1.5 mg/kg might be sufficient. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None

(Continues)

TABLE 100 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	**1.5**	0.09 (swine); 0.15 (bovine, sheep, goat and equine)	Max. dietary burden (beef): Australia, 65 ppm Mean/max. residues in fat: 1 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Meat (from mammals other than marine mammals)	**1.5**	– Muscle: 0.1 (swine); 0.15 (bovine, sheep, goat and equine)	Max. dietary burden (beef): Australia, 65 ppm Max. residues in muscle and fat: 1 mg/kg, respect Sufficiently supported by data: Yes Specific comments: It is noted that according to the new Codex food classification, CXLs are established for muscle (MM 0095); hence, the commodity description should be changed to 'Muscle (from mammals other than marine mammals)'. However, this is just an editorial issue **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Milks	**0.8**	0.06 (goat and sheep); 0.07 (cattle and horse)	Max. dietary burden (beef): Australia, 55 ppm Mean. residues in fat: 0.72 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Oats	**0.4**	0.2	cGAP: USA, 2 × 0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 16 trials on barley, extrapolated to oats Specific comments: See comments for barley **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified. See also follow-up action Follow-up action: See proposed follow-up actions for barley
Poultry, edible offal of	**4**	0.02* (kidney) 0.3 (liver and edible offals)	Max. dietary burden (layers): Europe, 9.1 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. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Poultry fats	**1**	0.07	Max. dietary burden (layers): Europe, 9.1 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. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None
Poultry meat	**1.5**	– Muscle: 0.07	Max. dietary burden (layers): Europe, 9.1 ppm Max. residues in muscle: 0.97 mg/kg Sufficiently supported by data: Yes Specific comments: It is noted that the commodity description for the code PM 0110 should be revised to be compliant with the new Codex Food Classification, i.e. Avian muscle, group of (editorial change only) **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a lower value of 1 mg/kg would be sufficient. EFSA also recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: None

TABLE 100 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Rye	**0.2**	0.07	cGAP: USA, 2×0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 18 trials on wheat, extrapolated to rye Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified. Further comments, see wheat Follow-up action: None
Sorghum	0.6	4	cGAP: USA, 1×0.2 kg/ha, 30-day PHI Number of trials: 16 trials on barley, extrapolated to sorghum Specific comments: The existing EU MRL is based on a US GAP, which seems to be no longer valid **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: The existing EU MRL might need to be revised, as it is based on an obsolete US GAP
Triticale	0.2	0.9	cGAP: USA, 2×0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 18 trials on wheat, extrapolated to rye Sufficiently supported by data: Yes Specific comments: See comments on wheat **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the EU position, noting the chronic intake concern identified. Further comments, see wheat Follow-up action: See wheat
Wheat	0.2	0.9	cGAP: USA, 2×0.125 kg/ha, 14-day RTI, 30-day PHI Number of trials: 18 Sufficiently supported by data: Yes Specific comments: For a very similar EU cGAP assessed in the MRL review (EFSA, 2020a) with a slightly longer PHI than in the US GAP (i.e. 35 days), lower MRLs have been derived from the NEU and SEU residue trials (0.03 and 0.07 mg/kg, respectively). The existing EU MRL is based on the CXL that is now proposed to be replaced with a lower CXL. The existing EU MRL reflects an obsolete US import tolerance/CXL **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, EFSA recommends to discuss with Member States the proposed follow-up action. EFSA also recommends to discuss with Member States the EU position, noting the chronic intake concern identified Follow-up action: To further investigate why for a similar GAP the Codex MRL proposal is significantly higher than the EU MRL proposal. The existing EU MRL should be reconsidered, as it is based on an obsolete CXL (reflecting an outdated US GAP)
Wheat bran	0.6	–	In 2017, JMPR derived a processing factor of 2.7. Currently, no EU MRLs are established for processed products
Wheat flour	–	–	In 2017, JMPR derived a processing factor of 0.12. Currently, no EU MRLs are established for processed products
Wheat germ	0.5	–	In 2017, JMPR derived a processing factor of 2.4. Currently, no EU MRLs are established for processed products
Aspirated grain fraction of wheat	–	–	JMPR derived a processing factor of 70. Currently, no EU MRLs are established for processed products
Barley, hay and/or straw	6 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Barley straw and fodder, dry	2 (W)	–	The existing CXL is proposed for withdrawal
Oat, hay and/or straw	6 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Oat straw and fodder, dry	2 (W)	–	The existing CXL is proposed for withdrawal

(Continues)

TABLE 100 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Rye, forage	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rye, hay and/or straw	6 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rye straw and fodder, dry	23 (W)	–	The existing CXL is proposed for withdrawal
Sorghum, forage (green)	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Sorghum, stover	3 (dw)	–	Based on residue trials, JMPR derived a MRL proposal for sorghum stover. Currently, no EU MRLs are established for processed products
Triticale, forage	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Triticale, hay and/or straw	6 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Triticale straw and fodder, dry	23 (W)	–	The existing CXL is proposed for withdrawal
Wheat, forage	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat, hay and/or straw	6 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat straw and fodder, dry	23 (W)	–	The existing CXL is proposed for withdrawal
General comments	In the EU assessment, residues in rotational crops were considered for calculating the dietary burden for livestock. For cereal grains, the uptake of residues from soil was low compared to the residues related to the primary crop treatment		

Abbreviations: cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; dw, dry weight; GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, Northern European Union; PHI, pre-harvest interval; RTI, re-treatment interval; SEU, Southern European Union; 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.

5.16.6 | Consumer risk assessment

TABLE 101 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (see table above, Codex MRL proposals highlighted in bold). In addition, EFSA also revised the input values for wheat and sorghum. As the existing EU MRLs are based on obsolete US import tolerances 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 EFSA calculated two scenarios: **Scenario 1:** The input values of the most recent long-term risk assessment (EFSA, 2020a) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (see table above, Codex MRL proposals highlighted in bold). In addition, the following modifications were introduced in the PRIMo calculation: – Inclusion of new MRL and STMR for pumpkin seeds (derived by fast-track procedure); – Removal of MRL proposals of the MRL review that were not taken over in EU legislation. – Replacement of existing MRL for wheat and sorghum with new Codex MRL proposal (as existing EU MRL was based on an obsolete US import tolerance/CXL). The new MRL proposals derived in EFSA (2023e) have not been included, as a decision has not yet been taken, which EU MRLs should be lowered to allow increasing of other MRLs	**Specific comments:** –

TABLE 101 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
	Scenario 2: Same assumptions as in scenario 1, but maintaining the existing EU MRLs (and the corresponding risk assessment values) for animal products, except for eggs, where the Codex MRL proposal (and the corresponding HR and STMR) were implemented **Scenario 3:** Same as scenario 2, but implementing the MRLs proposed in EFSA (2023e) (lowering of the EU MRL for pome fruit, increasing the EU MRL for kiwi, some stem vegetables, peanuts, soybeans, spices seeds) 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	
Results: No short-term consumer health risk was identified for the crops under assessment The highest exposure among the commodities for which Codex MRLs are higher than the existing EU MRL were identified for Bovine liver: 12% of ARfD Cattle milk: 12% of ARfD Other edible offals of bovine: 11% of ARfD	**Results:** Scenario 1: The calculated long-term exposure exceeded the ADI. The overall chronic exposure accounted for up to 331% of the ADI (NL toddler) Among the commodities under consideration, cattle milk was identified as the main contributor, accounting for up to 239% of the ADI Scenario 2: No long-term consumer health risk was identified, but the safety margin was very narrow The overall chronic exposure accounted for up to 96% of the ADI (NL toddler) Among the commodities under consideration, wheat was identified as the main contributor, accounting for up to 2.2% of the ADI Scenario 3: No long-term consumer health risk was identified, but the safety margin was very narrow The overall chronic exposure accounted for up to 88% of the ADI (NL toddler) The main contributors among the Codex MRL proposals are the same as in scenario 2	**Results:** Long-term exposure: IEDI: Max 80% of the JMPR ADI. GECDE mean: Max. 270% (infants and toddler) GECDE max: Max. 920% (infants and toddler) Short-term exposure: Highest result for milks and edible offal (mammalian): respectively, 10% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; IEDI: international estimated daily intake; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.16.7 | Conclusions

TABLE 102 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 submitted by the applicant, RMS assessment ongoing)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs are identical, except the RD for RA for plant products, where the EU RD is wider
Analytical methods	Sufficiently validated analytical methods are available for relevant matrices except for meat/muscle, fat and liver/kidney
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	A chronic intake concern was identified by EFSA, if all Codex MRLs are taken over. In the scenario assuming implementation of MRL proposals for plant products only, the exposure was slightly below the ADI. Further risk management discussions are required
Final conclusion	EU position to be discussed/decided by risk managers

Abbrveiations: ADI, acceptable daily intake; a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.17 | Thiamethoxam (245) R

5.17.1 | Background information

TABLE 103 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Not approved	In the light of the restrictions defined by Regulation (EU) No 2018/785,[49] 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	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, 2018h)
MRL review performed	Yes, see comments	EFSA (2014h)
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 (2019f), ATP17[50]
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Thiamethoxam belongs to the group of neonicotinoids; this a.s. is used as a biocide and is subject to the PIC regulation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.17.2 | Toxicological reference values

TABLE 104 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.08 mg/kg bw per day	JMPR (2010)	0.026 mg/kg bw per day	Reg. 07/6/EC	No
ARfD	1 mg/kg bw	JMPR (2010)	0.5 mg/kg bw	Reg. 07/6/EC	No
Conclusion/comments a.s.	–				
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. 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				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

[49]Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam. OJ L 132, 30.5.2018, p. 40–44.

[50]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.

5.17.3 | Residue definitions

TABLE 105 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Thiamethoxam	Reg. 396/2005 (implementing MRL review): Thiamethoxam MRL review (EFSA, 2014h): 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, 2014h): 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, 2014h): 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, 2014h): Ruminants and pigs: Thiamethoxam and clothianidin (considered separately). Poultry products: No residue definition proposed	Yes, except for poultry
Conclusion, comments	The EU residue definition for MRL enforcement and risk assessment in plants and livestock are equivalent to the JMPR residue definitions, except the RD for RA for poultry			

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition;; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.17.4 | Analytical methods

TABLE 106 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content High oil content	Yes	0.01	Extraction with REM 179.06, using water/methanol mixture, clean-up by solvent partition and cartridge columns, determination with LC–MS/MS (FAO and WHO, 2015a) Method AG-765 and method R20013B: Extraction with acetonitrile/water, (microwave extraction), clean-up by liquid–liquid partition with hexane, and on cartridge columns, determination with LC–MS (FAO and WHO, 2011c)
Plant commodities: Difficult matrices (cumin seed)	Yes, details on method validation not reported in JMPR report	0.1	Method AG-765 and method R20013B: Extraction with acetonitrile/water, (microwave extraction), clean-up by liquid–liquid partition with hexane, and on cartridge columns, determination with LC–MS (FAO and WHO, 2011c)
Conclusion	The JMPR received new recovery data for the use of Method AG-765 and validation data for method R20013B, used for goji berry, and the method used for cumin seeds. Method AG-765 and R20013B were demonstrated to have adequate performance for recovery of thiamethoxam, with an LOQ of 0.01 mg/kg Sufficiently validated analytical methods for the enforcement of the MRLs for the relevant matrices are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LC–MS, liquid chromatography with mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level.

5.17.5 | Codex MRL proposals

TABLE 107 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL[a]/new EU MRL[b]	Comment
Almond hulls	2 (dw)	–	Currently, no EU MRLs are established for products exclusively used for feed purpose
Celery	1 (W)	1/0.01*	The existing CXL is proposed for withdrawal. It will be replaced by the new Codex MRL proposal for Subgroup of stems and petioles
Cumin seed	**1**	0.05*/0.05*	cGAP: No GAP information or residue trials for the use of thiamethoxam or clothianidin on cumin seed were provided Number of trials: The JMPR received monitoring data from India and of the 1089 samples analysed, 328 samples contained quantified residues Sufficiently supported by data: Yes Specific comments: The JMPR noted that according to the current Codex procedure (FAO, 2016) sufficient data of detected residues were available to estimate a maximum residue level. The upper 95% one-tailed confidence limit of the 95th percentile of the detected residues is 0.97 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 in view of possible risks for pollinators, noting that details on the authorised uses (cGAPs) are not available Follow-up action: None
Fruiting vegetables other than cucurbits	0.7 (W)	–	The existing CXL is proposed for withdrawal, to be replaced by the new MRL proposal for fruiting vegetables other than cucurbits, except goji berries
Fruiting vegetables other than cucurbits except goji berry	**0.7**	0.2/0.01* (tomatoes and aubergines/ eggplants) 0.7/0.01* (sweet peppers/bell peppers) 0.01*/0.01* (okra/lady's fingers)	Italian GAP in sweet peppers, 1 × 0.1 kg a.s./ha, 3-day PHI) was assessed by JMPR in 2010 Specific comments: The CXL derived by JMPR in 2010 and adopted by CCPR in 2011 was now restricted, excluding goji berries, for which a separate Codex MRL proposal was derived in 2023 The CXL derived in 2011 has not been taken over in the EU legislation, because the extrapolation approach taken by JMPR was considered not acceptable. (Trials on pepper compliant with the Italian cGAP from greenhouse treatment were used to derive Codex MRLs for the whole group of 'Fruiting vegetables other than cucurbits except goji berry'.) The previously expressed EU reservation on the Codex MRL derived in 2011 has not been withdrawn In addition, it is noted that the EU uses of thiamethoxam which are the basis of the Codex MRL are no longer authorised in the EU **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs in view of the appropriate level of protection for pollinators Follow-up action: None
Goji berry	**1.5**	0.2/0.01*	cGAP: China, 1 × 0.01 kg a.s./hL, 3-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: The cGAP is reported as 0.01 kg/hL. The water amount per hectare is not defined in the GAP **Conclusion:** 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 appropriate level of protection for pollinators Follow-up action: To check details in JMPR evaluation
Goji berry, dried	5	–	JMPR derived a processing factor of 2.53, derived from sun dried goji berry and from hot air-dried goji berry. Currently, no EU MRLs are established for processed products
Group of tree nuts	0.01*	0.02*/0.01* (pecans) 0.01*/0.01* (other tree nuts)	cGAP: USA, 2 × 70 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed with pecan (5) and almonds (5). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators Follow-up action: None

TABLE 107 (Continued)

Commodity	Codex MRL proposal	EU MRL[a]/new EU MRL[b]	Comment
Onion, bulb	**0.02**	0.01*/0.01*	cGAP: USA, Seed treatment, 1 × 0.2 mg a.s./seed Number of trials: 7 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators. Follow-up action: None
Pecan	0.01* (W)	0.02*/0.01*	The existing CXL is proposed for withdrawal, to be replaced by the new Codex MRL proposal for tree nuts
Subgroup of stems and petioles	**0.8**	1/0.01* (celeries) 0.01*/0.01* (Florence fennels and rhubarbs)	cGAP: USA, Foliar, 2 × 96 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 4 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. 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 appropriate level of protection for pollinators
General comments	–		

Abbreviations: a.s., active substance; CXL, Codex maximum residue limit; cGAP, critical Good Agricultural Practice; dw, dry weight; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval; 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]The EU MRLs currently applicable are set according to Commission Regulation (EU) 2017/671.

[b]New MRLs established by Commission Regulation (EU) 2023/334 (not yet applicable).

5.17.6 | Consumer risk assessment

TABLE 108 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. cumin seed, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, goji berry, cardoons, Florence fennels, rhubarbs and celeries) 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 (not yet applicable) where all MRLs are set at the LOQ, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. cumin seed, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, goji berry, cardoons, Florence fennels, rhubarbs and celeries) 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:** –
Results: No short-term consumer health risk was identified for the crops under assessment **Thiamethoxam** Highest individual results for Celeries: 3% of the ARfD **Combined risk assessment (thiamethoxam and clothianidin)** Highest exposure among the commodities under consideration Celeries: 3% of the ARfD	**Results:** No long-term consumer health risk was identified **Thiamethoxam** The overall chronic exposure accounted for 5% of the ADI (NL toddler) The crops under consideration contributed for < 1% of the ADI **Combined risk assessment (thiamethoxam and clothianidin)** The overall chronic exposure accounted for 6% (NL toddler)	**Results:** Long-term exposure: Max 7% of the JMPR ADI GECDE mean: Max 40% (children and adolescents) GECDE max: Max. 80% (infants and toddlers) Short-term exposure: Highest result for celery: 1% of ARfD (all populations)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; MRL, maximum residue level; GECDE, global estimate of chronic dietary exposure; RA, risk assessment; STMR, supervised trials median residue.

5.17.7 | Conclusions

TABLE 109 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 April 2019, as the application for renewal was withdrawn)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs for plant commodities (enforcement and risk assessment) are equivalent
Analytical methods	Sufficiently validated analytical methods are available for the relevant matrices
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 discussion with risk managers are recommended in view of the EU policy on protection of pollinators

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.18 | Acetamiprid (246) R

5.18.1 | Background information

TABLE 110 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) 2018/113[51]
EFSA conclusion available	Yes, see comments	EFSA (2016g)
MRL review performed	Yes, see comments	EFSA (2011d)
EU MRL applications or other EU assessments	Yes, see comments	Art. 10 in peach and escarole (ongoing) EFSA (2024e) Art. 31 on toxicological properties and maximum residue levels of acetamiprid and its metabolites EFSA (2022h) (honey and various oilseed crops) EFSA PPR Panel (2022a) (Statement on acetamiprid – Art. 69 of Regulation (EC) No 1107/2009) EFSA (2021h) (various crops) EFSA (2018j) (Art. 43 assessment and modification of the existing MRLs in table olives, olives for oil production, barley and oats) EFSA (2016b) (various crops) EFSA (2015f) (leafy brassicas) EFSA (2014f) (bananas) EFSA PPR Panel (2013) (Scientific opinion on the developmental neurotoxicity potential) EFSA (2013f) (apricots and tree nuts) EFSA (2012e) (purslane, legume vegetables, pulses, beans and peas)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria Annex VI of Regulation (EC) No 1272/2008 (Classification, Labelling and Packaging (CLP) Regulation); ECHA (2020a); ATP18[52]
Endocrine effects of a.s.	Not assessed	Not assessed under the new criteria established by Regulation (EU) 2018/605[53] (EFSA, 2016g)
Other relevant information	Acetamiprid belongs to the group of neonicotinoides; the a.s. is approved for use as biocide	

Abbreviations: a.s., active substance; MRL, maximum residue level.

[51]Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance). OJ L 20, 25.1.2018, p. 7–10.

[52]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.

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

5.18.2 | Toxicological reference values

TABLE 111 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.07 mg/kg bw per day	JMPR (2011)	0.025 mg/kg bw per day	Reg. (EU) 2018/113	No
ARfD	0.1 mg/kg bw	JMPR (2011)	0.025 mg/kg bw	Reg. (EU) 2018/113	No
Conclusion/comments a.s.	At EU level, a re-evaluation of the toxicological properties of acetamiprid and its metabolites has been recently completed; EFSA recommended to lower the toxicological reference values (ADI and ARfD 0.005 mg/kg bw (per day)), introducing an additional UF of 5 (EFSA, 2024e)				
Comments on metabolites	Metabolites included in JMPR RD for RA: – *N*-desmethyl-acetamiprid (IM-2-1) The metabolite was considered of lower toxicity than the parent Metabolites included in EU RD for RA: – *N*-desmethyl-acetamiprid (IM-2-1) The metabolite is covered by the TRV derived for the parent compound. In the recently published EFSA statement, EFSA recommended the same HBGVs (ADI of 0.005 mg/kg bw per day and ARfD of 0.005 mg/kg bw) proposed for the parent should also apply to the metabolite (EFSA, 2024e)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition; UF, uncertainty factor.

5.18.3 | Residue definitions

TABLE 112 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Acetamiprid	Reg. 396/2005: Acetamiprid Peer review (EFSA, 2016g): Acetamiprid MRL review (EFSA, 2011d): Acetamiprid	Yes
	Animal products	Sum of acetamiprid and *N*-desmethyl-acetamiprid, expressed as acetamiprid The residue is not fat soluble	Reg. 396/2005: Sum of acetamiprid and *N*-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid Peer review (EFSA, 2016g): *N*-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid MRL review (EFSA, 2011d): Sum of acetamiprid and *N*-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid The residue is not fat soluble	Yes
RD-RA	Plant products	Acetamiprid	Peer review (EFSA, 2016g): Acetamiprid MRL review (EFSA, 2011d): Acetamiprid	Yes
	Animal products	Sum of acetamiprid and *N*-desmethyl-acetamiprid, expressed as acetamiprid	Peer review (EFSA, 2016g): Sum of acetamiprid and metabolite IM-2-1 (*N*-desmethyl-acetamiprid), expressed as acetamiprid MRL review (EFSA, 2011d): Sum of acetamiprid and *N*-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid	Yes
Conclusion, comments	At EU level, a review of the residue definition is currently ongoing, since in certain plant products, significant amounts of metabolite IM-2-1 (*N*-desmethyl-acetamiprid were detected in the framework of pesticide monitoring analysis			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.18.4 | Analytical methods

TABLE 113 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High oil content	Yes	0.01	Extraction with QuEChERS (EN 15662), LC–MS/MS (FAO and WHO, 2018a; EFSA, 2016g)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is identical with the JMPR residue definition The current EU MRL for the commodity under discussion (soya bean) is set at the same level as the proposed Codex MRL Sufficiently validated analytical methods for the enforcement of the MRLs for this matrix are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.18.5 | Codex MRL proposals

TABLE 114 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL[a]/new EU regulation[b]	Comment
Soya bean (dry)	0.01	0.01*/0.01*	cGAP: Australia, 2 × 70 g/ha, RTI not reported, 42-day PHI Number of trials: 1 trial approximating AUS GAP, supported by 4 overdosed trials (Brazil, 3 × 113 g/ha) Sufficiently supported by data: Yes Specific comments: In none of the trials, residues above the LOQ were detected **Conclusion:** The Codex MRL should be flagged with an asterisk, indicating that residues above the LOQ are not expected Follow-up action: None
General comments	The use in soya bean did not have an impact on the previously calculated dietary burden and therefore the existing Codex MRLs for animal products do not need to be modified		

Abreviations: cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; LOQ, limit of quantification; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

[a]The EU MRLs currently applicable are set according to Commission Regulation (EU) 2019/88.

[b]The draft Regulation SANTE/11278/2021 was voted favourably in the Standing Committee on Plants, Animals, Food and Feed held on 22–23 February 2022 (not yet applicable).

5.18.6 | Consumer risk assessment

TABLE 115 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: EFSA calculated two scenarios: Scenario 1: The risk assessment was performed with the EU ARfD Scenario 2: The risk assessment was performed with the ARfD recommended by EFSA in 2024. In this scenario, EFSA also included the MRL proposals derived in EFSA (2024e) The short-term dietary risk assessment (PRIMo rev. 3.1) focussed on soya beans only) The calculations are indicative, because the ARfD established at EU level may need to be modified, following an ongoing EU assessment Therefore, the calculations are affected by additional, non-standard uncertainties	**RA assumptions:** EFSA calculated two scenarios: Scenario 1: The risk assessment was performed with the EU ADI Scenario 2: The risk assessment was performed with the ADI recommended by EFSA in 2024. In this scenario, EFSA also included the MRL proposals derived in EFSA (2024e) 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, 2022h) were updated, including the STMR values derived by JMPR soya beans The calculations are indicative, because the EU residue definition for risk assessment and the EU ADI may need to be modified, following an ongoing EU assessment Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** –

TABLE 115 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: Scenarios 1 and 2: No short-term consumer health risk was identified for the soya beans Scenario 1: Soya beans: 0.2% of ARfD Scenario 2: Soya beans: 1% of ARfD	**Results:** Scenarios 1 and 2: No long-term consumer health risk was identified Scenario 1: The overall chronic exposure accounted for 16% of the ADI (NL toddler) Soybeans for up to 0.15% of the ADI Scenario 2: The overall chronic exposure accounted for 44% of the ADI (NL toddler) Soybeans for up to 0.7% of the ADI	**Results:** Long-term exposure: Max 3% of the JMPR ADI GECDE mean: Max. 10% (infants and toddler) GECDE max: Max. 30% (infants and toddler) Short-term exposure: Highest result for soya bean: 0% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.18.7 | Conclusions

TABLE 116 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU; a.s. belongs to the class of neonicotinoids
Toxicological assessment	EU TRV available. A review of the toxicological properties of the a.s. is ongoing which may trigger a revision of the ADI/ARfD
Residue definitions	EU and Codex RDs are identical. However, a review of the residue definitions in currently ongoing, which may trigger a modification of the residue definitions for some crop groups
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	No acute and no chronic intake concern identified in the indicative risk assessment, based on the current EU TRV and residue definitions
Final conclusion	Further discussion with risk managers are recommended in view of the EU policy on protection of pollinators

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.19 | Emamectin (247) T

5.19.1 | Background information

TABLE 117 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Other evaluation, see comment	Emamectin was evaluated by JMPR 2023 due to a request for additional information on analytical methodology, storage stability and MRLs
RMS	NL	
Approval status	Approved. Renewal process ongoing	Commission Implementing Regulation (EU) No 828/2013[54] Dossier submitted by the applicant
EFSA conclusion available	Yes, see comments	EFSA (2012d)
MRL review performed	Yes, see comments	EFSA (2019c)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2021g) (various crops) EFSA (2018i) (leafy brassica and beans and peas with pods)
Classification of a.s. (cut-off criteria)	No, see comments	Emamectin benzoate does not fall under cut-off criteria ECHA (2019b); ATP17[55]

(Continues)

[54]Commission Implementing Regulation (EU) No 828/2013 of 29 August 2013 approving the active substance emamectin, 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 232, 30.8.2013, p. 23–28.

[55]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.

TABLE 117 (Continued)

		Comments, references
Classification of a.s. (cut-off criteria)	No, see comments	Emamectin benzoate does not fall under cut-off criteria ECHA (2019b); ATP17[54]
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Emamectin is approved in Europe as candidate for substitution and it is authorised for use in veterinary medicine	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.19.2 | Toxicological reference values

TABLE 118 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.0005 mg/kg bw per day	JMPR (2011)	0.0005 mg/kg bw per day as emamectin; 0.0007 mg/kg bw per day as emamectin benzoate	Regulation (EU) No 828/2013	No
ARfD	0.02 mg/kg bw	JMPR (2014)	0.01 mg/kg bw as emamectin; 0.011 mg/kg bw as emamectin benzoate	Regulation (EU) No 828/2013	No
Conclusion/ comments a.s.	The ADI/ARfD established by JMPR refer to emamectin benzoate Newly submitted studies on a number of photodegradation metabolites (L-657,831, L-653,649, L-695,638 and L-660,599) were assessed by JMPR 2023; they did not affect the previously established ADI an ARfD for emamectin benzoate				
Comments on metabolites	Metabolites included in JMPR RD for RA: not relevant, as currently no metabolites are included in the RD However, JMPR noted that currently it is unknown whether photodegradation metabolites occur as residues in commodities Data were provided for the following metabolites: – L-657,831 (FAB1a), – L-653,649 (AB1a), – L-695,638 (8,9-Z MAB1a), – L-660,599 (MFB1a)) For all these metabolites, JMPR concluded that the ADI and the ARfD of the parent compound should be used as reference values JMPR noted that the ADI for the parent and for these metabolites is lower than the Cramer class III threshold of 1.5 µg/kg bw per day Metabolites included in EU RD for RA: – Emamectin B1b – 8,9-Z-MBA_{1a} – AB_{1a} – MFB_{1a} – FAB_{1a} For metabolite 8,9-Z-MBA_{1a}, a relative potency factor (RPF) of 1 may apply (EFSA, 2018i) According to the MRL review (EFSA, 2019c), metabolite AB_{1a}, MFB_{1a} and FAB_{1a} are considered more toxic than the parent and a relative potency factor (RPF) of 3 needs to be applied. Hence, for these three metabolites, the JMPR assessment differs from the EU assessment No toxicological information was retrieved specifically for emamectin B1b (and its metabolism/degradation enantiomers), representing < 10% of emamectin technical (EFSA, 2012d)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.19.3 | Residue definitions

TABLE 119 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Emamectin B1a benzoate	Reg. 396/2005 (implementing MRL review): Emamectin B_{1a} and its salts, expressed as emamectin B_{1a} (free base) Peer review (EFSA, 2012d): Emamectin B_{1a} and its salts, expressed as emamectin B_{1a} benzoate	No
	Animal products	Emamectin B1a benzoate The residue is not fat soluble	Reg. 396/2005: Emamectin B_{1a} MRL review (EFSA, 2019c): <u>Ruminants and swine:</u> Emamectin B1a and its salts, expressed as emamectin B1a (free base) Peer review (EFSA, 2012d): Not required The residue is fat soluble	No

TABLE 119 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD-RA	Plant products	Emamectin B1a benzoate	MRL review (EFSA, 2019c): Sum of emamectin B_{1a}, emamectin B_{1b}, 8,9-Z-MAB_{1a}, plus 3 times AB_{1a}, plus 3 times MFB_{1a} and 3 times FAB_{1a}, expressed as emamectin B_{1a} (free base) Peer review (EFSA, 2012d): Emamectin B_{1a} and emamectin B_{1b} and photo metabolites 8,9-Z-MBA_{1a}, AB_{1a}, MFB_{1a} and FaB_{1a} (Provisionally, pending information on the toxicity of the photo-metabolites)	No
	Animal products	Emamectin B1a benzoate	MRL review (EFSA, 2019c): Ruminants and swine: Emamectin B1a and its salts, expressed as emamectin B1a (free base) Peer review (EFSA, 2012d): Not required	No
Conclusion, comments	The Codex MRLs can be converted to match with the EU residue definition, by applying a conversion factor of 0.88 The metabolites included in the EU residue definition for risk assessment were assessed by JMPR. JMPR did not modify the residue definition, as the scope of 2023 JMPR was to assess new toxicological studies and not to re-evaluate the residue definition. However, JMPR noted that it is currently unknown whether the photodegradation metabolites occur as residues in commodities In the EU residue definition these metabolites were included, as they might not only be formed in the crops on the field, but also during sample preparation in the course of the residue analysis			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.19.4 | Analytical methods

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

5.19.5 | Codex MRL proposals

No new CXL proposals were derived by JMPR.

5.19.6 | Consumer risk assessment

Not relevant, no new CXL proposals were derived by JMPR; the previously established TRV were confirmed by JMPR 2023.

5.19.7 | Conclusions

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 (dossier submitted by the applicant) JMPR assessed new studies which did not affect the end points previously derived by JMPR
Toxicological assessment	The previously derived TRV for emamectin benzoate were confirmed by JMPR 2023 In the EU, the toxicity of three of the metabolites assessed by JMPR in 2023 (FAB1a, AB1a and MFB1a) is considered higher than the toxicity of the parent compound (reflected by a relative potency factor in the EU RD for RA), while JMPR considered the metabolites are covered by the parent
Residue definitions	No modifications of the previously derived residue definitions proposed by JMPR
Analytical methods	No new information assessed by JMPR
Codex MRL proposals	No new Codex MRL proposals
Dietary risk assessment	No modification of the previous risk assessments required
Final conclusion	No modification of TRV or Codex MRL proposals suggested. No EU position required on this a.s.

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.20 | Dinotefuran (255) R

5.20.1 | Background information

TABLE 121 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	No RMS assigned	Formally, no RMS nominated, but DE kindly volunteered for providing support to prepare comments on this a.s
Approval status	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	Art. 10 import tolerance in various crops (additional data requested)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2023b)
Endocrine effects of a.s.	Assessment ongoing	Assessment in the framework of the biocide assessment and import tolerance assessment is ongoing (EMS PT)
Other relevant information	Dinotefuran is an a.s. belonging to the group of neonicotinoids It is approved as a biocide for controlling insects, ants, etc. by means other than repulsion or attraction In 2014, CXLs for peaches, grapes, cranberries, onion, spring onions, water cresses, celeries, cotton seeds, rice and a number of animal products have been taken over in the EU MRL legislation[56]	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.20.2 | Toxicological reference values

TABLE 122 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.2 mg/kg bw per day	JMPR (2012)	0.22 mg/kg bw per day (AEL systemic medium/long-term)	ECHA (2014)	No
ARfD	1 mg/kg bw	JMPR (2012)	1.75 mg/kg bw (AEL systemic, acute)	ECHA (2014)	No
Conclusion/ comments a.s.	Dinotefuran has previously been assessed as insecticide under EU biocide legislation (Biocidal Products Regulation (BPR)). An acceptable exposure level (AEL) (systemic medium/long term) of 0.22 mg/kg bw/day was agreed by EU MS and ECHA; an AEL (systemic acute) of 1.75 mg/kg bw was derived (ECHA, 2014b) In the framework of the renewal of dinotefuran as biocide, ADI and ARfD values of 0.22 mg/kg bw per day and 1.25 mg/kg bw, respectively, were discussed/agreed by the experts, but the conclusion is not yet published				
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; according to the 2023 report, both metabolites are covered by the TRVs established for the parent Metabolites included in EU RD for RA: – Not EU residue definition for risk assessment established.				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

[56]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, p. 1–91.

5.20.3 | Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Dinotefuran	Reg. 396/2005: Dinotefuran No EU peer review and no MRL review	Yes
	Animal products	Sum of dinotefuran and UF (1-methyl-3-(tetrahydro-3-furylmethyl) urea), expressed as dinotefuran The residue is not fat soluble	Reg. 396/2005: Dinotefuran The residue is not fat soluble	No, see comment below
RD-RA	Plant products	Sum of dinotefuran, UF and DN, expressed as dinotefuran	RD for RA not yet formally established (assessment of IT application is ongoing, proposal from zRMS: Sum of dinotefuran, UF and DN, expressed as dinotefuran)	Not applicable
	Animal products	Sum of dinotefuran and UF, expressed as dinotefuran	RD for RA not yet formally established (assessment of IT application is ongoing)	Not applicable
Conclusion, comments	In 2014, the CXLs for a number of plant and animal products have been taken over in the EU. However, the EU residue definition for animal products was not aligned with the Codex residue definition for animal products. Hence, EFSA recommends a reconsideration of the residue definition/MRLs for animal products in Regulation (EC) No 396/2005			

Abbreviations: CXL, Codex maximum residue limit; MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; zRMS, zonal Rapporteur Member State.

5.20.4 | Analytical methods

TABLE 124 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content	Yes	0.01	Extraction with acetonitrile/water clean-up with EXtrelut 20 column and ENVI Carb cartridge, LC–MS/MS
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is identical with the JMPR residue definition The current EU MRLs for the commodity under discussion (goji berries, fruiting vegetables other than cucurbits) are lower than the Codex MRL proposals under discussion Sufficiently analytical methods for the enforcement of the MRLs for these matrices are available The method validation reported in the JMPR assessment (FAO and WHO, 2012) was performed on 3 replicates only However, EU validation data on QuEChERS method at 0.002 mg/kg are available		

Abbreviatins: LOQ, limit of quantification; LC–MS/MS, liquid chromatography with tandem mass spectrometry; MRL: maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.20.5 | Codex MRL proposals

TABLE 125 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Goji berry	**0.6**	0.01* (default MRL)	cGAP: China, 1 × 5 g/hL, 5-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: JMPR proposed to revise the existing CXL for fruiting vegetables other than cucurbits (VO 0050), taking out goji berries. In the EU, goji berries are covered by the MRL set for tomatoes **Conclusion:** The proposed Codex MRL is sufficiently supported by data. To discuss with risk managers, if and how the Codex MRL for goji berries could be implemented in EU legislation, as this commodity is listed in Part B of the EU food classification under tomatoes (e.g. introducing a footnote to tomatoes to specify that for goji berry, a higher MRL of 0.6 would be applicable). See also Codex MRL proposal for the Group of fruiting vegetables other than cucurbits (except goji berry) Follow-up action: None

(Continues)

TABLE 125 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Goji berry, dried	2	–	JMPR derived a processing factor of 3 for the RD for enforcement and a factor of 3.3 for the residue definition for risk assessment. Currently, no EU MRLs are established for processed products
Group of fruiting vegetables other than cucurbits (except sweet corn and mushrooms)	0.5 (W)	–	The existing CXL is proposed for withdrawal, and shall be replaced by the new CXL for goji berries and the CXL below, excluding goji berries
Group of fruiting vegetables other than cucurbits (except goji berry)	**0.5**	0.01* (default MRL)	The existing CXL established in 2013 shall continue to apply to all commodities of the group of fruiting vegetables, other than cucurbits, excluding goji berries The EU did not take over this CXL because it was based on a combined data set of residue trials on peppers (8) and tomatoes (15) reflecting a US GAP According to EU guidelines in place in 2013, the setting of a group MRL was not considered appropriate. EFSA recommended to set separate MRLs for peppers (0.3 mg/kg) and tomatoes (0.7 mg/kg), with the option to extrapolate the MRL from tomatoes to aubergines. However, this proposal was not supported by CCPR According to the current extrapolation rules agreed at Codex level, the data set would not be sufficient to set a Codex MRL for this group: studies would be required on – one cultivar of large variety of tomatoes and – one cultivar of small variety of tomatoes and – Sweet Pepper and – Chilli pepper and – one cultivar of a large variety of eggplant and/or tomato and – one cultivar of small variety eggplant and/or tomato. According to the information presented in the JMPR evaluation of 2012 (which was not available for deriving the EU position for CCPR 2013), the residue trials used to derive the MRL proposal for fruiting vegetables other than cucurbits were not representative for the cGAP **Conclusion:** The proposed Codex MRL is not acceptable because it does not reflect the cGAP for fruiting vegetables Follow-up action: None
General comments	–		

Abbreviations: cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; 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.

5.20.6 | Consumer risk assessment

TABLE 126 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 ARfD derived by ECHA for biocides 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. tomatoes (covering goji berries), peppers, aubergines; for okra, no consumption data are available in EFSA PRIMo)	**RA assumptions:** The risk assessment was performed with the ADI derived by ECHA for biocides A long-term dietary risk assessment was performed using PRIMo rev. 3.1., including the proposed Codex MRLs and existing EU MRLs (derived from Codex MRLs) and the related risk assessment input values derived by 2013 and 2023 JMPR. For the remaining commodities, the existing default MRL of 0.01 mg/kg was used as input value	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment Tomatoes and sweet peppers: 2% of ARfD, respectively, Aubergines: 0.8% of the ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 3% of the ADI (GEMS/Food G06) Among the crops under consideration, tomatoes were identified as the main contributor, accounting for up to 0.3% of the ADI	**Results:** Long-term exposure: Max 2% of the JMPR ADI. GECDE mean: Max. 30% (children and adolescents) GECDE max: Max. 60% (infants and toddler) Short-term exposure: Result for goji berries: 0% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment.

5.20.7 | Conclusions

TABLE 127 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	TRV have been derived by ECHA in the framework of the biocide assessment available
Residue definitions	EU and Codex RDs for MRL enforcement in plant commodities are identical. The EU residue definition for animal products should be re-considered: Codex MRLs for animal products have been taken over in the EU, but the residue definition was not aligned with the Codex residue definition
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRL for goji berries is sufficiently supported by data. However, further discussion required for the revised MRL for fruiting vegetables
Dietary risk assessment	No acute and no chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.21 | Cyantraniliprole (263) R

5.21.1 | Background information

TABLE 128 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Approved. Renewal process ongoing	Commission Implementing Regulation (EU) 2016/1414[57] Dossier submitted by the applicant
EFSA conclusion available	Yes, see comments	EFSA (2014e)
MRL review performed	Yes, see comments	EFSA (2017e) (Statement; no MRL review required)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2022d) (Art. 10 in apricots and import tolerance in various crops) EFSA (2021e) (olives) EFSA (2019e) (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	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.21.2 | Toxicological reference values

TABLE 129 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.03 mg/kg bw per day	JMPR (2013)	0.01 mg/kg bw per day	Reg. (EU) 2016/1414	No
ARfD	Unnecessary	JMPR (2013)	Not necessary	Reg. (EU) 2016/1414	Yes

(Continues)

[57]Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 230, 25.8.2016, p. 16–19.

TABLE 129 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Conclusion/ comments a.s.	JMPR has based the ADI on the 90-day and 1-year toxicity studies (dog) applying a safety factor of 100 The EU ADI is based on a 1-year dog study and applying an uncertainty factor of 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile (IN-J9Z38) – 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-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)amino]carbonyl]-6-methylphenyl]-1*H*-pyrazole-5-carboxamide (IN-MYX98) These metabolites have been tested in rodents through their formation from the parent compound and are therefore covered by the ADI for cyantraniliprole – 3-Bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide (IN-N7B69) There is no information about toxicity of IN-7B69. In 2013, JMPR concluded that as the estimated exposure to IN-N7B69 (metabolite in livestock, cotton, rice, tomato leaves and lettuce) was below the threshold of toxicological concern for Cramer class III compounds, there is no concern for this metabolite Metabolites included in EU RD for RA: – 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile (IN-J9Z38) The toxicity of the plant metabolite IN-J9Z38, was considered to be covered by the TRVs of the parent cyantraniliprole – 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-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]-1*H*-pyrazole-5-carboxamide (IN-N7B69) No toxicological information is available on the two other metabolites IN-MLA84 and IN-N7B69 included in the EU RD for animal products (EFSA, 2014e)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.21.3 | Residue definitions

TABLE 130 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyantraniliprole	Reg. 396/2005: Cyantraniliprole Peer review (EFSA, 2014e): Cyantraniliprole	Yes
	Animal products	Cyantraniliprole The residue is not fat soluble	Reg. 396/2005: Cyantraniliprole Peer review (EFSA, 2014e): Cyantraniliprole The residue is not fat soluble	Yes
RD-RA	Plant products	Cyantraniliprole For processed commodities: Sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole	Peer review (EFSA, 2014e): 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)-1*H*-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazoline carbonitrile [**IN-J9Z38**], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazoline carbonitrile [**IN-MLA84**], 3-Bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl] phenyl]-1*H*-pyrazole-5-carboxamide [**IN-N7B69**] and 3-Bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2[[(hydroxymethyl)amino] carbonyl]-6-methylphenyl]-1*H*-pyrazole-5-carboxamide [IN-MYX98], expressed α cyantraniliprole	Peer review (EFSA, 2014e): Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole	No

TABLE 130 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	**EU plant**: Metabolism studies were conducted on four crop categories: cereals (rice), leafy crops (lettuce), pulses/oilseeds (cotton) and fruit crops (tomato). Each crop underwent metabolism investigations after either three foliar or three soil drench applications at 150 g/ha (except for rice, which had a single soil application at 300 g/ha). Regardless of application method, a similar metabolic profile was observed across different crop groups, with cyantraniliprole being the major component of the residues. Thus, the RDs for both enforcement and risk assessment were proposed as cyantraniliprole **Processed commodities:** Cyantraniliprole remained stable under standard hydrolysis conditions simulating pasteurisation and sterilisation but degraded under boiling conditions, leading to the formation of metabolites IN-J9Z38 (12%–14% AR), IN-N5M09 and IN-F6L99 (5%–8% AR). Processing studies confirmed this degradation, with IN-J9Z38 observed at higher levels than cyantraniliprole. Residue definitions for processed commodities were proposed as 'cyantraniliprole' for enforcement and 'sum of cyantraniliprole and IN-J9Z39 expressed as cyantraniliprole' for risk assessment. JMPR proposed similar residue definitions in plant and processed products **EU animal:** Metabolism studies on goats and poultry using ^{14}C-cyantraniliprole labelled on either the cyano or pyrazole part were assessed. The majority of administered radioactivity was excreted, only limited residues were found in tissues, milk or eggs (less than 1% in poultry, 2% in goats). Besides cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N7B69, IN-MYX98 were found in animal products. Based on the overall findings the RD-RA was proposed as 'sum cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N7B69, expressed as cyantraniliprole'. A conversion factor of 2 (except for meat and honey) derived from feeding studies. The JMPR evaluated the same metabolism studies; in addition to the metabolites included in the EU RD, JMPR also included IN-MYX98 into the risk assessment residue definition, as it was identified in significant amounts in metabolism studies (muscle, milk)			

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

5.21.4 | Analytical methods

TABLE 131 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High acid content	Yes	0.01	Aqueous acetonitrile extraction and LC–MS/MS analysis (validation study using cranberry, strawberry, grape, lime); DFG S19 extraction (aqueous acetone) and LC–MS/MS analysis (validation study using oranges)
Plant commodities: High oil content	Yes	0.01	DFG S19 extraction (aqueous acetone) and LC–MS/MS analysis (validation study using almonds)
Plant commodities: Dry commodities	Yes	0.01	DFG S19 extraction (aqueous acetone) and LC–MS/MS analysis (validation study using wheat grain)
Plant commodities: Difficult matrices	No validation data reported in JMPR report	0.04	Aqueous acetonitrile extraction, SPE clean-up by C18, SCX and SAX columns, LC–MS/MS analysis (tea leaves and tea infusion) No validation data available at the EURLs
Animal commodities: Eggs	Yes	0.01	DFG S19 extraction (aqueous acetone), SPE clean-up and LC–MS/MS; aqueous acetonitrile extraction, SPE clean-up, LC–MS/MS analysis
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The current EU MRLs for the commodities under discussion (except the MRL for olives) are lower than the Codex MRL proposal Analytical methods for the enforcement of the MRLs for the relevant matrices are available. Validation data were available for all commodity groups in previous JMPR assessments, with the exception of validation data for difficult matrices (relevant for tea). As the method for tea has not been assessed previously, the validation data are probably reported in detail in the 2023 JMPR evaluation		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; SPE, solid-phase extraction.

5.21.5 | Codex MRL proposals

TABLE 132 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	**0.4**	0.01*	cGAP: Mexico: 2 × 0.08 kg/ha, 14-day RTI, 1-day PHI Number of trials: 7 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

(Continues)

TABLE 132 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Bean (dry)	0.3 (W)	0.3	The existing CXL is replaced with the new proposal for beans, dry subgroup of. See the comments below
Beans, dry, subgroup of	**0.6**	0.3 (beans) 0.01* (lupins/lupini beans) 0.4 (soybeans)	cGAP: 4 × 0.15 kg a.s./ha, 5-day RTI, 7-day PHI Number of trials: 34 (10 beans, 3 peas, 21 soya beans) Sufficiently supported by data: Yes Specific comments: JMPR proposed combining residues from soybeans, peas and beans to establish the Codex MRL for beans, dry, subgroup of and for peas, dry, subgroup of. The subgroup of dry beans would cover dry beans, lupins and soybeans Using the soybeans data set alone, a MRL proposal of 0.4 mg/kg is derived. It is noted that in 2014, JMPR assessed the same studies to derive the MRL for soya beans **Conclusion:** The proposed Codex MRL is sufficiently supported by data; however, as for soya beans a lower MRLs would be sufficient, it is proposed to set the Codex MRL for beans, dry, subgroup of (except soya bens) Follow-up action: None
Cane berries, subgroup of	**4**	0.01* (blackberries, dewberries, raspberries)	cGAP: Canada: 3 × 0.15 kg/ha, 5-day RTI, 1-day PHI Number of trials: 9 (4 in blackberries and 5 in raspberries) Sufficiently supported by data: Yes Specific comments: The residues in blackberries and raspberries are from similar populations (Mann–Whitney test) **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Eggs	**0.3**	0.15	Max dietary burden (poultry layers): 5.14 ppm Max. residues in eggs: 0.203 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR recalculated the dietary burden, including the new feed items (grape pomace, dry beans, dry peas). As for poultry the DB changed compared to the calculations of 2015 JMPR (+9% for maximum DB, +14% for mean DB), JMPR re-evaluated the MRLs for poultry products. Only for eggs a change of the existing CXL was considered necessary **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Grape pomace, dried	15	–	JMPR derived a processing factor of 6.1. Currently, no EU MRLs are established for processed products
Grape, dried (=currants, raisins and sultanas)	3	–	JMPR derived a processing factor of 1.4. Currently, no EU MRLs are established for processed products
Grapes	**2**	1.5	cGAP: Chile: 2 × 0.01 kg a.s./hL with 1500 L/ha, 21-day RTI, not mentioned PHI Number of trials: 9 Sufficiently supported by data: No Specific comments: Trials conducted in Chile involved three applications at the GAP application rate, with the first application at BBCH 65 before fruit formation and 21-day RTI between applications, the first application was deemed insignificant for grape residue levels at harvest. JMPR concluded that the trials in Chile were suitable for CXL proposal **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: To check details on residue decline and PHI in JMPR evaluation report
Olives	1	3	cGAP: Malta: 3 × 7.5 g/ha, 7-day RTI, 7-day PHI; the GAP specifies spraying only on one side of the three row Number of trials: 9 Sufficiently supported by data: Yes Specific comments: The existing EU MRL was derived in 2021 based on a SEU use (3 × 15 g/ha (for treatment on each tree) or 7.5 g/ha on every row, 7-day RTI, 7-day PHI). Hence, the GAP was more critical that the GAP assessed by JMPR. At EU level, the same residue trials were provided (one additional trial was submitted to JMPR). The trials were conducted with 15 g a.s./ha (application on both sides of the trees). JMPR concluded that the field application pattern reflects a double application rate and therefore scaled down the results of the residue trial, using scaling factors ranging from 1.87–2.13

TABLE 132 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL reflects the GAP correctly or whether the EU MRL of 3 mg/kg would be the representative MRL for the EU GAP Follow-up action: None
Olives for oil production	1	3	See above the comments on olives
Peas, dry, subgroup of	**0.6**	0.01* (peas, lentils, dry)	See the comments on **Beans, dry, subgroup of Conclusion:** The proposed Codex MRL for peas, dry, subgroup of is sufficiently supported by data Follow-up action: None
Soya bean (dry)	0.4 (W)	0.4	Specific comments: The existing CXL is proposed for withdrawal. The proposed Codex MRL for beans, dry, subgroup of will cover also soya beans However, the residue trials in soya beans demonstrate that the current CXL of 0.4 mg/kg is sufficient. In 2014, based on the same data set on soybeans (21 trials, see beans subgroup of), JMPR derived a Codex MRL proposal result in a MRL proposal of 0.4 mg/kg **Conclusion:** The existing CXL for soya bean (dry) should be maintained. The new Codex MRL proposal for beans, dry, subgroup of should be modified, excluding soya beans
Tea, green, black (black, fermented and dried)	**50**	0.05*	cGAP: Japan: 1 × 5 g a.s./hL (with spray rate of 4000 L/ha), 7-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: None
Wine-grapes	1 (W)	1.5	The existing CXL is proposed for withdrawal
Bottled wine	–	–	JMPR derived a processing factor (for MRL enforcement) of 1.7. Currently, no EU MRLs are established for processed products
Grape juice	–	–	JMPR derived a processing factor (for MRL enforcement) of 0.83. Currently, no EU MRLs are established for processed products.
Malolactic fermentation wine	–	–	JMPR derived a processing factor (for MRL enforcement) of 1.8. Currently, no EU MRLs are established for processed products
Must (grapes)	–	–	JMPR derived a processing factor (for MRL enforcement) of 2.7. Currently, no EU MRLs are established for processed products
Wet pomace (grapes)	–	–	JMPR derived a processing factor (for MRL enforcement) of 4.8. Currently, no EU MRLs are established for processed products
Processed olives	–	–	JMPR derived a processing factor (for MRL enforcement) of 0.38. Currently, no EU MRLs are established for processed products
Raw oil (olives)	–	–	JMPR derived a processing factor (for MRL enforcement) of 1.2. Currently, no EU MRLs are established for processed products
Refined oil (olives)	–	–	JMPR derived a processing factor (for MRL enforcement) of 0.65. Currently, no EU MRLs are established for processed products
Tea Infusion	–	–	JMPR did not derive any processing factor
Poultry fat	–	0.04	JMPR confirmed its previous CXL proposal of 0.04 mg/kg
Poultry meat	–	Muscle: 0.02	JMPR confirmed its previous CXL proposal of 0.02 mg/kg
Poultry offal	–	0.15	JMPR confirmed its previous CXL proposal of 0.15 mg/kg
General comments	JMPR was also asked to re-evaluate the MRL for tomatoes (0.5 mg/kg) to reflect the indoor use. JMPR concluded that the existing MRL set for the group of fruiting vegetables other than cucurbits is sufficient to cover the residues expected in glasshouse grown tomatoes		

Abbreviations: a.s., active substance; BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval; 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.

5.21.6 | Consumer risk assessment

TABLE 133 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, 2022d) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL: table and wine grapes; blackberries, dewberries, raspberries, avocado, beans dry; dry; lentils, dry; peas, dry; lupins, dry; soya beans, dry and eggs 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:** No long-term consumer health risk was identified The overall chronic exposure accounted for 20% of the ADI (refined mode)/81% of the ADI (normal mode) Among the crops under consideration, wine grapes was identified as the main contributor, accounting for up to 14% of the ADI	**Results:** Long-term exposure: Max 40% of the JMPR ADI GECDE mean: Max. 110% (infants and toddler) GECDE max: Max. 420% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; RD, residue definition; STMR, supervised trials median residue.

5.21.7 | Conclusions

TABLE 134 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 submitted by the applicant)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RD for enforcement and RA in plant and processed are identical; for RA animal commodities, Codex RDs are more comprehensive
Analytical methods	Sufficiently validated analytical methods are available for all relevant commodity groups; however, validation data for difficult matrices need to be verified in 2023 JMPR Evaluation
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data except grapes
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.22 | Imazapyr (267) R

5.22.1 | Background information

TABLE 135 Background information.

	Comments, references
JMPR assessment	JMPR meeting September 2023
Type of JMPR evaluation	New use
RMS	No RMS assigned

TABLE 135 (Continued)

		Comments, references
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[58]
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2014c) (genetically modified soya bean, oilseeds, lentils)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria CLP00[59] (no Risk Assessment Committee opinion available)
Endocrine effects of a.s.	Not assessed	–
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.22.2 | Toxicological reference values

TABLE 136 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**TRV comparable**
ADI	3 mg/kg bw per day	JMPR (2013)	2.5 mg/kg bw per day	EFSA (2014)	Yes, see comment below
ARfD	Unnecessary	JMPR (2013)	Not necessary	EFSA (2014)	Yes
Conclusion/comments a.s.	Although the ADI values are established at different levels, they are in the same order of magnitude				
Comments on metabolites	–				

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

5.22.3 | Residue definitions

TABLE 137 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Imazapyr	Reg. 396/2005: Imazapyr	Yes
			EFSA (2014c) (genetically modified soya bean, oilseeds, lentils): Imazapyr	
	Animal products	Imazapyr	Reg. 396/2005: Imazapyr	Yes
		The residue is not fat soluble	The residue is not fat soluble	
RD-RA	Plant products	Imazapyr	EFSA (2014c) (genetically modified soya bean, oilseeds, lentils): Imazapyr	Yes
	Animal products	Imazapyr	EFSA (2014c): Imazapyr	Yes
Conclusion, comments	The residue definitions derived by JMPR are similar with the EU			

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

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

[59]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.

5.22.4 | Analytical methods

TABLE 138 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: Dry commodities	Yes	0.01	Methods involving extraction with an acetone/water/hydrochloric acid-mixture followed by purification and concentration steps; determination by LC–MS/MS EURL validation data show successful validation in dry commodities (LOQ of 0.01 mg/kg)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix group is identical with the JMPR residue definition The current EU MRL for rice is lower than the Codex MRL proposal Sufficiently validated analytical methods for the enforcement of the MRLs for dry commodities is available		

Abbreviations: LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level.

5.22.5 | Codex MRL proposals

TABLE 139 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Rice	0.06	–	See husked rice. EU MRLs are set for husked rice, but not for rice grain
Rice bran, unprocessed	0.2	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice, hay and/or straw	0.015	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice, husked	**0.07**	0.01*	cGAP: Malaysia: 1 × 0.11 kg/ha, 7–14 days after sowing, ground spray application Number of trials: 9 (6 from Vietnam and 3 from Philippines) approximating the cGAP Sufficiently supported by data: Yes Specific comments: Two trials from Philippines were conducted in the same area, but applications were made more than 30 days apart. JMPR considered them as independent **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Rice, polished	0.05	–	JMPR derived a processing factor of 0.89. Currently, no EU MRLs are established for processed products
Wheat	**0.6**	0.05*	cGAP: Australia: 1 × 0.011 kg/ha, ground spray application, BBCH 31 Number of trials: 9 (6 from Australia and 3 from USA) Sufficiently supported by data: Yes Specific comments: JMPR combined trials conducted in Australia at 1-2N rates with trials from the USA conducted at a 4N rate. The trials from the USA were specifically designed for processing studies. Scaling factors were applied to all overdosed trials accordingly **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Wheat bran, unprocessed	1	–	JMPR derived a processing factor of 1.47. Currently, no EU MRLs are established for processed products
Wheat germ	1	–	JMPR derived a processing factor of 1.39. Currently, no EU MRLs are established for processed products
Wheat straw and fodder, dry	0.05* (W)	–	The existing CXL is proposed for withdrawal and will be replaced by the new MRL proposal for wheat hay and/or straw
Wheat, hay and/or straw	1 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat gluten	–	–	JMPR derived a processing factor of 0.4. Currently, no EU MRLs are established for processed products
Wheat starch	–	–	JMPR derived a processing factor of 0.05. Currently, no EU MRLs are established for processed products
Wheat whole meal (flour)	–	–	JMPR derived a processing factor of 0.99. Currently, no EU MRLs are established for processed products
Wheat whole meal bread	–	–	JMPR derived a processing factor of 0.79. Currently, no EU MRLs are established for processed products
Wheat, flour	–	–	JMPR derived a processing factor of 0.63. Currently, no EU MRLs are established for processed products

TABLE 139 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Rice straw	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat gluten meal	–	–	JMPR derived a processing factor of 0.44. Currently, no EU MRLs are established for processed products
Wheat hay	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat middlings	–	–	JMPR derived a processing factor of 0.72. Currently, no EU MRLs are established for processed products
Wheat milled by-products	–	–	JMPR derived a processing factor of 0.99. Currently, no EU MRLs are established for processed products
Wheat shorts	–	–	JMPR derived a processing factor of 0.8. Currently, no EU MRLs are established for processed products
Wheat straw	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
General comments			

Abbreviations: BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; dw, dry weight; MRL, maximum residue level; 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.

5.22.6 | Consumer risk assessment

TABLE 140 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, including the STMR values derived by JMPR for wheat and rice. For the remaining commodities, the calculations were performed using STMR values related to the existing EU MRLs or the MRLs set at the LOQ	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 0.13% of the ADI (GEMS/Food G11) Among the crops under consideration, wheat was identified as the main contributor, accounting for up to 0.02% of the ADI	**Results:** Long-term exposure: Max < 0.1% of the JMPR ADI GECDE (mean and high) 0% of ADI Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.22.7 | Conclusions

TABLE 141 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. is not approved in the EU
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs are identical
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	The Codex MRL proposals are sufficiently supported by data and risk for consumers is unlikely

Abbreviations: ARfD, acute reference dose; a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.23 | Cyflumetofen (273) R

5.23.1 | Background information

TABLE 142 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	First assessment by JMPR 2014
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Approved. Renewal process ongoing	Commission Implementing Regulation (EU) No 22/2013[60] Renewal Assessment Report (RAR) submitted, EFSA peer review ongoing (representative uses assessed in renewal process: ornamentals and cucumbers)
EFSA conclusion available	Yes, see comments	EFSA (2012a) EFSA (2016h) (conclusion confirmatory data) EFSA (2016i) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for cyflumetofen in light of confirmatory data) EFSA peer review ongoing
MRL review performed	Yes, see comments	EFSA (2021f), implemented in Regulation (EU) 2023/173[61]
EU MRL applications or other EU assessments	No	–
Classification of a.s. (cut-off criteria)	No, see comments	Cyflumetofen does not fall under cut-off criteria ECHA (2017); ATP14[62]
Endocrine effects of a.s.	Assessment ongoing	
Other relevant information	Cyflumetofen meets the definition of per- and polyfluoroalkyl substances (PAFS) based on its chemical structure	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.23.2 | Toxicological reference values

TABLE 143 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.1 mg/kg bw per day	JMPR (2014)	0.17 mg/kg bw per day	Reg. (EU) No 2019/716	No
ARfD	Unnecessary	JMPR (2014)	Not necessary	Reg. (EU) No 2019/716	Yes
Conclusion/comments a.s.	The EU ADI is based on 90-day and 2-year rat studies (NOAEL 16.5 mg/kg bw per day, UF 100) The ADI derived by JMPR is based on a two-generation reproductive toxicity study (rat), UF 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 2-trifluoromethylbenzoic acid (metabolite B-1) The metabolite was considered unlikely to be genotoxic in vivo; LD_{50} > 2000 mg/kg bw. JMPR 2014: B-1 was also found in rat metabolism and is considered to be no more toxic than the parent and, therefore, toxicologically covered by the ADI Metabolites included in EU RD for RA: – 2-(trifluoromethyl) benzoic acid (metabolite B-1). The reference values of the parent cyflumetofen are applicable to this metabolite (B-1)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; LD_{50}, lethal dose, median; NOAEL, no observed adverse effect level; RA, risk assessment; RD: residue definition; UF, uncertainty factor.

[60]Commission Implementing Regulation (EU) No 22/2013 of 15 January 2013 approving the active substance cyflumetofen, 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. OJ L 11, 16.1.2013, p. 8–11.

[61]Commission Regulation (EU) 2023/173 of 26 January 2023 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 1-methyl-3-(trifluoromethyl)-1*H*-pyrazole4-carboxamide (PAM), cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products. OJ L 25, 27.1.2023, p. 1–35.

[62]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.

5.23.3 | Residue definitions

TABLE 144 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyflumetofen	Reg. 396/2005 (implementing MRL review): Cyflumetofen (sum of isomers) Peer review (EFSA, 2012a): Cyflumetofen (sum of isomers)	Yes
	Animal products	Sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen The residue is not fat soluble	Reg. 396/2005: Cyflumetofen (sum of isomers) MRL review (EFSA, 2021f): 2-(trifluoromethyl) benzoic acid (metabolite B-1), expressed as cyflumetofen Peer review (EFSA, 2012a): not applicable The residue is not fat soluble	No
RD-RA	Plant products	Sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen	MRL review (EFSA, 2021f) and Peer review (EFSA, 2012a): Sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl) benzoic acid (metabolite B-1), expressed as cyflumetofen	Yes
	Animal products	Sum of cyflumetofen and 2 trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen	MRL review (EFSA, 2021f): Sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl) benzoic acid (metabolite B-1), expressed as cyflumetofen Peer review (EFSA, 2012a): not applicable	Yes
Conclusion, comments	**Plant commodities**: Metabolism of cyflumetofen was investigated in fruit crops (mandarin, apple and eggplant) at EU and JMPR level (JMPR 2014). Cyflumetofen constituted the major portion of total radioactive residue (TRR), ranging from 67% to 84% TRR initially and 44%–65% TRR after 30 days on fruits, and 77%–87% TRR initially and 44%–81% TRR after 30 days on leaves. Among identified metabolites, only 2-(trifluoromethyl) benzoic acid (metabolite B-1) (free and conjugated), exceeded 10% TRR (up to 15% and 16% TRR, free and conjugated, respectively, in eggplant fruits), and AB-6 at 10% TRR in eggplant leaves The current residue definitions at EU and JMPR levels are similar During EU MRL review, the lack of metabolism studies in leafy crops was considered acceptable only for hops, assuming that the metabolic pattern is similar to eggplant leaves at 14 PHI and field trials on hops. However, it was highlighted that a metabolism study on leafy would be desirable to confirm this assumption Under the current evaluation, JMPR received new GAPs for hops, tea and coffee beans. As JMPR noted that no metabolism studies exist for leafy crops and pulses/oilseeds, essential for hops, tea and coffee beans uses, JMPR re-evaluated the metabolism studies submitted in 2014. JMPR concluded that the metabolism observed in apple and mandarin tree leaves can be considered representative for tea leaves, as both are permanent woody crops. Metabolism in hops was found to be sufficiently addressed by the metabolism studies in eggplants (leaves), mandarin and apple tree leaves. For coffee beans, JMPR considered the metabolism studies in fruit being sufficiently representative, as coffee berries are categorised as fruits Overall, the previously derived residue definitions were confirmed for the additional commodities under assessment The approach used by JMPR to extrapolate the results of metabolism studies in fruit crops to coffee beans is not fully in line with the EU practices and with the requirements described in the FAO manual. Risk management discussion is therefore recommended to decide whether the approach is acceptable **Processed commodities**: In standard hydrolysis studies, cyflumetofen was found to degrade to B-1 (44–75% AR) and AB-1 (32–49% AR) under boiling/brewing and sterilisation conditions These findings suggest that the setting of a separate residue definition for processed products should be considered, as previously suggested in the MRL review (EFSA, 2021f) **Animal commodities**: The RDs for enforcement derived by JMPR and at EU level are different: At EU level, it was therefore decided not to include metabolite B-1 in the enforcement residue definition for animal products, since this metabolite is not specific for cyflumetofen (it can be also formed from flutolanil and fluopyram and any of their metabolites containing the 2-trifluoromethylbenzyl moiety)		

Abbreviations: AR; applied radioactivity. MRL, maximum residue level; PHI, pre-harvest interval; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.23.4 | Analytical methods

TABLE 145 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Cyflumetofen			
Plant commodities: High water content Difficult matrices	Yes	0.01	Methods involving extraction with acetone/water- or acetonitrile/water mixtures followed by several partitioning and/or concentration steps, determination by LC–MS/MS or LC coupled with other detection techniques. EURL validation data show successful validation in high water content commodities (LOQs of 0.01 mg/kg) No validation data are available within the EURLs for cyflumetofen in difficult commodities
2-trifluoromethylbenzoic acid (metabolite B-1) (not relevant for the commodities under discussion, since the metabolite is not included in RD for MRL enforcement)			
Plant commodities: High water content Difficult matrices	Yes	0.01	The above described methods were also successfully validated for metabolite B1 on the same commodities and levels EURL validation data show successful validation in high water content commodities (LOQ of 0.01 mg/kg). No validation data are available within the EURLs for metabolite B-1 in difficult commodities
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups are identical with the JMPR residue definition The current EU MRLs for the commodities under discussion (except the MRL for hops) are lower than the Codex MRL proposal Sufficiently validated analytical methods for the enforcement of the MRLs for cyflumetofen in the relevant matrices are available		

Abbreviations: LC, liquid chromatography; LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; RD, residue definition.

5.23.5 | Codex MRL proposals

TABLE 146 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Coffee bean	**0.08**	0.05*	cGAP: Brazil: 2 × 0.16 kg a.s./ha, 15-day RTI, 14-day PHI Number of trials: 8 Sufficiently supported by data: No Specific comments: See comment on the lack of metabolism studies representative for coffee (classified in metabolism group under pulses/oilseeds) **Conclusion:** The proposed Codex MRL is not acceptable due to the lack of a metabolism studies on pulses/oilseeds Follow-up action: None
Coffee beans instant powder	–	–	JMPR derived a processing factor of 0.24 based on one study only. Currently, no EU MRLs are established for processed products
Coffee beans roasted		–	JMPR derived a processing factor of 0.63 based on one study only. Currently, no EU MRLs are established for processed products
Cucumber	**0.5**	0.4	cGAP: NL, 2 × 0.02 kg a.s./hL, 7-day RTI, 1-day PHI Number of trials: 10 (2 from Japan and 8 from EU) Sufficiently supported by data: Yes Specific comments: EU trials were conducted at a higher application rate (2 × 0.026–0.04 kg/hL) and a scaling factor of 0.48–1 was applied by the JMPR for the EU trials **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Hops beer	–	–	JMPR derived a processing factor of 0.0135, However one trials was below 0.01 mg/kg. Currently, no EU MRLs are established for processed products
Hops extract	–	–	JMPR derived a processing factor of 3.85. Currently, no EU MRLs are established for processed products
Hops, dried	15	30	cGAP: USA 2 × 0.2 kg a.s./ha, 14-day RTI, 14-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: It is noted that at EU level a slightly more critical GAP was assessed, supported by residue trials which lead to a higher MRL (cGAP: Netherlands, 2 × 0.2 kg a.s./ha, 10-day RTI, 14-day PHI) **Conclusion:** The proposed Codex MRL is sufficiently supported by data. The manufacturer should be encouraged to submit the cGAP authorised in the EU and the supporting residue trials to Codex Follow-up action: None

TABLE 146 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Nectarine canned	–	–	JMPR derived a processing factor of < 0.1. Currently, no EU MRLs are established for processed products
Nectarine jam	–	–	JMPR derived a processing factor of 0.22. Currently, no EU MRLs are established for processed products
Nectarine, dried	2	–	JMPR derived a processing factor of 7.2. Currently, no EU MRLs are established for processed products
Peach canned	–	–	JMPR derived a processing factor of < 0.1. Currently, no EU MRLs are established for processed products
Peach jam	–	–	JMPR derived a processing factor of 0.22. Currently, no EU MRLs are established for processed products
Peach, dried	2	–	JMPR derived a processing factor of 7.2. Currently, no EU MRLs are established for processed products
Subgroup of cherries	**0.4**	0.01*	cGAP: Republic of Korea, 2 × 0.01 kg a.s./hL, not specified RTI, 7-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: Trials were conducted at the rate of 2 × 0.018–0.033 kg a.s./hL, RTI (6–7 days). The results were scaled to match with the Korean GAP **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the scaling of the residue trials should be checked in the JMPR evaluation. Follow-up action: To check details in JMPR evaluation.
Subgroup of peaches	0.3	0.3 (peaches, apricots)	cGAP: USA: 2 × 0.2 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials: 12 (10 peach and 2 apricot) Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data, at EU level the same MRL is in place Follow-up action: None
General comments	PF derived for the processed products of coffee beans were based on one study only; these factors are therefore not sufficiently robust to be used for MRL enforcement		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

5.23.6 | Consumer risk assessment

TABLE 147 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, 2021f) 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. cherries, cucumber, coffee beans)	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2% of the ADI (NL toddler) Among the crops under consideration, coffee was identified as the main contributor, accounting for up to 0.14% of the ADI	**Results:** Long-term exposure: Max 1% of the JMPR ADI GECDE mean: Max. 5% (infants and toddler) GECDE max: Max. 20% (infants and toddler, children and adolescents) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.23.7 | Conclusions

TABLE 148 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 (Renewal Assessment Report (RAR) submitted)
Toxicological assessment	EU TRV available

(Continues)

TABLE 148 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Residue definitions	EU and Codex RDs for plant commodities are identical
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data except coffee beans
Dietary risk assessment	No acute and no chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.24 | Oxathiapiprolin (291) R

5.24.1 | Background information

TABLE 149 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New use	
RMS	IE	
Approval status	Approved	Commission Implementing Regulation (EU) 2017/239[63]
EFSA conclusion available	Yes, see comments	EFSA (2016d) EFSA (2018r) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for oxathiapiprolin in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2016d) 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	EFSA (2022f) (import tolerance in blueberries) EFSA (2022a) (kales/radish leaves) EFSA (2020b) (import tolerance in various crops) EFSA (2019b) (Art. 10 and import tolerance in various commodities)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2018); ATP15[64]
Endocrine effects of a.s.	Not assessed	Not assessed under the new criteria established by Regulation (EU) 2018/605[65] EFSA (2016d)
Other relevant information	A.s. meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.24.2 | Toxicological reference values

TABLE 150 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	4 mg/kg bw per day	JMPR (2016)	0.14 mg/kg bw per day	Reg. (EU) 2017/239	No
ARfD	Unnecessary	JMPR (2016)	Not needed	Reg. (EU) 2017/239	Yes

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

[64]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.

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

TABLE 150 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Conclusion/comments a.s.	The JMPR derived an ADI of 4 mg/kg bw per day, based on the NOAEL of 430 mg/kg bw per day for delayed balanopreputial separation in offspring in a two-generation reproductive toxicity study in rats.; UF of 100 applied In the EU assessment, the ADI of 0.14 mg/kg bw per day is based on the NOAEL of 13.6 mg/kg bw per day for increased relative liver weight in a 1-year dog toxicity study and applying an UF of 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 5-(Trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-E8S72) – 1-b-D-Glucopyranosyl-3-(–(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-SXS67) The metabolites are covered by genotoxicity assays and a subacute toxicity study in rat, including IN-SXS67, a glucose conjugate of IN-E8S72 Metabolites included in EU RD for RA: –				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RD, residue definition; RA, risk assessment; UF, uncertainty factor.

5.24.3 | Residue definitions

TABLE 151 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Oxathiapiprolin	Reg. 396/2005: Oxathiapiprolin Peer review (EFSA, 2016d): oxathiapiprolin	Yes
	Animal products	Oxathiapiprolin The residue is not fat soluble	Reg. 396/2005: Oxathiapiprolin Peer review (EFSA, 2016d): Oxathiapiprolin The residue is not fat soluble	Yes
RD-RA	Plant products	Sum of oxathiapiprolin, 5-(trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-E8S72) and 1-b-D-Glucopyranosyl-3-(-(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-SXS67), expressed as parent equivalents	Peer review (EFSA, 2016d): Oxathiapiprolin	No
	Animal products	Sum of oxathiapiprolin, 5-(trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-E8S72) and 1-b-D-glucopyranosyl-3-(-(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-SXS67), expressed as parent equivalents	Peer review (EFSA, 2016d): Oxathiapiprolin	No
Conclusion, comments	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The JMPR RD for RA proposed for plants and livestock includes additional metabolites (IN-E8S72 and IN-SXS67)			

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.24.4 | Analytical methods

TABLE 152 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High acid content High oil content Low water content High water content	Yes	0.01	Extraction with acetonitrile/formic acid/water extraction aqueous formic acid/methanol dilution SPE clean-up (some matrices) reverse-phase LC–MS/MS
Plant commodities: High acid content	Yes	0.01	QuEChERS acetonitrile/water extraction, SPE, LC–MS/MS

(Continues)

TABLE 152 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High oil content	Yes	0.01	DuPont 30422 Acetonitrile/formic acid/water extraction acetonitrile/water dilution reverse-phase LC–MS/MS
Plant commodities: Dry commodities	Yes	0.01	DuPont 30422 Acetonitrile/formic acid/water extraction acetonitrile/water dilution reverse-phase LC–MS/MS
Plant commodities: Difficult matrices	Yes	0.01	Ginseng: DuPont 30422 Supplement No. 1 Acetonitrile/formic acid/water extraction aqueous formic acid/methanol dilution SPE clean-up (some matrices) reverse-phase LC–MS/MS
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups is identical with the JMPR residue definition The current EU MRLs for the commodities under discussion are higher than the Codex MRL proposal, except the MRL for avocados Analytical method DuPont 30422 Supplement No. 1 was previously evaluated by the JMPR (FAO and WHO, 2017); it can be used to determine oxathiapiprolin, IN-E8S72 and IN-SXS67 Sufficiently validated analytical methods for the enforcement of the MRLs for the relevant matrices are available		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); SPE, solid-phase extraction.

5.24.5 | Codex MRL proposals

TABLE 153 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Almond hulls	0.05	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Avocado	**0.09**	0.01*	cGAP: USA, Foliar, 2 × 34 g a.s./ha 14-day RTI, 1-day PHI (maximum seasonal application 67 g a.s./ha) Number of trials: 5 Sufficiently supported by data: Yes Specific comments: A second GAP was assessed by JMPR (USA, Soil application, 2 × 134 g a.s./ha at a 30-day RTI, 30-day PHI (maximum seasonal application 280 g a.s./ha). However, residues were higher following foliar application and thus, MRL and risk assessment values were derived from the GAP with foliar application According to the Codex classification and the FAO Manual, the commodity to be analysed is the whole avocado after removal of pit where the residue is calculated and expressed on a whole fruit basis. As the pits account for an average of 15% of the whole fruit weight, for MRL calculation, the residues for pitted avocadoes were adjusted by multiplying the results with a factor of 1.15 for MRL calculation. EFSA noted that the re-calculation was performed incorrectly: the residues measured in avocado without pit and stem should be recalculated to the whole fruit by multiplying the result with a factor of 0.85 (instead of 1.15). For dietary risk assessment, no residues were reported for pulp, per se, therefore, the total residues reported for pitted avocadoes (peel and pulp) were considered **Conclusion:** The proposed Codex MRL is not acceptable because the recalculation of the residues measured in avocados without pit to the whole fruit would result in a lower MRL of 0.07 mg/kg Follow-up action: None
Group of tree nuts	0.01*	0.01*	cGAP: USA, Soil application, 2 × 0.134 kg a.s./ha, 30-day RTI, 30-day PHI (maximum seasonal application 280 g a.s./ha) Number of trials: 10 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed on almonds (5) and pecan nuts (5). **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: To verify the maximum seasonal application rate in the JMPR evaluation
Hops, dried	5	8	cGAP: USA, Foliar, 3 × 34 g a.s./ha 7-day RTI, 7-day PHI (maximum seasonal application 101 g a.s./ha) OR USA, Soil application, 1 × 280 g a.s./ha, 7-day PHI Number of trials: 6 Sufficiently supported by data: Yes

TABLE 153 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments: None of the trials matched GAP as they involved both soil and foliar applications. The current JMPR noted that residues of oxathiapiprolin following soil application were all < LOQ in previous assessments (EFSA, 2016d, 2018r). However, EFSA would not agree with this conclusion as residues above the LOQ were reported in JMPR 2016, following soil applications, for several crops (e.g. cucumber, summer squash, melons, peppers, tomatoes, lettuces, spinaches) Residues of the metabolites in trials on hops with a soil and three foliar applications were all < LOQ for IN-SXS67 and IN-E8S72. The current JMPR agreed that the contribution of the soil applications to the final residue would be minor and noted that any additional residue would lead to a slight overestimate of consumer exposure and that this would be acceptable **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the details on the residue trials should be checked in the JMPR evaluation. As for the EU uses a higher MRL was derived, the manufacturer should be encouraged to share the EU GAP and the supporting trials with JMPR in view of aligning the Codex MRL with the EU MRL Follow-up action: To check details in JMPR evaluation
Subgroup of bush berries	**0.5**	0.5 (blueberries) 0.01* (currants, gooseberries and rose hips)	cGAP: USA, Foliar, 2 × 0.280 kg a.s./ha, 7-day RTI, 1-day PHI (maximal season application is 580 g a.s./ha (which is probably a wrong value and should read 560 g/ha); the US GAP which refers the US Bush berry subgroup 13-07B, except lowbush blueberry covers also currants, gooseberries, rose hips and some minor crops listed only in Part B of the EU food classification Number of trials: 8 trials in blueberry (highbush) Sufficiently supported by data: Yes Specific comments: The extrapolation to the whole subgroup of bush berries (FB 2006) is in line with the Codex extrapolation rules. In the JMPR report the seasonal maximum seasonal rate is reported as 580 g a.s./ha **Conclusion:** The proposed Codex MRL is sufficiently supported by data. The proposed Codex MRL is higher than the current EU MRLs for currants, gooseberries and rose hips Follow-up action: None
General comments	The current EU MRLs for the commodities under discussion are higher than the Codex MRL proposals, except the MRL for avocados, currants, gooseberries and rose hips For determining the sum of oxathiapiprolin and metabolites IN-E8S72 and IN-SXS67 (according to the residue definition for dietary assessment proposed by JMPR), the concentration of oxathiapiprolin in each sample was added to the concentration of IN-E8S72 multiplied by 2.99 [the ratio of the molecular weights of oxathiapiprolin (539 amu) and IN-E8S72 (180 amu)] and the concentration of IN-SXS67 multiplied by 1.58 [the ratio of the molecular weights of oxathiapiprolin (539 amu) and IN-SXS67 (342 amu)]. When calculating total residues, values reported as below the LOQ were assumed to be at the LOQ The registered GAPs require an SC (suspension concentrate) formulation. The residue trials submitted for all crops, except for blueberries, applied oxathiapiprolin as an oil dispersion (OD) formulation. Side-by-side residue trials performed with cucumber, brassica, potato and tobacco for the two formulations were made available to the JMPR and demonstrated that residues following use of SC and OD formulations are equivalent. The JMPR agreed that trials using an OD formulation could be used to support estimation of maximum residue levels for oxathiapiprolin when the GAP is for an SC formulation		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; LOQ, limit of quantification; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

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

5.24.6 | Consumer risk assessment

TABLE 154 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, 2022f) (import tolerance in blueberries)) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL/risk assessment value is higher than the EU MRL (i.e. avocados, blueberries, currants, gooseberries and rose hips) The calculations are indicative, because the RD for RA derived by JMPR is wider than the EU RD for RA Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** –

(Continues)

TABLE 154 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: Not relevant	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 3% of the ADI (NL toddler) Among the crops under consideration, currants and rose hips were identified as the main contributors, accounting for up to 0.01% of the ADI	**Results:** Long-term exposure: Max 1% of the JMPR ADI GECDE mean: Max. 0% (infants and toddlers) GECDE max: Max. 2% (infants and toddlers)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; RD, residue definition; STMR, supervised trials median residue.

5.24.7 | Conclusions

TABLE 155 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 TRV available
Residue definitions	EU and Codex RD for enforcement are identical; for RA, Codex RDs are more comprehensive
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. However, the Codex MRL proposal for avocado should be re-considered by JMPR
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.25 | Tetraniliprole (324) R

5.25.1 | Background information

TABLE 156 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	Other evaluation, see comment	Follow-up assessment of MRL proposal for mandarins (including mandarin-like hybrids) (subgroup) See below other relevant information
RMS	No RMS assigned	Formally, no RMS nominated, but DE volunteered for providing support to prepare comments on this a.s
Approval status	Not approved	Not authorised in EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2024c) Assessment of toxicological data of tetraniliprole)
Classification of a.s. (cut-off criteria)	Not assessed	–
Endocrine effects of a.s.	Not assessed	–
Other relevant information	In CCPR 2023, the EU made a general reservation on tetraniliprole, as the EU assessment of the substance has not been completed. In addition, the EU noted that the number of residue trials were insufficient to derive a MRL proposal for mandarins (subgroup) JMPR agreed with the comment and informed the CCPR meeting that the MRL proposal will be re-evaluated by JMPR 2023. CCPR therefore retained the MRL proposals for mandarins (1 mg/kg) at step 4. New Codex MRL proposal is presented in the table below	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.25.2 | Toxicological reference values

TABLE 157 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	2 mg/kg bw per day	JMPR (2021)	–	No EU value derived	Not applicable
ARfD	Unnecessary	JMPR (2021)	–	No EU value derived	Not applicable
Conclusion/comments a.s.	EFSA reviewed the toxicological assessment performed by JMPR in 2021 (EFSA, 2024c)				
Comments on metabolites	Metabolites included in JMPR RD for RA: – tetraniliprole-*N*-methyl-quinazolinone-carboxylic acid (BCS-CT30673) – tetraniliprole-benzyl alcohol (BCS-CZ91631) The ADI applies to these metabolites; JMPR also concluded that no ARfD is required for these two metabolites. Further details, see EFSA (2023f) Metabolites included in EU RD for RA: not relevant				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.25.3 | Residue definitions

TABLE 158 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tetraniliprole	Reg. 396/2005: Tetraniliprole (default MRLs/RD according to Art. 18(1)(b))	Yes
	Animal products	Tetraniliprole The residue is not fat soluble	Reg. 396/2005: Tetraniliprole (default MRLs/RD according to Art. 18(1)(b))	Yes
RD-RA	Plant products	Tetraniliprole + tetraniliprole-*N*-methyl-quinazolinone, expressed as tetraniliprole	No EU assessment for residue definitions	Not applicable
	Animal products	Tetraniliprole + tetraniliprole-*N*-methyl-quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole	No EU assessment for residue definitions	Not applicable
Conclusion, comments	The JMPR evaluated tetraniliprole for residue definitions and dietary risk assessment. In plant metabolism studies, tetraniliprole was the predominant component across the investigated crops. Although other metabolites were identified, tetraniliprole was considered the marker compound for the enforcement residue definition. Notably, tetraniliprole-*N*-methyl-quinazolinone was detected in plant matrices and processed commodities and therefore included in the RA-RD alongside with tetraniliprole (see CCPR 2023 for detailed assessment) For livestock assessment (which is not relevant for the current CXL proposal), EFSA disagreed with JMPR proposal for the residue definition in animal commodities (EFSA, 2023f)			

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.25.4 | Analytical methods

A validated analytical method is readily available for analysing tetraniliprole and tetraniliprole-N-methyl-quinazolinone at (LOQ) of 0.01 mg/kg in various plant matrices, including citrus. The method's principle involves extraction with water and acetonitrile, followed by determination using LC–MS/MS (JMPR, 2022). For more details, see EFSA (2023f).

5.25.5 | Codex MRL proposals

Commodity	Codex MRL proposal	EU MRL	Comment
Mandarins (including Mandarin-like hybrids), Subgroup of	**1.5**	0.01* default MRL Art. 18(1)(b) (mandarins)	cGAP: USA, foliar, 3 × 60 g a.s./ha, 5-day RTI, 1-day PHI Number of trials: 9 (5 lemon and 4 in mandarins) Sufficiently supported by data: Yes Specific comments: In 2022, JMPR assessed the GAP on mandarins based on only 4 trials which was considered insufficient for a major crop. JMPR 2023 revised the MRL proposal, as suggested by the EU, and derived a new MRL proposal based on the combined residue trials on lemons and mandarins for the commodity code FC 0003. The STMR for the new MRL proposal is slightly higher than the one derived by JMPR in 2022 (0.19 vs. 0.185 mg/kg) For lemons and lime (including citron) subgroup (FC 0002), a Codex MRL of 1.5 mg/kg was adopted in 2023, based on the same residue trials **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
General comments	–		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; RTI, re-treatment interval; PHI, pre-harvest interval; STMR, supervised trials median residue.

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

5.25.6 | Consumer risk assessment

TABLE 159 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 risk assessment was performed with the JMPR ADI An indicative long-term dietary risk assessment was performed for mandarins only, using PRIMo rev. 3.1 The calculations are affected by additional, non-standard uncertainties, related to the fact that the active substance was never assessed at the EU level	**Specific comments:** JMPR did not update the risk assessment performed in 2022. However, the small increase of the STMR from 0.185 to 0.19 mg/kg is expected not to have a significant impact on the results
Results: Not relevant	**Results:** No long-term consumer health risk was identified The chronic exposure accounted for 0.01% of the ADI (NL toddler)	**Results of risk assessment performed by JMPR in 2022:** Long-term exposure: Max 0.1% of the JMPR ADI Short-term exposure: Not relevant (JMPR did not derive an ARfD)

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

5.25.7 | Conclusions

TABLE 160 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	No EU TRV available; EFSA recently assessed toxicological data presented in JMPR Evaluation. Discussion with risk managers still pending
Residue definitions	Specific residue definitions are not established in the EU, since the a.s. has not been assessed at EU level
Analytical methods	According to JMPR assessment, sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRL is sufficiently supported by data
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified (indicative risk assessment)
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; ARfD, acute reference dose; MRL, maximum residue level; TRV, toxicological reference value.

5.26 | Isoflucypram (330) R/T

5.26.1 | Background information

TABLE 161 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	FR	
Approval status	Approval process ongoing	EFSA conclusion published; Discussion at risk management level ongoing
EFSA conclusion available	Yes, see comments	EFSA (2022e)
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2020b), ATP18[66]
Endocrine effects of a.s.	No conclusion derived	Because of the lack of data in the most sensitive population of concern, the ED assessment for the **T-modality** for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, cannot be concluded The data set for the **EAS-modalities** was considered as sufficiently investigated with no evidence of adversity (scenario 1a). Therefore, for the EAS-modalities, the ED criteria for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU)2018/605, were considered not met EFSA (2022e)
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.26.2 | Toxicological reference values

TABLE 162 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.06 mg/kg bw per day	JMPR (2023)	0.04 mg/kg bw per day	EFSA (2022)	No
ARfD	Unnecessary	JMPR (2023)	0.1 mg/kg bw	EFSA (2022)	No
Conclusion/comments a.s.	The JMPR established an ADI of 0.06 mg/kg bw per day based on a NOAEL of 6.27 mg/kg bw per day from the long-term toxicity and carcinogenicity study in rats and applying an UF of 100. The parent ADI applies to M01, M02, M11, M12, M62, M66, M67, M68 and M69 The EU ADI was set at 0.04 mg/kg bw per day, based on the short-term NOAEL of 4.2 mg/kg bw per day for reduced body weight gain, liver toxicity (hypertrophy) and clinical chemistry changes in the 90-day and 1-year toxicity studies in dogs and applying an UF of 100 The EU ARfD is 0.1 mg/kg bw based on the maternal NOAEL of 10 mg/kg bw per day for the early and significant onset of decreased body weight gain in a developmental toxicity study in rabbits; an UF of 100 was applied The experts considered that the margin of safety to the highest tested dose in the rat carcinogenicity would be 465 in males and 1165 in females, reassuring that the ADI would be protective enough regardless the limitation of the dose selected in the rat carcinogenicity study				
Comments on metabolites	Metabolites included in JMPR RD for RA: – isoflucypram-propanol (free (M01) and conjugated (M19)) – isoflucypram-carboxylic acid (M12) – isoflucypram-desmethyl-carboxylic acid (M11) – isoflucypram-2-propanol (free (M02) and conjugated (M20))				

(Continues)

[66]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.

TABLE 162 (Continued)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
	The toxicity of these metabolites is covered by the TRVs of the parent – isoflucypram desmethyl-propanol (M06) This metabolite was assessed using TTC approach (Cramer Class III) Metabolites included in EU RD for RA: – *N*-{[5-chloro-2-(1-hydroxypropan-2-yl) phenyl]methyl}-*N*-cyclopropyl-3(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carboxamide (M01) – *N*-{[5-chloro-2-(1-hydroxypropan-2-yl) phenyl]methyl}-*N*-cyclopropyl-3(difluoromethyl)-5-fluoro-1*H*-pyrazole-4-carboxamide (M06) – 2-[4-chloro-2-({cyclopropyl[3(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carbonyl]amino}methyl)phenyl] propyl D-glucopyranosiduronic acid (M19), (conjugate of M01) – *N*-{[5-chloro-2-(2-hydroxypropan-2-yl) phenyl]methyl}-*N*-cyclopropyl-3(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carboxamide (M02) – 2-[4-chloro-2-({cyclopropyl[3(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carbonyl]amino}methyl)phenyl] propan-2-yl b-D-glucopyranosiduronic acid (M20) (conjugate of M02) – 2-[4-chloro-2-({cyclopropyl[3(difluoromethyl)-5-fluoro-1*H*-pyrazole-4-carbonyl]amino}methyl)phenyl] propanoic acid (M11) The TRVs of the parent apply to the metabolites M01, M06, M19, M02, M20 and M11 In addition, the toxicity of metabolites M07, M10, M12, M18, M21, M22, M36, M37, M41, M49, M58 is also covered by the TRVs of the parent, based on structural similarity, QSAR-negative QSAR predictions and/or plasma levels of metabolites in toxicity studies A potential concern was identified for metabolites M50, M66, M67 and M77, based on positive genotoxicity QSAR predictions. M66 and M67 were observed in rotational crop studies. M50 is a rat metabolite (urine) which was also identified in goat (urine and kidney). M77 occurred in standard hydrolysis studies as a degradation product of M06			

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition; TTC, threshold of toxicological concern; UF, uncertainty factor.

5.26.3 | Residue definitions

TABLE 163 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Isoflucypram	Reg. 396/2005: Isoflucypram (default MRLs/RD according to Art. 18(1)(b)) Peer review (EFSA, 2022e): Isoflucypram	Yes
	Animal products	Isoflucypram The residue is fat soluble	Reg. 396/2005: Isoflucypram (default MRLs/RD according to Art. 18(1)(b)) Peer review (EFSA, 2022e): Isoflucypram	Yes
RD-RA	Plant products	Sum of isoflucypram and isoflucypram-propanol (M01) (free and conjugated), expressed as isoflucypram	Peer review (EFSA, 2022e): Sum of isoflucypram, M01 and its conjugates, M06 and its conjugates, expressed as isoflucypram (RD applies only for cereals after foliar application) The residue definition for plant products is provisional, pending toxicological data on M77, a degradation product of M06 and M66 and M67 (both metabolites observed in rotational crop studies. For these metabolites, genotoxicity potential needs to be addressed)	No
	Animal products	Sum of isoflucypram, isoflucypram-propanol (M01) (free and conjugated), isoflucypram-carboxylic acid (M12), isoflucypram-desmethyl-carboxylic acid (M11) and isoflucypram-2-propanol (M02) (free and conjugated), expressed as isoflucypram	Peer review (EFSA, 2022e): Sum of isoflucypyram, M01 and its conjugates M19, M02 and its conjugates M20 and M11 expressed as isoflucypyram The residue definition for animal products is provisional, pending toxicological data on M50 (metabolite in ruminant kidney observed at a level of 0.011 mg/kg). No conclusion could be drawn on its genotoxic potential Honey: Sum of isoflucypram, M01 and its conjugates, M06 and its conjugates, expressed as isoflucypram (see RD-RA for plants)	No

TABLE 163 (Continued)

Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	The same metabolism studies in plant and animal were assessed at JMPR and EU level **Primary crops:** Metabolism studies were conducted on various crops such as tomatoes, wheat, soybeans, rapeseed and potatoes. Isoflucypram was the primary compound found in these crops, with significant residues in their edible parts and cereals feed items. Other relevant compounds were also identified in different crops Residue trials on cereals showed that metabolites M01 and M06 were present at levels comparable or higher than the parent compound The proposed residue definition for risk assessment at the EU level included the sum of isoflucypram, M01 and its conjugates, M06 and conjugates expressed as isoflucypram, limited to cereals. (N.B: The metabolic pattern was found to be different in the metabolism studies representative for different crop groups.) For enforcement purposes, the residue definition was proposed as isoflucypram alone JMPR also includes M01 for risk assessment considering the results from the field trials; however, JMPR found M06 not relevant for risk assessment using the TTC approach (Cramer Class III) **In rotational crops**, several compounds, including M49, M52, M66 and M67, occurred at levels above 10% of TRRs, differing from primary crops. Isoflucypram was detected only in wheat forage Concerns regarding the potential genotoxicity of metabolites M66 and M67 in wheat forage and grain led to a data gap for genotoxicity data during the peer review JMPR proposed applying the (TTC) approach to assess M66 and M67 for genotoxicity Additionally, M52 was found in Swiss chard at 0.015 mg/kg Confined rotational field trials analysing isoflucypram and M49 were conducted in cereals, root and leafy crops, with isoflucypram found only in carrot tops at 0.066 mg/kg. JMPR proposed to apply the TTC approach to assess M66 and M67 for the genotoxicity. As regards the occurrence of residues in rotational crops, JMPR consider the current levels are not relevant, especially for feed items, but may need to be re-evaluated for more critical future GAPs **Processed commodities**: Isoflucypram and M01 remain stable (98%) under standard hydrolysis conditions, while M06 degrades into M77 during boiling/brewing/baking (up to 66%) and sterilisation (up to 98%) Due to the potential genotoxicity of M77, additional genotoxicity testing is necessary, particularly because M06 was found in barley grain at significant levels At EU level the residue definitions were proposed provisionally for processed similar to plants. JMPR also proposed a similar residue definition as for plants. JMPR concluded that M77 is not relevant for processing based on processing trials where M77 was found to be below 0.01 mg/kg **Animal commodities:** Animal metabolism studies revealed the presence of isoflucypram in all animal tissues, milk, eggs, liver and ruminant fat. M01 and M06 were detected in significant amounts in most matrices, except for M01 in milk and ruminant fat. Although M07, M11 and M12 were found above 10% TRRs in poultry muscle and liver, poultry feeding studies suggested M07 levels would likely be below 0.01 mg/kg Additional compounds like M02, M19, M20 and M50 were found in ruminants, with the genotoxic potential of M50 remaining not addressed The EU proposed a residue definition for risk assessment including isoflucypram, M01, M19, M02, M20 and M11 expressed as isoflucypram For enforcement, both the EU and JMPR proposed isoflucypram alone. For risk assessment besides the compounds included in the residue definition at EU level, JMPR included M12 (isoflucypram carboxylic acid) found in poultry metabolism studies at max 12% TRRs but not expected above 0.01 mg/kg (1N) from the feeding studies results		

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TTC, threshold of toxicological concern; TRR, total radioactive residues.

5.26.4 | Analytical methods

TABLE 164 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: Dry commodities	Yes, but no details on validation provided in JMPR report	0.01	According to the peer review of the pesticide risk assessment of the active substance and EURLs, isoflucypram residue can be monitored in food and feed of plant origin by high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodities The validation data are not presented in JMPR report. To check details in JMPR Evaluation
Animal products Muscle/meat Fat Liver/kidney Milk Eggs	Yes, but no details on validation provided in JMPR report	0.05 except for eggs (0.005)	Isoflucypram residue in food of animal origin can be determined by QuEChERS method with HPLC–MS/MS. The validation data are not presented in JMPR report. To check details in JMPR Evaluation

(Continues)

TABLE 164 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups are identical with the JMPR residue definition The current EU MRLs for food commodities belonging to the matrix groups of dry commodities and edible offal (liver/kidney) are lower than the Codex MRL proposal under discussion. For the remaining commodities, the EU and the proposed Codex MRLs are at the same level Validated analytical methods for the enforcement of the MRLs for these matrices are available to EFSA. See remarks above		

Abbreviations: MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.26.5 | Codex MRL proposals

TABLE 165 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	**0.1**	0.01*	cGAP: New Zealand, 1 × 75 g a.s./ha, 56-day PHI Number of trials: 21 Sufficiently supported by data: Yes Specific comments: The highest residue (0.1 mg/kg) appears to be an outlier, as it is significantly higher than the remaining residue trial values (19 trials were below 0.01 mg/kg) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Triticale	**0.05**	0.01*	cGAP: New Zealand, 1 × 75 g a.s./ha, 42-day PHI Number of trials: 29 Sufficiently supported by data: Yes Specific comments: extrapolation from data set on wheat **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Wheat	**0.05**	0.01*	cGAP: New Zealand, 1 × 75 g a.s./ha up to BBCH 69, 42-day PHI Number of trials: 29 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Barley, hay and/or straw	5	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Triticale, hay and/or straw	5	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Wheat, hay and/or straw	5	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Milks	0.005*	0.01*	Max. dietary burden (dairy cattle): 2.5 ppm Max. residues in milk: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Milk fats	0.005*	–	Residue of 0.005 mg/kg at the 15.5 ppm feeding level was used for the determination of the residue in milk fats
Meat (from mammals other than marine mammals)	0.01*	– Muscle: 0.01*	Max. dietary burden (beef cattle): 3.6 ppm Max. residues in muscle: < 0.01 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)	0.01*	0.01*	Max. dietary burden (beef cattle): 3.6 ppm Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 165 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	0.01*	0.01*	Max. dietary burden (beef cattle): 3.6 ppm Max. residues in muscle/liver/kidney: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data Follow-up action: None
Eggs	0.01*	0.01*	Max. dietary burden (poultry layer): 0.37 ppm. Max. residues in egg: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action:
Poultry meat	0.01*	– Muscle: 0.01*	Max. dietary burden (poultry layer): 0.37 ppm Max. residues in muscle: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Poultry fats	0.01*	0.01*	Max. dietary burden (poultry layer): 0.37 ppm Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry, edible offal of	0.01*	0.01*	Max. dietary burden (poultry layer): 0.37 ppm Max. residues in liver/kidney: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Barley flour	0.02	–	JMPR derived a processing factor of 1.7. Currently, no EU MRLs are established for processed products
Barley bran, unprocessed	0.05	–	JMPR derived a processing factor of 4.3. Currently, no EU MRLs are established for processed products
Wheat germ	0.015	–	JMPR derived a processing factor of 1.1. Currently, no EU MRLs are established for processed products
Wheat bran, unprocessed	0.015	–	JMPR derived a processing factor of 1.2. Currently, no EU MRLs are established for processed products
General comments	–		

Abbreviations: a.s., active substance; BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval.

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

5.26.6 | Consumer risk assessment

TABLE 166 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 (barley and wheat/triticale)	**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 STMR values derived by JMPR for the commodities for which Codex MRLs were derived (barley and wheat/triticale). For the remaining commodities, the calculations were performed with the existing MRLs (set at the default LOQ of 0.01 mg/kg)	**Specific comments:** –

(Continues)

TABLE 166 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The calculations are indicative, because the residue definitions for risk assessment derived by JMPR are different from the EU residue definitions. In addition, the residue definitions for risk assessment derived in the EU are provisional, pending further data on genotoxicity of some metabolites	The calculations are indicative, because residue definitions for risk assessment derived by JMPR are different from the EU residue definitions. In addition, the residue definitions for risk assessment derived in the EU are provisional, pending further data on genotoxicity of some metabolites	
Results: No short-term consumer health risk was identified for the crops under assessment Wheat: 0.3% of ARfD Barley: 0.1% of ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 3% of the ADI (NL toddler). Among the crops under consideration, wheat was identified as the main contributor, accounting for up to 0.4% of the ADI	**Results:** Long-term exposure: Max 0.3% of the JMPR ADI GECDE (mean): 1% (infants and toddler, children adolescents) GECDE (max): 2% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.26.7 | Conclusions

TABLE 167 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	The assessment of the a.s. for approval in the EU is ongoing
Toxicological assessment	EU TRVs available for the parent compound which are applicable also to the metabolites included in the provisional RD for RA. For additional metabolites (M50, M66, M67 and M77), positive genotoxicity QSAR predictions still need to be addressed by providing genotoxicity studies JMPR applied TTC approach (genotoxicity threshold) for M66 and M67
Residue definitions	EU and Codex RDs are different for the risk assessment
Analytical methods	Validated analytical methods are available. The validation data need to be checked once the JMPR evaluation is published
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	No acute and no chronic intake concern identified in an indicative risk assessment (further toxicological data are required to derive conclusion on genotoxicity potential of some metabolites)
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TTC, threshold of toxicological concern; TRV, toxicological reference value.

5.27 | 1,4-Dimethylnaphthalene (331) R/T

5.27.1 | Background information

TABLE 168 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	NL	
Approval status	Approved. Renewal process ongoing	Commission Implementing Regulation (EU) No 192/2014[67] Dossier submitted by the applicant

[67]Commission Implementing Regulation (EU) No 192/2014 of 27 February 2014 approving the active substance 1,4-dimethylnaphthalene, 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 Text with EEA relevance. OJ L 59, 28.2.2014, p. 20–24.

TABLE 168 (Continued)

		Comments, references
EFSA conclusion available	Yes, see comments	EFSA (2013d) EFSA (2017g) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for 1,4-dimethylnaphthalene in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2021c)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2023g) (potatoes)
Classification of a.s. (cut-off criteria)	No, see comments	1,4-Dimethylnaphthalene does not fall under cut-off criteria ECHA (2019d); ATP17[68]
Endocrine effects of a.s.	Not assessed	–
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.27.2 | Toxicological reference values

TABLE 169 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.3 mg/kg bw per day	JMPR (2023)	0.1 mg/kg bw per day	Commission Implementing Regulation (EU) No 192/2014	No
ARfD	Unnecessary	JMPR (2023)	Not necessary	Commission Implementing Regulation (EU) No 192/2014	Yes
Conclusion/ comments a.s.	JMPR derived the ADI based on the NOAEL of 27 mg/kg bw per day in the 104-week combined chronic toxicity and carcinogenicity study in rats, UF 100, supported by the NOAEL of 32 mg/kg bw per day in the 90-day rat dietary study EU: The ADI is 0.1 mg/kg bw per day, based on the 2-year study in rats NOAEL with an UF of 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 1-hydroxymethyl-4-methylnaphthalene (M21) – 4-methyl-1-naphthoic acid (M23) – Glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23: M02) The ADI applies also to M21, M23 and M02, expressed as parent The ADI covers additional metabolites not included in the RD (i.e., M01 and M03) Metabolites included in EU RD for RA: – 1-hydroxymethyl-4-naphthalene (M21) – 4-methyl-1-naphtanoic acid (M23) The metabolites are covered by ADI of parent as they are major rat metabolites and therefore contribute substantially to the toxicological profile of 1,4-dimethylnaphthalene; it is very unlikely that they have higher toxicity compared to the parent (EFSA, 2013d)				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RD, residue definition; RA, risk assessment; UF, uncertainty factor.

5.27.3 | Residue definitions

TABLE 170 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	1,4-dimethylnaphthalene	Reg. 396/2005: 1,4-dimethylnaphthalene MRL review (EFSA, 2017c): Root crops: 1,4-dimethylnaphthalene Processed potato (tentative): 1,4-dimethylnaphthalene	Yes

(Continues)

[68]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.

TABLE 170 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	For milk: Glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23) Other animal products: Sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23), expressed as 1,4-dimethylnaphthalene The residue is fat soluble The residue definition in milk is not fat-soluble	Reg. 396/2005: Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene The residue is fat soluble	Not fully comparable
RD-RA	Plant products	Sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene	MRL review (EFSA, 2021c): Root crops: Sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene (RMS noted that the determination of M21 conjugates is technically not possible) Processed potato (tentative): Sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene	Slightly different
	Animal products	Sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic acid (M23) and its glycine conjugate 4-methyl-1-naphthoic acid (Gly-M23) expressed as 1,4-dimethyl naphthalene	MRL review (EFSA, 2017c): Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene	No
Conclusion, comments	**Plants (root)**: Metabolism studies in potatoes are available, where 1,4-dimethylnaphthalene was the major component identified in the whole tuber (79–93% TRRs), in peeled potato and potato peel (57–94% TRR). Additionally, in peeled potato, metabolite M21 accounted for up to 20% TRR 30 days after the sixth application, while M23 was either not detected or in low proportions. Other minor polar compounds were detected after six applications (7–10% TRR) further identified as 1,4-dimethylnaphthol and glycoside conjugates of metabolite M21. Based on these results, the residue for enforcement was defined as 1,4-dimethylnaphthalene while for risk assessment it was defined as sum of 1,4-dimethylnaphthalene and M21 and its conjugates expressed as 1,4-dimethylnaphthalene At JMPR level the same metabolism study was assessed. JMPR derived an enforcement residue definition similar to the EU, while for risk assessment a slightly different residue definition was proposed, which does not comprise the glucoside conjugates of M21. However, their contribution to the dietary exposure is expected to be insignificant **Processed commodities:** Standard hydrolysis studies to investigate 1,4-dimethylnaphthalene, M21 and M23 were not available at the EU level. However, a study simulating household processing of potatoes (boiling, frying and baking) was conducted with radiolabelled 1,4-dimethylnaphthalene and submitted under the MRL review (EFSA, 2021c) In all samples of processed potatoes, 1,4-dimethylnaphthalene was the major compound identified (47–58% TRR), while M21 and M23 were identified at 0.5%–7.2% TRR and < 0.6%–5.6% TRR, respectively. In the MRL application (EFSA, 2023g), additional confirmation was provided for the compounds provisionally identified as glycoside conjugates of M21 and 1,4-dimethylnaphthol during the MRL review. The same residue definitions as for plants are applicable for processed commodities Based on the same processing study in potatoes, JMPR concluded that for dietary intake of processed commodities, the same residue definition as for unprocessed products should apply **Animal commodities:** Livestock metabolism studies were conducted with 1,4-dimethylnaphthalene. In goat study the major compound found was the conjugate of M23, accounting for 18% and 16% TRR in milk and in kidney, respectively, while the parent was rapidly absorbed and excreted. In poultry M23 (free and conjugated) was the major compound accounting up to 71% of TRRs in all matrices except fat, where the parent compound was the most predominant (94% of TRRs). 1,4-Dimethylnaphthalene was also present in eggs and muscle at relevant amounts (29–35% TRR). The residue definitions at EU level for both, enforcement and risk assessment were defined as the sum of 1,4-dimethylnaphthalene and its metabolite M23 (free and conjugated), expressed as 1,4-dimethylnaphthalene JMPR derived a slightly different residue definition for animal matrices except milk based on the same livestock metabolism studies, including the glycine conjugate of M23, while in the EU residue definition, free and conjugated M23 was included, without specifying the type of conjugate. For milk, JMPR proposed a separate residue definition The EURLs noted that 1,4-DMN and other DMN-isomers may occur naturally in various plants (EFSA, 2021c). DMN isomers also occur in mineral oils (naphtha), that are commonly used in agriculture, either as adjuvants in plant protection products or even as active ingredients		

Abbreviations: MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TRR, total radioactive residues.

5.27.4 | Analytical methods

TABLE 171 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
1,4-Dimethylnaphthalene			
All plant commodities except high protein	Yes	0.05	QuEChERS-extraction and determination by LC–MS/MS. EURL data show successful validation, of 1,4-DMN in high water content commodities of plant origin with an LOQ of 0.01 mg/kg
Animal products Muscle/meat Fat Liver/kidney Milk (only relevant for EU RD) Eggs	Yes	0.01–0.06 (unspecified)	Extraction with acetonitrile or ethanol followed by a clean-up procedure and determination by GC–MS/MS. EURL data show successful validation, of 1,4-DMN in in milk and liver with an LOQ of 0.01 mg/kg. Based on the experience gained for milk and liver, an LOQ of 0.01 mg/kg could be achievable also for the other matrices of animal origin
4-Methyl-1-naphthoic acid (M23)			
Animal products Muscle/meat Fat Liver/kidney Milk (glycine conjugate of M23) Eggs	Yes	0.01–0.06 (unspecified)	Extraction with acetonitrile or ethanol followed by a clean-up procedure and determination by GC–MS/MS The detailed validation data are not reported in the JMPR report
Conclusion	The EU residue definition for MRL enforcement for the plant products is identical with the JMPR residue definition. For animal commodities except milk, the EU residue definition also comprises the conjugates of metabolite M23 (without specifying) and therefore differs from the JMPR residue definition which does not include any conjugates of M23 The JMPR RD for milk is set for the glycine-conjugate of M23 and therefore also differs from the EU RD Sufficiently analytical methods for the enforcement of the MRL for this matrix are available, both at JMPR and EU level		

Abbreviations: GC–MS/MS, gas chromatography with tandem mass spectrometry; LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.27.5 | Codex MRL proposals

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

Commodity	Codex MRL proposal	Existing EU MRL/new MRLs[a]	Comment
Baked potato (unpeeled)	–	–	JMPR derived a processing factor of 0.59. Currently, no EU MRLs are established for processed products
Boiled potato (peeled)	–	–	JMPR derived a processing factor (PF) of < 0.02. Currently, no EU MRLs are established for processed products
Boiled potato (unpeeled)	–	–	JMPR derived a processing factor of 0.26. Currently, no EU MRLs are established for processed products
Canned potatoes (unpeeled)	–	–	JMPR derived a PF of 0.25. Currently, no EU MRLs are established for processed products
Edible offal (mammalian)	0.5	Liver from – swine: 1.5/1.5; – bovine and equine: 3/**2**; – sheep and goat: 4/**3** Kidney from: – swine: 1.5/1.5; – bovine and equine: 3/**2** sheep and goat: 3/**3** Edible offals (other than liver and kidney) from: – swine: 1.5/1.5; – bovine and equine: 3/**2**; – sheep and goat: 4/**3**	Max. dietary burden (EU dairy cattle): 33 ppm Max. residues in liver: 0.42 mg/kg Max. residues in kidney: 0.21 mg/kg Sufficiently supported by data: Yes Specific comments: In the EU assessment (EFSA, 2023g), a higher dietary burden was estimated for dairy cattle (207 ppm). This difference is explained by the use of default processing factors for feed items based on potatoes (N.B.: the EU dietary burden calculation is mainly driven by potato dried pulp, using a PF of 38, while JMPR used an empirical PF of 3.2). In addition, in the EU dietary burden calculation, for all feed items, the occurrence of a natural background level of 1,4-DMN at a level of 0.1 (multiplied by the default PF) was assumed. Hence, the EU assessment was following a very conservative approach **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

(Continues)

TABLE 172 (Continued)

Commodity	Codex MRL proposal	Existing EU MRL/new MRLs[a]	Comment
Eggs	0.03	0.15/**0.4**	Max. dietary burden (EU poultry layer): 13 ppm Max. residues in eggs: 0.025 mg/kg Sufficiently supported by data: Yes Specific comments: In the EU assessment (EFSA, 2023g), a higher dietary burden was estimated for dairy cattle (69 ppm). This difference is explained by the use of default PFs for feed items based on potatoes (see also edible offal (mammalian). In addition, in the EU dietary burden calculation, for all feed items, the occurrence of a natural background level of 1,4-DMN at a level of 0.1 (multiplied by the default PF) was assumed **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Fried potato (unpeeled)	–	–	JMPR derived a PF of 0.6 based on one processing study only. Currently, no EU MRLs are established for processed products
Mammalian fats	0.03	0.4/**0.3** (swine); 1/**0.5** (bovine and equine); 1.5/**0.6** (sheep and goat)	Max. dietary burden (EU beef cattle): 35 ppm Max. residues in fat: 0.025 mg/kg Sufficiently supported by data: Yes Specific comments: See also comments on edible offal (mammalian) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	0.03 (fat)	– Muscle: 0.03/0.03 (swine); 0.04/**0.03** (bovine, sheep, goat and equine)	Max. dietary burden (EU beef cattle): 35 ppm. Max. residues in muscle: < 0.016 mg/kg Sufficiently supported by data: Yes Specific comments: The Codex MRL proposal is flagged with the suffix (fat). Hence it refers to fat. The corresponding MRL for muscle would be slightly lower (0.02 mg/kg) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Microwaved potatoes (unpeeled)	–	–	JMPR derived a PF of 0.17. Currently, no EU MRLs are established for processed products
Milks	0.03	0.4/**0.3** (cattle and horse); 0.5/**0.3** (sheep and goat)/	Max. dietary burden dairy cattle: 33 ppm Mean/max. residues in milk: 0.022 mg/kg Sufficiently supported by data: Yes Specific comments: See specific comments on edible offal (mammalian) Since the enforcement residue definitions are different, the EU MRL and the Codex MRL are not directly comparable. In theory, the Codex MRL could be recalculated to match with the EU residue definition, using molecular weight correction factors. However, this conversion is not necessary, considering that the EU MRL is set at a significantly higher level than the proposed Codex MRL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Peeled potato	-	-	JMPR derived a PF of 0.24. Currently, no EU MRLs are established for processed products
Potato	15 (Po)	15/**20**	cGAP: Germany: 6 × 20 mL a.s./1000 kg, 28- to 42-days RTI, 30-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: Trials were performed in UK and NL within 25% GAP deviation. The GAP assessed in the EU (EFSA, 2023g) is more critical (i.e. 6 × 19.6 g a.s./1000 kg, 30- to 40-day RTI, 3-day PHI), leading to a higher MRL **Conclusion:** The proposed Codex MRL is sufficiently supported by data. In the EU a higher MRL will be implemented based on more critical data set Follow-up action: None
Potato crisps (peeled)	–	–	JMPR derived a PF of 0.14. Currently, no EU MRLs are established for processed products
Potato crisps (unpeeled)	–	–	JMPR derived a PF of 0.19. Currently, no EU MRLs are established for processed products

TABLE 172 (Continued)

Commodity	Codex MRL proposal	Existing EU MRL/new MRLs[a]	Comment
Potato dried pulp		–	JMPR derived a PF of 3.2. Currently, no EU MRLs are established for processed products
Potato flakes (flour)	–	–	JMPR derived a PF of 0.15. Currently, no EU MRLs are established for processed products
Potato fries (chips) (peeled)	–	–	JMPR derived a PF of < 0.05. Currently, no EU MRLs are established for processed products
Potato fries (chips) (unpeeled)	–	–	JMPR derived a PF of 0.18. Currently, no EU MRLs are established for processed products
Potato process waste	–	–	JMPR derived a PF of 0.29. Currently, no EU MRLs are established for processed products
Potato starch	–	–	JMPR derived a PF of 0.45. Currently, no EU MRLs are established for processed products
Poultry edible offal	0.2	0.6/**1.5** (liver) 0.7/**1.5** (kidney and edible offals)	Max. dietary burden (EU poultry broiler): 15 ppm Max. residues in liver: 0.18 mg/kg Sufficiently supported by data: Yes Specific comments: At EU level a higher MRL is in place. See also specific comments on eggs **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry fats	0.3	0.7/**1.5**	Max. dietary burden (EU poultry broiler): 15 ppm Max. residues in fat: 0.21 mg/kg Sufficiently supported by data: Yes Specific comments: At EU level a higher MRL is in place. See also specific comments on eggs **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry meat	**0.3** (fat)	– Muscle: 0.2/**0.3**	Max. dietary burden (EU poultry broiler): 15 ppm Max. residues in muscle: 0.51 mg/kg Sufficiently supported by data: Yes Specific comments: The See also specific comments on eggs. The Codex MRL proposal is flagged with the suffix (fat). Hence it refers to fat. The corresponding MRL for muscle would be slightly lower (0.06 mg/kg) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Sliced potato	–	–	JMPR derived a PF of 0.45. Currently, no EU MRLs are established for processed products
General comments	It is noted that that different PFs were derived at EU level and by JMPR. Thus, the details of the processing studies should be checked once the JMPR Evaluation is published, to identify the reason for the differences		

Abbreviations: a.s., active substance; cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; Po, the recommendation accommodates post-harvest treatment of the commodity; PHI, pre-harvest interval; RTI, re-treatment interval.

[a]New MRLs voted via written procedure following the PAFF meeting of February 2024 (PLAN/2023/2305).

5.27.6 | Consumer risk assessment

TABLE 173 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. For the commodities under assessment, the input values in the most recent long-term risk assessment (EFSA, 2023g) were higher than the values derived by JMPR. Therefore, the EU risk assessment of 2023 is still valid	**Specific comments:** –

(Continues)

TABLE 173 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
–	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 83% of the ADI (NL toddler) The most recently voted EU-MRLs are higher than the proposed CXL, thus the dietary exposure calculations were conducted with the inputs values from EU assessment	**Results:** Long-term exposure: Max 0.3% of the JMPR ADI GECDE mean: Max. 20% (infants and toddler, children and adolescents) GECDE max: Max. 60% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; CXL, Codex maximum residue limit; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment.

5.27.7 | Conclusions

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, renewal process ongoing (dossier submitted by the applicant)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RD for enforcement are similar for plants; in animal commodities, the RDs are slightly different; for RA, EU RDs are more comprehensive including also all conjugates
Analytical methods	Sufficiently validated analytical methods are available. However, the details on the validation are not reported in the JMPR report
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	Codex MRL proposals are sufficiently supported by data and risk for consumers is unlikely

Abbreviations: ARfD, acute reference dose; a.s., active substance; MRL, maximum residue level; RA, risk assessment; RD, residue definition; TRV, toxicological reference value.

5.28 | Florylpicoxamid (332) R/T

5.28.1 | Background information

TABLE 175 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	DK	
Approval status	Approval process ongoing	Dossier submitted by the applicant, RMS assessment ongoing
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	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.28.2 | Toxicological reference values

TABLE 176 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.1 mg/kg bw per day	JMPR (2023)	–	No EU assessment finalised	Not applicable
ARfD	Unnecessary	JMPR (2023)	–	No EU assessment finalised	Not applicable
Conclusion/comments a.s.	The JMPR ADI is based on the NOAEL of 9.58 mg/kg bw per day in the developmental toxicity study in rabbits (maternal toxicity) and applying a safety factor of 100				
Comments on metabolites	Metabolites included in JMPR RD for RA: – X12485649 The metabolite is covered by the parent compound Metabolites included in EU RD for RA: not relevant				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition.

5.28.3 | Residue definitions

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	Sum of florylpicoxamid and X12485649 expressed as florylpicoxamid	Reg. 396/2005: Florylpicoxamid (default MRLs/RD according to Art. 18(1)(b)) No EU peer review and no MRL review	No (compared with the default RD)
	Animal products	Sum of florylpicoxamid and X12485649 expressed as florylpicoxamid The residue is fat soluble	Reg. 396/2005: Florylpicoxamid (default MRLs/RD according to Art. 18(1)(b)) No EU peer review and no MRL review Fat solubility not specified	No (compared with the default RD)
RD-RA	Plant products	Sum of florylpicoxamid and X12485649 expressed as florylpicoxamid	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of florylpicoxamid and X12485649 expressed as florylpicoxamid	No EU peer review and no MRL review	Not applicable
Conclusion, comments	JMPR assessed metabolism studies with foliar application to tomatoes, lettuce and wheat with radiolabelled a.s. (phenyl-UL-14C label and pyrazol-2-14-C label). The residue definitions derived by JMPR cover the parent compound and metabolite X12485649, which were the major residues in metabolism studies in tomatoes (fruits), lettuce. In wheat grain, parent florylpicoxamid was not detected. Only limited results are reported for cereal grain. X12485649 was also often unquantified in cereal grain Follow-up action: To check details in JMPR evaluation, whether metabolite X12485649 is a suitable marker for cereal grain. The RMS also proposed to align the EU enforcement residue definitions for plant and animal products with the residue definition derived by JMPR (including metabolite X12485649)			

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.28.4 | Analytical methods

TABLE 178 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content High oil content Dry commodities	Yes	0.01	Extraction with acetonitrile/waters acidified with H_3PO_4, purified with SPE, LC–MS/MS

(Continues)

TABLE 178 (Continued)

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Animal products Muscle/meat Fat Liver/kidney Milk Eggs	Yes	0.01	Extraction with acetonitrile/waters acidified with H_3PO_4, purified with SPE, LC–MS/MS
Conclusion	In the EU, the default residue definition (i.e. parent compound only) is applicable, as the a.s. has not been assessed previously in the EU Sufficiently validated analytical methods for the enforcement of the MRLs for the matrix groups for which Codex MRL proposals were derived by JMPR are available for the residue definition suggested by JMPR. Validation data shows sufficient data for recovery and relative standard deviations		

Abbreviations: a.s., active substance; LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; SPE, solid-phase extraction.

5.28.5 | Codex MRL proposals

TABLE 179 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Grapes	**3**	0.01* default MRL Art. 18(1)(b) (table and wine grapes)	cGAP: AUS, 3 × 15 g/hL, 10-day RTI, 10-day PHI Number of trials: 14 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Strawberry	**1.5**	0.01* default MRL Art. 18(1)(b)	cGAP: AUS, 3 × 0.150 kg/ha, 7-day RTI, 1-day PHI Number of trials: 26 (19 trials on outdoor strawberries and 7 trials on protected strawberries) Sufficiently supported by data: Yes Specific comments: the GAP refers to outdoor and protected conditions **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Banana	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Panama, 3 × 50 g/ha, 7-day RTI, 0-day PHI Number of trials: 23 (7 trials in Australia, 3 in Colombia, 4 in Costa Rica, 3 in Ecuador, 6 in Brazil) Sufficiently supported by data: Yes Specific comments: In all trials, residues were measured in bagged and unbagged bananas. The highest result of a site was selected for calculating the MRL. In all trials except the Brazilian trials, also the pulp was analysed **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Mango	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Nicaragua, 3 × 0.15 kg/ha, 7-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Residues analysed in whole fruit (without stone) and in pulp. For calculating the MRL, a pit weight of 15% was assumed **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of fruiting vegetables, cucurbits – cucumbers and summer squashes	**0.3**	0.01* default MRL Art. 18(1)(b)	cGAP: Australia, 3 × 0.15 kg/ha, 7-day RTI, 1-day PHI Number of trials: 29 (12 trials in summer squash and 13 in cucumbers) Sufficiently supported by data: Yes Specific comments: In addition to the outdoor GAP, JMPR also received information on an indoor GAP. Since this gave lower residues, the MRL proposal was based on the outdoor GAP. The data sets for cucumbers and summer squash were merged **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of fruiting vegetables, cucurbits – melons, pumpkins and winter squashes	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: no country reported, 3 × 0.15 kg/ha, 7-day RTI, 1-day PHI (outdoor use) Number of trials: 16 trials on melons Sufficiently supported by data: Yes Specific comments: The trials were performed under outdoor conditions **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 179 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of tomatoes	**0.9**	0.01* default MRL Art. 18(1)(b)	cGAP: Australia, 3 × 0.15 kg/ha, 7-day RTI, 1-day PHI (outdoor use) Number of trials: 35 Sufficiently supported by data: Yes Specific comments: For the indoor use, the residues were lower **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Peppers, chilli	**0.8**	0.01* default MRL Art. 18(1)(b)	See sweet peppers
Peppers, sweet	**0.8**	0.01* default MRL Art. 18(1)(b)	cGAP: Australia, 3 × 0.15 kg/ha, 7-day RTI, 1-day PHI (outdoor use) Number of trials: 30 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Peppers, chilli, dried	8	–	The Codex MRL proposal was derived by applying the default dehydration factor of 10 to the MRL for sweet peppers.. Currently, no EU MRLs are established for processed products
Subgroup of eggplants	**0.9**	0.01* default MRL Art. 18(1)(b)	cGAP: Australia, 3 × 0.15 kg/ha, 7-day RTI, 1-day PHI (outdoor use) Number of trials: 35 trials on tomatoes Sufficiently supported by data: Yes Specific comments: The MRL proposal for eggplants was derived by extrapolation from tomatoes (see above) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Lentil (dry)	**0.02**	0.01* default MRL Art. 18(1)(b)	cGAP: Canada, 1 × 50 g/ha, up to BBCH 72, 30-day PHI Number of trials: 10 (5 trials on dry beans and 5 on peas) Sufficiently supported by data: Yes Specific comments: Trials were performed with exaggerated rates (2 × 100 – 260 g/ha, PHI ranging from 21 to 36 days. As in none of the trials residues above the LOQ of 0.021 mg/kg were detected, the trials were considered acceptable **Conclusion:** To discuss with MS whether the trials are sufficiently representative for the cGAP and to conclude that residues above the LOQ are unlikely to occur. If this is agreed, the MRL proposals should be flagged with an asterisk, indicating that it is set at the LOQ Follow-up action: To check details in JMPR evaluation
Sugar beet	**0.05**	0.01* default MRL Art. 18(1)(b)	cGAP: Canada, 2 × 0.15 kg/ha, 10-day RTI, 21-day PHI Number of trials: 18 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Wheat	**0.03**	0.01* default MRL Art. 18(1)(b)	cGAP: Canada and Australia, 2 × 50 g/ha up to BBCH 69, 14-day RTI, PHI not required Number of trials: 69 Sufficiently supported by data: Yes Specific comments: Trials from Australia, Europe, US and Canada were merged. In all trials except one residues were below the LOQ **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Rape seed	**0.15**	0.01* default MRL Art. 18(1)(b)	cGAP: Canada, 2 × 0.15 kg/ha, 7-day RTI, 21-day PHI Number of trials: 20 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Grape, dried	7	–	JMPR derived a processing factor of 2.1. Currently, no EU MRLs are established for processed products
Grape, juice	–	–	JMPR derived a processing factor of 0.25. Currently, no EU MRLs are established for processed products
Grape, jelly	–	–	JMPR derived a processing factor of 0.061 Currently, no EU MRLs are established for processed products
Grape, wine (red)	–	–	JMPR derived a processing factor of 0.064. Currently, no EU MRLs are established for processed products

(Continues)

TABLE 179 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Grape, wine (white)	–	–	JMPR derived a processing factor of 0.023. Currently, no EU MRLs are established for processed products
Tomato, dried	6	–	JMPR derived a processing factor of 6. Currently, no EU MRLs are established for processed products
Tomato, paste/puree	–	–	JMPR derived a processing factor of 0.63 for paste and 0.19 for puree. Currently, no EU MRLs are established for processed products
Tomato, juice	–	–	JMPR derived a processing factor of 0.11. Currently, no EU MRLs are established for processed products
Tomato, canned fruit	–	–	JMPR derived a processing factor of < 0.03. Currently, no EU MRLs are established for processed products
Refined sugar	–	–	JMPR derived a processing factor of < 0.2. Currently, no EU MRLs are established for processed products
Wheat bran (unprocessed)	0.07	–	JMPR derived a processing factor of 2.2. Currently, no EU MRLs are established for processed products
Wheat white flour (550)	–	–	JMPR derived a processing factor of < 0.91. Currently, no EU MRLs are established for processed products
Wheat wholemeal flour	–	–	JMPR derived a processing factor of 1.2. Currently, no EU MRLs are established for processed products
Wheat wholemeal bread	–	–	JMPR derived a processing factor of 1. Currently, no EU MRLs are established for processed products
Wheat germ	–	–	JMPR derived a processing factor of < 0.91. Currently, no EU MRLs are established for processed products
Wheat starch	–	–	JMPR derived a processing factor of < 0.91. Currently, no EU MRLs are established for processed products
Wheat gluten	0.04	–	JMPR derived a processing factor of 1.3. Currently, no EU MRLs are established for processed products
Edible offal (Mammalian)	**0.09**	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (Australian beef cattle): 24 ppm Mean/max. residues in liver: 0.086 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Eggs	**0.02**	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (Canadian layer): 0.43 ppm. Max. residues in eggs: < 0.021 mg/kg Sufficiently supported by data: Yes Specific comments: To request clarifications whether the Codex MRL proposal reflects the expected dietary burden. From the table presented in the JMPR report, it seems that the MRL was based on a dietary burden of 3.47 ppm instead of 0.43 ppm. As the residues are not expected to exceed the LOQ at the higher dietary burden, the level of the Codex MRL proposal will not be affected. However, the value should be flagged with an asterisk as being a LOQ **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the MRL should be flagged with an asterisk Follow-up action: None
Mammalian fats (except milk fats)	**0.15**	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (Australian beef cattle): 24 ppm Max. residues in fat: 0.15 mg/kg Sufficiently supported by data: Yes Specific comments: the MRL **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	**0.15**	– Muscle: 0.01*	Max. residues in muscle/fat: 0.03/0.15 mg/kg Sufficiently supported by data: Yes Specific comments: The Codex MRL should be flagged with the suffix 'fat', since according to Codex policy, for fat soluble substances, MRLs are set on fat basis In future, Codex MRLs will be established for muscle (new commodity description for Code MM 0095 'Group of muscle (from mammals other than marine mammals)'. To ask for clarification if the new food classification will have an impact on the policy for setting MRLs for fat soluble substances (e.g. will Codex MRLs be established for the code MM 0095 with suffix rat or only for MF 0100) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 179 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Milks	**0.03**	0.01*	Max. dietary burden (Australian dairy cattle): 24 ppm Max. residues in milk: 0.023 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry fats	**0.02**	0.01*	Max. dietary burden (Canadian layer): 0.43 ppm Max. residues in eggs: < 0.021 mg/kg Sufficiently supported by data: Yes Specific comments: To request clarifications whether the Codex MRL proposal reflects the expected dietary burden. From the table presented in the JMPR report, it seems that the MRL was based on a dietary burden of 3.47 ppm instead of 0.43 ppm. As the residues are not expected to exceed the LOQ at the higher dietary burden, the level of the Codex MRL proposal will not be affected. However, the value should be flagged with an asterisk as being a LOQ In future, the **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the MRL should be flagged with an asterisk Follow-up action: None
Poultry meat	**0.02**	– Muscle: 0.01* default MRL Art. 18(1)(b)	Max. dietary burden (Canadian layer): 0.43 ppm Max. residues in muscle: < 0.021 mg/kg Sufficiently supported by data: Yes Specific comments: To request clarifications whether the Codex MRL proposal reflects the expected dietary burden. From the table presented in the JMPR report, it seems that the MRL was based on a dietary burden of 3.47 ppm instead of 0.43 ppm. As the residues are not expected to exceed the LOQ at the higher dietary burden, the level of the Codex MRL proposal will not be affected. However, the value should be flagged with an asterisk as being a LOQ In future, Codex MRLs will be established for muscle (new commodity code and description: Code PM 0110, Group of avian muscle). To ask for clarification if the new food classification will have an impact on the policy for setting MRLs for fat soluble substances (e.g. will Codex MRLs be established for the code PM 0110 with suffix rat or only for PF 0111 Group of avian fats) **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the MRL should be flagged with an asterisk Follow-up action: None
Poultry, edible offal of	**0.02**	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (Canadian layer): 0.43 ppm Max. residues in liver and kidney: < 0.021 mg/kg Sufficiently supported by data: Yes Specific comments: To request clarifications whether the Codex MRL proposal reflects the expected dietary burden. From the table presented in the JMPR report, it seems that the MRL was based on a dietary burden of 3.47 ppm instead of 0.43 ppm. As the residues are not expected to exceed the LOQ at the higher dietary burden, the level of the Codex MRL proposal will not be affected. However, the value should be flagged with an asterisk as being a LOQ **Conclusion:** The proposed Codex MRL is sufficiently supported by data, but the MRL should be flagged with an asterisk Follow-up action: None
Wheat, hay and/or straw	2 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
General comments	–		

Abbreviations: BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; LOQ, limit of quantification; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval.

*Indicates that the input value is proposed at the limit of quantification; dw: dry weight.

5.28.6 | Consumer risk assessment

TABLE 180 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. The calculations were performed with the STMR values derived by JMPR for the crops for which the Codex MRLs were proposed. For commodities for which no Codex MRLs were proposed, EFSA used the default MRL of 0.01 mg/kg for the exposure calculation The calculations are indicative, because no agreed toxicological reference values and residue definitions for risk assessment are established in the EU 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 2% of the ADI (NL toddler) Among the crops under consideration, cattle milk was identified as the main contributor, accounting for up to 0.8% of the ADI	**Results:** Long-term exposure: Max 1% of the JMPR ADI GECDE mean: Max. 3% (infants and toddler) GECDE max: Max. 10% (infants and toddler) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.28.7 | Conclusions

TABLE 181 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 (RMS assessment is ongoing)
Toxicological assessment	JMPR did not derive an ARfD; no EU assessment finalised
Residue definitions	At EU level, the default RD are applicable. At EU level, the setting of a specific residue definition for MRL enforcement should be considered (including metabolite(s) in the RD that are a valid marker substance for the use of the a.s.)
Analytical methods	Sufficiently validated analytical methods are available
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. However, discussion with RM on the proposal for lentils are recommended. In addition, EFSA identified additional points for discussion for the Codex MRL proposal for animal products
Dietary risk assessment	Acute risk assessment not required (no ARfD derived in the EU). No chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; ARfD, acute reference dose; MRL, maximum residue level; RD, residue definition.

5.29 | Fluazinam (333) R/T

5.29.1 | Background information

TABLE 182 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	JMPR assessed fluazinam already in 2018, but due to missing information, the assessment could not be concluded
RMS	AT	

TABLE 182 (Continued)

		Comments, references
Approval status	Approved. Renewal process ongoing	Commission Directive 2008/108/EC[69] Renewal Assessment Report (RAR) submitted, EFSA peer review on ED clock-stop
EFSA conclusion available	Yes, see comments	EFSA (2008a) EFSA peer review ongoing including Art. 12 confirmatory data currently ongoing (additional data requested)
MRL review performed	Yes, see comments	EFSA (2015g)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2017d) (onions, shallots and garlic) EFSA (2016c) (import tolerance in blueberries)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not fall under cut-off criteria ECHA (2012a); ATP06[70]
Endocrine effects of a.s.	Assessment ongoing	–
Other relevant information	Fluazinam meets the definition of per- and polyfluoroalkyl substances (PAFS) based on its chemical structure	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.29.2 | Toxicological reference values

TABLE 183 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	Not established	JMPR (2023)	0.01 mg/kg bw per day	Commission Directive 2008/108/EC[71]	Not applicable
ARfD	Not established	JMPR (2023)	0.07 mg/kg bw	Commission Directive 2008/108/EC	Not applicable
Conclusion/comments a.s.	In 2018, when fluazinam was assessed for the first time by JMPR, ADI/ARfD were not derived, because information on the level of impurity B-1457 (5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine) in batches used for toxicity studies was not reported. The FAO specification for fluazinam limits the level of this impurity to 0.3% This year, JMPR noted again outstanding issues regarding metabolites, impurities and carcinogenicity; as information was submitted too late for evaluation, the assessment was again postponed As the renewal process is ongoing, the TRV might change				
Comments on metabolites	Metabolites included in JMPR RD for RA: Not relevant, as JMPR was unable to conclude on a residue definition for risk assessment Metabolites included in EU RD for RA: – 4-chloro-*N*2-[3-chloro-5-(trifluoromethyl)-2pyridinyl]-3-nitro-5-(trifluoromethyl)-1,2-benzenediamine (AMPA-fluazinam) – (2*S*)-3-{[4-amino-3-{[3-chloro-5-(trifluoromethyl)2-pyridinyl]amino}-2-nitro-6(trifluoromethyl)phenyl]thio}-2-(β-Dglucopyranosyloxy)propanoic acid (AMGT) The assessment of the metabolites is ongoing. In 2008, the toxicity of the metabolites AMPA-fluazinam and AMGT was considered covered by the TRVs established for the parent				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RA, risk assessment; RD, residue definition.

[69]Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.

[70]Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and 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 167, 6.6.2014, p. 36–49.

[71]Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.

5.29.3 | Residue definitions

TABLE 184 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fluazinam	Reg. 396/2005 (implementing Peer review and MRL review): Fluazinam MRL review (EFSA, 2015g): Raw commodities: fluazinam Processed commodities: sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (tentative) Peer review (EFSA, 2008a): Fluazinam	Yes
	Animal products	No residue definition derived (see comments below). Fat solubility not specified	Reg. 396/2005: Fluazinam MRL review (EFSA, 2015g): No proposal, MRLs not needed Peer review (EFSA, 2008a): Not required as animal exposure is extremely low The residue is fat soluble	Not applicable
RD-RA	Plant products	The Meeting was unable to conclude on a residue definition for risk assessment	MRL review (EFSA, 2015g): Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam Peer review (EFSA, 2008a): Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (provisional)	Not applicable
	Animal products	No residue definition derived (see comments below)	MRL review (EFSA, 2015g): No proposal, MRLs not needed Peer review (EFSA, 2008a) Not required as animal exposure is extremely low	Not applicable
Conclusion, comments	Plant products: In 2023, JMPR noted that as the WHO core assessment group could not conclude on Health based guidance values for fluazinam, a decision on the residue definition for risk assessment could not be made Animal products: In 2018, JMPR decided that due to deficiencies of the livestock metabolism studies (lack of stability of residues in muscle samples (hen and goat) and the changes observed in the HPLC profiles for hen liver and egg) residue definitions for animal commodities could not be recommended In 2023, no new information was provided to JMPR			

Abbreviations: HPLC, high-performance liquid chromatography; MRL, maximum residue level; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.29.4 | Analytical methods

No new information was provided to JMPR in 2023. In 2018, sufficient methods were provided for fluazinam and its metabolites. No Codex MRL proposals derived by JMPR in 2023.

5.29.5 | Codex MRL proposals

No CXL proposals were derived by JMPR.

5.29.6 | Consumer risk assessment

Not relevant, no CXL proposals were derived by JMPR.

5.29.7 | Conclusions

TABLE 185 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, A.s. approved in the EU, renewal process ongoing (EFSA peer review currently on clock-stop)
Toxicological assessment	EU TRV available. JMPR could not complete the toxicological evaluation of fluazinam and therefore did not derive TRV

TABLE 185 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Residue definitions	The EU and JMPR RD for MRL enforcement in plant products are identical. For other matrices and for risk assessment JMPR did not derive residue definitions
Analytical methods	Analytical methods for MRL enforcement in plant products were assessed in 2018. They were considered sufficiently validated for crops of high starch, high acid, high water, high protein and high oil content
Codex MRL proposals	No Codex MRL proposals were derived
Dietary risk assessment	Not relevant, as no TRV and no Codex MRL proposals were derived
Final conclusion	See also point General considerations, section 2.6 on the rolling submission of data (FAO and WHO, 2024). In order to avoid waste of JMPR resources, a complete dossier needs to be submitted. Multiple assessments of studies submitted to JMPR over the years should be avoided

Abbreviations: a.s., active substance; MRL, maximum residue level; TRV, toxicological reference value; RD, residue definition.

5.30 | Isocycloseram (334) R/T

5.30.1 | Background information

TABLE 186 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status	Not approved	Not 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	Isocycloseram meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure	

Abreviations: a.s., active substance; MRL, maximum residue level.

5.30.2 | Toxicological reference values

TABLE 187 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.02 mg/kg bw per day	JMPR (2023)	–	No EU assessment	Not applicable
ARfD	0.5 mg/kg bw general population 0.08 mg/kg bw females of child- bearing age	JMPR (2023)	–	No EU assessment	Not applicable
Conclusion/ comments a.s.	With regard to isocycloseram, although of slow elimination in ADME studies in rats (overall with 6$–10% of administered dose still retained in the carcass, organs and gastrointestinal tract after 168–192 h, and 16% after 72 h), the JMPR concluded that based on data from repeated administration, there was no evidence of accumulation The JMPR concluded that isocycloseram is not carcinogenic in mice or rats. Reproductive toxicity was observed together with parental toxicity and developmental toxicity was observed a doses lower than those exhibiting maternal toxicity				
Comments on metabolites	Metabolites included in JMPR RD for RA: – *N*-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-benzamide (SYN549544) Not genotoxic based on QSAR and read-across analysis; indirectly covered by the TRVs of the parent as it is a precursor of metabolite SYN549543 (the latter being a major rat metabolite) – 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-*N*-(3-oxoisoxazolidin-4-yl) benzamide (SYN549436) Not genotoxic based on QSAR and read-across analysis; its toxicity is covered by the TRVs of the parent as it was identified as a major metabolite in rats Accordingly, the ADI and ARfD of the parent also apply to these two metabolites In addition, metabolite SYN549543 is covered by the TRV derived for parent isocycloseram Metabolites included in EU RD for RA: not relevant				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.30.3 | Residue definitions

TABLE 188 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Isocycloseram	Default RD (i.e. parent compound). A.s. was never notified and authorised in the EU No EU peer review and no MRL review	Yes, compared to default RD
	Animal products	Isocycloseram The residue is fat soluble	Default RD (i.e. parent compound). A.s. was never notified and authorised in the EU No EU peer review and no MRL review Fat solubility not specified	Yes, compared to default RD
RD-RA	Plant products	Isocycloseram	No RD for RA formally established. No EU peer review and no MRL review	Not applicable
	Animal products	Sum of isocycloseram and metabolites *N*-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-benzamide (SYN549544) and 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-*N*-(3-oxoisoxazolidin-4-yl) benzamide (SYN549436) (expressed as isocycloseram)	No RD for RA formally established. No EU peer review and no MRL review	Not applicable
Conclusion, comments	This active substance has never been notified or authorised in the EU. Therefore, In the EU, there is no residue definition for risk assessment (for plants and animals) The residue definitions for enforcement are similar in the JMPR and in the EU (parent by default) The JMPR assessed metabolism studies for isocycloseram (SYN547407) conducted in fruiting vegetables (tomato), leafy vegetables (mustard greens), cereals (rice, paddy conditions) and oilseeds (soybeans), confined rotational crops (lettuce, radish and wheat) and livestock (lactating goats and laying hens). The studies were conducted with isocycloseram radiolabelled in 3 different positions: halophenyl-U-14C]-radiolabel, a [methylphenyl-U-14C]-radiolabel and an [oxoisoxazolidinyl-4,5-14C]-labelled)] According to the JMPR, the metabolism in primary crops was similar in all crops (foliar: tomato, soya bean, mustard greens and paddy rice, and in-furrow: mustard greens). Parent was the main component in plants. Metabolite SYN549431 was the major metabolite identified in all studies and accounted for 0.7%–6.0% TRR (food commodities) and 0.7%–25% (feed commodities) across all commodities and radiolabels for foliar treatments. SYN549431 was also at 7.7% TRR in immature mustard greens from the in-furrow application (methylphenyl-labelled only) In confined rotational crop metabolism studies, the TRRs generally decreased with increasing PBIs. At PBIs of 30 days, isocycloseram was the predominant residue in most cases, with increasing proportions of the metabolites SYN552188 and/or SYN549431 becoming predominant at longer PHIs. Concentrations of those residues in food for human consumption were low (typically < 0.01 mg eq/kg; radish root, 30-day PBI is an exception at 0.059 mg/kg isocycloseram) In the supervised field trials, isocycloseram and SYN549431 were the most frequently detected residues. Residues of SYN549431 were always lower than parent isocycloseram residues and were, on average, < 8% compared to parent residues. This ratio was consistent across all processed fractions analysed. Therefore, the JMPR determined that SYN549431 can be considered a minor metabolite Residues of metabolite SYN548569 were typically not observed above 0.01 mg/kg with limited exceptions in processed commodities In deciding which compounds should be included in the residue definition for risk assessment for plants, the JMPR considered the likely occurrence of the compounds and the toxicological properties of isocycloseram and SYN549431 The JMPR determined that SYN549431 does not have similar toxicity to parent isocycloseram and is not covered by the HBGVs for isocycloseram and could be assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw per day. The JMPR concluded that SYN549431 is unlikely to present a dietary exposure concern from the uses evaluated by the current JMPR The JMPR proposed the following residue definition for enforcement and dietary risk assessment for plant commodities: isocycloseram The JMPR considered the metabolism of isocycloseram in lactating goats and laying hens was qualitatively similar and that no tissue unique metabolites were detected. Using estimates of livestock dietary burden for each of the compounds and assuming the same transfer rate to animal commodities as for isocycloseram, the JMPR noted that the metabolites SYN549544 and SYN549436 could make a significant contribution to overall consumer exposure. Residues of SYN549544 were greater than 10% TRR relative to parent in almost all tissue samples in the animal metabolism studies. In addition, the JMPR determined that the submitted feeding studies showed residues of SYN549436 were found at similar levels to residues of SYN549544 The JMPR considered that it was not necessary to include SYN549431 in the residue definition for risk assessment for animal commodities as it was only occasionally detected in the field trials on feed commodities		

Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	The JMPR proposed following definition of the residue for dietary risk assessment for animal commodities: isocycloseram and the metabolites *N*-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-benzamide (SYN549544) and 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-*N*-(3-oxoisoxazolidin-4-yl)benzamide (SYN549436) (expressed as isocycloseram) The JMPR proposed as residue definition for enforcement for animal commodities: isocycloseram		
	The JMPR considered isocycloseram residue as fat-soluble		

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment; TRR, total radioactive residues.

5.30.4 | Analytical methods

TABLE 189 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content	Yes, but no validation data is published in JMPR report	0.01	QuEChERS extraction, LC–MS/MS
Animal products Muscle/meat Fat Liver/kidney Milk	Yes, but no validation data is published in JMPR report	0.01	QuEChERS extraction, LC–MS/MS
Conclusion	Sufficiently validated analytical methods for the enforcement of the MRLs for the matrix groups for which Codex MRL proposals were derived by JMPR are available. No details and validation data reported No validation data available at the EURLs		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.30.5 | Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Apple pomace, wet	1	–	JMPR derived a processing factor of 2.4 (1.9; 2.8). Currently, no EU MRLs are established for processed products
Broccoli	**0.7**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 1-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: None
Brussels sprouts	**2**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 4 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Cabbages, head	**4**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: Trials on head cabbage were analysed with wrapper leaves (to derive MRL proposal and input values for dietary burden calculation) and without wrapper leaves (to derive STMR/HR) **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

(Continues)

TABLE 190 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Cauliflower	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Citrus Oil	80	–	JMPR derived a processing factor of 200 (127; 256). Currently, no EU MRLs are established for processed products
Coffee bean	**0.04**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 30-day RTI, 40-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Cotton seed	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 4 × 75 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 11 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Cucumber	**0.1**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 3-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Edible offal (Mammalian)	**0.3**	0.01* default MRL Art. 18(1)(b)	Max./Mean dietary burden (Australian beef cattle): 14.89/0.955 ppm Max residues in liver: 0.099 mg/kg (RD enf)/0.266 mg/kg (RD for RA) Sufficiently supported by data: Yes Specific comments: Although the tables reporting the results are not very clear, apparently, a MRL of 0.1 mg/kg (based on the results for isocycloseram in kidney) would be sufficient. See also general comments on feeding studies in cattle, as regards the metabolites included in the RD for risk assessment **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that apparently a lower MRL of 0.1 mg/kg would be sufficient Follow-up action: None
Eggplant	**0.3**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 120 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 12 (4 trials in eggplants and 8 trials in peppers, sweet) Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed on sweet peppers (8) and eggplants (4). The JMPR concluded that there are insufficient trials on eggplants to estimate a maximum residue level, however, the JMPR has previously reviewed residues in peppers, sweet and eggplants and noted that residues in peppers, sweet and eggplants are similar and that residues in peppers, sweet can be used to support a maximum residue for eggplants Since the Mann–Whitney test suggests the distributions are similar the JMPR decided to combine the residues from pepper and eggplants for estimating a Codex MRL proposal for eggplants. This would not be acceptable in the EU. However, in JMPR report 2018, the extrapolation of residue trials in peppers or tomatoes (whatever would lead to a higher MRL) was recommended. **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: To check details in JMPR evaluation.

TABLE 190 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Group of pome fruits	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 3 × 90 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 30 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed on apples (18) and pears (12). The JMPR noted that the cGAP covers pome fruits and that median residues of apples and pears were within a fivefold difference. A Mann–Whitney U-Test demonstrate that populations of apple and pear were not significantly different and therefore could be combined. This extrapolation would be also acceptable in the EU **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Maize	0.01*	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, one in-furrow at-planting application at 150 g a.s./ha followed by two foliar applications at 30 g a.s./ha, 7-day RTI, 21-day PHI Number of trials: 27 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Maize, stover	1.5	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Mammalian fats (except milk fats)	**0.4**	0.01* default MRL Art. 18(1)(b)	Max./Mean dietary burden (Australia beef cattle): 14.89/0.955 ppm Max residues in fat: 0.362 mg/kg Sufficiently supported by data: Yes Specific comments: See also general comments on feeding studies in cattle, as regards the metabolites included in the RD for risk assessment **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	**0.02**	– Muscle: 0.01* default MRL Art. 18(1)(b)	Max./Mean dietary burden (Australia beef cattle): 14.89/0.955 ppm Max residues in liver: 0.011 mg/kg Sufficiently supported by data: Yes Specific comments: See also general comments on feeding studies in cattle, as regards the metabolites included in the RD for risk assessment **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Melons, except watermelon	**0.15**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 3-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Milks	**0.05**	0.01* default MRL Art. 18(1)(b)	Max./Mean dietary burden (Australia dairy cattle): 9.388/0.923 ppm. Mean residues in milk: 0.021 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Onion, bulb	0.01*	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 120 g a.s./ha, 7-day RTI, 7-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: None
Oranges, dried pulp	3	–	JMPR derived a processing factor of 6.4 (4.4; 8.4). Currently, no EU MRLs are established for processed products

(Continues)

TABLE 190 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Peppers, chilli	**0.6**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Details of the GAP not reported in the JMPR report Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: To check details on the cGAP in JMPR evaluation
Peppers, chilli, dried	4.2	–	No processing factor was reported by JMPR for peppers, chilli, dried. The MRL proposal was derived by applying the default factor of 7. Currently, no EU MRLs are established for processed products
Peppers, sweet	**0.3**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 120 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Potato	0.01*	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 26 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Prune, dried	1.5	–	JMPR derived a processing factor of 3.1 (2.6; 3.7). Currently, no EU MRLs are established for processed products
Soya bean (dry)	**0.15**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 3 × 75 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 21 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Soya bean hulls	1	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Soya bean, hay and/or straw	20	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Squash, summer	**0.09**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 60 g a.s./ha, 7-day RTI, 3-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Subgroup of cherries	**1**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 3 × 90 g a.s./ha, 7-day RTI, 14-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: None
Subgroup of lemons and limes (including citron)	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 2 × 90 g a.s./ha followed by 2 × 30 g a.s./ha, 7-day RTI, 7-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: None
Subgroup of Mandarins (including mandarin-like hybrids)	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 2 × 90 g a.s./ha followed by 2 × 30 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 4 trials in mandarins and 5 trials in lemons Sufficiently supported by data: Yes Specific comments: As the number of trials in mandarins was not sufficient, JMPR merged the mandarin trials with the data set on lemons and limes **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 190 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of oranges, sweet, sour (including orange-like hybrids)	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 2 × 90 g a.s./ha followed by 2 × 30 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 9 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of peaches (including nectarine and apricots)	**0.3**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 3 × 90 g a.s./ha, 7-day RTI, 14-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of plums (including fresh prunes)	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 3 × 90 g a.s./ha, 7-day RTI, 14-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: None
Subgroup of pummelo and grapefruits (including shaddock-like hybrids, among others grapefruit)	**0.3**	0.01* default MRL Art. 18(1)(b)	cGAP: Paraguay, Foliar, 2 × 90 g a.s./ha followed by 2 × 30 g a.s./ha, 7-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
Tomato	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Guatemala, Foliar, 3 × 120 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: Four trials were performed with cherry tomatoes, leading to 4 highest residue levels of the data set **Conclusion:** The proposed Codex MRL is sufficiently supported by data
Tomato, dried	2	–	JMPR derived a processing factor of 3.2 (3.1; 3.2) Currently, no EU MRLs are established for processed products
Tomato, pomace	8	–	JMPR derived a processing factor of 16 (13; 18) in tomato wet pomace and 72 (53; 90) in tomato dry pomace. Currently, no EU MRLs are established for processed products
General comments	Feeding study (cattle): It is noted that the residue definition for risk assessment for animal products was established as parent plus metabolite SYN549544 and SYN549436, expressed as parent. In the feeding study in cattle (p. 268 of JMPR report), however, it is reported that the results refer to parent plus SYN549543 and SYN549436. As SYN549543 was a minor metabolite identified in livestock metabolism studies, it was decided not to include it in the residue definition. The details need to be checked in the JMPR Evaluation. If the document is published late, JMPR should be asked for clarification According to our understanding, the first table refers to the results for parent isocycloseram (footnote 4 highlighted in yellow probably should be removed) The second table should describe the results for the residue definition for risk assessment and was used to derive the HR and STMR values. In this table, the metabolite was incomplete in the table header; in the footnote it defines the residue as SYN549543 (instead of SYN549544) Regarding establishing Codex MRL proposal for poultry, the JMPR noted that the maximum dietary burden for poultry (2.566 mg/kg; EU poultry layer) was more than 150% the highest feeding rate (1.7 mg/kg) that was used in the poultry feeding study. Therefore, the JMPR determined that the poultry feeding study was unsuitable for the estimation of residues levels based on the uses considered by the JMPR. Consequently, the JMPR considered that a new poultry feeding study would be desirable To discuss with Member States, whether the estimated dietary burden for EU poultry is relevant, considering that the a.s. is not approved in the EU. Unfortunately, the dietary burden calculation for isocycloseram are not presented in Annex 6 of the JMPR report to identify the main drivers of the dietary burden for EU poultry		

Abbreviations: a.s., active substance; CXL, Codex maximum residue limit; cGAP, critical Good Agricultural Practice; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval; RA, risk assessment; RD, residue definition; RTI, re-treatment interval; STMR, supervised trials median residue.

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

5.30.6 | Consumer risk assessment

TABLE 191 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 established for child-bearing population (0.08 mg/kg bw). A higher JMPR ARfD was established for the general population (0.5 mg/kg bw) 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. citrus fruits, pome fruits, stone fruits, kumquats, kaki, broccoli, Brussels sprouts, head cabbages, cauliflower, coffee bean, cotton seed, cucumber, eggplant, maize, melons, soybeans, ruminants tissues and milk) The calculations are indicative, because no agreed toxicological reference values are established in the EU and a residue definition for risk assessment has not been established in the EU 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 (default MRLs established in the EU) 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. citrus fruits, pome fruits, stone fruits, kumquats, kaki, broccoli, Brussels sprouts, head cabbages, cauliflower, coffee bean, cotton seed, cucumber, eggplant, maize, melons, soybeans, ruminants tissues and milk). For the remaining commodities, the EU default MRL was used as input value for the exposure calculations The calculations are indicative, because no agreed toxicological reference values are established in the EU and a residue definition for risk assessment has not been established in the EU Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** It was noted that the short-term intake calculations were not reported in Annex 4 of the JMPR report For the following metabolites not covered by the TRVs, TTC approach was used (Cramer Class III) (in brackets the estimated exposure, in µg/kg bw per day) SYN549431 (0.1314) SYN548569: 0.0164 SYN550402: 0.0031 SYN550737 (0.0094) SYN551583 (0.0031) SYN551474 (0.0006) SYN551475 (0.0006) SYN551479 (0.0000) SYN4549107 (0.0000) The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds (1.5 µg/kg bw per day). Therefore, the JMPR concluded that these metabolites were unlikely to present a dietary exposure concern from the uses evaluated by the current JMPR It would be desirable to present more details in the JMPR report how the calculations were performed (e.g. input values for the exposure calculation, diets, etc.)
Results: No short-term consumer health risk was identified for the crops under assessment Head cabbages: 66% of ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 13% of the ADI (NL toddler) Among the crops under consideration, apples were identified as the main contributor, accounting for up to 6% of the ADI	**Results:** Long-term exposure: Max 4% of the JMPR ADI (G04) GECDE mean: 20% (infants and toddlers) GECDE max: Max. 80% (infants and toddlers) Short-term exposure: Highest result: 9% of ARfD (no information on the commodity which lead to the highest result)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.30.7 | Conclusions

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 TRV available
Residue definitions	No EU residue definitions established (default RD for enforcement with parent compound is similar to residue definition proposed by JMPR for MRL enforcement). Further clarifications are required as regards the residue definition for risk assessment for animal products and the related feeding study
Analytical methods	Validated analytical methods are available. Validation data need to be checked in JMPR evaluation, once this document is published
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	No acute and no chronic intake concern identified (indicative calculations)
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.31 | Isotianil (335) R/T

5.31.1 | Background information

TABLE 193 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	Formally, no RMS nominated, but NL kindly volunteered for providing support to prepare comments on this a.s
Approval status	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	An import tolerance application for citrus and banana was submitted to NL. The assessment by the EMS is ongoing
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.31.2 | Toxicological reference values

TABLE 194 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.05 mg/kg bw per day	JMPR (2023)	–	No EU assessment	Not applicable
ARfD	Unnecessary	JMPR (2023)	–	No EU assessment	Not applicable
Conclusion/comments a.s.	–				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 3,4-dichloro-1,2-thiazole-5-carboxylic acid (DCIT-acid) Acutely more toxic than the parent. The ADI also applies to DCIT-acid Metabolites included in EU RD for RA: Not relevant, as no RD for risk assessment is established in the EU				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition.

5.31.3 | Residue definitions

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	Isotianil	Reg. 396/2005: Isotianil (default MRLs/RD according to Art. 18(1)(b)) No EU peer review and no MRL review	Yes (compared with the default EU RD)
	Animal products	Sum of isotianil and 3,4-dichloro-1,2-thiazole-5-carboxylic acid (DCIT-acid) expressed as isotianil The residue is not fat soluble	Reg. 396/2005: Isotianil (default MRLs/RD according to Art. 18(1)(b)) No EU peer review and no MRL review Fat solubility not specified	No
RD-RA	Plant products	Sum of isotianil and 3,4-dichloro-1,2-thiazole-5-carboxylic acid (DCIT-acid) expressed as isotianil	No residue definition established as no EU peer review and no MRL review	Not applicable
	Animal products	Sum of isotianil and 3,4-dichloro-1,2-thiazole-5-carboxylic acid (DCIT-acid) expressed as isotianil	No residue definition established as no EU peer review and no MRL review	Not applicable

(Continues)

TABLE 195 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	For plant products, JMPR derived a residue definition for MRL enforcement including only the parent compound as marker substance based on the findings in metabolism studies (e.g. metabolism studies in lemon with 4 foliar treatments, RTI 21 days and sampling 1 day after the last treatment). The parent compound might be a sufficient marker if samples are taken shortly after treatment. However, considering the degradation kinetics, it might be appropriate, to include also the cleavage product DCIT-acid in the residue definition for MRL enforcement, considering also the results of the residue trials			

Abbreviations: MRL, maximum residue level; RD-RA, residue definition for risk assessment; RD enf, residue definition for enforcement practice.

5.31.4 | Analytical methods

TABLE 196 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High water content High acid content	Yes	0.01	Aqueous acetonitrile extraction; SPE clean up; eluted with cyclohexane/ethyl acetate; LC–MS/MS; matrices not specified
Animal products Muscle/meat Fat Liver/kidney Milk Eggs	Partially (see remarks)	0.01	QuEChERS extraction and LC–MS/MS (milk, cream, whey, eggs, muscle, fat, kidney and liver) applicable for parent, only For animal commodities, two extractions with acetonitrile/water. After centrifuging, an aliquot of the extract was analysed for isotianil and DCIT-acid by reversed-phase LC–MS/MS Detailed validation data are not reported in the JMPR report Additional metabolites (not included in the RD for MRL enforcement) can be determined, with the following steps: A second aliquot was derivatised with benzoyl chloride, and subsequently analysed by reversed-phase LC–MS/MS for 'free' 2-aminobenzonitrile and 2-amino-5-hydroxybenzonitrile A third aliquot was enzymatically treated with β-glucuronidase/arylsulphatase to cleave potential glucuronide and sulphate conjugates of 2-aminobenzonitrile and 2-amino-5-hydroxybenzonitrile, cleaned up, derivatised with benzoyl chloride and subsequently analysed by reversed-phase LC–MS/MS for 2-amino-benzonitrile and 2-amino-5-hydroxybenzonitrile
Conclusion	The EU default residue definition for MRL enforcement for the plant products is comparable with the proposed RD For animal products, the RD for enforcement are not identical The current EU MRLs for the commodities under discussion are all set at the default level of 0.01 mg/kg, hence, lower than or equal to the Codex MRL proposal Analytical methods for the enforcement of the MRLs for the relevant matrices are available. However, the details on the method validation were not reported in the JMPR report		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; RD, residue definition; SPE, solid-phase extraction; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

5.31.5 | Codex MRL proposals

TABLE 197 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Banana	0.01*	0.01* default MRL Art. 18(1)(b)	cGAP for bagged bananas: Guatemala, Honduras, Panama, Dominican Republic, 4 × 0.05 kg/ha, 90-day RTI for the last two applications, PHI 0 or not required when used directly AUS, 4 × 0.05 kg/ha, 56-day RTI, use up to 8-leaf stage Colombia, 4 × 0.05 kg/ha, 42-day RTI, PHI 0 or not required when used directly Number of trials: 12 trials with exaggerated number of applications and shorter RTI Sufficiently supported by data: Yes Specific comments: Although the trials did not match the cGAPs, they were found acceptable, as the residues resulting from a more critical treatment regime were all below the LOQ **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 197 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus oil, edible	40	–	JMPR derived a processing factor of 85 (for MRL enforcement) and 65 (for risk assessment). Currently, no EU MRLs are established for processed products
Edible offal (Mammalian)	**0.02***	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (AUS beef/dairy cattle): 0.038 ppm Max. residues in kidney: 0.000067 mg/kg Sufficiently supported by data: Yes Specific comments: The MRL proposal is equal to the LOQ for the enforcement residue definition **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Mammalian fats (except milk fats)	**0.02***	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (AUS beef/dairy cattle): 0.038 ppm Max. residues in fat: 0.00002 mg/kg Sufficiently supported by data: Yes Specific comments: The MRL proposal is equal to the LOQ for the enforcement residue definition **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Marmalade		–	JMPR derived a processing factor of 0.11 (for MRL enforcement) and 0.17 (for risk assessment). Currently, no EU MRLs are established for processed products. As marmalade is a composite product, containing fruit and sugar, for a correct application of the processing factor, it would be necessary to describe the sugar content of the marmalade
Meat (from mammals other than marine mammals)	**0.02***	– Muscle: 0.01* default MRL Art. 18(1)(b)	Max. dietary burden (AUS beef/dairy cattle): 0.038 ppm. Max. residues in muscle: 0.00002 mg/kg Sufficiently supported by data: Yes Specific comments: The MRL proposal is equal to the LOQ for the enforcement residue definition **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Milks	**0.02***	0.01* default MRL Art. 18(1)(b)	Max. dietary burden (AUS dairy cattle): 0.038 ppm. Max. residues in muscle: 0.00002 mg/kg Sufficiently supported by data: Yes Specific comments: The MRL proposal is equal to the LOQ for the enforcement residue definition **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Orange juice		–	JMPR derived a processing factor of 0.11 (for MRL enforcement)) and 0.17 (for risk assessment). Currently, no EU MRLs are established for processed products
Orange oil		–	JMPR derived a processing factor of 85 (for MRL enforcement) and 65 (for risk assessment). Currently, no EU MRLs are established for processed products
Orange peel processed		–	JMPR derived a processing factor of 1.75 (for MRL enforcement)) and 1.8 (for risk assessment). Currently, no EU MRLs are established for processed products
Poultry fats	**0.02***	0.01* default MRL Art. 18(1)(b)	Dietary burden: 0 ppm Sufficiently supported by data: Yes Specific comments: The proposed Codex MRL reflects the LOQ of the analytical method for animal products **Conclusion:** The proposed Codex MRL is considered acceptable Follow-up action: None
Poultry meat	**0.02***	– Muscle: 0.01* default MRL Art. 18(1)(b)	Dietary burden: 0 ppm. Sufficiently supported by data: Yes Specific comments: The proposed Codex MRL reflects the LOQ of the analytical method for animal products **Conclusion:** The proposed Codex MRL is considered acceptable Follow-up action: None

(Continues)

(Continues)

TABLE 197 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Poultry, edible offal of	**0.02***	0.01* default MRL Art. 18(1)(b)	Dietary burden: 0 ppm. Sufficiently supported by data: Yes Specific comments: The proposed Codex MRL reflects the LOQ of the analytical method for animal products **Conclusion:** The proposed Codex MRL is considered acceptable Follow-up action: None
Subgroup of lemons and limes (including citron)	**0.5**	0.01* default MRL Art. 18(1)(b)	cGAP: Cambodia, 5 × 0.075 kg/ha, 21-day RTI, 1-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: For estimating the residues in the edible portion (STMR), JMPR used a factor of 0.098 derived from metabolism studies reflecting the expected residues in pulp. Considering that the processing factor for orange juice is in a similar range (0.17), STMR derived for pulp can be used for performing an indicative consumer risk assessment **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of Mandarins (including mandarin-like hybrids)	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Cambodia, 5 × 0.075 kg/ha, 21-day RTI, 1-day PHI Number of trials: 9 (4 trials in mandarins and 5 trials in lemons) Sufficiently supported by data: Yes Specific comments: As the number of trials in mandarins was not sufficient, JMPR combined the trials of lemons and mandarins to derive the MRL proposal for mandarins. Similar to lemons and lime, the STMR for pulp was calculated using the correction factor of 0.098. See also comments on lemons and limes **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Subgroup of oranges, sweet, sour (including orange-like hybrids)	**0.4**	0.01* default MRL Art. 18(1)(b)	cGAP: Cambodia, 5 × 0.075 kg/ha, 21-day RTI, 1-day PHI Number of trials: 9 Sufficiently supported by data: Yes Specific comments: Similar to lemons and lime, the STMR for pulp was calculated using the correction factor of 0.098. See also comments on lemons and limes **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Subgroup of pummelo and grapefruits (including shaddock-like hybrids, among other grapefruit)	**0.2**	0.01* default MRL Art. 18(1)(b)	cGAP: Cambodia, 5 × 0.075 kg/ha, 21-day RTI, 1-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: Similar to lemons and lime, the STMR for pulp was calculated using the correction factor of 0.098. See also comments on lemons and limes **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
General comments	One MS proposed the pooling of all residue trials in citrus, deriving a MRL proposal of 0.4 mg/kg for all citrus fruit. EFSA recommends further discussion in the Council, bearing in mind the ALARA principle		

Abbreviations: cGAP, critical good agricultural practice; GAP, good agricultural Practice; LOQ, limit of quantification; MRL, maximum residue level; PHI, pre-harvest interval; RTI, re-treatment interval; STMR, supervised trials median residue.

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

5.31.6 | Consumer risk assessment

TABLE 198 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 An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1. was performed for the commodities, for which the Codex MRLs are proposed (i.e. bananas, citrus fruits, animal products), using the STMR values derived by JMPR; for bananas and animal products, the exposure calculations are performed with the proposed MRL (as the STMR-P was reported as being 0 mg/kg). For the remaining commodities, the default EU MRL was used as input value The calculations are indicative, because the a.s. has never been assessed at EU level and therefore no EU end points (RD, TRV) are available. In addition, the use of a correction factor for citrus fruit derived from metabolism studies is based on assumptions that should be verified with specific studies investigating the transfer of residues to the edible part of the fruits Therefore, the calculations are affected by additional, non-standard uncertainties	**Specific comments:** For one metabolite (2-aminobenzonitrile, JMPR estimated the long-term exposure based on metabolism and processing studies and compared it with the TTC for Cramer Class III compounds (1.5µg/kg bw per day For another group of metabolites (sulphate conjugates of 2-aminohydroxybenzonitrile) the long-term exposure calculated based on metabolism studies and compared with the TTC for genotoxic substances (0.025 µg/kg bw per day) Details on the calculations are not reported. For transparency reasons, JMPR should be invited to present the details of the calculation in the JMPR report According to EFSA, for potentially genotoxic substances, an additional short-term exposure calculation would be required
Results: Not relevant	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 4% of the ADI (NL toddler) Among the crops under consideration, cattle milk was identified as the main contributor, accounting for up to 2% of the ADI	**Results:** Long-term exposure: 0% of the JMPR ADI GECDE mean: 0% (all population groups) GECDE max: Max. 3% (infants and toddler, children and adolescents) Exposure of 2-aminobenzonitrile: < TTC (Cramer class III) Exposure of 2-aminohydroxybenzonitrile: < TTC (genotoxic compounds) Short-term exposure: Not relevant (JMPR did not derive an ARfD)

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; RD, residue definition; STMR, supervised trials median residue; TTC, threshold of toxicological concern; TRV, toxicological reference value.

5.31.7 | Conclusions

TABLE 199 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, but an assessment of an import tolerance application is ongoing
Toxicological assessment	No EU TRV available
Residue definitions	The default residue definition for plant products is identical with the proposed Codex RDs; for animal products and for risk assessment, the Codex RD covers the parent and a metabolite
Analytical methods	Analytical methods are available. The details on the method validation should be checked in the JMPR evaluation
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data
Dietary risk assessment	Acute risk assessment not performed/required (no ARfD derived by JMPR). No chronic intake concern identified in the indicative risk assessment performed with the ADI and RD proposed by JMPR
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; a.s., active substance; MRL, maximum residue level; TRV, toxicological reference value; RD, residue definition.

5.32 | Mepiquat-chloride (336) R/T

5.32.1 | Background information

TABLE 200 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	FI	
Approval status	Approved. Renewal process ongoing	Commission Directive 2008/108/EC Renewal Assessment Report (RAR) submitted, EFSA peer review ongoing
EFSA conclusion available	Yes, see comments	EFSA (2008b) EFSA peer review ongoing
MRL review performed	Yes, see comments	EFSA (2015d)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2024a) (cultivated fungi and oyster mushrooms) EFSA (2019a) (oyster mushrooms) EFSA (2018o) (cotton seeds and animal commodities) EFSA (2018l) (oilseeds and animal commodities) EFSA (2018g) (cotton seeds) EFSA (2016a) (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.	Assessment ongoing	–
Other relevant information	–	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.32.2 | Toxicological reference values

TABLE 201 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.3 mg/kg bw per day	JMPR (2023)	0.2 mg/kg bw per day	Commission Directive 2008/108/EC	No
ARfD	0.6 mg/kg bw	JMPR (2023)	0.3 mg/kg bw	Commission Directive 2008/108/EC	No
Conclusion/comments a.s.	The ADI/ARfD derived by JMPR apply to mepiquat chloride and 4-hydroxy-mepiquat, expressed as mepiquat chloride The TRVs derived in the EU in 2008 apply to mepiquat-chloride and 4-hydroxy mepiquat chloride As the renewal process is ongoing, the EU TRV might change				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat) The metabolite is covered by the TRVs established for the parent Metabolites included in EU RD for RA: – 4-hydroxy mepiquat The metabolite is considered covered by the toxicity profile of the parent				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; RA, risk assessment; RD, residue definition; UF, uncertainty factor.

5.32.3 | Residue definitions

TABLE 202 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 and peer review): Mepiquat (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 and peer review): Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) The residue is not fat soluble	No, but MRLs can be recalculated

TABLE 202 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD-RA	Plant products	Mepiquat cation	MRL review (EFSA, 2015d) and Peer review (EFSA, 2008b): Sum of mepiquat and its salts, expressed as mepiquat chloride	No
	Animal products	Mepiquat cation and 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated), expressed as mepiquat cation	MRL review (EFSA, 2015d) and Peer review (EFSA, 2008b): Sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride	No
Conclusion, comments	The metabolism studies in plants and livestock assessed by the JMPR were performed with mepiquat-chloride The EU residue definition for MRL enforcement for the relevant matrix groups are 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 It is noted that the proposed RDs for enforcement in the context of renewal assessment are comparable with the existing EU RDs for enforcement It is noted that the proposed RD for RA for plant products in the context of the renewal assessment is comparable with the existing RD for RA. For animal products the proposed RD for RA is: Sum of mepiquat and 4-hydroxy mepiquat chloride (free and conjugated) and their salts, expressed as mepiquat chloride			

Abbreviations: MRL, maximum residue level; RA, risk assessment; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.32.4 | Analytical methods

TABLE 203 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: High acid content High oil content	Yes	0.01 (referring to mepiquat chloride)	Extraction with methanol/aqueous hydrochloric acid- or acetone/water mixtures, determination by LC–MS/MS. EURL validation data show that mepiquat chloride can be monitored in high acid and high oil content commodities of plant origin with an LOQ of 0.01 mg/kg and 0.02 mg/kg, respectively
Animal products Muscle/meat Fat Liver/kidney Milk Eggs	Yes	0.01 (referring to mepiquat chloride)	Extraction with methanol/aqueous hydrochloric acid- or acetone/water mixtures, determination by LC–MS/MS. EURL validation data show that mepiquat chloride can be monitored in muscle, animal fat, liver, kidney, milk and eggs with an LOQ of 0.01 mg/kg
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups are 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. The current EU MRLs for grapes is lower than the Codex MRL proposal under discussion; the EU MRLs for cotton seeds and for animal products however are higher than the Codex MRL proposal Sufficiently analytical methods for the enforcement of the MRL for this matrix are available, both at JMPR and EU level		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL, maximum residue level.

5.32.5 | Codex MRL proposals

TABLE 204 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton seed	4	6	cGAP: Greece, Foliar, 1 × 75 g a.s./ha, BBCH 69 Number of trials: 8 Sufficiently supported by data: Yes Specific comments: The analytical results expressed as mepiquat chloride were converted into mepiquat cation by the ratio of their molecular weights (×0.763) The same cGAP was assessed in an Art 10 (EFSA, 2018o) (cotton seeds and animal commodities). The different MRLs derived for the same GAP by JMPR and at EU level is resulting from the different residue definitions. However, the two MRLs are considered equivalent **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

(Continues)

TABLE 204 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton seed oil, crude	–	–	JMPR derived a processing factor of 0.043. Currently, no EU MRLs are established for processed products
Cotton seed oil, edible	–	–	JMPR derived a processing factor of 0.040. Currently, no EU MRLs are established for processed products
Edible offal (mammalian)	0.04	Liver from – bovine and equine: 0.5; – swine: 0.07; – sheep and goat: 0.6 Kidney from – ruminants and equine: 0.8; – swine: 0.07 Edible offal (other than liver and kidney) from – ruminants and equine: 0.8; – swine: 0.05*	Max. dietary burden (AUS beef cattle): 2.4 ppm Mean/max. residues in liver/kidney: 0.027/0.034 Sufficiently supported by data: Yes Specific comments: As the samples were not analysed for the metabolite included in the RD for RA, JMPR re-calculated the results for liver derived in the feeding study, using a conversion factor derived from the metabolism study It is noted that in the table presented in the JMPR report (FAO and WHO, 2024), Section 5.23, the values for the HR and the STMR were interchanged. However, the risk assessment was performed with the correct values **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Eggs	0.008*	0.07	Max. dietary burden (US-Canada layer): 0.56 ppm Mean/max. residues in eggs: < 0.0073 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Grapes	**4**	0.02*	cGAP: Japan, Foliar, 2 × 88 g a.s./ha, at (1) 7–11 shoot leaves or pre-flowering stage and (2) 10–20 days after full bloom, 60-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: The analytical values of mepiquat chloride were converted into mepiquat cation by the ratio of their molecular weights (× 0.763). The JMPR noted that although the trials were not conducted in strict accordance with the GAP in terms of the timing of the second application, it was agreed that the trials likely reflect the cultivation practice for faster growing varieties and that the trials could be used to support a Codex MRL recommendation **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: If risk managers decide to take over the Codex MRL for grapes, which is higher than the current EU MRL set for grapes in EU legislation, the Codex MRL needs to be recalculated to match with the EU residue definition. The corresponding EU MRL would be 5 mg/kg
Grape, dried (=currants, raisins and sultanas)	20	–	JMPR derived a processing factor of 2.6. Currently, no EU MRLs are established for processed products
Grape juice		–	JMPR derived a processing factor of 0.91. Currently, no EU MRLs are established for processed products
Mammalian fat (except milk fats)	0.01	0.05 (swine) 0.06 (bovine, sheep, goat and equine)	Max. dietary burden (AUS beef cattle): 2.4 ppm. Mean/max. residues in fat: < 0.0092 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	0.01	– Muscle: 0.05 (swine); 0.09 (bovine, sheep, goat and equine)	Max. dietary burden (AUS beef cattle): 2.4 ppm. Mean/max. residues in in muscle: < 0.0092 mg/kg Sufficiently supported by data: Yes Specific comments: It is noted that according to the new Codex food classification, CXLs are established for muscle (MM 0095); hence, the commodity description should be changed to 'Muscle (from mammals other than marine mammals)' **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None

TABLE 204 (Continued)

Commodity	Codex MRL proposal	EU MRL	Comment
Milk	0.008*	0.07 (cattle and horse); 0.15 (sheep and goat)	Mean/max. dietary burden (AUS dairy cattle): 1.8/1.8 ppm. Mean/max. residues in milk: 0.0069 mg/kg Sufficiently supported by data: Yes Specific comments: As the samples were not analysed for the metabolite included in the RD for RA, JMPR re-calculated the results for milk derived in the feeding study, using a conversion factor derived from the metabolism study **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry, edible offal of	0.008*	0.05* (kidney and edible offals); 0.05 (liver)	Mean/max. dietary burden (US-Canada broiler): 0.56/0.56 ppm Mean/max. residues in liver: < 0.0025 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry fats	0.008*	0.05	Mean/max. dietary burden (US-Canada broiler): 0.56/0.56 ppm Mean/max. residues in fat: < 0.0025 mg/kg Sufficiently supported by data: Yes Specific comments:– **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Poultry meat	0.008*	– Muscle: 0.05	Mean/max. dietary burden (US-Canada broiler): 0.56/0.56 ppm. Mean/max. residues in muscle: < 0.0025 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Cotton delinted seed		–	JMPR derived a processing factor of 1.2. Currently, no EU MRLs are established for processed products
Cotton seed hulls		–	JMPR derived a processing factor of 0.28. Currently, no EU MRLs are established for processed products
Cotton seed meal	8	–	JMPR derived a processing factor of 1.9. Currently, no EU MRLs are established for processed products
Grape pomace, dried	15	–	JMPR derived a processing factor of 2.6. Currently, no EU MRLs are established for processed products
Grape pomace, wet		–	JMPR derived a processing factor of 1.1. Currently, no EU MRLs are established for processed products
General comments	–		

Abbreviations: a.s., active substance; BBCH, growth stages of mono- and dicotyledonous plants; cGAP, critical Good Agricultural Practice; CXL, Codex maximum residue limit; GAP, Good Agricultural Practice; MRL, maximum residue level; PHI, pre-harvest interval.

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

5.32.6 | Consumer risk assessment

TABLE 205 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) 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) (cultivated fungi and oyster mushrooms) 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). 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, 2015d)	**Specific comments:** Methylpiperidine was found in animal metabolism study but not in plant metabolism study The JMPR noted that methylpiperidine was not considered to be genotoxic. As no further information was available, the JMPR agreed to apply the TTC approach (Cramer Class III, 1.5 µg/kg bw/day) for toxicity In the goat metabolism study fed at 800 ppm of mepiquat chloride (610 ppm as mepiquat cation), methylpiperidine was detected at 0.052 mg mepiquat cation eq/kg in liver (0.034 mg/kg expressed as methylpiperidine using the ratio of their molecular weights of 0.661), 0.255 mg eq/kg in kidney (0.17 mg/kg), 0.061 mg eq/kg in muscle (0.040 mg/kg) and 0.018 mg eq/kg in fat (0.012 mg/kg). Methylpiperidine was not found in milk. In the hen metabolism study fed at 254 ppm (194 ppm as mepiquat cation), methylpiperidine was found only in muscle at 0.02 mg eq/kg (0.013 mg/kg) After scaling the above levels to account for the dietary burden of the parent compound (2.4 ppm cattle, 0.56 ppm poultry), the dietary exposure to methylpiperidine calculated using the 17 cluster diets were < 0.001 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 considered by the Meeting is unlikely to present a public health concern
Results: No short-term consumer health risk was identified for the crops under assessment Table grapes: 83% of ARfD EFSA noted a narrow safety margin to the ARfD. If grapes contain residues at the level of the MRL, the exposure would exceed the ARfD	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 8% of the ADI (NL toddler) The contribution of table and wine grapes to the overall chronic exposure accounted for a maximum of 0.71% and 1.2% of the ADI, respectively	**Results:** Long-term exposure: Max 1% of the JMPR ADI GECDE mean: Max. 1% (infants and toddler) GECDE max: Max. 10% (infants and toddler) Short-term exposure: Highest result for children: 40% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE, global estimate of chronic dietary exposure; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue; TTC, threshold of toxicological concern.

5.32.7 | Conclusions

TABLE 206 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 (EFSA peer review ongoing)
Toxicological assessment	EU TRV available
Residue definitions	EU and Codex RDs are not fully comparable, but the Codex MRLs can be recalculated to match with the EU RD
Analytical methods	Sufficiently validated analytical methods are available
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 proposed Codex MRLs are sufficiently supported by data and risk to consumers is unlikely

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

5.33 | Tricyclazole (337) R/T

5.33.1 | Background information

TABLE 207 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2023	
Type of JMPR evaluation	New compound evaluation	
RMS	IT	
Approval status	Not approved	Commission Implementing Regulation (EU) 2016/1826[72]
EFSA conclusion available	Yes, see comments	EFSA (2015b) EFSA (2018k) (conclusion confirmatory data on TDMs)
MRL review performed	Yes, see comments	EFSA (2017e) (Statement; no MRL review required)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2023a) (import tolerance in rice)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria CLP00[73] (not reviewed by ECHA)
Endocrine effects of a.s.	No, see comment	Tricyclazole is not an endocrine disruptor in humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009,[74] as amended by Commission Regulation (EU) 2018/605[75] (EFSA, 2023a)
Other relevant information	Tricyclazole belongs to the class of triazole fungicides and it is subject to PIC Regulation The measure implementing the MRL proposal for rice (0.09 mg/kg) derived in the EFSA assessment (EFSA, 2023a) was presented for vote in the PAFF meeting in May 2023; no qualified majority. In August 2023, a modified draft was presented to the Council and the European Parliament (EP); no opinion delivered by the Council; response from EP pending. The European Parliament opposed the adoption of the MRL proposal for rice (P9_TA(2023)0474)). Hence, the MRL for tricyclazole in rice remains at 0.01 mg/kg in the EU legislation	

Abbreviations: a.s., active substance; MRL, maximum residue level.

5.33.2 | Toxicological reference values

TABLE 208 Comparison of toxicological reference values (TRVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.05 mg/kg bw per day	JMPR (2023)	0.05 mg/kg bw per day	EFSA (2023) (Developmental NOAEL in the developmental toxicity study in rat, supported by 2-year rat study; UF 100)	Yes
ARfD	0.05 mg/kg bw	JMPR (2023)	0.05 mg/kg bw	EFSA (2023) (Developmental NOAEL in the rat developmental toxicity study); UF 100)	Yes
Conclusion/ comments a.s.	In the EU assessment, parent tricyclazole was found unlikely to be genotoxic and unlikely to be carcinogenic (EFSA, 2023a) Similar conclusion was derived by the JMPR				
Comments on metabolites	Metabolites included in JMPR RD for RA: – 1,3,4-triazolo[3,4-b][1,3]benzo-thiazol-5-methanol (X355227) Covered by parent based on lower toxicity of metabolite Metabolites included in EU RD for RA: – tricyclazole-OH ([1,2,4]triazolo[3,4-b][1,3]benzothiazol-5-yl)methanol, X355227: The metabolite is unlikely to be genotoxic. Similar toxicity profile to parent (equally or less toxic than parent tricyclazole). Reference values of tricyclazole are applicable (EFSA, 2023a) Based on overall evidence, EFSA concluded that metabolite tricyclazole-OH has a similar toxicity profile and is equally or less toxic than tricyclazole parent compound				

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RD, residue definition; RA, risk assessment; UF, uncertainty factor.

[72]Commission Implementing Regulation (EU) 2016/1826 of 14 October 2016 concerning the non-approval of the active substance tricyclazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 279, 15.10.2016, p. 88–89.

[73]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.

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

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

5.33.3 | Residue definitions

TABLE 209 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tricyclazole	Reg. 396/2005: Tricyclazole Peer review (EFSA, 2015b): Tricyclazole	Yes
	Animal products	Tricyclazole The residue is not fat soluble	Reg. 396/2005: Tricyclazole Peer review (EFSA, 2015b): None proposed The residue is not fat soluble	Yes
RD-RA	Plant products	Sum of tricyclazole and 1,3,4-triazolo[3,4-b][1,3]benzothiazol-5-methanol, expressed as tricyclazole	Art. 10. reasoned opinion (EFSA, 2023a): Sum of tricyclazole and tricyclazole-OH, expressed as tricyclazole Peer review (EFSA, 2015b): Provisionally proposed as tricyclazole and tricyclazole-OH (not finalised; genotoxicity and carcinogenicity potential to be defined for parent)	Yes
	Animal products	Sum of tricyclazole and 1,3,4-triazolo[3,4-b][1,3]benzothiazol-5-methanol, expressed as tricyclazole	Art. 10. reasoned opinion (EFSA, 2023a): No RD derived, as calculated DB did not exceed the trigger value Peer review (EFSA, 2015b): None proposed, assessment currently not triggered by primary crop (rice), however pending the finalisation of the assessment of rotational crop residues	Not applicable
Conclusion, comments	Metabolism was investigated only in rice (flooded conditions). The experimental conditions were representative for the GAP in rice			

Abbreviations: GAP, Good Agricultural Practice; RD, residue definition; RD enf, residue definition for enforcement practice; RD-RA, residue definition for risk assessment.

5.33.4 | Analytical methods

TABLE 210 Summary of available analytical methods.

Matrices (relevant for Codex MRL proposals)	Validated methods available (incl. extraction efficiency)	LOQ (mg/kg)	Remark
Plant commodities: Dry commodities	No validation data reported in JMPR report	0.05	Extraction using various organic solvents and LC–MS/MS analysis (rice)
Animal products Muscle/meat Fat Liver/kidney Milk Eggs	No validation data reported in JMPR report	0.01	Extraction using various organic solvents and LC–MS/MS analysis (ruminant and poultry tissues); QuEChERS extraction, clean-up with SPE, LC–MS/MS analysis (egg, milk, kidney and fat)
Conclusion	The EU residue definition for MRL enforcement for the relevant matrix groups are identical with the JMPR residue definition The current EU MRLs for food commodities belonging to the matrix groups of dry commodities and edible offal (liver/kidney) are lower than the Codex MRL proposal under discussion. For the remaining commodities, the EU and the proposed Codex MRLs are at the same level Analytical methods were assessed by JMPR and were considered sufficiently validated for the enforcement of the MRLs for relevant matrices. However, in the JMPR report, the data are not presented in detail, but most likely, the validation data will be reported JMPR evaluation which is not yet published EURL data show successful validation of tricyclazole in dry commodities (cereal grain) with an LOQ of 0.005 mg/kg using QuEChERS and LC–MS/MS. In muscle/meat with a screening detection limit (SDL) of 0.005 mg/kg, in egg with an SDL of 0.001 mg/kg, and in milk with an LOQ of 0.001 mg/kg using QuEChERS-AO and LC–MS/MS or LC-QTOF		

Abbreviations: LC–MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification; MRL: maximum residue level; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); SPE: solid-phase extraction.

5.33.5 | Codex MRL proposals

TABLE 211 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity	Codex MRL proposal	EU MRL/ proposed MRL	Comment
Edible offal (mammalian)	**0.1**	0.01*	Max. dietary burden (beef): Japan, 2.15 ppm Max. residues in liver: 0.07 mg/kg Sufficiently supported by data: Yes Specific comments: It is noted that the dietary burden calculation for tricyclazole was not presented in Annex VI of the JMPR report. A slightly lower MRL might be sufficient (e.g. 0.07 or 0.08 mg/kg) **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Risk managers to discuss the EU position, considering that a lower MRL would be considered sufficient Follow-up action: None
Eggs	0.01*	0.01*	Max. dietary burden (poultry layer): 0.442 or 0.289 ppm (see specific comments) Mean/max. residues in eggs: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: EFSA noted a discrepancy regarding the information reported in the JMPR Report on the mean and maximum dietary burden for poultry. In the table summarising the dietary burden (p. 470), it is reported as 0.442 ppm, while on p. 471, 0.289 ppm are reported. As the dietary burden calculation for tricyclazole was not presented in Annex VI of the JMPR report, the correct value could not be retrieved. However, residues above the LOQ are not expected **Conclusion:** The proposed Codex MRL is sufficiently supported by data. JMPR should be asked to provide further information on the expected dietary burden Follow-up action: None
Husked rice	**0.3**	0.01*/0.09[a]	cGAP: Uruguay, 2 × 0.3 kg/ha, 14-day RTI, 30-day PHI Number of trials: 12 trials matching or approximating the cGAP Sufficiently supported by data: Yes Specific comments: A slightly less critical GAP was assessed in the EU (EFSA, 2023a) 2×0.225 kg/ha, 14- or 30-day RTI, 30-day PHI, leading to a MRL proposal of 0.09 mg/kg **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, details on the residue trials should be checked in the JMPR evaluation Follow-up action: To check in the JMPR evaluation whether the trials are sufficiently representative for the GAP and to understand why EU trials for a similar GAP lead to a significantly different MRL
Mammalian fats (except milk fats)	0.01*	0.01*	Max. dietary burden (beef): Japan, 2.15 ppm Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Sufficiently supported by data: Yes Specific comments: It is noted that the dietary burden calculation for tricyclazole was not presented in Annex VI of the JMPR report **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Meat (from mammals other than marine mammals)	0.01*	– Muscle: 0.01*	Max. dietary burden (beef): Japan, 2.15 ppm. Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Sufficiently supported by data: Yes Specific comments: The dietary burden calculation for tricyclazole is missing in Annex VI of the JMPR report. It is noted that according to the new Codex food classification, CXLs are established for muscle (MM 0095); hence, the commodity description should be changed to 'Muscle (from mammals other than marine mammals)' **Conclusion:** The proposed Codex MRL is sufficiently supported by data Follow-up action: None
Milks	0.01*	0.01*	Max. dietary burden (dairy): Japan, 0.976 ppm Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Sufficiently supported by data: Yes Specific comments: Even at the highest dose level of the feeding study (15N), neither tricyclazole nor tricyclazole-OH was detected in milk. It is noted that the dietary burden calculation for tricyclazole was not presented in Annex VI of the JMPR report **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Polished rice	0.3	–	JMPR estimated that in polished rice the same residue levels as in husked rice will occur

(Continues)

TABLE 211 (Continued)

Commodity	Codex MRL proposal	EU MRL/ proposed MRL	Comment
Poultry fats	0.01*	0.01*	Max. dietary burden (poultry layer and broiler): 0.442 or 0.289 ppm (see specific comments) Mean/max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: See specific comments reported for eggs. Residues above the LOQ are not expected **Conclusion:** The proposed Codex MRL is sufficiently supported by data. JMPR should be asked to provide further information on the expected dietary burden Follow-up action: None
Poultry meat	0.01*	– Muscle: 0.01*	Max. dietary burden (poultry layer and broiler): 0.442 or 0.289 ppm (see specific comments) Mean/max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: See specific comments reported for eggs. Residues above the LOQ are not expected **Conclusion:** The proposed Codex MRL is sufficiently supported by data. JMPR should be asked to provide further information on the expected dietary burden Follow-up action: None
Poultry, edible offal of	0.01*	0.01*	Max. dietary burden (poultry layer and broiler): 0.442 or 0.289 ppm (see specific comments). Mean/max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: See specific comments reported for eggs. Residues above the LOQ are not expected **Conclusion:** The proposed Codex MRL is sufficiently supported by data. JMPR should be asked to provide further information on the expected dietary burden Follow-up action: None
Rice	5	–	See husked rice. EU MRLs are set for husked rice, but not for rice grain
Rice, hay and/or straw	5 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice, hulls	15 (dw)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice bran, unprocessed	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
Rice germ	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose
General comments	–		

Abbreviations: CXL, Codex maximum residue limit; cGAP, critical Good Agricultural Practice; dw, dry weight; LOQ, limit of quantification; MRL, maximum residue level; PHI, pre-harvest interval; RTI: re-treatment interval.

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

[a]MRL proposal derived in EFSA (2023a). The MRL was not implemented in Regulation (EC) No 396/2005.

5.33.6 | Consumer risk assessment

TABLE 212 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. husked rice, animal products). For animal products, except edible offal (mammalian) and edible offal of poultry, the calculations were performed with the LOQ of 0.01 mg/kg	**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), including the STMR values derived by JMPR for the commodities for which Codex MRLs were derived For animal products, except edible offal (mammalian) and edible offal of poultry, the calculations were performed with the LOQ of 0.01 mg/kg	**Specific comments:** –

TABLE 212 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the commodities under assessment Results for the most important commodities Bovine liver: 3% of ARfD Milk, cattle: 2% Rice: 0.3%	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2% of the ADI (NL toddler) Among the crops under consideration, cattle milk was identified as the main contributor, accounting for up to 1.2% of the ADI	**Results:** Long-term exposure: 0% of the JMPR ADI GECDE mean: Max. 1% (infants and toddler) GECDE max: Max. 1% (infants and toddler) Short-term exposure: Highest result for rice: 20% of ARfD

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; GECDE: global estimate of chronic dietary exposure; LOQ, limit of quantification; MRL, maximum residue level; RA, risk assessment; STMR, supervised trials median residue.

5.33.7 | Conclusions

TABLE 213 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 TRV available
Residue definitions	EU and Codex RDs are identical
Analytical methods	According to JMPR assessment, sufficiently validated analytical methods are available. EURLs confirm the availability of analytical methods for MRL enforcement
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. Details of the residue trials should be checked in the JMPR Evaluation (to ensure the trials are sufficiently representative for the GAP)
Dietary risk assessment	No acute and no chronic intake concern identified
Final conclusion	EU position to be discussed/decided by risk managers

Abbreviations: a.s., active substance; MRL, maximum residue level; RD, residue definition; TRV, toxicological reference value.

ABBREVIATIONS

AChE	acetylcholinesterase
ADI	acceptable daily intake
AEL	acceptable exposure level
AhR	aryl hydrocarbon receptor
ARfD	acute reference dose
a.s.	active substance
bw	body weight
BBCH	growth stages of mono- and dicotyledonous plants
BMD	benchmark dose
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
EURLs	European Reference Laboratories
EWG	electronic working group
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GECDE	global estimate of chronic dietary exposure
GLC-EC	gas–liquid chromatography with electron-capture detection
GLP	Good Laboratory Practice
HPLC–MS	liquid chromatography with tandem mass spectrometry

HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high-performance liquid chromatographic method coupled with ultraviolet detector
HR	highest residue
IEDI	international estimated daily intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
KMD	kinetically derived maximum dose
LC–MS	liquid chromatography–mass spectrometry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LC-QTOF	liquid chromatography quadrupole time-of-flight mass spectrometry
LC-UV	liquid chromatography with ultraviolet detection
LD_{50}	lethal dose, median
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
MOE	margin of exposure
MRL	maximum residue level
MS	Member States
MTD	maximum tolerated dose
NEU	Northern European Union
NOAEL	no observed adverse effect level
NOEL	no observed effect level
n.a.	not applicable
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
Po	post-harvest
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	Committee for Risk Assessment
RAR	Renewal Assessment Report
RD	residue definition
RD enf	residue definition for enforcement practice
RD-RA	residue definition for risk assessment
RMS	rapporteur Member State
RPF	relative potency factor
RTI	re-treatment interval
SEU	Southern European Union
SPE	solid-phase extraction
STMR	supervised trials median residue
TDM	triazole derivative metabolite
ToR	Terms of Reference
TRV	toxicological reference value
TTC	threshold of toxicological concern
TRR	total radioactive residues
WHO	World Health Organization
UF	uncertainty factor

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00897

COPYRIGHT FOR NON-EFSA CONTENT

REFERENCES

CCPR (Codex Committee on Pesticide Residues). (2023). Report of the 54th Session of the Codex Committee on Pesticide Residues, 26 June – 1 July 2023.

ECHA (European Chemicals Agency). (2012a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of fluazinam (ISO), June 2012. www.echa.europa.eu

ECHA (European Chemicals Agency). (2012b). Assessment report on diflubenzuron prepared by the Evaluating Competent Authority Sweden in the framework of Directive 98/8/EC, September 2012. www.echa.europa.eu

ECHA (European Chemicals Agency). (2014a). Assessment report on permethrin prepared by the Evaluating Competent Authority Ireland in the framework of Regulation (EU) No 528/2012 the making available on the market and use of biocidal products, April 2014. www.echa.europa.eu

ECHA (European Chemicals Agency). (2014b). Assessment report on dinotefuran prepared by the Evaluating Competent Authority UK in the framework of Regulation (EU) No 528/2012, June 2014. www.echa.europa.eu

ECHA (European Chemicals Agency). (2014c). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of fluopyram, December 2014. www.echa.europa.eu

ECHA (European Chemicals Agency). (2016). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole, December 2016. www.echa.europa.eu

ECHA (European Chemicals Agency). (2017). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of cyflumetofen (ISO); 2-methoxyethyl (RS) -2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,αtrifluoro-o-tolyl)propionate, December 2017. www.echa.europa.eu

ECHA (European Chemicals Agency). (2018). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of oxathiapiprolin (ISO); 1-(4-{4-[5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3- thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone, November 2018. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of thiophanate-methyl (ISO); dimethyl (1,2- phenylenedicarbamothioyl)biscarbamate; dimethyl 4,4′-(o-phenylene)bis(3- thioallophanate), March 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019b). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of emamectin benzoate (ISO); (4″R)-4″-deoxy-4″-(methylamino)avermectin B1 benzoate, September 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019c). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of carbendazim (ISO); methyl benzimidazol-2- ylcarbamate, December 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019d). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of 1,4-dimethylnaphthalene, December 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019e). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3- (2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/– 40/60, December 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2019f). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine, December 2019. www.echa.europa.eu

ECHA (European Chemicals Agency). (2020a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3- yl)methyl]-N'-cyano-N-methylethanimidamide; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1- methylacetamidine, May 2020. www.echa.europa.eu

ECHA (European Chemicals Agency). (2020b). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3- (difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole4-carboxamide; isoflucypram, October 2020. www.echa.europa.eu

ECHA (European Chemicals Agency). (2021a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride, March 2021. www.echa.europa.eu

ECHA (European Chemicals Agency). (2021b). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of difenoconazole (ISO); 1-({2-[2-chloro-4-(4- chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4- chlorophenyl ether, June 2021. www.echa.europa.eu

ECHA (European Chemicals Agency). (2021c). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5- ylmethyl)-3-methyl-2-nitroguanidine, September 2021. www.echa.europa.eu

ECHA (European Chemicals Agency). (2022). Biocidal Products Committee (BPC). Opinion on the application for approval of the active substance: propiconazole. ECHA/BPC/324/2022. www.echa.europa.eu

ECHA (European Chemicals Agency). (2023a). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents, June 2023. www.echa.europa.eu

ECHA (European Chemicals Agency). (2023b). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of dinotefuran (ISO); (RS)-1-methyl-2-nitro-3- (tetrahydro-3-furylmethyl)guanidine, September 2023. www.echa.europa.eu

EFSA (European Food Safety Authority). (2008a). Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam. *EFSA Journal*, *6*(7), 137r. https://doi.org/10.2903/j.efsa.2008.137r

EFSA (European Food Safety Authority). (2008b). Conclusion regarding the peer review of the pesticide risk assessment of the active substance mepiquat. *EFSA Journal*, *6*(7), RN-146. https://doi.org/10.2903/j.efsa.2008.146r

EFSA (European Food Safety Authority). (2008c). Reasoned opinion on the MRLs of concern for the active substances benfuracarb and carbosulfan. *EFSA Scientific Report*, *6*(11), 171. https://doi.org/10.2903/j.efsa.2008.171

EFSA (European Food Safety Authority). (2009a). Conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. *EFSA Journal*, *7*(1), RN-196. https://doi.org/10.2903/j.efsa.2009.196r

EFSA (European Food Safety Authority). (2009b). Reasoned opinion on the refined risk assessment regarding certain MRLs of concern for the active substances carbendazim and thiophanate-methyl. *EFSA Scientific Report*, 289. https://doi.org/10.2903/j.efsa.2009.289r

EFSA (European Food Safety Authority). (2009c). Conclusion on pesticide peer review regarding the risk assessment of the active substance carbofuran. *EFSA Scientific Report*, 310. https://doi.org/10.2903/j.efsa.2009.310r

EFSA (European Food Safety Authority). (2009d). Conclusion on pesticide peer review regarding the risk assessment of the active substance diflubenzuron. *EFSA Scientific Report*, 332. https://doi.org/10.2903/j.efsa.2009.332r

EFSA (European Food Safety Authority). (2009e). Reasoned opinion on the modification of the existing MRLs for difenoconazole in various leafy vegetables. *EFSA Scientific Report*, 337. https://doi.org/10.2903/j.efsa.2009.337r

EFSA (European Food Safety Authority). (2009f). Conclusion on the peer review of the pesticide risk assessment of the active substance carbosulfan. *EFSA Journal*, *7*(10), 1354. https://doi.org/10.2903/j.efsa.2009.1354

EFSA (European Food Safety Authority). (2010a). Reasoned opinion on the modification of the existing MRLs for difenoconazole in swedes and turnips. *EFSA Journal*, *8*(2), 1510. https://doi.org/10.2903/j.efsa.2010.1510
EFSA (European Food Safety Authority). (2010b). Conclusion on the peer review of the pesticide risk assessment of the active substance carbendazim. *EFSA Journal*, *8*(5), 1598. https://doi.org/10.2903/j.efsa.2010.1598
EFSA (European Food Safety Authority). (2010c). Reasoned opinion on the modification of the existing MRLs for difenoconazole in peppers and aubergines. *EFSA Journal*, *8*(6), 1651. https://doi.org/10.2903/j.efsa.2010.1651
EFSA (European Food Safety Authority). (2011a). Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole. *EFSA Journal*, *9*(1), 1967. https://doi.org/10.2903/j.efsa.2011.1967
EFSA (European Food Safety Authority). (2011b). Reasoned opinion on the modification of the existing MRLs for difenoconazole in beet leaves (chard), globe artichokes, broccoli, cardoons and strawberries. *EFSA Journal*, *9*(5), 2153. https://doi.org/10.2903/j.efsa.2011.2153
EFSA (European Food Safety Authority). (2011c). Conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz. *EFSA Journal*, *9*(7), 2323. https://doi.org/10.2903/j.efsa.2011.2323
EFSA (European Food Safety Authority). (2011d). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for acetamiprid according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *9*(7), 2328. https://doi.org/10.2903/j.efsa.2011.2328
EFSA (European Food Safety Authority). (2012a). Conclusion on the peer review of the pesticide risk assessment of the active substance cyflumetofen. *EFSA Journal*, *10*(1), 2504. https://doi.org/10.2903/j.efsa.2012.2504
EFSA (European Food Safety Authority). (2012b). Reasoned opinion on the modification of the existing MRLs for difenoconazole in raspberries, blackberries and cucurbits (edible peel). *EFSA Journal*, *10*(8), 2867. https://doi.org/10.2903/j.efsa.2012.2867
EFSA (European Food Safety Authority). (2012c). Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance diflubenzuron. *EFSA Journal*, *10*(9), 2870. https://doi.org/10.2903/j.efsa.2012.2870
EFSA (European Food Safety Authority). (2012d). Conclusion on the peer review of the pesticide risk assessment of the active substance emamectin. *EFSA Journal*, *10*(11), 2955. https://doi.org/10.2903/j.efsa.2012.2955
EFSA (European Food Safety Authority). (2012e). Reasoned opinion on the modification of the existing MRLs for acetamiprid in purslane, legume vegetables and pulses (beans and peas). *EFSA Journal*, *10*(12), 3051. https://doi.org/10.2903/j.efsa.2012.3051
EFSA (European Food Safety Authority). (2013a). Conclusion on the peer review of the pesticide risk assessment of the active substance pyrethrins. *EFSA Journal*, *11*(1), 3032. https://doi.org/10.2903/j.efsa.2013.3032
EFSA (European Food Safety Authority). (2013b). Conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram. *EFSA Journal*, *11*(4), 3052. https://doi.org/10.2903/j.efsa.2013.3052
EFSA (European Food Safety Authority). (2013c). Reasoned Opinion on the modification of the existing MRLs for difenoconazole in various crops. *EFSA Journal*, *11*(3), 3149. https://doi.org/10.2903/j.efsa.2013.3149
EFSA (European Food Safety Authority). (2013d). Conclusion on the peer review of the pesticide risk assessment of the active substance 1,4-dimethylnaphthalene. *EFSA Journal*, *11*(10), 3229. https://doi.org/10.2903/j.efsa.2013.3229
EFSA (European Food Safety Authority). (2013e). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for iprodione according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *11*(10), 3438. https://doi.org/10.2903/j.efsa.2013.3438
EFSA (European Food Safety Authority). (2013f). Reasoned opinion on the modification of the existing maximum residue level (MRL) for acetamiprid in apricots and tree nuts. *EFSA Journal*, *11*(12), 3506. https://doi.org/10.2903/j.efsa.2013.3506
EFSA (European Food Safety Authority). (2014a). Reasoned opinion on the review of the existing MRLs for carbofuran, carbosulfan, benfuracarb and furathiocarb and the setting of an import tolerance for carbofuran in cultivated mushrooms. *EFSA Journal*, *12*(2), 3559. https://doi.org/10.2903/j.efsa.2014.3559
EFSA (European Food Safety Authority). (2014b). Reasoned opinion on the modification of the existing MRLs for difenoconazole in peppers and aubergines. *EFSA Journal*, *12*(4), 3676. https://doi.org/10.2903/j.efsa.2014.3676
EFSA (European Food Safety Authority). (2014c). Reasoned opinion on the setting of MRLs for imazapyr in genetically modified soya bean and other oilseeds and in lentils. *EFSA Journal*, *12*(6), 3743. https://doi.org/10.2903/j.efsa.2014.3743
EFSA (European Food Safety Authority). (2014d). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *12*(7), 3799. https://doi.org/10.2903/j.efsa.2014.3799
EFSA (European Food Safety Authority). (2014e). Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. *EFSA Journal*, *12*(9), 3814. https://doi.org/10.2903/j.efsa.2014.3814
EFSA (European Food Safety Authority). (2014f). Reasoned opinion on the modification of the existing MRL for acetamiprid in bananas. *EFSA Journal*, *12*(9), 3824. https://doi.org/10.2903/j.efsa.2014.3824
EFSA (European Food Safety Authority). (2014g). Reasoned opinion on the modification of the existing MRLs for difenoconazole in lettuce and other salad plants including Brassicaceae and in basil (mint). *EFSA Journal*, *12*(10), 3882. https://doi.org/10.2903/j.efsa.2014.3882
EFSA (European Food Safety Authority). (2014h). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *12*(12), 3918. https://doi.org/10.2903/j.efsa.2014.3918
EFSA (European Food Safety Authority). (2014i). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiophanate-methyl and carbendazim according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *12*(12), 3919. https://doi.org/10.2903/j.efsa.2014.3919
EFSA (European Food Safety Authority). (2014j). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance difenoconazole. *EFSA Supporting Publications*, EN-680. https://doi.org/10.2903/sp.efsa.2014.EN-680
EFSA (European Food Safety Authority). (2015a). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propiconazole according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *13*(1), 3975. https://doi.org/10.2903/j.efsa.2015.3975
EFSA (European Food Safety Authority). (2015b). Conclusion on the peer review of the pesticide risk assessment of the active substance tricyclazole. *EFSA Journal*, *13*(2), 4032. https://doi.org/10.2903/j.efsa.2015.4032
EFSA (European Food Safety Authority). (2015c). Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for boscalid in beans and peas with pods. *EFSA Journal*, *13*(3), 4045. https://doi.org/10.2903/j.efsa.2015.4045
EFSA (European Food Safety Authority). (2015d). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mepiquat according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *13*(8), 4214. https://doi.org/10.2903/j.efsa.2015.4214
EFSA (European Food Safety Authority). (2015e). Conclusion on the pesticides peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. *EFSA Journal*, *13*(12), 4222. https://doi.org/10.2903/j.efsa.2015.4222
EFSA (European Food Safety Authority). (2015f). Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in leafy brassicas. *EFSA Journal*, *13*(10), 4229. https://doi.org/10.2903/j.efsa.2015.4229
EFSA (European Food Safety Authority). (2015g). Reasoned opinion on the review of the existing maximum residue levels for fluazinam according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *13*(9), 4240. https://doi.org/10.2903/j.efsa.2015.4240
EFSA (European Food Safety Authority). (2015h). Reasoned opinion on the review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *13*(11), 4309. https://doi.org/10.2903/j.efsa.2015.4309

EFSA (European Food Safety Authority). (2015i). Technical report on the outcome of the consultation with member states, applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance prochloraz. *EFSA Supporting Publications*, EN-730. https://doi.org/10.2903/sp.efsa.2015.EN-730

EFSA (European Food Safety Authority). (2015j). Technical report on the outcome of the consultation with member states, the applicants and EFSA on the pesticide risk assessment for pyrethrins in light of confirmatory data. *EFSA Supporting Publications*, EN-800. doi:10.2903/sp.efsa.2015.EN-800

EFSA (European Food Safety Authority). (2016a). Reasoned opinion on the setting of a temporary maximum residue level for mepiquat in cultivated fungi. *EFSA Journal*, *14*(2), 4315. https://doi.org/10.2903/j.efsa.2016.4315

EFSA (European Food Safety Authority). (2016b). Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in various crops. *EFSA Journal*, *14*(2), 4385. https://doi.org/10.2903/j.efsa.2016.4385

EFSA (European Food Safety Authority). (2016c). Reasoned opinion on the setting of import tolerance for fluazinam in blueberries. *EFSA Journal*, *14*(4), 4460. https://doi.org/10.2903/j.efsa.2016.4460

EFSA (European Food Safety Authority). (2016d). Conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin. *EFSA Journal*, *14*(7), 4504. https://doi.org/10.2903/j.efsa.2016.4504

EFSA (European Food Safety Authority). (2016e). Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione. *EFSA Journal*, *14*(11), 4609. https://doi.org/10.2903/j.efsa.2016.4609

EFSA (European Food Safety Authority). (2016f). Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. *EFSA Journal*, *14*(11), 4610. https://doi.org/10.2903/j.efsa.2016.4610

EFSA (European Food Safety Authority). (2016g). Reasoned opinion on the setting of maximum residue levels for amitraz, coumaphos, flumequine, oxytetracycline, permethrin and streptomycin in certain products of animal origin. *EFSA Journal*, *14*(8), 4570. https://doi.org/10.2903/j.efsa.2016.4570

EFSA (European Food Safety Authority). (2016h). Conclusion on the peer review of the pesticide risk assessment for the active substance cyflumetofen in light of confirmatory data submitted. *EFSA Journal*, *14*(12), 4635. https://doi.org/10.2903/j.efsa.2016.4635

EFSA (European Food Safety Authority). (2016i). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for cyflumetofen in light of confirmatory data. *EFSA Supporting Publications*, EN-997. https://doi.org/10.2903/sp.efsa.2016.EN-997

EFSA (European Food Safety Authority). (2017a). Reasoned opinion on the modification of the existing maximum residue levels for deltamethrin in celery, Florence Fennel and Rhubarb. *EFSA Journal*, *15*(1), 4683. https://doi.org/10.2903/j.efsa.2017.4683

EFSA (European Food Safety Authority), Arena, M., Auteri, D., Barmaz, S., Bellisai, G., Brancato, A., Brocca, D., Bura, L., Byers, H., Chiusolo, A., Court Marques, D., Crivellente, F., De Lentdecker, C., De Maglie, M., Egsmose, M., Erdos, Z., Fait, G., Ferreira, L., Goumenou, M., … Villamar-Bouza, L. (2017b). Conclusion on the peer review of the pesticide risk assessment of the active substance propiconazole. *EFSA Journal*, *15*(7), 4887. https://doi.org/10.2903/j.efsa.2017.4887

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2017c). Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. *EFSA Journal*, *15*(7), 4893. https://doi.org/10.2903/j.efsa.2017.4893

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2017d). Reasoned opinion on the modification of the existing maximum residue levels for fluazinam in onions, shallots and garlic. *EFSA Journal*, *15*(7), 4904. https://doi.org/10.2903/j.efsa.2017.4904

EFSA (European Food Safety Authority). (2017e). Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *15*(12), 5080. https://doi.org/10.2903/j.efsa.2017.5080

EFSA (European Food Safety Authority). (2017f). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for pyrethrins in light of confirmatory data. *EFSA Supporting Publications*, EN-1212. https://doi.org/10.2903/sp.efsa.2017.EN-1212

EFSA (European Food Safety Authority). (2017g). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for 1,4-dimethylnaphthalene in light of confirmatory data. *EFSA Supporting Publications*, EN-1225. https://doi.org/10.2903/sp.efsa.2017.EN-1225

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2018a). Reasoned opinion on the setting of a maximum residue level for cyantraniliprole in leeks. *EFSA Journal*, *16*(1), 5124. https://doi.org/10.2903/j.efsa.2018.5124

EFSA (European Food Safety Authority), Arena, M., Auteri, D., Barmaz, S., Bellisai, G., Brancato, A., Brocca, D., Bura, L., Byers, H., Chiusolo, A., Court Marques, D., Crivellente, F., De Lentdecker, C., Egsmose, M., Erdos, Z., Fait, G., Ferreira, L., Goumenou, M., Greco, L., … Villamar-Bouza, L. (2018b). Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl. *EFSA Journal*, *16*(1), 5133. https://doi.org/10.2903/j.efsa.2018.5133

EFSA (European Food Safety Authority), Arena, M., Auteri, D., Barmaz, S., Bellisai, G., Brancato, A., Brocca, D., Bura, L., Byers, H., Chiusolo, A., Court Marques, D., Crivellente, F., De Lentdecker, C., Egsmose, M., Erdos, Z., Fait, G., Ferreira, L., Goumenou, M., Greco, L., … Villamar-Bouza, L. (2018c). Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. *EFSA Journal*, *16*(1), 5140. https://doi.org/10.2903/j.efsa.2018.5140

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Janossy, J., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., … Villamar-Bouza, L. (2018d). Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. *EFSA Journal*, *16*(1), 5143. https://doi.org/10.2903/j.efsa.2018.5143

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Ferreira, L., Greco, L., Jarrah, S., Leuschner, R., Medina, P., Miron, I., Nougadere, A., Pedersen, R., Reich, H., Santos, M., Stanek, A., Tarazona, J., Theobald, A., & Villamar-Bouza, L. (2018e). Guidance on use of EFSA pesticide residue intake model (EFSA PRIMo revision 3). *EFSA Journal*, *16*(1), 5147. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2018f). Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in kale. *EFSA Journal*, *16*(1), 5153. https://doi.org/10.2903/j.efsa.2018.5153

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2018g). Reasoned opinion on the modification of a maximum residue level for mepiquat in cotton seeds. *EFSA Journal*, *16*(2), 5162. https://doi.org/10.2903/j.efsa.2018.5162

EFSA (European Food Safety Authority). (2018h). Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules. *EFSA Journal*, *16*(2), 5177. https://doi.org/10.2903/j.efsa.2018.5177

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Cabrera, L. C., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Pedersen, R., Reich, H., Riemenschneider, C., Sacchi, A., … Villamar-Bouza, L. (2018i). Reasoned opinion on the modification of the existing maximum residue levels for emamectin in leafy brassica and beans and peas with pods. *EFSA Journal*, *16*(4), 5255. https://doi.org/10.2903/j.efsa.2018.5255

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Pedersen, R., Reich, H., Riemenschneider, C., Sacchi, A., … Villamar-Bouza, L. (2018j). Reasoned opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. *EFSA Journal*, *16*(5), 5262. https://doi.org/10.2903/j.efsa.2018.5262

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., Chiusolo, A., Civitella, C., Court Marques, D., Crivellente, F., De Lentdecker, C., Erdös, Z., Ferreira, L., Goumenou, M., Greco, L., Istace, F., Jarrah, S., Kardassi, D., Leuschner, R., Medina, P., Mineo, D., … Villamar-Bouza, L. (2018k). Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. *EFSA Journal*, *16*(7), 5376. https://doi.org/10.2903/j.efsa.2018.5376

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., De Lentdecker, C., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., Santos, M., … Villamar-Bouza, L. (2018l). Reasoned opinion on the modification of the existing maximum residue levels for mepiquat in various oilseeds and animal commodities. *EFSA Journal*, *16*(7), 5380. https://doi.org/10.2903/j.efsa.2018.5380

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lostia, A., Lythgo, C., Medina, P., Miron, I., Molnar, T., Pedersen, R., Reich, H., Sacchi, A., … Villamar-Bouza, L. (2018m). Reasoned opinion on the review of the existing maximum residue levels for prochloraz according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *16*(8), 5401. https://doi.org/10.2903/j.efsa.2018.5401

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lostia, A., Lythgo, C., Medina, P., Miron, I., Molnar, T., Pedersen, R., Reich, H., Sacchi, A., … Villamar-Bouza, L. (2018n). Reasoned opinion on the modification of the existing maximum residue level for clothianidin in potatoes. *EFSA Journal*, *16*(9), 5413. https://doi.org/10.2903/j.efsa.2018.5413

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Carrasco Cabrera, L., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Jarrah, S., Kardassi, D., Leuschner, R., Lostia, A., Lythgo, C., Medina, P., Miron, I., Molnar, T., Pedersen, R., Reich, H., Sacchi, A., … Villamar-Bouza, L. (2018o). Reasoned opinion on the modification of the existing maximum residue levels for mepiquat in cotton seeds and animal commodities. *EFSA Journal*, *16*(10), 5428. https://doi.org/10.2903/j.efsa.2018.5428

EFSA (European Food Safety Authority). (2018p). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for fluopyram in light of confirmatory data. *EFSA Supporting Publications*, EN-1359. https://doi.org/10.2903/sp.efsa.2018.EN-1359

EFSA (European Food Safety Authority). (2018q). Technical report on the follow up assessment of MRLs for the active substance iprodione. *EFSA Supporting Publications*, EN-1404. https://doi.org/10.2903/sp.efsa.2018.EN-1404

EFSA (European Food Safety Authority). (2018r). Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for oxathiapiprolin in light of confirmatory data. *EFSA Supporting Publications*, EN-1434. https://doi.org/10.2903/sp.efsa.2018.EN-1434

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Raczyk, M., Reich, H., Ruocco, S., Sacchi, A., Santos, M., Stanek, A., … Verani, A. (2019a). Reasoned opinion on the modification of the temporary maximum residue level for mepiquat in oyster mushrooms. *EFSA Journal*, *17*(7), 5744. https://doi.org/10.2903/j.efsa.2019.5744

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Raczyk, M., Reich, H., Ruocco, S., Sacchi, A., Santos, M., Stanek, A., Theobald, A., … Verani, A. (2019b). Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for oxathiapiprolin in various commodities. *EFSA Journal*, *17*(7), 5759. https://doi.org/10.2903/j.efsa.2019.5759

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Raczyk, M., Reich, H., Rojas, A., Ruocco, S., Sacchi, A., Santos, M., … Verani, A. (2019c). Reasoned opinion on the review of the existing maximum residue levels for emamectin according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *17*(8), 5803. https://doi.org/10.2903/j.efsa.2019.5803

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., Vagenende, B., & Verani, A. (2019d). Reasoned opinion on the modification of the existing maximum residue level for boscalid in honey. *EFSA Journal*, *17*(11), 5897. https://doi.org/10.2903/j.efsa.2019.5897

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., Vagenende, B., & Verani, A. (2019e). Reasoned opinion on the modification of the existing maximum residue levels for cyantraniliprole in Chinese cabbages, blackberries and raspberries. *EFSA Journal*, *17*(11), 5903. https://doi.org/10.2903/j.efsa.2019.5903

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Pedersen, R., Raczyk, M., Reich, H., Ruocco, S., Sacchi, A., Santos, M., Stanek, A., Tarazona, J., … Verani, A. (2019f). Pesticide residue intake model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). *EFSA Supporting Publications*, EN-1605. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., … Verani, A. (2020a). Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *18*(4), 6059. https://doi.org/10.2903/j.efsa.2020.6059

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., … Verani, A. (2020b). Reasoned opinion on the setting of import tolerances for oxathiapiprolin in various crops. *EFSA Journal*, *18*(6), 6155. https://doi.org/10.2903/j.efsa.2020.6155

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Theobald, A., … Verani, A. (2020c). Reasoned opinion on the modification of the existing maximum residue level for boscalid in pomegranates. *EFSA Journal*, *18*(9), 6236. https://doi.org/10.2903/j.efsa.2020.6236

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Theobald, A., … Verani, A. (2020d). Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in carobs/Saint John's breads. *EFSA Journal*, *18*(10), 6271. https://doi.org/10.2903/j.efsa.2020.6271

EFSA (European Food Safety Authority). (2020e). Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *18*(12), 6318. https://doi.org/10.2903/j.efsa.2020.6318

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Scarlato, A. P., … Verani, A. (2021a). Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for propiconazole. *EFSA Journal*, *19*(2), 6405. https://doi.org/10.2903/j.efsa.2021.6405

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Scarlato, A. P., … Verani, A. (2021b). Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in leafy brassica. *EFSA Journal*, *19*(2), 6407. https://doi.org/10.2903/j.efsa.2021.6407

EFSA (European Food Safety Authority), Anastassiadou, M., Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Santos, M., Scarlato, A. P., Theobald, A., … Verani, A. (2021c). Reasoned opinion on the review of the existing maximum residue levels for 1,4-dimethylnaphthalene according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *19*(5), 6597. https://doi.org/10.2903/j.efsa.2021.6597

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2021d). Reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. *EFSA Journal*, *19*(7), 6773. https://doi.org/10.2903/j.efsa.2021.6773

EFSA (European Food Safety Authority), Anastassiadou, M., Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., … Verani, A. (2021e). Reasoned opinion on the modification of the existing maximum residue levels for cyantraniliprole in olives. *EFSA Journal*, *19*(8), 6805. https://doi.org/10.2903/j.efsa.2021.6805

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2021f). Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *19*(8), 6812. https://doi.org/10.2903/j.efsa.2021.6812

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2021g). Reasoned opinion on the modification of the existing maximum residue levels for emamectin in various crops. *EFSA Journal*, *16*(8), 682. https://doi.org/10.2903/j.efsa.2021.6824

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2021h). Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in various crops. *EFSA Journal*, *19*(9), 6830. https://doi.org/10.2903/j.efsa.2021.6830

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Cabrera, L. C., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., Theobald, A., … Verani, A. (2022a). Reasoned opinion on the modification of the existing maximum residue level for oxathiapiprolin in kales/radish leaves. *EFSA Journal*, *20*(1), 7049. https://doi.org/10.2903/j.efsa.2022.7049

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Cabrera, L. C., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Pia Scarlato, A., Theobald, A., … Verani, A. (2022b). Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for deltamethrin in tomatoes and okra/lady's fingers. *EFSA Journal*, *20*(3), 7107. https://doi.org/10.2903/j.efsa.2022.7107

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Cabrera, L. C., Castellan, I., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., Santos, M., … Verani, A. (2022c). Reasoned opinion on the setting of import tolerances for deltamethrin in mangoes and papayas. *EFSA Journal*, *20*(3), 7198. https://doi.org/10.2903/j.efsa.2022.7198

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Castellan, I., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2022d). Reasoned opinion on the modification of the existing maximum residue level for apricots and setting of import tolerances for cyantraniliprole in various crops. *EFSA Journal*, *20*(3), 7219. https://doi.org/10.2903/j.efsa.2022.7219

EFSA (European Food Safety Authority), Alvarez, F., Arena, M., Auteri, D., Binaglia, M., Castoldi, A. F., Chiusolo, A., Colagiorgi, A., Colas, M., Crivellente, F., De Lentdecker, C., Egsmose, M., Fait, G., Ferilli, F., Gouliarmou, V., Nogareda, L. H., Ippolito, A., Istace, F., Jarrah, S., … Villamar-Bouza, L. (2022e). Conclusion on the peer review of the pesticide risk assessment of the active substance isoflucypram. *EFSA Journal*, *20*(6), 7328. https://doi.org/10.2903/j.efsa.2022.7328

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Castellan, I., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., Santos, M., … Verani, A. (2022f). Reasoned opinion on the setting of an import tolerance for oxathiapiprolin in blueberries. *EFSA Journal*, *20*(5), 7347. https://doi.org/10.2903/j.efsa.2022.7347

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Cabrera, L. C., Castellan, I., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., Santos, M., … Verani, A. (2022g). Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in maize/corn. *EFSA Journal*, *20*(7), 7446. https://doi.org/10.2903/j.efsa.2022.7446

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Cabrera, L. C., Castellan, I., Ferreira, L., Giner, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., Santos, M., … Verani, A. (2022h). Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in honey and various oilseed crops. *EFSA Journal*, *20*(8), 7535. https://doi.org/10.2903/j.efsa.2022.7535

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Castellan, I., Del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., … Theobald, A. (2023a). Reasoned opinion on the setting of import tolerance for tricyclazole in rice. *EFSA Journal*, *21*(1), 7757. https://doi.org/10.2903/j.efsa.2023.7757

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Binaglia, M., Brancato, A., Cabrera, L. C., Castellan, I., Castoldi, A. F., Chiusolo, A., Crivellente, F., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Istace, F., Jarrah, S., Lanzoni, A., Leuschner, R., Magrans, J. O., … Verani, A. (2023b). Reasoned opinion on the review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *21*(3), 7800. https://doi.org/10.2903/j.efsa.2023.7800

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Castellan, I., Del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Jarrah, S., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Robinson, T., Ruocco, S., … Theobald, A. (2023c). Reasoned opinion on the review of the existing maximum residue levels for dithiocarbamates according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal*, *21*(3), 7864. https://doi.org/10.2903/j.efsa.2023.7987

EFSA (European Food Safety Authority). (2023d). Statement on the review of the residue definitions for risk assessment of pyrethroids forming common metabolites. *EFSA Journal*, *21*(5), 8022. https://doi.org/10.2903/j.efsa.2023.8022

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Castellan, I., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023e). Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for fluopyram in various crops. *EFSA Journal*, *21*(6), 8036. https://doi.org/10.2903/j.efsa.2023.8036

EFSA (European Food Safety Authority). (2023f). Scientific report on the scientific support for preparing an EU position in the 54th session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, *21*(8), 8111. https://doi.org/10.2903/j.efsa.2023.8111

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Cabrera, L. C., Castellan, I., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023g). Reasoned opinion on the modification of the existing maximum residue levels for 1,4-dimethylnaphthalene in potatoes. *EFSA Journal*, *21*(8), 8190. https://doi.org/10.2903/j.efsa.2023.8190

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023h). Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in wheat and rye. *EFSA Journal*, *21*(8), 8207. https://doi.org/10.2903/j.efsa.2023.8207

EFSA (European Food Safety Authority). (2023i). Statement on the targeted risk assessment for prochloraz. *EFSA Journal*, *21*(8), 8231. https://doi.org/10.2903/j.efsa.2023.8231

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023j). Reasoned opinion on the modification of the existing maximum residue levels for mefentrifluconazole in various commodities. *EFSA Journal*, *21*(9), 8237. https://doi.org/10.2903/j.efsa.2023.8237

EFSA (European Food Safety Authority). (2023k). *Technical report on the outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for difenoconazole in light of confirmatory data* (EN-8474). EFSA Supporting publication. https://doi.org/10.2903/sp.efsa.2023.EN-8474

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Cabrera, L. C., Castellan, I., Del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., Szot, M., … Verani, A. (2024a). Reasoned opinion on the modification of the temporary maximum residue levels for mepiquat in cultivated fungi and oyster mushrooms. *EFSA Journal*, *22*(1), e8476. https://doi.org/10.2903/j.efsa.2024.8476

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Binaglia, M., Carrasco Cabrera, L., Castellan, I., Castoldi, A. F., Chiusolo, A., Crivellente, F., Del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Istace, F., Jarrah, S., Lanzoni, A., Leuschner, R., Mangas, I., Mioc, A., … Verani, A. (2024b). Updated reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. *EFSA Journal*, *22*(2), e8569. https://doi.org/10.2903/j.efsa.2024.8569

EFSA (European Food Safety Authority). (2024c). Scientific report on the assessment of fall-back MRLs for revoked CXLs previously implemented in the EU legislation and review of the JMPR evaluation of the toxicological data related to pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole. *EFSA Journal*, *22*(4), e8693. https://doi.org/10.2903/j.efsa.2024.8693

EFSA (European Food Safety Authority). (2024d). Statement on the assessment of quality of data available to EFSA to derive the health-based guidance values for carbendazim. *EFSA Journal*, *22*(5), e8756. https://doi.org/10.2903/j.efsa.2024.8756

EFSA (European Food Safety Authority), Hernandez-Jerez, A., Coja, T., Paparella, M., Price, A., Henri, J., Focks, A., Louisse, J., Terron, A., Binaglia, M., Guajardo, I. M., Mangas, I., Guajardo, I. M., Ferreira, L., Kardassi, D., De Lentdecker, C., Molnar, T., & Vianello, G. (2024e). Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites. *EFSA Journal*, *22*(5), e8759. https://doi.org/10.2903/j.efsa.2024.8759

EFSA (European Food Safety Authority). (2024f). Member States consultation report prepared by EFSA for preparing an EU position for the 55th Session of the Codex Committee on Pesticide Residues (CCPR), 22 May 2024. www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues). (2013). Scientific opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid. *EFSA Journal*, *11*(12), 3471. https://doi.org/10.2903/j.efsa.2013.3471

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Hernandez Jerez, A., Adriaanse, P., Berny, P., Coja, T., Duquesne, S., Focks, A., Marinovich, M., Millet, M., Pelkonen, O., Pieper, S., Tiktak, A., Topping, C., Widenfalk, A., Wilks, M., Wolterink, G., Rundlöf, M., Ippolito, A., Linguadoca, A., … Aldrich, A. (2022a). Statement on the active substance acetamiprid. *EFSA Journal*, *20*(1), 7031. https://doi.org/10.2903/j.efsa.2022.7031

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Hernandez-Jerez, A. F., Adriaanse, P., Aldrich, A., Berny, P., Duquesne, S., Focks, A., Marinovich, M., Millet, M., Pelkonen, O., Pieper, S., Tiktak, A., Topping, C. J., Widenfalk, A., Wilks, M., Wolterink, G., Binaglia, M., Chiusolo, A., Serafimova, R., … Coja, T. (2022b). Scientific opinion on toxicity of pyrethroid common metabolites. *EFSA Journal*, *20*(10), 7582. https://doi.org/10.2903/j.efsa.2022.7582

EFSA Scientific Committee, More, S. J., Bampidis, V., Benford, D., Bragard, C., Halldorsson, T. I., Hernández-Jerez, A. F., Bennekou, S. H., Koutsoumanis, K., Lambré, C., Machera, K., Mennes, W., Mullins, E., Nielsen, S. S., Schrenk, D., Turck, D., Younes, M., Aerts, M., Edler, L., … Schlatter, J. (2022). Guidance on the use of the benchmark dose approach in risk assessment. *EFSA Journal*, *20*(10), 7584. https://doi.org/10.2903/j.efsa.2022.7584

European Commission. (2005). Review report for the active substance clothianidin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of clothianidin in Annex I of Council Directive 91/414/EEC. SANCO/10533/05-Final, 18 January 2005.

FAO (Food and Agriculture Organization of the United Nations). (2016). Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. Pesticide Residues. Third Edition. FAO Plant Production and Protection Paper 225.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2002a). Report 2002 – Pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. Rome.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2002b). Deltamethrin. In: Evaluation 2002, part I, residues, volume 1 - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 175/1.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2004a). Carbosulfan. In: Evaluation 2003, part I – Residues. Pesticides residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 177.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2004b). Evaluation 2004, Part II, Toxicological - Pesticide residues in food 2004. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticides Residues.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2011a). Evaluation 2010, Part II, Toxicological - Pesticide residues in food 2010. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticides Residues.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2011b). Fluopyram. In: Evaluation 2010, part I, residues - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO expert group. FAO Plant Production and Protection Paper 206.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2011c). In: Thiamethoxam. In: Evaluation 2010, part I– Residues. Pesticides residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. Rome. FAO Plant Production and Protection Paper 206.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2012). Dinotefuran. In: Evaluation 2012, part I, residues - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 216.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2013). Report 2012 – Pesticide residues in food 2012. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 215.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2015a). Thiamethoxam. In: Evaluation 2014, part I– Residues. Pesticides residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. Rome. FAO Plant Production and Protection Paper 222.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2015b). Clothianidin. In: Evaluation 2014, part I, residues - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 222.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2017). Oxathiapiprolin. In: Evaluation 2016, part I, residues - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 231.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2018a). Acetamiprid. In: Evaluation 2017, part I, residues - pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 233.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2018b). Difenoconazole. In: Evaluation 2017, part I, residues - pesticide residues in food 2017. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. FAO Plant Production and Protection Paper 233.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2019). Boscalid. In: Evaluation 2019, part I, residues - pesticide residues in food. Extra joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2024). Report 2023 – Pesticide residues in food. Joint meeting of the FAO panel of experts on pesticide residues in food and the environment and the WHO Core assessment group on pesticides residues. Rome. https://doi.org/10.4060/cc9755en

France. (2017). Revised Renewal Assessment Report (RAR) on indoxacarb prepared by the rapporteur Member State France in the framework of Commission Implementing Regulation (EU) No 844/2012, August 2017. www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development). (2011). OECD MRL calculator: Spreadsheet for single data set and spreadsheet for multiple data set, 2 march 2011. In: Pesticide Publications/Publications on Pesticide Residues.

Parrilla Vázquez, P., Hakme, E., Uclés, S., Cutillas, V., Martínez Galera, M., Mughari, A. R., & Fernández-Alba, A. R. (2016). Large multiresidue analysis of pesticides in edible vegetable oils by using efficient solid-phase extraction sorbents based on quick, easy, cheap, effective, rugged and safe methodology followed by gas chromatography–tandem mass spectrometry. *Journal of Chromatography A*, *1463*, 20–31. https://doi.org/10.1016/j.chroma.2016.08.008

How to cite this article: EFSA (European Food Safety Authority), (2024). Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR). *EFSA Journal*, *22*(7), e8841. https://doi.org/10.2903/j.efsa.2024.8841

APPENDIX A

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mefentrifluconazole (F)

LOQs (mg/kg) range from:	0.01	to:	2.0
Toxicological reference values			
ADI (mg/kg bw/day):	0.035	ARfD (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARfD:	EC
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	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)
	33%	NL toddler	11.66	17%	Spinaches	2%	Apples	2%	Milk: Cattle	0.1%	17%
	21%	DE child	7.40	5%	Spinaches	3%	Apples	2%	Oranges	0.1%	6%
	17%	NL child	5.99	6%	Spinaches	1%	Apples	1%	Wheat	0.1%	7%
	16%	GEMS/Food G07	5.49	3%	Lettuces	2%	Wine grapes	2%	Sugar canes	0.1%	4%
	15%	GEMS/Food G10	5.32	4%	Lettuces	1%	Sugar canes	1%	Spinaches	0.0%	5%
	15%	GEMS/Food G08	5.26	2%	Lettuces	2%	Sugar canes	2%	Wine grapes	0.0%	3%
	15%	GEMS/Food G06	5.20	2%	Wheat	2%	Sugar canes	1%	Tomatoes	0.0%	2%
	15%	GEMS/Food G11	5.16	2%	Spinaches	2%	Sugar canes	2%	Wine grapes	0.1%	3%
	15%	IE adult	5.14	3%	Spinaches	2%	Wine grapes	1%	Lettuces	0.1%	4%
	14%	ES child	4.87	5%	Lettuces	2%	Spinaches	1%	Oranges	0.1%	7%
	14%	ES adult	4.85	6%	Lettuces	2%	Spinaches	0.8%	Oranges	0.0%	8%
	13%	GEMS/Food G15	4.42	2%	Wine grapes	1%	Sugar canes	1%	Lettuces	0.0%	2%
	13%	SE general	4.40	5%	Lettuces	2%	Spinaches	0.8%	Wheat	0.0%	6%
	11%	FR child 3 15 yr	4.02	2%	Spinaches	2%	Oranges	1%	Wheat	0.1%	3%
	11%	IT adult	3.88	5%	Lettuces	2%	Spinaches	1%	Wheat	0.0%	7%
	11%	FR toddler 2 3 yr	3.70	4%	Spinaches	0.9%	Oranges	0.8%	Milk: Cattle	0.1%	4%
	10%	DE women 14-50 yr	3.66	1%	Lettuces	1%	Wine grapes	1%	Oranges	0.0%	3%
	10%	IT toddler	3.55	3%	Lettuces	2%	Wheat	1%	Spinaches	0.1%	5%
	10%	DE general	3.48	1%	Wine grapes	1%	Lettuces	1%	Spinaches	0.0%	2%
	10%	NL general	3.48	4%	Spinaches	1%	Lettuces	0.9%	Wine grapes	0.1%	5%
	10%	PT general	3.39	4%	Wine grapes	1%	Lettuces	1%	Wheat	0.0%	1%
	9%	FR infant	3.20	6%	Spinaches	0.5%	Milk: Cattle	0.4%	Apples	0.0%	6%
	9%	DK child	3.01	2%	Lettuces	1%	Rye	1%	Wheat	0.0%	2%
	8%	RO general	2.93	3%	Wine grapes	1%	Wheat	0.8%	Tomatoes	0.0%	
	8%	FR adult	2.89	4%	Wine grapes	1%	Spinaches	0.6%	Wheat	0.1%	1%
	7%	UK toddler	2.61	1%	Oranges	1%	Wheat	0.6%	Spinaches	0.0%	0.9%
	7%	FI 3 yr	2.48	2%	Spinaches	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.0%	2%
	7%	UK vegetarian	2.34	2%	Lettuces	1%	Wine grapes	0.8%	Spinaches	0.0%	2%
	7%	UK infant	2.29	1%	Milk: Cattle	0.8%	Oranges	0.7%	Wheat	0.0%	0.3%
	6%	FI adult	2.16	2%	Lettuces	2%	Coffee beans	0.5%	Wine grapes	0.0%	2%
	6%	FI 6 yr	2.12	1%	Spinaches	1.0%	Lettuces	0.4%	Oat	0.0%	2%
	6%	UK adult	2.06	2%	Wine grapes	1%	Lettuces	0.4%	Wheat	0.0%	2%
	5%	DK adult	1.85	1%	Wine grapes	1%	Lettuces	0.3%	Wheat	0.0%	1%
	3%	LT adult	1.09	0.8%	Lettuces	0.4%	Apples	0.3%	Rye	0.0%	0.8%
	3%	PL general	0.91	0.5%	Apples	0.4%	Tomatoes	0.3%	Cherries (sweet)	0.0%	0.2%
	1%	IE child	0.46	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rice	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 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 of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			2	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
271%	Spinaches	30 / 18	407	67%	Lettuces	15 / 8.3	101
211%	Lettuces	15 / 8.3	316	48%	Spinaches	30 / 18	72
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)			2				

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			1	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
167%	Spinaches / frozen; boiled	30 / 18	250	99%	Spinaches / frozen; boiled	30 / 18	149
Expand/collapse list							

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Carbendazim

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

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2021	Year of evaluation:	2021

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL child	0.22	0.8%	Mandarins	0.2%	Lemons	0.0%	Limes		1%
	1%	FR toddler 2 3 yr	0.21	1%	Mandarins	0.0%	Lemons	0.0%	Almonds		1%
	0.8%	GEMS/Food G06	0.16	0.4%	Mandarins	0.4%	Lemons	0.0%	Okra/lady's fingers		0.8%
	0.8%	IE adult	0.16	0.7%	Mandarins	0.1%	Lemons	0.1%	Limes		0.8%
	0.8%	DE child	0.15	0.5%	Mandarins	0.2%	Lemons	0.0%	Limes		0.8%
	0.7%	NL toddler	0.14	0.5%	Mandarins	0.2%	Lemons	0.0%	Limes		0.7%
	0.7%	GEMS/Food G11	0.14	0.5%	Lemons	0.2%	Mandarins	0.0%	Almonds		0.7%
	0.7%	SE general	0.14	0.6%	Mandarins	0.1%	Lemons	0.0%	Limes		0.7%
	0.7%	GEMS/Food G08	0.13	0.3%	Lemons	0.3%	Mandarins	0.0%	Almonds		0.7%
	0.5%	FI 3 yr	0.10	0.5%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.5%
	0.5%	GEMS/Food G10	0.10	0.3%	Lemons	0.2%	Mandarins	0.0%	Okra/lady's fingers		0.5%
	0.5%	GEMS/Food G07	0.10	0.3%	Mandarins	0.2%	Lemons	0.0%	Almonds		0.5%
	0.4%	DE women 14-50 yr	0.09	0.3%	Lemons	0.1%	Mandarins	0.0%	Limes		0.4%
	0.4%	FI 6 yr	0.09	0.4%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.4%
	0.4%	UK toddler	0.08	0.4%	Mandarins	0.0%	Limes	0.0%	Lemons		0.4%
	0.4%	DE general	0.08	0.3%	Lemons	0.1%	Mandarins	0.0%	Limes		0.4%
	0.3%	GEMS/Food G15	0.07	0.2%	Mandarins	0.1%	Lemons	0.0%	Almonds		0.3%
	0.3%	IT toddler	0.06	0.3%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.3%
	0.3%	NL general	0.05	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.3%
	0.2%	IT adult	0.05	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.2%	FR child 3 15 yr	0.05	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.2%	ES child	0.05	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.2%	ES adult	0.04	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.2%	FI adult	0.04	0.2%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.2%	FR infant	0.04	0.2%	Mandarins	0.0%	Lemons				0.2%
	0.2%	PT general	0.03	0.1%	Mandarins	0.1%	Lemons				0.2%
	0.2%	DK adult	0.03	0.1%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.2%
	0.1%	DK child	0.03	0.1%	Mandarins	0.0%	Lemons	0.0%	Limes		0.1%
	0.1%	RO general	0.03	0.1%	Lemons	0.1%	Lemons				0.1%
	0.1%	PL general	0.02	0.1%	Lemons	0.0%	Mandarins				0.1%
	0.1%	FR adult	0.02	0.1%	Mandarins	0.0%	Lemons	0.0%	Almonds		0.1%
	0.1%	UK vegetarian	0.02	0.1%	Mandarins	0.023%	Lemons	0.0%	Limes		0.1%
	0.1%	UK adult	0.02	0.1%	Mandarins	0.0%	Lemons	0.0%	Limes		0.1%
	0.0%	UK infant	0.01	0.0%	Lemons		FRUIT AND TREE NUTS				0.0%
	0.0%	LT adult	0.01	0.0%	Mandarins	0.0%	Lemons				0.0%
	0.0%	IE child	0.00	0.0%	Lemons	0.0%	Mandarins	0.0%	Almonds		0.0%

Conclusion:

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

The long-term intake of residues of Carbendazim is unlikely to present a public health concern.

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): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
178%	Mandarins	0.7 / 0.6	36
103%	Lemons	0.7 / 0.6	21
60%	Limes	0.7 / 0.6	12
0.7%	Almonds	0.01 / 0.05	0.14

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)
54%	Mandarins	0.7 / 0.6	11
27%	Lemons	0.7 / 0.6	5.4
21%	Limes	0.7 / 0.6	4.2
0.4%	Almonds	0.01 / 0.05	0.07

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)
4%	Lemons / jam	0.7 / 0.26	0.79
0.1%	Limes / juice	0.7 / 0.26	0.02

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Okra, lady's fingers / boiled	1.5 / 0.87	1.4
2%	Lemons / juice	0.7 / 0.26	0.49

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Thiophanate-methyl

LOQs (mg/kg) range from: **0.01** to: **0.15**

Toxicological reference values

ADI (mg/kg bw/day):	**0.02**	ARfD (mg/kg bw):	**0.02**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2021**	Year of evaluation:	**2021**

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.1%	IE adult	0.01	0.1%	Limes	0.0%	Almonds			0.0%	0.1%
	0.0%	DE child	0.01	0.0%	Almonds	0.0%	Limes			0.0%	0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Okra/lady's fingers	0.0%	Almonds			0.0%	0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Almonds	0.0%	Limes			0.0%	0.0%
	0.0%	UK toddler	0.00	0.0%	Limes	0.0%	Almonds			0.0%	0.0%
	0.0%	SE general	0.00	0.0%	Limes		FRUIT AND TREE NUTS				0.0%
	0.0%	DE general	0.00	0.0%	Almonds	0.0%	Limes			0.0%	0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Almonds	0.0%	Okra/lady's fingers			0.0%	0.0%
	0.0%	ES adult	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	UK vegetarian	0.00	0.0%	Limes	0.0%	Almonds			0.0%	0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	NL general	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	NL child	0.00	0.0%	Almonds	0.0%	Limes			0.0%	0.0%
	0.0%	GEMS/Food G15	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	ES child	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	UK adult	0.00	0.0%	Limes	0.0%	Almonds			0.0%	0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	FR adult	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	FI adult	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	IT toddler	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	DK child	0.00	0.0%	Almonds	0.0%	Limes			0.0%	0.0%
	0.0%	FI 6 yr	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	FI 3 yr	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	NL toddler	0.00	0.0%	Limes		FRUIT AND TREE NUTS				0.0%
	0.0%	IT adult	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	DK adult	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%
	0.0%	IE child	0.00	0.0%	Almonds		FRUIT AND TREE NUTS			0.0%	0.0%

Conclusion:

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

The long-term intake of residues of Thiophanate-methyl 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)
48%	Limes	6 / 0.47	9.5
2%	Almonds	0.15 / 0.15	0.43

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)
17%	Limes	6 / 0.47	3.3
1%	Almonds	0.15 / 0.15	0.21

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%	Limes / juice	6 / 2.5	0.23

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%	Okra, lady's fingers / boiled	0.9 / 0.41	0.66

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Thiophanate-methyl is unlikely to present a public health risk.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Iprodione

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

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.06
Source of ADI:	EC	Source of ARfD:	EC
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)
	49%	NL toddler	9.86	27%	Broccoli	11%	Raspberries (red and yellow)	3%	Milk: Cattle	6%	43%
	21%	NL child	4.14	9%	Raspberries (red and yellow)	5%	Broccoli	2%	Blackberries	3%	18%
	20%	IE adult	4.02	10%	Broccoli	8%	Blackberries	0.6%	Potatoes	2%	19%
	19%	FI 3 yr	3.72	13%	Raspberries (red and yellow)	4%	Broccoli	1%	Potatoes	0.7%	18%
	15%	UK toddler	2.94	7%	Raspberries (red and yellow)	3%	Broccoli	1%	Dewberries	2%	13%
	14%	DE child	2.89	6%	Broccoli	4%	Raspberries (red and yellow)	1.0%	Milk: Cattle	3%	11%
	12%	FI 6 yr	2.31	9%	Raspberries (red and yellow)	1.0%	Broccoli	1.0%	Potatoes	0.5%	11%
	11%	FR toddler 2 3 yr	2.24	5%	Broccoli	1%	Milk: Cattle	1%	Raspberries (red and yellow)	3%	9%
	10%	SE general	2.10	4%	Broccoli	2%	Dewberries	1%	Potatoes	2%	9%
	10%	FR infant	1.94	7%	Broccoli	0.8%	Milk: Cattle	0.7%	Beans (with pods)	1%	8%
	7%	NL general	1.50	3%	Broccoli	2%	Raspberries (red and yellow)	0.6%	Potatoes	1%	6%
	7%	FR child 3 15 yr	1.46	2%	Broccoli	1%	Milk: Cattle	1%	Raspberries (red and yellow)	3%	5%
	7%	GEMS/Food G11	1.44	3%	Broccoli	1%	Raspberries (red and yellow)	1.0%	Potatoes	2%	5%
	7%	DE women 14-50 yr	1.42	3%	Broccoli	2%	Raspberries (red and yellow)	0.6%	Milk: Cattle	2%	5%
	7%	GEMS/Food G15	1.41	2%	Raspberries (red and yellow)	2%	Broccoli	0.9%	Potatoes	2%	5%
	7%	GEMS/Food G07	1.40	3%	Broccoli	0.9%	Potatoes	0.5%	Raspberries (red and yellow)	2%	5%
	7%	DE general	1.31	3%	Broccoli	2%	Raspberries (red and yellow)	0.6%	Milk: Cattle	2%	5%
	6%	UK vegetarian	1.24	4%	Broccoli	0.6%	Raspberries (red and yellow)	0.3%	Potatoes	0.6%	6%
	6%	UK infant	1.20	2%	Milk: Cattle	2%	Dewberries	0.8%	Potatoes	3%	3%
	6%	FI adult	1.19	3%	Raspberries (red and yellow)	1%	Coffee beans	1%	Broccoli	2%	4%
	6%	GEMS/Food G08	1.18	1%	Broccoli	1%	Raspberries (red and yellow)	1.0%	Potatoes	2%	4%
	5%	UK adult	1.04	4%	Broccoli	0.4%	Raspberries (red and yellow)	0.3%	Potatoes	0.6%	5%
	5%	GEMS/Food G06	1.02	1%	Blackberries	0.9%	Broccoli	0.5%	Potatoes	2%	3%
	5%	DK child	0.97	2%	Broccoli	0.6%	Milk: Cattle	0.6%	Potatoes	2%	3%
	5%	GEMS/Food G10	0.93	1%	Raspberries (red and yellow)	0.7%	Potatoes	0.4%	Broccoli	2%	3%
	4%	IE child	0.72	3%	Broccoli	0.2%	Raspberries (red and yellow)	0.2%	Milk: Cattle	0.4%	3%
	3%	DK adult	0.70	2%	Broccoli	0.7%	Raspberries (red and yellow)	0.3%	Potatoes	0.8%	3%
	3%	RO general	0.61	0.9%	Potatoes	0.6%	Milk: Cattle	0.3%	Wheat	2%	1%
	3%	FR adult	0.59	0.9%	Broccoli	0.4%	Raspberries (red and yellow)	0.4%	Beans (with pods)	1%	2%
	3%	ES child	0.54	0.6%	Milk: Cattle	0.5%	Potatoes	0.4%	Beans (with pods)	2%	1.0%
	2%	PT general	0.46	1%	Potatoes	0.2%	Wheat	0.1%	Wine grapes	0.8%	2%
	2%	PL general	0.46	0.9%	Potatoes	0.5%	Raspberries (red and yellow)	0.5%	Broccoli	0.3%	2%
	2%	IT adult	0.45	1%	Broccoli	0.2%	Beans (with pods)	0.2%	Wheat	0.6%	2%
	2%	LT adult	0.44	0.8%	Potatoes	0.7%	Raspberries (red and yellow)	0.2%	Milk: Cattle	0.7%	1%
	2%	IT toddler	0.39	0.5%	Broccoli	0.3%	Wheat	0.2%	Potatoes	0.8%	1%
	2%	ES adult	0.33	0.4%	Beans (with pods)	0.2%	Milk: Cattle	0.2%	Potatoes	1.0%	0.7%

Conclusion:

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

The long-term intake of residues of Iprodione 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): 3

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1664%	Broccoli	40 / 24	998
404%	Blackberries	50 / 22.6	242
348%	Raspberries (red and yellow)	50 / 22.6	209
66%	Dewberries	50 / 22.6	40
15%	Beans (with pods)	1.5 / 0.81	9.3
13%	Potatoes	0.05 / 0.05	7.7
8%	Peaches	0.05 / 0.05	4.8
4%	Onions	0.15 / 0.11	2.5
3%	Apricots	0.05 / 0.05	1.7
3%	Cherries (sweet)	0.3 / 0.14	1.7
3%	Melons	0.01 / 0.01	1.5
2%	Pears	0.01 / 0.01	1.4
2%	Oranges	0.01 / 0.01	1.3
2%	Milk: Cattle	0.01 / 0.01	1.2
2%	Watermelons	0.01 / 0.01	1.2

Expand/collapse list

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

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)
953%	Broccoli	40 / 24	572
309%	Blackberries	50 / 22.6	185
203%	Raspberries (red and yellow)	50 / 22.6	122
54%	Dewberries	50 / 22.6	33
10%	Beans (with pods)	1.5 / 0.81	6.2
3%	Onions	0.15 / 0.11	1.6
2%	Potatoes	0.05 / 0.05	1.5
2%	Cherries (sweet)	0.3 / 0.14	1.4
2%	Peaches	0.05 / 0.05	0.94
0.9%	Apricots	0.05 / 0.05	0.54
0.7%	Head cabbages	0.01 / 0.01	0.42
0.7%	Watermelons	0.01 / 0.01	0.41
0.7%	Melons	0.01 / 0.01	0.39
0.6%	Milk: Cattle	0.01 / 0.01	0.39
0.6%	Swedes/rutabagas	0.01 / 0.01	0.34

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3151%	Broccoli / boiled	40 / 24	1891
263%	Raspberries / juice	50 / 13.5	158
17%	Beans (with pods) / boiled	1.5 / 0.81	10
8%	Potatoes / fried	0.05 / 0.05	4.7
5%	Potatoes / dried (flakes)	0.05 / 0.23	3.0
2%	Peaches / canned	0.05 / 0.05	1.3
2%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
1%	Pumpkins / boiled	0.01 / 0.01	0.89
1%	Witloofs / boiled	0.01 / 0.01	0.89
1%	Peaches / juice	0.05 / 0.05	0.83
1%	Cauliflowers / boiled	0.01 / 0.01	0.70
1%	Escaroles/broad-leaved endives / boiled	0.01 / 0.01	0.66
1.0%	Leeks / boiled	0.01 / 0.01	0.57
0.9%	Apples / juice	0.01 / 0.01	0.54
0.9%	Oranges / juice	0.01 / 0.01	0.53

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)
963%	Broccoli / boiled	40 / 24	578
2%	Onions / boiled	0.15 / 0.11	1.0
0.9%	Pumpkins / boiled	0.01 / 0.01	0.55
0.7%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.7%	Potatoes / chips	0.05 / 0.05	0.42
0.7%	Cauliflowers / boiled	0.01 / 0.01	0.42
0.7%	Peaches / canned	0.05 / 0.05	0.41
0.6%	Beetroots / boiled	0.01 / 0.01	0.39
0.6%	Celeries / boiled	0.01 / 0.01	0.34
0.6%	Apples / juice	0.01 / 0.01	0.33
0.5%	Potatoes / dried (flakes)	0.05 / 0.23	0.29
0.4%	Maize / oil	0.02 / 0.5	0.25
0.4%	Coffee beans / extraction	0.05 / 0.01	0.24
0.4%	Courgettes / boiled	0.01 / 0.01	0.23
0.4%	Parsnips / boiled	0.01 / 0.01	0.21

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 3 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

zeta cypermethrin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.0015	ARfD (mg/kg bw):	0.0015
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2023	Year of evaluation:	2023

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)	16%	NL toddler	0.24	9%	Currants (red, black and white)	5%	Rose hips	0.8%	Blueberries		16%
	9%	NL child	0.14	7%	Currants (red, black and white)	2%	Rose hips	0.5%	Onions		9%
	5%	GEMS/Food G15	0.07	2%	Rose hips	2%	Onions	0.3%	Currants (red, black and white)		5%
	5%	FI 3 yr	0.07	2%	Currants (red, black and white)	1%	Onions	1%	Rose hips		5%
	4%	GEMS/Food G08	0.07	2%	Currants (red, black and white)	2%	Onions	0.5%	Gooseberries (green, red and yellow)		4%
	4%	DE child	0.06	2%	Currants (red, black and white)	0.6%	Onions	0.5%	Blueberries		4%
	4%	UK toddler	0.06	3%	Currants (red, black and white)	0.8%	Onions				4%
	4%	GEMS/Food G10	0.05	2%	Onions	0.7%	Currants (red, black and white)	0.4%	Blueberries		4%
	3%	GEMS/Food G06	0.05	3%	Onions	0.4%	Rose hips	0.2%	Garlic		3%
	3%	SE general	0.05	2%	Onions	0.4%	Currants (red, black and white)	0.4%	Currants (red, black and white)		3%
	3%	RO general	0.04	3%	Onions	0.3%	Garlic				3%
	3%	UK infant	0.04	2%	Currants (red, black and white)	0.6%	Onions	0.3%	Gooseberries (green, red and yellow)		3%
	3%	DE women 14-50 yr	0.04	1%	Currants (red, black and white)	0.5%	Rose hips	0.3%	Onions		3%
	2%	IE adult	0.04	2%	Avocados	0.5%	Onions	0.3%	Shallots		2%
	2%	FI 6 yr	0.04	1%	Currants (red, black and white)	1.0%	Onions	0.2%	Rose hips		2%
	2%	PL general	0.03	1%	Gooseberries (green, red and yellow)	1%	Onions	0.1%	Blueberries		2%
	2%	DE general	0.03	1%	Currants (red, black and white)	0.4%	Onions	0.4%	Rose hips		2%
	2%	GEMS/Food G07	0.03	1%	Onions	0.4%	Avocados	0.3%	Rose hips		2%
	2%	NL general	0.03	0.9%	Currants (red, black and white)	0.7%	Onions	0.3%	Rose hips		2%
	2%	FI adult	0.02	0.9%	Currants (red, black and white)	0.5%	Onions	0.1%	Gooseberries (green, red and yellow)		2%
	1%	UK vegetarian	0.02	0.8%	Onions	0.4%	Currants (red, black and white)	0.2%	Gooseberries (green, red and yellow)		1%
	1%	GEMS/Food G11	0.02	0.6%	Onions	0.2%	Currants (red, black and white)	0.2%	Avocados		1%
	1%	PT general	0.02	1%	Onions	0.0%	Garlic				1%
	1%	FR child 3 15 yr	0.02	0.7%	Onions	0.3%	Avocados	0.1%	Currants (red, black and white)		1%
	1%	IE child	0.02	0.9%	Currants (red, black and white)	0.2%	Onions	0.1%	Garlic		1%
	1%	UK adult	0.02	0.5%	Onions	0.5%	Currants (red, black and white)	0.1%	Avocados		1%
	1%	DK child	0.02	0.9%	Onions	0.1%	Currants (red, black and white)	0.1%	Currants (red, black and white)		1%
	0.9%	FR toddler 2 3 yr	0.01	0.7%	Onions	0.2%	Avocados	0.0%	Currants (red, black and white)		0.9%
	0.8%	ES adult	0.01	0.7%	Onions	0.1%	Avocados	0.1%	Garlic		0.8%
	0.8%	DK adult	0.01	0.5%	Onions	0.3%	Avocados	0.0%	Garlic		0.8%
	0.7%	FR adult	0.01	0.4%	Onions	0.2%	Avocados	0.0%	Currants (red, black and white)		0.7%
	0.7%	ES child	0.01	0.6%	Onions	0.1%	Garlic	0.0%	Avocados		0.7%
	0.6%	LT adult	0.01	0.6%	Currants (red, black and white)		FRUIT AND TREE NUTS				0.6%
	0.5%	IT toddler	0.01	0.4%	Onions	0.0%	Garlic	0.0%	Blueberries		0.5%
	0.4%	FR infant	0.01	0.4%	Onions	0.0%	Currants (red, black and white)	0.0%	Garlic		0.4%
	0.4%	IT adult	0.01	0.3%	Onions	0.0%	Garlic	0.0%	Gooseberries (green, red and yellow)		0.4%

Conclusion:

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

The long-term intake of residues of zeta cypermethrin (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): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
806%	Avocados	0.5 / 0.24	12
279%	Currants (red, black and white)	1.5 / 0.53	4.2
211%	Blueberries	1.5 / 0.53	3.2
208%	Gooseberries (green, red and yellow)	1.5 / 0.53	3.1
76%	Onions	0.05 / 0.05	1.1
12%	Garlic	0.05 / 0.05	0.18
1%	Shallots	0.05 / 0.05	0.02

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
322%	Blueberries	1.5 / 0.53	4.8
240%	Avocados	0.5 / 0.24	3.6
233%	Currants (red, black and white)	1.5 / 0.53	3.5
159%	Gooseberries (green, red and yellow)	1.5 / 0.53	2.4
78%	Rose hips	1.5 / 0.53	1.2
50%	Onions	0.05 / 0.05	0.74
9%	Shallots	0.05 / 0.05	0.13
2%	Garlic	0.05 / 0.05	0.03

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
762%	Currants (red, black and white) / juice	1.5 / 0.4	11
81%	Rose hips / jam	1.5 / 0.4	1.2
54%	Shallots / boiled	0.05 / 0.05	0.81

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)
340%	Currants (red, black and white) / juice	1.5 / 0.4	5.1
33%	Rose hips / jam	1.5 / 0.4	0.50
31%	Onions / boiled	0.05 / 0.05	0.47
21%	Shallots / boiled	0.05 / 0.05	0.31

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Cypermethrins - combined (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.00125	ARfD (mg/kg bw):	0.00125
Source of ADI:	EC	Source of ARfD:	EC
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: Combined risk assessment based on all uses identified as safe in the previous scenarios, except from the import tolerance GAP for zeta-cypermethrin on wheat. For this commodities, the northern outdoor GAP for cypermethrin was considered to derive a fall-back MRL.

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)
110%	NL toddler	1.37	48%	Milk: Cattle	20%	Maize/corn	9%	Currants (red, black and white)		110%
55%	NL child	0.68	20%	Milk: Cattle	7%	Sugar beet roots	7%	Currants (red, black and white)		55%
51%	GEMS/Food G11	0.63	15%	Soyabeans	7%	Sugar canes	6%	Milk: Cattle		51%
49%	GEMS/Food G10	0.61	13%	Soyabeans	4%	Milk: Cattle	4%	Sugar canes		49%
48%	UK infant	0.60	31%	Milk: Cattle	3%	Maize/corn	2%	Bovine: Muscle/meat		48%
47%	GEMS/Food G08	0.59	8%	Soyabeans	5%	Sugar canes	4%	Milk: Cattle		47%
43%	GEMS/Food G07	0.54	7%	Soyabeans	5%	Milk: Cattle	5%	Sugar canes		43%
43%	GEMS/Food G15	0.53	7%	Soyabeans	6%	Milk: Cattle	4%	Sugar canes		43%
41%	FI adult	0.52	37%	Coffee beans	0.9%	Currants (red, black and white)	0.4%	Rye		41%
41%	GEMS/Food G06	0.51	6%	Sugar canes	5%	Soyabeans	4%	Wheat		41%
41%	FR child 3 15 yr	0.51	18%	Milk: Cattle	3%	Sugar beet roots	3%	Wheat		41%
39%	FR toddler 2 3 yr	0.49	23%	Milk: Cattle	2%	Sugar beet roots	2%	Bovine: Muscle/meat		39%
39%	DE child	0.48	16%	Milk: Cattle	3%	Oranges	3%	Wheat		39%
37%	UK toddler	0.46	17%	Milk: Cattle	3%	Currants (red, black and white)	3%	Beans		37%
29%	DE women 14-50 yr	0.36	10%	Milk: Cattle	4%	Sugar beet roots	3%	Coffee beans		29%
29%	DE general	0.36	10%	Milk: Cattle	3%	Sugar beet roots	3%	Coffee beans		29%
27%	SE general	0.34	10%	Milk: Cattle	7%	Bovine: Muscle/meat	2%	Wheat		27%
27%	ES child	0.34	10%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat		27%
27%	RO general	0.33	9%	Milk: Cattle	3%	Wheat	3%	Maize/corn		27%
25%	DK child	0.32	10%	Milk: Cattle	3%	Rye	3%	Wheat		25%
25%	IE adult	0.31	3%	Milk: Cattle	2%	Avocados	1%	Wheat		25%
25%	NL general	0.31	7%	Milk: Cattle	2%	Sugar beet roots	2%	Coffee beans		25%
19%	FR infant	0.24	13%	Milk: Cattle	1%	Sugar beet roots	0.5%	Bovine: Muscle/meat		19%
16%	FR adult	0.20	4%	Milk: Cattle	3%	Coffee beans	1%	Wheat		16%
15%	ES adult	0.19	4%	Milk: Cattle	1%	Wheat	1%	Barley		15%
12%	PT general	0.15	2%	Wheat	1%	Maize/corn	1%	Soyabeans		12%
11%	DK adult	0.14	4%	Milk: Cattle	1%	Bovine: Fat tissue	1.0%	Swine: Muscle/meat		11%
11%	FI 3 yr	0.14	2%	Currants (red, black and white)	1%	Oat	1%	Rose hips		11%
10%	UK vegetarian	0.13	3%	Milk: Cattle	1%	Wheat	1%	Beans		10%
10%	LT adult	0.13	3%	Milk: Cattle	1%	Swine: Muscle/meat	0.6%	Rye		10%
10%	UK adult	0.12	2%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Wheat		10%
8%	FI 6 yr	0.10	1%	Currants (red, black and white)	0.8%	Potatoes	0.8%	Oat		8%
7%	IT toddler	0.09	4%	Wheat	0.6%	Tomatoes	0.3%	Oranges		7%
6%	IE child	0.08	3%	Milk: Cattle	0.9%	Currants (red, black and white)	0.7%	Wheat		6%
5%	IT adult	0.07	2%	Wheat	0.5%	Tomatoes	0.3%	Rice		5%
4%	PL general	0.04	1%	Gooseberries (green, red and yellow)	0.7%	Potatoes	0.4%	Tomatoes		4%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 109.7 % 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.

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): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
806%	Avocados	0.5 / 0.2	10
279%	Currants (red, black and white)	1.5 / 0.44	3.5
211%	Blueberries	1.5 / 0.44	2.6
208%	Gooseberries (green, red and yellow)	1.5 / 0.44	2.6
99%	Milk: Cattle	0.02 / 0.01	1.2
98%	Watermelons	0.07 / 0.01	1.2
92%	Potatoes	0.05 / 0.01	1.2
89%	Carrots	0.1 / 0.02	1.1
89%	Equine: Muscle/meat	0.05 / 0.18	1.1
88%	Oranges	0.3 / 0.01	1.1
88%	Table grapes	0.15 / 0.02	1.1
81%	Lentils (fresh)	0.7 / 0.18	1.0
80%	Sheep: Muscle/meat	0.05 / 0.18	1.0
80%	Beetroots	0.1 / 0.02	1.00
77%	Celeriacs/turnip rooted celeries	0.1 / 0.02	0.97
77%	Asparagus	0.4 / 0.05	0.96
72%	Swedes/rutabagas	0.1 / 0.02	0.91
71%	Head cabbages	0.15 / 0.02	0.88
71%	Carambolas	0.2 / 0.02	0.88
65%	Strawberries	0.07 / 0.05	0.82
61%	Beans	0.05 / 0.04	0.76
56%	Globe artichokes	0.1 / 0.04	0.70
54%	Chervil	5 / 0.53	0.68
53%	Sorghum	0.8 / 0.21	0.67
52%	Grapefruits	0.5 / 0.01	0.65
51%	Parsnips	0.1 / 0.02	0.63
50%	Turnips	0.1 / 0.02	0.63
48%	Coconuts	0.05 / 0.04	0.60
47%	Tomatoes	0.07 / 0.01	0.58
46%	Parsley	5 / 0.53	0.57
43%	Salsifies	0.1 / 0.02	0.54
42%	Broccoli	0.1 / 0.01	0.52
40%	Aubergines/egg plants	0.07 / 0.02	0.50
40%	Mandarins	0.3 / 0.01	0.49
39%	Quinces	0.15 / 0.02	0.49
37%	Celeries	0.05 / 0.01	0.47
37%	Rhubarbs	0.05 / 0.01	0.47
34%	Chives	5 / 0.53	0.43
34%	Radishes	0.1 / 0.02	0.43
34%	Lamb's lettuce/corn salads	1.5 / 0.15	0.42
33%	Bovine: Fat tissue	0.2 / 0.2	0.42
32%	Roman rocket/rucola	1.5 / 0.15	0.40
32%	Poultry: Muscle/meat	0.05 / 0.02	0.40
32%	Sage	5 / 0.53	0.40
31%	Basil and edible flowers	5 / 0.53	0.38
29%	Sweet corn	0.05 / 0.01	0.36
28%	Rice	0.2 / 0.03	0.35
27%	Onions	0.09 / 0.02	0.34
26%	Melons	0.04 / 0	0.33
26%	Bovine: Liver	0.05 / 0.04	0.32
25%	Beans (with pods)	0.2 / 0.03	0.31
25%	Yams	0.01 / 0.01	0.31
23%	Cauliflowers	0.04 / 0.01	0.29
23%	Lemons	0.3 / 0.01	0.29
22%	Lentils	0.05 / 0.04	0.28
22%	Medlar	0.15 / 0.02	0.28
22%	Peas	0.05 / 0.04	0.27
22%	Bovine: Muscle/meat	0.03 / 0.04	0.27
21%	Pumpkins	0.07 / 0.01	0.27
21%	Milk: Goat	0.05 / 0.01	0.27
21%	Vanilla pods	0.5 / 0.43	0.26
21%	Swine: Muscle/meat	0.03 / 0.02	0.26
20%	Celery leaves	5 / 0.53	0.25
19%	Pistachios	0.05 / 0.04	0.24
19%	Kumquats	0.3 / 0.13	0.24
19%	Maize/corn	0.3 / 0.04	0.24
19%	Watercress	4 / 0.5	0.23
18%	Peas (with pods)	0.2 / 0.03	0.22
16%	Florence fennels	0.05 / 0.01	0.20
16%	Spring onions/green onions and Welsh onions	0.05 / 0.01	0.20
14%	Table olives	0.4 / 0.05	0.18
14%	Chestnuts	0.05 / 0.04	0.17
14%	Buckwheat and other pseudo-cereals	0.3 / 0.04	0.17
13%	Barley	0.4 / 0.03	0.17
13%	Limes	0.3 / 0.01	0.17
13%	Cucumbers	0.01 / 0	0.16

Results for adults

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
322%	Blueberries	1.5 / 0.44	4.0
240%	Avocados	0.5 / 0.2	3.0
233%	Currants (red, black and white)	1.5 / 0.44	2.9
159%	Gooseberries (green, red and yellow)	1.5 / 0.44	2.0
78%	Rose hips	1.5 / 0.44	0.97
71%	Equine: Muscle/meat	0.05 / 0.18	0.88
70%	Sheep: Muscle/meat	0.05 / 0.18	0.87
67%	Head cabbages	0.15 / 0.02	0.84
64%	Red mustards	1.5 / 0.15	0.80
50%	Parsley	5 / 0.53	0.63
48%	Swedes/rutabagas	0.1 / 0.02	0.60
48%	Watercress	4 / 0.5	0.59
46%	Lentils (fresh)	0.7 / 0.18	0.58
43%	Aubergines/egg plants	0.07 / 0.02	0.54
41%	Globe artichokes	0.1 / 0.04	0.52
41%	Table grapes	0.15 / 0.02	0.51
37%	Grape leaves and similar species	0.7 / 0.52	0.47
37%	Strawberries	0.07 / 0.05	0.47
32%	Watermelons	0.07 / 0.01	0.41
32%	Beetroots	0.1 / 0.02	0.40
31%	Milk: Cattle	0.02 / 0.01	0.39
31%	Asparagus	0.4 / 0.05	0.38
30%	Carambolas	0.2 / 0.02	0.37
29%	Coconuts	0.05 / 0.04	0.36
28%	Wine grapes	0.15 / 0.02	0.36
28%	Carrots	0.1 / 0.02	0.34
24%	Quinces	0.15 / 0.02	0.30
24%	Gherkins	0.2 / 0.05	0.30
24%	Broccoli	0.1 / 0.01	0.30
24%	Cardamom	3 / 2.97	0.30
23%	Goat: Muscle	0.05 / 0.18	0.29
23%	Yams	0.01 / 0.01	0.28
23%	Lamb's lettuce/corn salads	1.5 / 0.15	0.28
22%	Poultry: Muscle	0.05 / 0.02	0.28
22%	Soyabeans	0.1 / 0.05	0.28
22%	Beans	0.05 / 0.04	0.27
20%	Lentils	0.05 / 0.04	0.26
20%	Oranges	0.3 / 0.01	0.26
20%	Parsnips	0.1 / 0.02	0.25
19%	Rice	0.2 / 0.03	0.23
19%	Florence fennels	0.05 / 0.01	0.23
18%	Potatoes	0.05 / 0.01	0.22
18%	Onions	0.09 / 0.02	0.22
17%	Bovine: Muscle	0.03 / 0.04	0.21
17%	Beans (with pods)	0.2 / 0.03	0.21
17%	Celeriacs/turnip rooted celeries	0.1 / 0.02	0.21
16%	Milk: Goat	0.05 / 0.01	0.20
16%	Celeries	0.05 / 0.01	0.20
16%	Turnips	0.1 / 0.02	0.19
16%	Bovine: Fat tissue	0.2 / 0.2	0.19
15%	Cress and other sprouts and shoots	4 / 0.5	0.19
15%	Chestnuts	0.05 / 0.04	0.19
15%	Salsifies	0.1 / 0.02	0.19
15%	Radishes	0.1 / 0.02	0.18
14%	Parsley roots/Hamburg roots parsley	0.1 / 0.02	0.18
14%	Roman rocket/rucola	1.5 / 0.15	0.18
14%	Celery leaves	5 / 0.53	0.17
13%	Milk: Sheep	0.05 / 0.01	0.17
13%	Jerusalem artichokes	0.1 / 0.02	0.16
13%	Bovine: Liver	0.05 / 0.04	0.16
13%	Tomatoes	0.07 / 0.01	0.16
12%	Mandarins	0.3 / 0.01	0.15
12%	Grapefruits	0.5 / 0.01	0.15
12%	Pumpkins	0.07 / 0.01	0.15
12%	Barley	0.4 / 0.03	0.15
11%	Peas	0.05 / 0.04	0.14
11%	Swine: Fat tissue	0.15 / 0.07	0.14
11%	Medlar	0.15 / 0.02	0.14
11%	Sweet corn	0.05 / 0.01	0.13
10%	Cardoons	0.05 / 0.01	0.13
10%	Horseradishes	0.1 / 0.02	0.13
10%	Buckwheat and other pseudo-cereals	0.3 / 0.04	0.12
10%	Other farmed animals: Muscle/meat	0.03 / 0.02	0.12
9%	Rhubarbs	0.05 / 0.01	0.12
9%	Cauliflowers	0.04 / 0.01	0.12
9%	Peanuts/groundnuts	0.1 / 0.05	0.12

13%	Sunflower seeds	0.1 / 0.05	0.16
12%	Grape leaves and similar species	0.7 / 0.52	0.16
12%	Bovine: Kidney	0.05 / 0.04	0.15
12%	Other farmed animals: Muscle/meat	0.03 / 0.02	0.15
12%	Cress and other sprouts and shoots	4 / 0.5	0.15
12%	Peanuts/groundnuts	0.1 / 0.05	0.15
11%	Gherkins	0.2 / 0.05	0.14
11%	Walnuts	0.05 / 0.04	0.14
11%	Wine grapes	0.15 / 0.02	0.14
11%	Hazelnuts/cobnuts	0.05 / 0.04	0.14
10%	Brussels sprouts	0.15 / 0.02	0.13
10%	Eggs: Chicken	0.01 / 0.01	0.12
10%	Almonds	0.05 / 0.04	0.12
9%	Courgettes	0.01 / 0	0.12
9%	Swine: Fat tissue	0.15 / 0.07	0.12
9%	Soyabeans	0.1 / 0.05	0.12
9%	Pecans	0.05 / 0.04	0.11
9%	Kales	0.01 / 0	0.11
9%	Wheat	0.08 / 0.01	0.11
8%	Cashew nuts	0.05 / 0.04	0.11
8%	Witloofs/Belgian endives	0.01 / 0	0.10
6%	Chinese cabbages/pe-tsai	0.01 / 0	0.08
6%	Cassava roots/manioc	0.01 / 0.01	0.08
6%	Parsley roots/Hamburg roots parsley	0.1 / 0.02	0.08
6%	Sesame seeds	0.1 / 0.05	0.07
6%	Rapeseeds/canola seeds	0.1 / 0.05	0.07
5%	Coffee beans	0.1 / 0.08	0.06
4%	Linseeds	0.1 / 0.05	0.05
4%	Garlic	0.09 / 0.02	0.05
4%	Mustard seeds	0.1 / 0.05	0.05
4%	Swine: Kidney	0.05 / 0.04	0.05
4%	Swine: Liver	0.05 / 0.04	0.05
4%	Common millet/proso millet	0.3 / 0.04	0.05
4%	Rye	0.08 / 0.01	0.05
3%	Juniper berry	0.5 / 0.43	0.04
3%	Milk: Sheep	0.05 / 0.01	0.04
3%	Brazil nuts	0.05 / 0.04	0.04
3%	Olives for oil production	0.4 / 0.03	0.03
3%	Oat	0.4 / 0.03	0.03
3%	Thyme	5 / 0.53	0.03
2%	Cardamom	3 / 2.97	0.03
2%	Sweet potatoes	0.03 / 0.01	0.03
2%	Sugar canes	0.2 / 0.14	0.03
2%	Poultry: Liver	0.05 / 0.02	0.02
2%	Macadamia	0.05 / 0.04	0.02
2%	Bamboo shoots	0.05 / 0.01	0.02
2%	Peas (without pods)	0.01 / 0	0.02
2%	Beans (without pods)	0.01 / 0	0.02
1%	Peppercorn (black, green and white)	0.5 / 0.43	0.02
1%	Rosemary	5 / 0.53	0.02
1%	Pine nut kernels	0.05 / 0.04	0.01
0.8%	Allspice/pimento	0.5 / 0.43	0.01
0.7%	Ginger	0.2 / 0.11	0.01
0.7%	Caraway	0.5 / 0.43	0.01
0.6%	Horseradishes	0.1 / 0.02	0.01
0.4%	Laurel/bay leaves	5 / 0.53	0.01
0.4%	Strawberry leaves	0.1 / 0.03	0.01
0.4%	Strawberry leaves	0.1 / 0.03	0.01
0.4%	Strawberry leaves	0.1 / 0.03	0.01
0.4%	Strawberry leaves	0.1 / 0.03	0.01
0.4%	Shallots	0.09 / 0.02	0.00
0.3%	Poultry: Fat tissue	0.1 / 0.04	0.00
0.2%	Turmeric/curcuma	0.2 / 0.12	0.00
0.06%	Hemp seeds	0.05 / 0.01	0.00
0.05%	Liquorice	0.2 / 0.12	0.00

9%	Sweet potatoes	0.03 / 0.01	0.11
9%	Sheep: Liver	0.05 / 0.04	0.11
9%	Pistachios	0.05 / 0.04	0.11
8%	Sage	5 / 0.53	0.11
8%	Swine: Muscle/meat	0.03 / 0.02	0.10
8%	Poultry: Liver	0.05 / 0.02	0.10
8%	Pecans	0.05 / 0.04	0.09
8%	Peas (with pods)	0.2 / 0.03	0.09
7%	Walnuts	0.05 / 0.04	0.09
7%	Brussels sprouts	0.15 / 0.02	0.09
7%	Chives	5 / 0.53	0.09
7%	Swine: Kidney	0.05 / 0.04	0.09
7%	Macadamia	0.05 / 0.04	0.09
7%	Bovine: Kidney	0.05 / 0.04	0.08
7%	Melons	0.04 / 0	0.08
6%	Maize/corn	0.3 / 0.04	0.08
6%	Lemons	0.3 / 0.01	0.07
6%	Cashew nuts	0.05 / 0.04	0.07
6%	Cucumbers	0.01 / 0	0.07
5%	Basil and edible flowers	5 / 0.53	0.06
5%	Chinese cabbages/pe-tsai	0.01 / 0	0.06
5%	Wheat	0.08 / 0.01	0.06
5%	Sorghum	0.8 / 0.21	0.06
5%	Sorghum	0.8 / 0.21	0.06
5%	Almonds	0.05 / 0.04	0.06
5%	Limes	0.3 / 0.01	0.06
5%	Courgettes	0.01 / 0	0.06
5%	Swine: Liver	0.05 / 0.04	0.06
4%	Spring onions/green onions and Welsh onions	0.05 / 0.01	0.06
4%	Rosemary	5 / 0.53	0.05
4%	Rosemary	5 / 0.53	0.05
4%	Rosemary	5 / 0.53	0.05
4%	Rosemary	5 / 0.53	0.05
4%	Table olives	0.4 / 0.05	0.05
4%	Sunflower seeds	0.1 / 0.05	0.05
4%	Hazelnuts/cobnuts	0.05 / 0.04	0.05
4%	Kales	0.01 / 0	0.05
4%	Witloofs/Belgian endives	0.01 / 0	0.05
3%	Vanilla pods	0.5 / 0.43	0.04
3%	Eggs: Chicken	0.01 / 0.01	0.04
3%	Chervil	5 / 0.53	0.04
3%	Pine nut kernels	0.05 / 0.04	0.04
3%	Shallots	0.09 / 0.02	0.04
3%	Rye	0.08 / 0.01	0.04
3%	Poppy seeds	0.1 / 0.05	0.04
3%	Poppy seeds	0.1 / 0.05	0.04
3%	Sesame seeds	0.1 / 0.05	0.04
3%	Common millet/proso millet	0.3 / 0.04	0.03
2%	Cassava roots/manioc	0.01 / 0.01	0.03
2%	Bamboo shoots	0.05 / 0.01	0.03
2%	Brazil nuts	0.05 / 0.04	0.03
2%	Rapeseeds/canola seeds	0.1 / 0.05	0.03
2%	Kumquats	0.3 / 0.13	0.02
2%	Linseeds	0.1 / 0.05	0.02
2%	Olives for oil production	0.4 / 0.03	0.02
2%	Tamarind	0.5 / 0.43	0.02
2%	Oat	0.4 / 0.03	0.02
1%	Strawberry leaves	0.1 / 0.03	0.02
1%	Strawberry leaves	0.1 / 0.03	0.02
1%	Palm hearts	0.05 / 0.01	0.01
1%	Eggs: Quail	0.01 / 0.01	0.01
1%	Peas (without pods)	0.01 / 0	0.01
1%	Peppercorn (black, green and white)	0.5 / 0.43	0.01
1.0%	Liquorice	0.2 / 0.12	0.01
1.0%	Liquorice	0.2 / 0.12	0.01
0.9%	Poultry: Fat tissue	0.1 / 0.04	0.01
0.8%	Rooibos	0.1 / 0.03	0.01
0.8%	Rooibos	0.1 / 0.03	0.01
0.8%	Beans (without pods)	0.01 / 0	0.01
0.8%	Garlic	0.09 / 0.02	0.01
0.7%	Caraway	0.5 / 0.43	0.01
0.4%	Eggs: Goose	0.01 / 0.01	0.01
0.3%	Allspice/pimento	0.5 / 0.43	0.00
0.3%	Sheep: Kidney	0.05 / 0.04	0.00
0.3%	Borage seeds	0.05 / 0.01	0.00
0.2%	Chicory roots	0.03 / 0.01	0.00
0.05%	Juniper berry	0.5 / 0.43	0.00
0.04%	Hemp seeds	0.05 / 0.01	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
762%	Currants (red, black and white) / juice	1.5 / 0.33	9.5
88%	Sugar beets (root) / sugar	0.1 / 0.12	1.1
81%	Rose hips / jam	1.5 / 0.33	1.0
79%	Gherkins / pickled	0.2 / 0.04	0.99
79%	Broccoli / boiled	0.1 / 0.01	0.98
71%	Turnips / boiled	0.1 / 0.02	0.89
71%	Parsnips / boiled	0.1 / 0.02	0.89
71%	Pumpkins / boiled	0.07 / 0.01	0.89
65%	Maize / oil	0.3 / 0.88	0.81
62%	Beetroots / boiled	0.1 / 0.02	0.78
56%	Potatoes / fried	0.05 / 0.01	0.70
54%	Rice / milling (polishing)	0.2 / 0.04	0.67
45%	Florence fennels / boiled	0.05 / 0.01	0.57
37%	Rhubarbs / sauce/puree	0.05 / 0.01	0.47
36%	Salsifies / boiled	0.1 / 0.02	0.45

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)
340%	Currants (red, black and white) / juice	1.5 / 0.33	4.3
54%	Beetroots / boiled	0.1 / 0.02	0.68
44%	Pumpkins / boiled	0.07 / 0.01	0.55
36%	Maize / oil	0.3 / 0.88	0.44
35%	Sugar beets (root) / sugar	0.1 / 0.12	0.44
35%	Grape leaves / canned	0.7 / 0.52	0.43
34%	Rice / milling (polishing)	0.2 / 0.04	0.43
34%	Celeries / boiled	0.05 / 0.01	0.42
33%	Rose hips / jam	1.5 / 0.33	0.42
32%	Coffee beans / extraction	0.1 / 0.02	0.40
30%	Parsnips / boiled	0.1 / 0.02	0.37
27%	Turnips / boiled	0.1 / 0.02	0.33
25%	Celeriacs / boiled	0.1 / 0.02	0.32
24%	Broccoli / boiled	0.1 / 0.01	0.30
24%	Beans / canned	0.05 / 0.04	0.30

Conclusion:

The estimated short term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Diflubenzuron (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):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
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 : ---

	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)	2%	IE adult	1.56	1%	Tea (dried leaves of Camellia sinensis)	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.3%	1%
	2%	FR adult	1.53	1%	Tea (dried leaves of Camellia sinensis)	0.0%	Milk: Cattle	0.0%	Wine grapes	0.2%	1%
	1%	NL toddler	1.34	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Tea (dried leaves of Camellia sinensi	1%	0.1%
	1%	UK infant	1.15	0.5%	Tea (dried leaves of Camellia sinensis)	0.4%	Milk: Cattle	0.0%	Potatoes	0.6%	0.5%
	0.9%	GEMS/Food G06	0.86	0.5%	Tea (dried leaves of Camellia sinensis)	0.1%	Wheat	0.0%	Tomatoes	0.4%	0.5%
	0.8%	GEMS/Food G07	0.84	0.5%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Wheat	0.4%	0.5%
	0.8%	NL child	0.82	0.2%	Milk: Cattle	0.2%	Tea (dried leaves of Camellia sinensis)	0.1%	Sugar beet roots	0.7%	0.2%
	0.8%	FR child 3 15 yr	0.78	0.2%	Tea (dried leaves of Camellia sinensis)	0.2%	Milk: Cattle	0.0%	Wheat	0.6%	0.2%
	0.8%	GEMS/Food G11	0.77	0.4%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Potatoes	0.4%	0.4%
	0.7%	DE child	0.73	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Tea (dried leaves of Camellia sinensi	0.6%	0.1%
	0.7%	UK toddler	0.70	0.3%	Tea (dried leaves of Camellia sinensis)	0.2%	Milk: Cattle	0.0%	Wheat	0.4%	0.3%
	0.7%	GEMS/Food G10	0.66	0.3%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Wheat	0.4%	0.3%
	0.7%	DE women 14-50 yr	0.65	0.3%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.4%	0.3%
	0.6%	GEMS/Food G08	0.65	0.3%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Wheat	0.4%	0.3%
	0.6%	DE general	0.65	0.3%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.4%	0.3%
	0.6%	UK adult	0.64	0.5%	Tea (dried leaves of Camellia sinensis)	0.0%	Milk: Cattle	0.0%	Wheat	0.1%	0.5%
	0.6%	NL general	0.63	0.3%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.3%	0.3%
	0.6%	UK vegetarian	0.61	0.5%	Tea (dried leaves of Camellia sinensis)	0.0%	Milk: Cattle	0.0%	Wheat	0.1%	0.5%
	0.6%	FR toddler 2 3 yr	0.60	0.3%	Milk: Cattle	0.0%	Tea (dried leaves of Camellia sinensis)	0.0%	Apples	0.6%	0.0%
	0.5%	GEMS/Food G15	0.51	0.1%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Wheat	0.4%	0.1%
	0.4%	DK child	0.41	0.1%	Milk: Cattle	0.1%	Rye	0.0%	Wheat	0.4%	
	0.4%	RO general	0.38	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.4%	
	0.4%	ES child	0.38	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Cocoa beans	0.4%	
	0.4%	SE general	0.37	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes	0.4%	
	0.4%	FI adult	0.35	0.3%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.4%	
	0.3%	FR infant	0.30	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.3%	0.0%
	0.3%	DK adult	0.25	0.1%	Tea (dried leaves of Camellia sinensis)	0.1%	Milk: Cattle	0.0%	Potatoes	0.2%	0.1%
	0.2%	PT general	0.21	0.1%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.2%	
	0.2%	ES adult	0.21	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.2%	
	0.2%	FI 3 yr	0.18	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%	
	0.2%	LT adult	0.16	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.2%	
	0.1%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.1%	
	0.1%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	
	0.1%	IE child	0.10	0.0%	Milk: Cattle	0.0%	Tea (dried leaves of Camellia sinensis)	0.0%	Wheat	0.1%	0.0%
	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 Diflubenzuron (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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Deltamethrin (F)

LOQs (mg/kg) range from:	0.01	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:	2003	Year of evaluation:	2003

Input values

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

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

Comments:

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)	96%	NL toddler	9.64	49%	Maize/corn	18%	Wheat	10%	Milk: Cattle		96%
	69%	DK child	6.89	39%	Rye	20%	Wheat	3%	Oat		69%
	57%	GEMS/Food G06	5.68	33%	Wheat	9%	Maize/corn	7%	Rice		57%
	43%	GEMS/Food G08	4.25	18%	Wheat	6%	Barley	4%	Rye		43%
	41%	GEMS/Food G10	4.06	18%	Wheat	6%	Rice	5%	Maize/corn		41%
	41%	GEMS/Food G15	4.06	20%	Wheat	5%	Barley	4%	Maize/corn		41%
	40%	DE child	4.01	19%	Wheat	6%	Rye	4%	Apples		40%
	37%	FR child 3 15 yr	3.68	21%	Wheat	4%	Milk: Cattle	3%	Maize/corn		37%
	36%	GEMS/Food G07	3.65	19%	Wheat	4%	Barley	2%	Maize/corn		36%
	36%	RO general	3.64	23%	Wheat	7%	Maize/corn	2%	Milk: Cattle		36%
	34%	UK infant	3.41	12%	Wheat	7%	Maize/corn	7%	Milk: Cattle		34%
	34%	ES child	3.38	20%	Wheat	2%	Rice	2%	Milk: Cattle		34%
	33%	NL child	3.34	19%	Wheat	4%	Milk: Cattle	2%	Maize/corn		33%
	33%	IT toddler	3.29	30%	Wheat	0.9%	Rice	0.4%	Tomatoes		33%
	32%	GEMS/Food G11	3.20	16%	Wheat	5%	Barley	1%	Milk: Cattle		32%
	29%	PT general	2.91	18%	Wheat	4%	Rice	3%	Maize/corn		29%
	28%	UK toddler	2.79	18%	Wheat	4%	Milk: Cattle	3%	Rice		28%
	27%	IE adult	2.74	10%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	2%	Buckwheat and other pseudo-cereals		27%
	27%	FR toddler 2 3 yr	2.74	14%	Wheat	5%	Milk: Cattle	3%	Rice		27%
	25%	SE general	2.51	14%	Wheat	2%	Bovine: Muscle/meat	2%	Milk: Cattle		25%
	24%	DE general	2.38	8%	Wheat	4%	Rye	4%	Barley		24%
	22%	DE women 14-50 yr	2.21	10%	Wheat	3%	Rye	2%	Milk: Cattle		22%
	21%	ES adult	2.14	11%	Wheat	3%	Barley	1%	Rice		21%
	21%	IT adult	2.14	19%	Wheat	0.8%	Rice	0.3%	Tomatoes		21%
	19%	FI 3 yr	1.90	5%	Wheat	5%	Rye	4%	Oat		19%
	19%	FR adult	1.89	10%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	0.9%	Wine grapes		19%
	19%	LT adult	1.86	8%	Rye	5%	Wheat	1%	Buckwheat and other pseudo-cereals		19%
	18%	NL general	1.83	9%	Wheat	2%	Barley	1%	Milk: Cattle		18%
	15%	UK vegetarian	1.50	9%	Wheat	2%	Rice	1%	Tea (dried leaves of Camellia sinensis		15%
	15%	FI 6 yr	1.49	4%	Wheat	4%	Rye	2%	Oat		15%
	13%	UK adult	1.30	8%	Wheat	2%	Rice	1%	Tea (dried leaves of Camellia sinensis		13%
	13%	DK adult	1.29	5%	Wheat	4%	Rye	0.9%	Milk: Cattle		13%
	9%	FI adult	0.93	5%	Rye	1%	Wheat	0.9%	Oat		9%
	9%	FR infant	0.91	4%	Wheat	3%	Milk: Cattle	0.5%	Apples		9%
	8%	IE child	0.81	5%	Wheat	1%	Rice	0.6%	Milk: Cattle		8%
	2%	PL general	0.16	0.6%	Apples	0.3%	Tomatoes	0.1%	Table grapes		2%

Conclusion:

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

The long-term intake of residues of Deltamethrin (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)
97%	Pears	0.09 / 0.07	9.7
86%	Apples	0.2 / 0.08	8.6
85%	Lettuces	0.4 / 0.22	8.5
84%	Wheat	1 / 0.58	8.4
77%	Leeks	0.3 / 0.13	7.7
76%	Peaches	0.15 / 0.08	7.6
75%	Celeries	0.3 / 0.2	7.5
74%	Rhubarbs	0.3 / 0.2	7.4
74%	Maize/corn	2 / 1.1	7.4
73%	Rice	1 / 0.58	7.3
72%	Kales	0.15 / 0.16	7.2
70%	Rye	2 / 1.1	7.0
66%	Table grapes	0.2 / 0.09	6.6
62%	Barley	2 / 1.1	6.2
59%	Cucumbers	0.2 / 0.09	5.9

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)
55%	Chamomille	9 / 9.1	5.5
55%	Chamomille	9 / 9.1	5.5
55%	Chamomille	9 / 9.1	5.5
55%	Chamomille	9 / 9.1	5.5
55%	Chamomille	9 / 9.1	5.5
54%	Aubergines/egg plants	0.4 / 0.2	5.4
53%	Rye	2 / 1.1	5.3
53%	Barley	2 / 1.1	5.3
53%	Red mustards	2 / 1	5.3
52%	Lentils	1 / 0.85	5.2
49%	Rice	1 / 0.58	4.9
49%	Wheat	1 / 0.58	4.9
38%	Buckwheat and other pseudo-cereals	2 / 1.1	3.8
37%	Florence fennels	0.3 / 0.2	3.7
36%	Rooibos	9 / 9.1	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)
91%	Florence fennels / boiled	0.3 / 0.2	9.1
80%	Pumpkins / boiled	0.2 / 0.09	8.0
75%	Rhubarbs / sauce/puree	0.3 / 0.2	7.5
74%	Leeks / boiled	0.3 / 0.13	7.4
70%	Wheat / milling (flour)	1 / 0.58	7.0
69%	Lentils / boiled	1 / 0.85	6.9
65%	Maize / oil	2 / 6.93	6.5
61%	Peas / canned	1 / 0.34	6.1
60%	Millet / boiled	2 / 0.44	6.0
59%	Buckwheat / bulgur and grits	2 / 1.1	5.9
45%	Kales / boiled	0.15 / 0.16	4.5
40%	Rye / boiled	2 / 1.1	4.0
40%	Oat / boiled	2 / 1.1	4.0
40%	Buckwheat / boiled	2 / 1.1	4.0
40%	Barley / cooked	2 / 1.1	4.0
39%	Rye / milling (wholemeal)-baking	2 / 1.1	3.9
35%	Rice / milling (polishing)	1 / 0.23	3.5
33%	Oat / milling (flakes)	2 / 1.1	3.3
32%	Wheat / milling (wholemeal)-baking	1 / 0.58	3.2
32%	Courgettes / boiled	0.2 / 0.09	3.2
32%	Broccoli / boiled	0.1 / 0.04	3.2
28%	Cauliflowers / boiled	0.1 / 0.04	2.8
23%	Maize / processed (not specified)	2 / 1.1	2.3
23%	Currants (red, black and white) / juice	0.6 / 0.08	2.3
21%	Peaches / canned	0.15 / 0.08	2.1
21%	Gherkins / pickled	0.2 / 0.09	2.1
20%	Barley / milling (flour)	2 / 1.1	2.0
18%	Beans (with pods) / boiled	0.2 / 0.14	1.8
17%	Wine grapes / juice	0.2 / 0.04	1.7
16%	Apples / juice	0.2 / 0.03	1.6
13%	Elderberries / juice	0.6 / 0.08	1.3
10%	Turnips / boiled	0.02 / 0.02	1.0
10%	Parsnips / boiled	0.02 / 0.02	1.0
9%	Beetroots / boiled	0.02 / 0.02	0.89
8%	Tea (dried leaves of Camellia sinensis) / infusion	5 / 0.02	0.77
7%	Pears / juice	0.09 / 0.02	0.65
6%	Shallots / boiled	0.06 / 0.04	0.65
6%	Tomatoes / juice	0.1 / 0.03	0.57
5%	Oranges / juice	0.02 / 0.01	0.53
5%	Salsifies / boiled	0.02 / 0.02	0.52
5%	Jerusalem artichokes / boiled	0.02 / 0.02	0.51
5%	Peaches / juice	0.15 / 0.03	0.50
5%	Cranberries / juice	0.6 / 0.08	0.46
4%	Azarole (mediteranean medlar) / juice	0.6 / 0.08	0.44
4%	Olives for oil production / oils	0.6 / 0.48	0.44
4%	Carrots / juice	0.02 / 0.01	0.36
4%	Raspberries / juice	0.08 / 0.03	0.35
3%	Celeriacs / juice	0.02 / 0.02	0.29
3%	Tomatoes / sauce/puree	0.1 / 0.03	0.29
2%	Rose hips / jam	0.6 / 0.08	0.24
2%	Table olives / canned	1 / 0.21	0.24
2%	Cultivated fungi / fried	0.05 / 0.03	0.16
2%	Ginger / jam	0.5 / 0.05	0.15
0.9%	Plums / juice	0.1 / 0.01	0.09
0.9%	Quinces / jam	0.1 / 0.03	0.09
0.8%	Peas (without pods) / canned	0.2 / 0.01	0.08
0.5%	Camomille flowers / infusion	9 / 0.01	0.05
0.5%	Camomille flowers / infusion	9 / 0.01	0.05
0.4%	Rapeseeds / oils	0.2 / 0.14	0.04
0.3%	Lemons / jam	0.02 / 0.01	0.03
0.1%	Hybiscus flowers / infusion	9 / 0.01	0.01
0.1%	Chicory roots / processed (not specified)	0.04 / 0.01	0.01
0.0%	Limes / juice	0.02 / 0.01	0.00
0.0%	Valerian root / infusion	0.3 / 0	0.00

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)
79%	Barley / beer	2 / 0.22	7.9
68%	Celeries / boiled	0.3 / 0.2	6.8
50%	Pumpkins / boiled	0.2 / 0.09	5.0
39%	Florence fennels / boiled	0.3 / 0.2	3.9
35%	Maize / oil	2 / 6.93	3.5
29%	Rhubarbs / sauce/puree	0.3 / 0.2	2.9
25%	Wheat / bread/pizza	1 / 0.58	2.5
25%	Millet / boiled	2 / 0.44	2.5
23%	Leeks / boiled	0.3 / 0.13	2.3
23%	Peas / canned	1 / 0.34	2.3
22%	Rice / milling (polishing)	1 / 0.23	2.2
22%	Wheat / pasta	1 / 0.58	2.2
21%	Courgettes / boiled	0.2 / 0.09	2.1
20%	Wheat / bread (wholemeal)	1 / 0.58	2.0
17%	Oat / boiled	2 / 1.1	1.7
17%	Cauliflowers / boiled	0.1 / 0.04	1.7
10%	Currants (red, black and white) / juice	0.6 / 0.08	1.0
10%	Apples / juice	0.2 / 0.03	1.00
10%	Broccoli / boiled	0.1 / 0.04	0.96
9%	Wine grapes / wine	0.2 / 0.09	0.85
8%	Grape leaves / canned	2 / 1	0.83
8%	Wine grapes / juice	0.2 / 0.04	0.83
8%	Beetroots / boiled	0.02 / 0.02	0.78
7%	Elderberries / juice	0.6 / 0.08	0.73
7%	Beans (without pods) / boiled	0.2 / 0.14	0.72
7%	Peaches / canned	0.15 / 0.08	0.65
5%	Table grapes / raisins	0.2 / 0.42	0.52
5%	Peas (with pods) / boiled	0.2 / 0.14	0.48
4%	Tea (dried leaves of Camellia sinensis) / infusion	5 / 0.02	0.45
4%	Peas (without pods) / boiled	0.2 / 0.14	0.44
4%	Parsnips / boiled	0.02 / 0.02	0.43
4%	Turnips / boiled	0.02 / 0.02	0.38
4%	Onions / boiled	0.06 / 0.04	0.38
4%	Celeriacs / boiled	0.02 / 0.02	0.36
3%	Carob (st johns bread) / flour	0.7 / 0.37	0.28
3%	Table olives / canned	1 / 0.21	0.27
2%	Shallots / boiled	0.06 / 0.04	0.25
2%	Tomatoes / sauce/puree	0.1 / 0.03	0.25
2%	Salsifies / boiled	0.02 / 0.02	0.16
2%	Jerusalem artichokes / boiled	0.02 / 0.02	0.16
2%	Oranges / juice	0.02 / 0.01	0.15
1%	Okra, lady's fingers / boiled	0.15 / 0.07	0.11
1%	Grapefruits / juice	0.02 / 0.01	0.11
1%	Rose hips / jam	0.6 / 0.08	0.10
0.8%	Carrots / canned	0.02 / 0.01	0.08
0.6%	Ginger / jam	0.5 / 0.05	0.06
0.6%	Cranberries / dried	0.6 / 0.08	0.06
0.4%	Quinces / jam	0.1 / 0.03	0.04
0.2%	Rooibos leaves / infusion	9 / 0.01	0.02
0.2%	Camomille flowers / infusion	9 / 0.01	0.02
0.2%	Lemons / juice	0.02 / 0.01	0.02
0.05%	Turmeric (Curcuma) / boiled	0.5 / 0.33	0.01
0.05%	Hybiscus flowers / infusion	9 / 0.01	0.00
0.03%	Chicory roots / processed (not specified)	0.04 / 0.01	0.00
0.00%	Valerian root / infusion	0.3 / 0	0.00

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Carbosulfan

LOQs (mg/kg) range from:	0.001	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:	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:

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)
	11%	NL toddler	0.54	1%	Maize/corn	1%	Milk: Cattle	1%	Bananas	10%	0.9%
	9%	GEMS/Food G06	0.45	2%	Aubergines/egg plants	1%	Wheat	0.6%	Cotton seeds	5%	3%
	7%	NL child	0.36	2%	Sugar beet roots	0.8%	Wheat	0.5%	Milk: Cattle	7%	0.4%
	7%	IE adult	0.35	2%	Aubergines/egg plants	1%	Mangoes	0.5%	Wheat	4%	3%
	6%	GEMS/Food G11	0.32	1%	Soyabeans	0.7%	Wheat	0.4%	Sugar canes	6%	0.5%
	6%	FI adult	0.32	6%	Coffee beans	0.1%	Rye	0.1%	Oranges	6%	0.0%
	6%	GEMS/Food G10	0.31	1%	Soyabeans	0.8%	Wheat	0.4%	Aubergines/egg plants	6%	0.5%
	6%	FR child 3 15 yr	0.30	0.9%	Wheat	0.7%	Sugar beet roots	0.7%	Oranges	6%	0.2%
	6%	GEMS/Food G07	0.29	0.8%	Wheat	0.7%	Soyabeans	0.4%	Cotton seeds	5%	0.3%
	6%	GEMS/Food G08	0.29	0.8%	Wheat	0.8%	Soyabeans	0.4%	Swine: Muscle/meat	5%	0.3%
	5%	DE child	0.27	0.8%	Wheat	0.8%	Oranges	0.4%	Milk: Cattle	5%	0.2%
	5%	GEMS/Food G15	0.27	0.9%	Wheat	0.7%	Soyabeans	0.5%	Aubergines/egg plants	5%	0.5%
	5%	RO general	0.25	2%	Aubergines/egg plants	1%	Wheat	0.3%	Sunflower seeds	3%	2%
	5%	FR toddler 2 3 yr	0.24	0.6%	Wheat	0.6%	Milk: Cattle	0.6%	Sugar beet roots	4%	0.4%
	4%	ES child	0.22	0.9%	Wheat	0.5%	Cocoa beans	0.4%	Oranges	4%	0.1%
	4%	DE women 14-50 yr	0.21	0.9%	Sugar beet roots	0.5%	Coffee beans	0.4%	Wheat	4%	0.4%
	4%	DK child	0.21	1%	Rye	0.9%	Wheat	0.4%	Swine: Muscle/meat	4%	0.1%
	4%	DE general	0.20	0.8%	Sugar beet roots	0.5%	Coffee beans	0.4%	Wheat	4%	0.3%
	4%	SE general	0.20	0.9%	Bovine: Muscle/meat	0.6%	Wheat	0.5%	Aubergines/egg plants	3%	0.6%
	4%	UK toddler	0.19	0.8%	Wheat	0.6%	Sugar beet roots	0.4%	Milk: Cattle	4%	0.1%
	4%	UK infant	0.19	0.8%	Milk: Cattle	0.5%	Wheat	0.3%	Bananas	4%	
	4%	NL general	0.18	0.6%	Sugar beet roots	0.4%	Wheat	0.3%	Coffee beans	3%	0.1%
	3%	IT toddler	0.15	1%	Wheat	0.7%	Aubergines/egg plants	0.3%	Other cereals	2%	0.7%
	3%	FR adult	0.14	0.4%	Wheat	0.4%	Coffee beans	0.2%	Aubergines/egg plants	3%	0.2%
	3%	ES adult	0.14	0.5%	Wheat	0.3%	Aubergines/egg plants	0.3%	Oranges	2%	0.3%
	2%	IT adult	0.12	0.8%	Wheat	0.8%	Aubergines/egg plants	0.1%	Other cereals	2%	0.8%
	2%	PT general	0.11	0.8%	Wheat	0.2%	Rice	0.1%	Oranges	2%	
	2%	FR infant	0.09	0.3%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Aubergines/egg plants	2%	0.2%
	2%	FI 3 yr	0.09	0.3%	Bananas	0.2%	Wheat	0.2%	Cocoa beans	2%	
	2%	UK vegetarian	0.09	0.4%	Wheat	0.2%	Aubergines/egg plants	0.2%	Oranges	1%	0.3%
	2%	FI 6 yr	0.08	0.2%	Cocoa beans	0.2%	Wheat	0.2%	Bananas	2%	0.0%
	1%	UK adult	0.07	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges	1%	0.1%
	1%	DK adult	0.07	0.2%	Wheat	0.2%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat	1%	0.1%
	1%	LT adult	0.07	0.2%	Rye	0.2%	Wheat	0.2%	Swine: Muscle/meat	1%	0.2%
	0.7%	IE child	0.03	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Rice	0.7%	0.0%
	0.5%	PL general	0.03	0.1%	Aubergines/egg plants	0.1%	Potatoes	0.0%	Apples	0.4%	0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Carbosulfan 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): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2044%	Mangoes	0.1 / 1.3	102
455%	Aubergines/egg plants	0.15 / 0.91	23
30%	Melons	0.01 / 0.01	1.5
27%	Oranges	0.01 / 0.01	1.3
24%	Watermelons	0.01 / 0.01	1.2
20%	Pineapples	0.01 / 0.01	1.0
19%	Bananas	0.01 / 0.01	0.97
16%	Grapefruits	0.01 / 0.01	0.79
12%	Kiwi fruits (green, red, yellow)	0.01 / 0.01	0.62
12%	Mandarins	0.01 / 0.01	0.59
11%	Granate apples/pomegranates	0.01 / 0.01	0.55
10%	Avocados	0.01 / 0.01	0.50
8%	Papayas	0.01 / 0.01	0.42
8%	Carobs/Staint John's bread	0.05 / 0.05	0.39
7%	Lemons	0.01 / 0.01	0.34

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
673%	Mangoes	0.1 / 1.3	34
493%	Aubergines/egg plants	0.15 / 0.91	25
8%	Watermelons	0.01 / 0.01	0.41
8%	Melons	0.01 / 0.01	0.39
6%	Oranges	0.01 / 0.01	0.31
6%	Pineapples	0.01 / 0.01	0.30
4%	Bananas	0.01 / 0.01	0.21
4%	Mandarins	0.01 / 0.01	0.18
4%	Grapefruits	0.01 / 0.01	0.18
4%	Guavas	0.01 / 0.01	0.18
4%	Granate apples/pomegranates	0.01 / 0.01	0.18
3%	Coconuts	0.02 / 0.02	0.17
3%	Avocados	0.01 / 0.01	0.15
3%	Pumpkins	0.01 / 0.01	0.15
3%	Papayas	0.01 / 0.01	0.14

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)
22%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
18%	Pumpkins / boiled	0.01 / 0.01	0.89
11%	Oranges / juice	0.01 / 0.01	0.53
8%	Pineapples / canned	0.01 / 0.01	0.41
6%	Currants (red, black and white) / juice	0.01 / 0.01	0.29
5%	Maize / oil	0.01 / 0.25	0.23
4%	Kiwi fruits / juice	0.01 / 0.01	0.18
4%	Witloofs / boiled	0 / 0	0.18
3%	Coconuts / drink	0.02 / 0.02	0.17
3%	Elderberries / juice	0.01 / 0.01	0.16
3%	Broccoli / boiled	0 / 0	0.16
3%	Chards/beet leaves / boiled	0.01 / 0.01	0.16
3%	Pineapples / juice	0.01 / 0.01	0.14
3%	Cauliflowers / boiled	0 / 0	0.14
3%	Beans (with pods) / boiled	0.01 / 0.01	0.13

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
5%	Coffee beans / extraction	0.05 / 0.01	0.24
3%	Oranges / juice	0.01 / 0.01	0.15
3%	Pineapples / canned	0.01 / 0.01	0.13
3%	Currants (red, black and white) / juice	0.01 / 0.01	0.13
3%	Maize / oil	0.01 / 0.25	0.13
2%	Grapefruits / juice	0.01 / 0.01	0.11
2%	Elderberries / juice	0.01 / 0.01	0.09
2%	Pineapples / juice	0.01 / 0.01	0.09
2%	Cauliflowers / boiled	0 / 0	0.08
2%	Beetroots / boiled	0 / 0	0.08
1%	Coconuts / drink	0.02 / 0.02	0.07
1%	Barley / beer	0.01 / 0	0.07
1%	Celeries / boiled	0 / 0	0.07

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Propiconazole

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.1
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:

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)	11%	NL toddler	4.59	4%	Milk: Cattle	3%	Rice	1%	Swine: Liver	2%	10%
	9%	GEMS/Food G06	3.69	8%	Rice	0.3%	Bovine: Liver	0.2%	Milk: Cattle	0.8%	8%
	9%	UK infant	3.46	3%	Rice	3%	Milk: Cattle	1.0%	Bovine: Edible offals (other than liver	0.5%	8%
	8%	GEMS/Food G10	3.38	6%	Rice	0.4%	Milk: Cattle	0.3%	Bovine: Liver	0.7%	8%
	7%	FR toddler 2 3 yr	2.68	3%	Rice	2%	Milk: Cattle	0.3%	Bovine: Liver	0.5%	6%
	6%	FR child 3 15 yr	2.36	2%	Rice	2%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.7%	5%
	6%	UK toddler	2.31	3%	Rice	2%	Milk: Cattle	0.2%	Bovine: Edible offals (other than liver	0.5%	5%
	5%	ES child	2.09	2%	Rice	0.9%	Milk: Cattle	0.4%	Swine: Liver	0.5%	5%
	5%	NL child	2.03	2%	Milk: Cattle	0.8%	Rice	0.5%	Swine: Liver	0.9%	4%
	5%	GEMS/Food G07	2.01	2%	Rice	0.8%	Bovine: Liver	0.5%	Swine: Liver	0.7%	4%
	5%	DK child	1.83	1%	Rice	0.9%	Milk: Cattle	0.6%	Swine: Liver	0.6%	4%
	5%	IE adult	1.80	1%	Sheep: Liver	1%	Rice	0.6%	Sheep: Edible offals (other than liver	0.6%	4%
	4%	DE child	1.74	1%	Milk: Cattle	1%	Rice	0.3%	Apples	1%	3%
	4%	PT general	1.73	4%	Rice	0.1%	Potatoes	0.1%	Wheat	0.5%	4%
	4%	SE general	1.73	2%	Rice	0.9%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.5%	4%
	4%	GEMS/Food G15	1.73	2%	Rice	0.6%	Swine: Liver	0.5%	Milk: Cattle	0.7%	4%
	4%	GEMS/Food G11	1.45	1%	Rice	0.6%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.7%	3%
	4%	GEMS/Food G08	1.43	1%	Rice	0.4%	Milk: Cattle	0.3%	Swine: Muscle/meat	0.7%	3%
	3%	FI 3 yr	1.27	3%	Rice	0.1%	Potatoes	0.0%	Bananas	0.4%	3%
	3%	RO general	1.27	1%	Rice	0.9%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.6%	3%
	3%	ES adult	1.05	1%	Rice	0.4%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.3%	2%
	3%	UK adult	1.03	2%	Rice	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.2%	2%
	2%	NL general	1.00	0.7%	Rice	0.6%	Milk: Cattle	0.2%	Swine: Liver	0.5%	2%
	2%	UK vegetarian	0.99	2%	Rice	0.2%	Milk: Cattle	0.1%	Eggs: Chicken	0.3%	2%
	2%	FI 6 yr	0.97	2%	Rice	0.1%	Potatoes	0.0%	Cocoa beans	0.3%	2%
	2%	FR adult	0.92	0.8%	Rice	0.3%	Milk: Cattle	0.1%	Bovine: Edible offals (other than liver	0.4%	2%
	2%	FR infant	0.87	1%	Milk: Cattle	0.3%	Rice	0.1%	Swine: Muscle/meat	0.3%	2%
	2%	LT adult	0.87	1%	Rice	0.3%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.2%	2%
	2%	DE general	0.80	0.9%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Sugar beet roots	0.5%	1%
	2%	DE women 14-50 yr	0.78	0.9%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Sugar beet roots	0.6%	1%
	2%	IE child	0.78	1%	Rice	0.3%	Milk: Cattle	0.0%	Swine: Fat tissue	0.1%	2%
	2%	DK adult	0.71	0.4%	Rice	0.4%	Milk: Cattle	0.2%	Swine: Liver	0.2%	2%
	2%	FI adult	0.60	0.7%	Coffee beans	0.6%	Rice	0.0%	Potatoes	0.9%	0.6%
	1%	IT toddler	0.54	0.9%	Rice	0.2%	Wheat	0.0%	Other cereals	0.4%	0.9%
	1%	IT adult	0.47	0.9%	Rice	0.1%	Wheat	0.0%	Tomatoes	0.3%	0.9%
	0.2%	PL general	0.10	0.1%	Potatoes	0.1%	Apples	0.0%	Tomatoes	0.2%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Propiconazole 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)
36%	Bovine: Edible offals (other than liver and kidney)	0.2 / 5	36
36%	Bovine: Liver	0.2 / 4.5	36
25%	Rice	4 / 1.95	25
19%	Bovine: Kidney	0.2 / 5	19
15%	Swine: Edible offals (other than liver and kidney)	0.2 / 5	15
6%	Swine: Kidney	0.2 / 5	6.3
6%	Avocados	0.02 / 0.12	6.0
6%	Swine: Liver	0.2 / 4.5	5.5
4%	Milk: Cattle	0.01 / 0.03	3.7
2%	Potatoes	0.01 / 0.01	1.5
2%	Melons	0.01 / 0.01	1.5
1%	Swine: Muscle/meat	0.01 / 0.12	1.5
1%	Pears	0.01 / 0.01	1.4
1%	Oranges	0.01 / 0.01	1.3
1%	Eggs: Chicken	0.01 / 0.1	1.2

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)
18%	Bovine: Liver	0.2 / 4.5	18
17%	Rice	4 / 1.95	17
17%	Bovine: Edible offals (other than liver and kidney)	0.2 / 5	17
13%	Swine: Edible offals (other than liver and kidney)	0.2 / 5	13
13%	Sheep: Liver	0.2 / 4.5	13
11%	Swine: Kidney	0.2 / 5	11
11%	Bovine: Kidney	0.2 / 5	11
6%	Swine: Liver	0.2 / 4.5	6.4
3%	Sheep: Edible offals (other than liver and kidney)	0.2 / 5	3.4
2%	Avocados	0.02 / 0.12	1.8
1%	Milk: Cattle	0.01 / 0.03	1.2
0.7%	Bovine: Muscle	0.01 / 0.12	0.68
0.7%	Other farmed animals: Muscle/meat	0.01 / 0.12	0.67
0.6%	Poultry: Muscle	0.01 / 0.05	0.59
0.6%	Swine: Muscle/meat	0.01 / 0.12	0.58

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)
12%	Rice / milling (polishing)	4 / 0.78	12
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 endives / boiled	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

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%	Rice / milling (polishing)	4 / 0.78	7.5
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 endives / boiled	0.01 / 0.01	0.20
0.2%	Florence fennels / 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 Propiconazole is unlikelv to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid (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:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)	75%	NL toddler	30.04	11%	Apples	10%	Spinaches	6%	Witloofs/Belgian endives		75%
	50%	DE child	19.90	13%	Apples	5%	Table grapes	3%	Spinaches	0.0%	50%
	40%	NL child	15.85	6%	Apples	4%	Table grapes	4%	Spinaches		40%
	37%	IE adult	14.78	4%	Wine grapes	3%	Sweet potatoes	2%	Tea (dried leaves of Camellia sinens	0.2%	37%
	35%	GEMS/Food G08	14.02	4%	Wine grapes	3%	Potatoes	3%	Onions		35%
	35%	GEMS/Food G06	14.00	4%	Onions	4%	Table grapes	4%	Tomatoes		35%
	34%	GEMS/Food G10	13.76	5%	Lettuces	3%	Onions	2%	Potatoes		34%
	34%	GEMS/Food G07	13.56	5%	Wine grapes	3%	Lettuces	3%	Potatoes		34%
	33%	GEMS/Food G11	13.10	4%	Wine grapes	3%	Potatoes	2%	Barley		33%
	33%	GEMS/Food G15	13.07	4%	Wine grapes	3%	Onions	3%	Potatoes		33%
	29%	SE general	11.74	6%	Lettuces	3%	Potatoes	2%	Onions		29%
	29%	RO general	11.68	6%	Wine grapes	4%	Onions	4%	Head cabbages		29%
	27%	PT general	10.71	9%	Wine grapes	4%	Potatoes	2%	Onions		27%
	27%	FR child 3 15 yr	10.63	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plants	0.1%	27%
	26%	NL general	10.30	3%	Witloofs/Belgian endives	2%	Spinaches	2%	Wine grapes	0.0%	26%
	25%	FR adult	10.14	8%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	2%	Other lettuce and other salad plants	0.0%	25%
	24%	FR toddler 2 3 yr	9.60	3%	Apples	2%	Spinaches	2%	Leeks	0.0%	24%
	23%	DK child	9.09	3%	Cucumbers	2%	Apples	2%	Rye		23%
	22%	DE women 14-50 yr	8.99	3%	Wine grapes	3%	Apples	2%	Lettuces	0.0%	22%
	22%	DE general	8.97	3%	Wine grapes	3%	Apples	1%	Barley	0.0%	22%
	22%	FI 3 yr	8.64	4%	Potatoes	2%	Onions	2%	Cucumbers		22%
	21%	IT adult	8.52	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		21%
	21%	ES adult	8.38	7%	Lettuces	1%	Wine grapes	1%	Barley	0.0%	21%
	20%	IT toddler	8.13	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		20%
	20%	ES child	7.91	6%	Lettuces	2%	Wheat	1%	Potatoes	0.1%	20%
	19%	UK toddler	7.49	3%	Potatoes	2%	Apples	2%	Wheat		19%
	18%	UK infant	7.39	2%	Potatoes	2%	Milk: Cattle	2%	Apples		18%
	18%	FR infant	7.23	4%	Spinaches	2%	Apples	2%	Leeks	0.0%	18%
	17%	FI 6 yr	6.71	3%	Potatoes	2%	Onions	1%	Strawberries		17%
	16%	UK vegetarian	6.23	3%	Wine grapes	2%	Lettuces	1%	Onions		16%
	14%	PL general	5.58	3%	Potatoes	2%	Apples	2%	Onions		14%
	14%	UK adult	5.50	4%	Wine grapes	2%	Lettuces	1%	Potatoes		14%
	13%	DK adult	5.31	3%	Wine grapes	1%	Lettuces	1%	Apples		13%
	11%	FI adult	4.36	2%	Lettuces	1%	Wine grapes	0.9%	Potatoes		11%
	11%	LT adult	4.24	2%	Potatoes	2%	Apples	1%	Head cabbages		11%
	4%	IE child	1.55	0.5%	Wheat	0.5%	Potatoes	0.3%	Apples		4%

Conclusion:

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Difenoconazole

LOQs (mg/kg) range from: 0.005 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:	2013	Year of evaluation:	2013

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	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)	97%	NL toddler	9.70	17%	Apples	8%	Beans (with pods)	8%	Table grapes	2%	5%
	95%	IE adult	9.52	43%	Sweet potatoes	7%	Wine grapes	4%	Other leafy brassica	1%	46%
	75%	DE child	7.54	20%	Apples	7%	Tomatoes	7%	Table grapes	1%	5%
	72%	GEMS/Food G06	7.21	26%	Tomatoes	14%	Rice	5%	Table grapes	1%	5%
	55%	GEMS/Food G10	5.51	11%	Rice	10%	Tomatoes	3%	Potatoes	1%	6%
	54%	GEMS/Food G11	5.41	7%	Tomatoes	6%	Celeriacs/turnip rooted celeries	5%	Wine grapes	2%	0.9%
	53%	GEMS/Food G07	5.30	8%	Tomatoes	8%	Wine grapes	4%	Potatoes	2%	2%
	52%	NL child	5.25	9%	Apples	5%	Table grapes	4%	Tomatoes	1%	4%
	51%	PT general	5.07	13%	Wine grapes	7%	Rice	6%	Tomatoes	0.2%	5%
	49%	GEMS/Food G08	4.90	8%	Tomatoes	5%	Wine grapes	4%	Potatoes	2%	2%
	45%	GEMS/Food G15	4.52	9%	Tomatoes	5%	Wine grapes	4%	Potatoes	1%	2%
	44%	FR child 3 15 yr	4.43	6%	Tomatoes	5%	Oranges	5%	Beans (with pods)	1%	1%
	42%	RO general	4.18	14%	Tomatoes	9%	Wine grapes	4%	Potatoes	0.7%	2%
	41%	FR toddler 2 3 yr	4.10	8%	Beans (with pods)	5%	Rice	5%	Apples	0.9%	0.6%
	37%	SE general	3.70	6%	Tomatoes	4%	Potatoes	4%	Rice	0.6%	6%
	36%	ES child	3.57	7%	Tomatoes	4%	Rice	3%	Oranges	0.7%	1%
	35%	DE women 14-50 yr	3.50	5%	Tomatoes	4%	Wine grapes	4%	Apples	0.7%	2%
	32%	UK toddler	3.21	5%	Rice	4%	Tomatoes	3%	Potatoes	0.6%	1%
	32%	DE general	3.20	5%	Tomatoes	4%	Wine grapes	4%	Apples	0.7%	2%
	32%	FR adult	3.20	12%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	0.7%	0.9%
	32%	UK infant	3.17	6%	Peas (without pods)	6%	Rice	3%	Potatoes	0.9%	1%
	31%	NL general	3.08	3%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	1%	2%
	29%	IT toddler	2.94	10%	Tomatoes	2%	Rice	2%	Lettuces	0.8%	2%
	29%	ES adult	2.88	6%	Tomatoes	3%	Lettuces	2%	Beans (with pods)	0.4%	1%
	28%	IT adult	2.77	8%	Tomatoes	2%	Lettuces	2%	Florence fennels	0.4%	2%
	27%	FI 3 yr	2.66	5%	Rice	5%	Potatoes	4%	Tomatoes	0.5%	2%
	24%	DK child	2.41	4%	Tomatoes	4%	Apples	3%	Rice	0.7%	0.9%
	23%	UK vegetarian	2.30	4%	Tomatoes	4%	Wine grapes	3%	Rice	0.4%	0.5%
	21%	FI 6 yr	2.09	4%	Potatoes	4%	Rice	3%	Tomatoes	0.4%	2%
	21%	UK adult	2.08	6%	Wine grapes	3%	Rice	3%	Tomatoes	0.3%	0.4%
	20%	PL general	2.00	6%	Tomatoes	3%	Potatoes	3%	Apples	0.1%	2%
	20%	FR infant	2.00	5%	Beans (with pods)	3%	Apples	2%	Potatoes	0.2%	0.2%
	19%	DK adult	1.94	5%	Wine grapes	4%	Tomatoes	2%	Apples	0.2%	0.6%
	17%	FI adult	1.68	4%	Tomatoes	3%	Coffee beans	2%	Wine grapes	3%	0.8%
	16%	LT adult	1.61	4%	Tomatoes	3%	Potatoes	3%	Apples	0.4%	0.3%
	7%	IE child	0.73	3%	Rice	0.9%	Beans (without pods)	0.6%	Potatoes	0.1%	0.1%

Conclusion:

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

The long-term intake of residues of Difenoconazole 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)
168%	Kales	8 / 6.1	268
123%	Chinese cabbages/pe-tsai	8 / 6.1	196
88%	Spring onions/green onions and Welsh onions	9 / 9	141
87%	Tomatoes	2 / 2.4	140
80%	Celeries	7 / 3.4	127
69%	Celeriacs/turnip rooted celeries	2 / 2	111
68%	Table grapes	3 / 1.5	109
61%	Peaches	1.5 / 1.02	97
60%	Rhubarbs	5 / 2.59	96
60%	Lettuces	4 / 2.51	96
55%	Witloofs/Belgian endives	4 / 2.2	87
41%	Pears	0.8 / 0.47	65
41%	Oranges	0.6 / 0.49	65
38%	Escaroles/broad-leaved endives	3 / 1.5	60
34%	Florence fennels	5 / 3.31	54

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)
97%	Chinese cabbages/pe-tsai	8 / 6.1	154
73%	Kales	8 / 6.1	117
39%	Florence fennels	5 / 3.31	62
34%	Celeries	7 / 3.4	54
32%	Table grapes	3 / 1.5	51
30%	Chards/beet leaves	4 / 2.51	47
25%	Witloofs/Belgian endives	4 / 2.2	40
25%	Spring onions/green onions and Welsh onions	9 / 9	40
25%	Sweet potatoes	4 / 1.9	39
24%	Tomatoes	2 / 2.4	38
22%	Wine grapes	3 / 1.5	36
22%	Cardoons	7 / 3.4	35
19%	Lettuces	4 / 2.51	30
19%	Escaroles/broad-leaved endives	3 / 1.5	30
15%	Rhubarbs	5 / 2.59	24

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): 2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
122%	Witloofs / boiled	4 / 2.2	195
105%	Kales / boiled	8 / 6.1	168
94%	Florence fennels / boiled	5 / 3.31	150
62%	Escaroles/broad-leaved endives / boiled	3 / 1.5	99
60%	Rhubarbs / sauce/puree	5 / 2.59	97
60%	Sweet potatoes / boiled	4 / 1.9	96
49%	Chards/beet leaves / boiled	4 / 2.51	78
20%	Broccoli / boiled	1 / 0.41	32
18%	Celeriacs / juice	2 / 2	29
17%	Peaches / canned	1.5 / 1.02	27
14%	Leeks / boiled	0.6 / 0.4	23
14%	Wine grapes / juice	3 / 0.52	23
13%	Spinaches / frozen; boiled	3 / 1.5	21
9%	Turnips / boiled	0.4 / 0.28	14
9%	Parsnips / boiled	0.4 / 0.28	14

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)
72%	Celeries / boiled	7 / 3.4	115
40%	Florence fennels / boiled	5 / 3.31	64
26%	Cardoons / boiled	7 / 3.4	41
25%	Witloofs / boiled	4 / 2.2	41
24%	Rhubarbs / sauce/puree	5 / 2.59	38
23%	Celeriacs / boiled	2 / 2	36
20%	Chards/beet leaves / boiled	4 / 2.51	31
19%	Escaroles/broad-leaved endives / boiled	3 / 1.5	31
18%	Sweet potatoes / boiled	4 / 1.9	29
9%	Wine grapes / wine	3 / 1.5	14
8%	Spinaches / frozen; boiled	3 / 1.5	12
7%	Beetroots / boiled	0.4 / 0.28	11
7%	Wine grapes / juice	3 / 0.52	11
6%	Broccoli / boiled	1 / 0.41	9.9
5%	Table grapes / raisins	3 / 7.05	8.6

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Clothianidin

LOQs (mg/kg) range from: 0.01 to: 0.07

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	1%	NL toddler	1.28	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn	1%	0.0%
	0.7%	NL child	0.69	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.6%	0.0%
	0.7%	DE child	0.66	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.6%	0.0%
	0.7%	UK infant	0.63	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.6%	0.0%
	0.6%	FR child 3 15 yr	0.59	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.5%	0.0%
	0.6%	FR toddler 2 3 yr	0.59	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.5%	0.0%
	0.5%	UK toddler	0.47	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.4%	0.0%
	0.5%	DK child	0.46	0.1%	Milk: Cattle	0.1%	Rye	0.0%	Swine: Muscle/meat	0.4%	0.0%
	0.5%	GEMS/Food G11	0.46	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Soyabeans	0.4%	0.0%
	0.5%	GEMS/Food G06	0.44	0.1%	Wheat	0.1%	Tomatoes	0.0%	Milk: Cattle	0.3%	0.1%
	0.4%	GEMS/Food G07	0.43	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.4%	0.0%
	0.4%	GEMS/Food G15	0.43	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.4%	0.0%
	0.4%	SE general	0.43	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes	0.3%	0.0%
	0.4%	GEMS/Food G08	0.43	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat	0.4%	0.0%
	0.4%	RO general	0.43	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Tomatoes	0.3%	0.1%
	0.4%	GEMS/Food G10	0.42	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans	0.4%	0.0%
	0.4%	ES child	0.42	0.1%	Milk: Cattle	0.05%	Wheat	0.0%	Bovine: Muscle/meat	0.3%	0.0%
	0.4%	DE women 14-50 yr	0.39	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.4%	0.0%
	0.4%	DE general	0.39	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.3%	0.0%
	0.4%	IE adult	0.36	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat	0.3%	0.0%
	0.4%	FI adult	0.36	0.3%	Coffee beans	0.0%	Potatoes	0.0%	Tomatoes	0.4%	0.0%
	0.3%	NL general	0.32	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.3%	0.0%
	0.3%	FR infant	0.30	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.3%	0.0%
	0.2%	FR adult	0.24	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.2%	0.0%
	0.2%	ES adult	0.24	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Tomatoes	0.2%	0.0%
	0.2%	PT general	0.22	0.1%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.2%	0.0%
	0.2%	DK adult	0.19	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Potatoes	0.1%	0.0%
	0.2%	LT adult	0.19	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Swine: Muscle/meat	0.1%	0.0%
	0.2%	IT toddler	0.18	0.1%	Wheat	0.0%	Tomatoes	0.0%	Other cereals	0.2%	0.0%
	0.2%	FI 3 yr	0.18	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.2%	0.0%
	0.2%	UK vegetarian	0.15	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.0%
	0.2%	UK adult	0.15	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.0%
	0.1%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Wheat	0.0%	Tomatoes	0.1%	0.0%
	0.1%	IT adult	0.13	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	0.0%
	0.1%	PL general	0.11	0.0%	Potatoes	0.0%	Apples	0.02%	Tomatoes	0.1%	0.0%
	0.1%	IE child	0.09	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	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 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 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)
2%	Sweet peppers/bell peppers	0.05 / 0.03	1.8
2%	Tomatoes	0.05 / 0.03	1.7
2%	Potatoes	0.01 / 0.01	1.5
2%	Melons	0.01 / 0.01	1.5
1%	Pears	0.01 / 0.01	1.4
1%	Oranges	0.01 / 0.01	1.3
1%	Milk: Cattle	0.01 / 0.01	1.2
1%	Watermelons	0.01 / 0.01	1.2
1%	Apples	0.01 / 0.01	1.1
1%	Pineapples	0.01 / 0.01	1.0
1.0%	Bananas	0.01 / 0.01	0.97
1.0%	Peaches	0.01 / 0.01	0.95
0.8%	Mangoes	0.01 / 0.01	0.79
0.8%	Grapefruits	0.01 / 0.01	0.79
0.8%	Aubergines/egg plants	0.05 / 0.03	0.75

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)
0.8%	Aubergines/egg plants	0.05 / 0.03	0.81
0.5%	Sweet peppers/bell peppers	0.05 / 0.03	0.49
0.5%	Tomatoes	0.05 / 0.03	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
0.4%	Milk: Cattle	0.01 / 0.01	0.39
0.4%	Florence fennels	0.04 / 0.02	0.37
0.3%	Swedes/rutabagas	0.01 / 0.01	0.34
0.3%	Table grapes	0.01 / 0.01	0.34
0.3%	Celeries	0.04 / 0.02	0.32
0.3%	Oranges	0.01 / 0.01	0.31
0.3%	Pears	0.01 / 0.01	0.31
0.3%	Potatoes	0.01 / 0.01	0.30
0.3%	Pineapples	0.01 / 0.01	0.30

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%	Florence fennels / boiled	0.04 / 0.02	0.91
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%	Rhubarbs / sauce/puree	0.04 / 0.02	0.75
0.7%	Cauliflowers / boiled	0.01 / 0.01	0.70
0.7%	Escaroles/broad-leaved endives / boiled	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

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)
0.7%	Celeries / boiled	0.04 / 0.02	0.68
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
0.4%	Florence fennels / boiled	0.04 / 0.02	0.39
0.3%	Apples / juice	0.01 / 0.01	0.33
0.3%	Rhubarbs / sauce/puree	0.04 / 0.02	0.29
0.2%	Cardoons / boiled	0.04 / 0.02	0.24
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

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.

Fluopyram – Scenario 1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

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

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)
331%	NL toddler	39.77	239%	Milk: Cattle	18%	Apples	9%	Bananas		331%
189%	UK infant	22.66	155%	Milk: Cattle	5%	Bovine: Muscle/meat	5%	Eggs: Chicken		189%
157%	FR toddler 2 3 yr	18.88	117%	Milk: Cattle	5%	Apples	5%	Bovine: Muscle/meat		157%
156%	NL child	18.70	98%	Milk: Cattle	10%	Apples	5%	Table grapes		156%
145%	DE child	17.35	79%	Milk: Cattle	21%	Apples	7%	Table grapes		145%
140%	FR child 3 15 yr	16.83	91%	Milk: Cattle	6%	Bovine: Muscle/meat	6%	Swine: Muscle/meat		140%
113%	UK toddler	13.57	83%	Milk: Cattle	5%	Bovine: Muscle/meat	3%	Eggs: Chicken		113%
94%	SE general	11.28	50%	Milk: Cattle	19%	Bovine: Muscle/meat	5%	Lettuces		94%
93%	DK child	11.19	51%	Milk: Cattle	9%	Swine: Muscle/meat	6%	Bovine: Muscle/meat		93%
91%	ES child	10.88	50%	Milk: Cattle	6%	Bovine: Muscle/meat	5%	Swine: Muscle/meat		91%
84%	FR infant	10.11	67%	Milk: Cattle	3%	Apples	2%	Beans (with pods)		84%
81%	DE women 14-50 yr	9.72	50%	Milk: Cattle	4%	Apples	4%	Swine: Muscle/meat		81%
81%	DE general	9.70	49%	Milk: Cattle	5%	Swine: Muscle/meat	4%	Apples		81%
78%	GEMS/Food G07	9.41	26%	Milk: Cattle	6%	Wine grapes	5%	Swine: Muscle/meat		78%
78%	RO general	9.33	46%	Milk: Cattle	6%	Wine grapes	5%	Swine: Muscle/meat		78%
74%	GEMS/Food G11	8.93	31%	Milk: Cattle	7%	Celeries	5%	Swine: Muscle/meat		74%
72%	IE adult	8.62	17%	Milk: Cattle	7%	Sheep: Liver	5%	Basil and edible flowers		72%
72%	GEMS/Food G15	8.59	28%	Milk: Cattle	6%	Swine: Muscle/meat	4%	Wine grapes		72%
65%	GEMS/Food G08	7.85	22%	Milk: Cattle	8%	Swine: Muscle/meat	4%	Wine grapes		65%
63%	NL general	7.50	34%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		63%
62%	GEMS/Food G10	7.49	22%	Milk: Cattle	4%	Lettuces	4%	Bovine: Muscle/meat		62%
50%	ES adult	6.06	20%	Milk: Cattle	7%	Lettuces	3%	Bovine: Muscle/meat		50%
49%	FR adult	5.91	18%	Milk: Cattle	9%	Wine grapes	3%	Swine: Muscle/meat		49%
46%	GEMS/Food G06	5.55	10%	Milk: Cattle	5%	Table grapes	4%	Tomatoes		46%
45%	DK adult	5.37	21%	Milk: Cattle	4%	Swine: Muscle/meat	4%	Wine grapes		45%
33%	LT adult	3.95	16%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Apples		33%
30%	UK adult	3.62	12%	Milk: Cattle	4%	Wine grapes	3%	Bovine: Muscle/meat		30%
29%	UK vegetarian	3.42	13%	Milk: Cattle	3%	Wine grapes	2%	Lettuces		29%
23%	PT general	2.73	10%	Wine grapes	2%	Apples	1%	Table grapes		23%
20%	IE child	2.39	14%	Milk: Cattle	0.7%	Swine: Fat tissue	0.7%	Swine: Muscle/meat		20%
17%	IT toddler	2.06	4%	Lettuces	2%	Wheat	2%	Tomatoes		17%
17%	FI 3 yr	2.01	2%	Bananas	2%	Raspberries (red and yellow)	2%	Apples		17%
16%	IT adult	1.95	5%	Lettuces	1%	Tomatoes	1%	Apples		16%
13%	FI 6 yr	1.54	1%	Raspberries (red and yellow)	1%	Bananas	1%	Lettuces		13%
11%	PL general	1.27	3%	Apples	2%	Table grapes	1%	Tomatoes		11%
9%	FI adult	1.13	2%	Lettuces	1%	Wine grapes	1.0%	Apples		9%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 331.5 % 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 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)
76%	Lettuces	15 / 10	381
73%	Celeries	20 / 9.74	364
18%	Peaches	1.5 / 0.95	90
17%	Pears	0.8 / 0.6	83
15%	Sweet peppers/bell peppers	2 / 1.23	73
15%	Table grapes	2 / 1	73
13%	Apples	0.8 / 0.6	65
12%	Bovine: Liver	8 / 7.4	60
12%	Milk: Cattle	0.8 / 0.48	60
11%	Bovine: Edible offals (other than liver and kidney)	8 / 7.4	54
10%	Bananas	0.8 / 0.52	50
8%	Oranges	0.5 / 0.32	42
8%	Escaroles/broad-leaved endives	2 / 0.98	39
7%	Apricots	1.5 / 0.95	33
6%	Lamb's lettuce/corn salads	20 / 10	28
6%	Bovine: Kidney	8 / 7.4	28
5%	Chinese cabbages/pe-tsai	2 / 0.84	27
5%	Roman rocket/rucola	20 / 10	27
5%	Blueberries	7 / 4.33	26
5%	Blackberries	5 / 2.39	26
5%	Grapefruits	0.5 / 0.32	25
5%	Globe artichokes	4 / 1.37	24
4%	Swine: Edible offals (other than liver and kidney)	8 / 7.4	22
4%	Spinaches	2 / 0.98	22
4%	Raspberries (red and yellow)	5 / 2.39	22
4%	Basil and edible flowers	60 / 30	22
4%	Cucumbers	0.6 / 0.3	20
4%	Mandarins	0.9 / 0.32	19
4%	Spring onions/green onions and Welsh onions	3 / 1.22	19
4%	Leeks	0.8 / 0.32	19
4%	Beans (with pods)	3 / 1.65	19
4%	Eggs: Chicken	2 / 1.5	19
3%	Currants (red, black and white)	4 / 2.1	17
3%	Strawberries	2 / 1.01	17
3%	Poultry: Muscle/meat	1.5 / 0.97	16
3%	Chards/beet leaves	2 / 0.98	15
3%	Quinces	0.8 / 0.6	15
3%	Watermelons	0.4 / 0.12	15
3%	Tomatoes	0.5 / 0.24	14
3%	Courgettes	0.6 / 0.3	14
3%	Peas (with pods)	3 / 1.65	13
3%	Cherries (sweet)	2 / 1.1	13
2%	Gooseberries (green, red and yellow)	4 / 2.1	12
2%	Swine: Muscle/meat	1.5 / 1	12
2%	Milk: Goat	0.8 / 0.48	12
2%	Plums	0.6 / 0.27	11
2%	Carrots	0.4 / 0.18	11
2%	Lemons	0.9 / 0.32	11
2%	Potatoes	0.08 / 0.07	11
2%	Celeriacs/turnip rooted celeries	0.4 / 0.18	10.0
2%	Broccoli	0.5 / 0.23	9.6
2%	Cranberries	4 / 2.1	9.4
2%	Swine: Kidney	8 / 7.4	9.4
2%	Swedes/rutabagas	0.4 / 0.18	9.3
2%	Swine: Liver	8 / 7.4	9.1
2%	Wine grapes	1.5 / 0.95	8.8
2%	Melons	0.9 / 0.06	8.7
2%	Medlar	0.8 / 0.6	8.3
2%	Cauliflowers	0.3 / 0.14	8.1
2%	Head cabbages	0.3 / 0.17	7.5
1%	Bovine: Muscle/meat	1.5 / 1	7.2
1%	Other farmed animals: Muscle/meat	1.5 / 1	6.9
1%	Parsnips	0.4 / 0.18	6.5
1%	Turnips	0.4 / 0.18	6.5
1%	Equine: Muscle/meat	1.5 / 1	6.0
1%	Aubergines/egg plants	0.4 / 0.23	5.8
1%	Beetroots	0.2 / 0.1	5.6
1%	Salsifies	0.4 / 0.18	5.6
1%	Witloofs/Belgian endives	0.3 / 0.14	5.6
1%	Sheep: Muscle/meat	1.5 / 1	5.4
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0
1%	Chamomille	40 / 25.2	5.0

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
8%	Blueberries	7 / 4.33	39
7%	Table grapes	2 / 1	34
6%	Bovine: Liver	8 / 7.4	30
5%	Bovine: Edible offals (other than liver and kidney)	8 / 7.4	25
5%	Swine: Other products	8 / 7.4	24
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 endives	2 / 0.98	20
4%	Blackberries	5 / 2.39	20
4%	Swine: Edible offals (other than liver and kidney)	8 / 7.4	19
4%	Purslanes	20 / 10	19
4%	Lamb's lettuce/corn salads	20 / 10	19
4%	Chards/beet leaves	2 / 0.98	19
4%	Milk: Cattle	0.8 / 0.48	19
4%	Pears	0.8 / 0.6	18
4%	Peaches	1.5 / 0.95	18
4%	Globe artichokes	4 / 1.37	18
3%	Apples	0.8 / 0.6	17
3%	Swine: Kidney	8 / 7.4	16
3%	Bovine: Kidney	8 / 7.4	16
3%	Chamomille	40 / 25.2	15
3%	Chamomille	40 / 25.2	15
3%	Chamomille	40 / 25.2	15
3%	Chamomille	40 / 25.2	15
3%	Chamomille	40 / 25.2	15
3%	Bovine: Other products	8 / 7.4	15
3%	Poultry: Liver	4 / 3.1	15
3%	Currants (red, black and white)	4 / 2.1	14
3%	Raspberries (red and yellow)	5 / 2.39	13
3%	Beans (with pods)	3 / 1.65	13
2%	Roman rocket/rucola	20 / 10	12
2%	Poultry: Muscle	1.5 / 0.97	11
2%	Cherries (sweet)	2 / 1.1	11
2%	Bananas	0.8 / 0.52	11
2%	Swine: Liver	8 / 7.4	10
2%	Apricots	1.5 / 0.95	10
2%	Rooibos	40 / 25.2	10
2%	Rooibos	40 / 25.2	10
2%	Oranges	0.5 / 0.32	9.8
2%	Gooseberries (green, red and yellow)	4 / 2.1	9.5
2%	Strawberries	2 / 1.01	9.4
2%	Quinces	0.8 / 0.6	9.1
2%	Milk: Goat	0.8 / 0.48	8.8
2%	Cucumbers	0.6 / 0.3	8.3
2%	Hybiscus/roselle	40 / 25.2	7.6
1%	Milk: Sheep	0.8 / 0.48	7.2
1%	Head cabbages	0.3 / 0.17	7.1
1%	Courgettes	0.6 / 0.3	7.0
1%	Eggs: Chicken	2 / 1.5	6.4
1%	Aubergines/egg plants	0.4 / 0.23	6.2
1%	Swedes/rutabagas	0.4 / 0.18	6.1
1%	Mandarins	0.9 / 0.32	5.8
1%	Grapefruits	0.5 / 0.32	5.7
1%	Bovine: Muscle	1.5 / 1	5.7
1%	Peas (with pods)	3 / 1.65	5.6
1%	Other farmed animals: Muscle/meat	1.5 / 1	5.6
1%	HOPS (dried)	60 / 30.48	5.6
1%	Spring onions/green onions and Welsh onions	3 / 1.22	5.5
1%	Broccoli	0.5 / 0.23	5.5
1%	Red mustards	2 / 0.98	5.2
1%	Sheep: Edible offals (other than liver and kidney)	8 / 7.4	5.1
1.0%	Watermelons	0.4 / 0.12	4.9
1.0%	Swine: Muscle/meat	1.5 / 1	4.8
1.0%	Plums	0.6 / 0.27	4.8
1.0%	Equine: Muscle/meat	1.5 / 1	4.8
0.9%	Sheep: Muscle/meat	1.5 / 1	4.7
0.9%	Parsley	6 / 3.64	4.4
0.8%	Leeks	0.8 / 0.32	4.2
0.8%	Medlar	0.8 / 0.6	4.1
0.8%	Poultry: Kidney	4 / 3.1	4.0
0.8%	Spinaches	2 / 0.98	3.9
0.8%	Tomatoes	0.5 / 0.24	3.8
0.8%	Cress and other sprouts and shoots	20 / 10	3.8
0.7%	Basil and edible flowers	60 / 30	3.7

0.9%	Chervil	6 / 3.64	4.7	0.7%	Carrots	0.4 / 0.18	3.5
0.9%	Kohlrabies	0.15 / 0.09	4.7	0.7%	Rose hips	3 / 1.58	3.5
0.9%	Radishes	0.4 / 0.18	4.4	0.7%	Dewberries	5 / 2.39	3.5
0.8%	Dewberries	5 / 2.39	4.2	0.6%	Cauliflowers	0.3 / 0.14	3.2
0.8%	Parsley	6 / 3.64	4.0	0.6%	Swine: Fat tissue	1.5 / 1.5	3.0
0.8%	Kales	0.15 / 0.09	4.0	0.6%	Lemons	0.9 / 0.32	2.9
0.7%	Poultry: Liver	4 / 3.1	3.4	0.5%	Witloofs/Belgian endives	0.3 / 0.14	2.6
0.6%	Pumpkins	0.4 / 0.12	3.2	0.5%	Parsnips	0.4 / 0.18	2.5
0.6%	Bovine: Fat tissue	1.5 / 1.5	3.1	0.5%	Cranberries	4 / 2.1	2.4
0.6%	Chives	6 / 3.64	3.0	0.5%	Beetroots	0.2 / 0.1	2.3
0.6%	Cress and other sprouts and shoots	20 / 10	2.9	0.4%	Melons	0.9 / 0.06	2.2
0.6%	Sage	6 / 3.64	2.8	0.4%	Celeriacs/turnip rooted celeries	0.4 / 0.18	2.1
0.5%	Swine: Fat tissue	1.5 / 1.5	2.6	0.4%	Eggs: Quail	2 / 1.5	2.1
0.4%	Brussels sprouts	0.4 / 0.23	1.9	0.4%	Potatoes	0.08 / 0.07	2.0
0.3%	Celery leaves	6 / 3.64	1.7	0.4%	Turnips	0.4 / 0.18	2.0
0.3%	Milk: Sheep	0.8 / 0.48	1.7	0.4%	Salsifies	0.4 / 0.18	1.9
0.3%	Yams	0.15 / 0.05	1.6	0.4%	Radishes	0.4 / 0.18	1.9
0.3%	HOPS (dried)	60 / 30.48	1.3	0.4%	Parsley roots/Hamburg roots parsley	0.4 / 0.18	1.8
0.2%	Onions	0.07 / 0.04	0.91	0.4%	Gherkins	0.6 / 0.3	1.8
0.2%	Gherkins	0.6 / 0.3	0.84	0.4%	Pumpkins	0.4 / 0.12	1.8
0.2%	Beans	0.5 / 0.04	0.81	0.3%	Kales	0.15 / 0.09	1.7
0.2%	Parsley roots/Hamburg roots parsley	0.4 / 0.18	0.81	0.3%	Jerusalem artichokes	0.4 / 0.18	1.7
0.2%	Peas (without pods)	0.15 / 0.09	0.78	0.3%	Goat: Muscle	1.5 / 1	1.6
0.1%	Beans (without pods)	0.15 / 0.09	0.75	0.3%	Yams	0.15 / 0.05	1.5
0.1%	Sorghum	0.6 / 0.18	0.58	0.3%	Bovine: Fat tissue	1.5 / 1.5	1.5
0.1%	Rapeseeds/canola seeds	1 / 0.4	0.55	0.3%	Brussels sprouts	0.4 / 0.23	1.4
0.1%	Lentils (fresh)	0.15 / 0.09	0.55	0.3%	Horseradishes	0.4 / 0.18	1.3
0.1%	Wheat	0.2 / 0.04	0.52	0.3%	Kohlrabies	0.15 / 0.09	1.3
0.09%	Sweet corn	0.02 / 0.01	0.43	0.2%	Celery leaves	6 / 3.64	1.2
0.09%	Coconuts	0.03 / 0.03	0.43	0.2%	Sweet potatoes	0.15 / 0.05	1.1
0.06%	Lentils	0.5 / 0.04	0.30	0.2%	Eggs: Goose	2 / 1.5	0.75
0.06%	Peas	0.5 / 0.04	0.29	0.1%	Sheep: Kidney	8 / 7.4	0.74
0.06%	Sweet potatoes	0.15 / 0.05	0.28	0.1%	Sage	6 / 3.64	0.73
0.05%	Sunflower seeds	0.7 / 0.08	0.24	0.1%	Chives	6 / 3.64	0.62
0.05%	Barley	0.4 / 0.04	0.23	0.1%	Onions	0.07 / 0.04	0.59
0.04%	Rye	0.2 / 0.04	0.22	0.1%	Peas (without pods)	0.15 / 0.09	0.51
0.04%	Thyme	6 / 3.64	0.22	0.07%	Beans (without pods)	0.15 / 0.09	0.37
0.04%	Buckwheat and other pseudo-cereals	0.4 / 0.04	0.20	0.07%	Rosemary	6 / 3.64	0.36
0.04%	Asparagus	0.01 / 0.01	0.19	0.07%	Rosemary	6 / 3.64	0.36
0.04%	Pumpkin seeds	0.4 / 0.13	0.19	0.07%	Rosemary	6 / 3.64	0.36
0.03%	Dill seed	70 / 29.6	0.16	0.07%	Rosemary	6 / 3.64	0.36
0.03%	Cassava roots/manioc	0.06 / 0.02	0.16	0.06%	Lentils (fresh)	0.15 / 0.09	0.31
0.03%	Cherimoyas	0.01 / 0.01	0.15	0.06%	Wheat	0.2 / 0.04	0.30
0.03%	Garlic	0.07 / 0.04	0.14	0.06%	Valerian root	1 / 0.5	0.30
0.03%	Pistachios	0.03 / 0.02	0.14	0.06%	Valerian root	1 / 0.5	0.30
0.03%	Mustard seeds	0.4 / 0.13	0.13	0.06%	Chervil	6 / 3.64	0.29
0.03%	Rice	0.02 / 0.01	0.13	0.06%	Beans	0.5 / 0.04	0.29
0.02%	Rosemary	6 / 3.64	0.11	0.05%	Lentils	0.5 / 0.04	0.27
0.02%	Chestnuts	0.03 / 0.02	0.10	0.05%	Poultry: Fat tissue	1.5 / 0.9	0.27
0.02%	Valerian root	1 / 0.5	0.10	0.05%	Coconuts	0.03 / 0.03	0.26
0.02%	Valerian root	1 / 0.5	0.10	0.04%	Rapeseeds/canola seeds	1 / 0.4	0.21
0.02%	Poultry: Fat tissue	1.5 / 0.9	0.09	0.04%	Pumpkin seeds	0.4 / 0.13	0.21
0.02%	Walnuts	0.03 / 0.02	0.08	0.04%	Barley	0.4 / 0.04	0.20
0.02%	Hazelnuts/cobnuts	0.03 / 0.02	0.08	0.03%	Rye	0.2 / 0.04	0.17
0.01%	Horseradishes	0.4 / 0.18	0.07	0.03%	Sweet corn	0.02 / 0.01	0.16
0.01%	Honey and other apiculture products	0.05 / 0.02	0.07	0.03%	Peas	0.5 / 0.04	0.15
0.01%	Almonds	0.03 / 0.02	0.07	0.03%	Buckwheat and other pseudo-cereals	0.4 / 0.04	0.14
0.01%	Maize/corn	0.02 / 0.01	0.07	0.02%	Chestnuts	0.03 / 0.02	0.11
0.01%	Pecans	0.03 / 0.02	0.07	0.02%	Cherimoyas	0.01 / 0.01	0.11
0.01%	Cashew nuts	0.03 / 0.02	0.06	0.02%	Watercress	0.15 / 0.09	0.11
0.01%	Oat	0.4 / 0.04	0.05	0.02%	Shallots	0.07 / 0.04	0.11
0.01%	Watercress	0.15 / 0.09	0.04	0.02%	Poppy seeds	0.4 / 0.13	0.09
0.01%	Laurel/bay leaves	6 / 3.64	0.04	0.02%	Poppy seeds	0.4 / 0.13	0.09
0.00%	Soyabeans	0.2 / 0.01	0.02	0.02%	Rice	0.02 / 0.01	0.09
0.00%	Brazil nuts	0.03 / 0.02	0.02	0.02%	Asparagus	0.01 / 0.01	0.08
0.00%	Common millet/proso millet	0.02 / 0.01	0.01	0.02%	Sunflower seeds	0.7 / 0.08	0.08
0.00%	Macadamia	0.03 / 0.02	0.01	0.01%	Pistachios	0.03 / 0.02	0.06
0.00%	Shallots	0.07 / 0.04	0.01	0.01%	Cassava roots/manioc	0.06 / 0.02	0.06
0.00%	Turmeric/curcuma	1 / 0.5	0.01	0.01%	Soyabeans	0.2 / 0.01	0.06
0.00%	Pine nut kernels	0.03 / 0.02	0.01	0.01%	Pecans	0.03 / 0.02	0.05
0.00%	Liquorice	1 / 0.5	0.00	0.01%	Sorghum	0.6 / 0.18	0.05
				0.01%	Walnuts	0.03 / 0.02	0.05
				0.01%	Macadamia	0.03 / 0.02	0.05
				0.01%	Liquorice	1 / 0.5	0.05
				0.01%	Liquorice	1 / 0.5	0.05
				0.01%	Dill seed	70 / 29.6	0.04
				0.01%	Cashew nuts	0.03 / 0.02	0.04
				0.01%	Almonds	0.03 / 0.02	0.03
				0.01%	Hazelnuts/cobnuts	0.03 / 0.02	0.03
				0.01%	Honey and other apiculture products	0.05 / 0.02	0.03
				0.01%	Oat	0.4 / 0.04	0.03

Expand/collapse list

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

Processed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Escaroles/broad-leaved endives / boiled	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 white) / juice	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%	Pumpkins / boiled	0.4 / 0.12	11
2%	Courgettes / boiled	0.6 / 0.3	11
2%	Cauliflowers / boiled	0.3 / 0.14	9.7
2%	Turnips / boiled	0.4 / 0.18	9.1

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)
66%	Celeries / boiled	20 / 9.74	329
8%	Purslanes / boiled	20 / 10	41
4%	Escaroles/broad-leaved endives / boiled	2 / 0.98	20
2%	Chards/beet leaves / boiled	2 / 0.98	12
2%	Currants (red, black and white) / juice	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%	Pumpkins / boiled	0.4 / 0.12	6.6
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
1%	Leeks / boiled	0.8 / 0.32	5.6
1%	Broccoli / boiled	0.5 / 0.23	5.5

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.

Fluopyram – Scenario 2

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

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

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: Scenario in which the existing EU MRLs for animal products (and the correlated HR/STMRs) except for eggs were used; for plant commodities and for eggs, the MRL proposals of JMPR were included. The proposed modifications of EU MRLs (EFSA, 2023) have not been taken on board in this scenario.

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)	96%	NL toddler	11.52	21%	Milk: Cattle	18%	Apples	9%	Bananas		96%
	68%	DE child	8.15	21%	Apples	7%	Milk: Cattle	7%	Table grapes		68%
	53%	NL child	6.36	10%	Apples	9%	Milk: Cattle	5%	Table grapes		53%
	40%	IE adult	4.83	5%	Basil and edible flowers	5%	Wine grapes	3%	Celeries		40%
	37%	FR child 3 15 yr	4.48	8%	Milk: Cattle	5%	Eggs: Chicken	3%	Oranges	0.0%	37%
	37%	GEMS/Food G07	4.40	6%	Wine grapes	3%	Celeries	3%	Lettuces		37%
	35%	FR toddler 2 3 yr	4.20	10%	Milk: Cattle	5%	Apples	3%	Beans (with pods)	0.0%	35%
	34%	UK infant	4.11	14%	Milk: Cattle	5%	Eggs: Chicken	3%	Apples		34%
	34%	GEMS/Food G11	4.04	7%	Celeries	4%	Wine grapes	3%	Milk: Cattle		34%
	33%	SE general	3.93	5%	Lettuces	4%	Milk: Cattle	3%	Eggs: Chicken		33%
	31%	GEMS/Food G06	3.73	5%	Table grapes	4%	Tomatoes	2%	Wheat		31%
	30%	GEMS/Food G08	3.62	4%	Wine grapes	2%	Lettuces	2%	Apples		30%
	30%	UK toddler	3.58	7%	Milk: Cattle	3%	Eggs: Chicken	3%	Apples		30%
	29%	GEMS/Food G15	3.54	4%	Wine grapes	2%	Milk: Cattle	2%	Celeries		29%
	29%	GEMS/Food G10	3.54	4%	Lettuces	2%	Milk: Cattle	2%	Tomatoes		29%
	29%	ES child	3.46	5%	Lettuces	4%	Milk: Cattle	3%	Eggs: Chicken		29%
	29%	DE women 14-50 yr	3.45	4%	Milk: Cattle	4%	Apples	3%	Wine grapes	0.0%	29%
	29%	DK child	3.44	4%	Milk: Cattle	4%	Apples	3%	Eggs: Chicken		29%
	28%	RO general	3.40	6%	Wine grapes	4%	Milk: Cattle	2%	Eggs: Chicken		28%
	27%	DE general	3.27	4%	Milk: Cattle	4%	Apples	3%	Wine grapes	0.0%	27%
	23%	ES adult	2.82	7%	Lettuces	2%	Eggs: Chicken	2%	Milk: Cattle		23%
	23%	FR adult	2.76	9%	Wine grapes	2%	Eggs: Chicken	2%	Milk: Cattle	0.0%	23%
	23%	NL general	2.74	3%	Milk: Cattle	2%	Apples	2%	Wine grapes		23%
	23%	PT general	2.73	10%	Wine grapes	2%	Apples	1%	Table grapes		23%
	19%	FR infant	2.27	6%	Milk: Cattle	3%	Apples	2%	Beans (with pods)	0.0%	19%
	17%	IT toddler	2.06	4%	Lettuces	2%	Wheat	2%	Tomatoes		17%
	17%	FI 3 yr	2.01	2%	Bananas	2%	Raspberries (red and yellow)	2%	Apples		17%
	16%	DK adult	1.97	4%	Wine grapes	2%	Milk: Cattle	2%	Apples		16%
	16%	UK vegetarian	1.97	3%	Wine grapes	2%	Lettuces	1%	Eggs: Chicken		16%
	16%	IT adult	1.95	5%	Lettuces	1%	Tomatoes	1%	Apples		16%
	15%	UK adult	1.81	4%	Wine grapes	1%	Lettuces	1%	Eggs: Chicken	0.0%	15%
	13%	FI 6 yr	1.54	1%	Raspberries (red and yellow)	1%	Bananas	1%	Lettuces		13%
	11%	LT adult	1.37	3%	Apples	1%	Milk: Cattle	1%	Eggs: Chicken		11%
	11%	PL general	1.27	3%	Apples	2%	Table grapes	1%	Tomatoes		11%
	9%	FI adult	1.13	2%	Lettuces	1%	Wine grapes	1.0%	Apples		9%
	5%	IE child	0.59	1%	Milk: Cattle	0.6%	Eggs: Chicken	0.5%	Apples		5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluopyram 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.

Fluopyram – Scenario 3

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

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

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: Scenario in which the existing EU MRLs for animal products (and the correlated HR/STMRs) except for eggs were used; for plant commodities and eggs, the MRL proposals of JMPR were included.
The MRL proposals derived in EFSA 2023 were included (lowering of the MRLs for pome fruit from 0.8 to 0.6, new MRLs for some stem vegetables, kiwi, soyabeans, peanuts and seeds spices).

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)
88%	NL toddler	10.58	21%	Milk: Cattle	12%	Apples	9%	Bananas		88%
64%	DE child	7.65	14%	Apples	7%	Milk: Cattle	7%	Table grapes		64%
49%	NL child	5.93	9%	Milk: Cattle	7%	Apples	5%	Table grapes		49%
40%	IE adult	4.86	5%	Basil and edible flowers	5%	Wine grapes	3%	Celeries		40%
37%	GEMS/Food G07	4.46	6%	Wine grapes	3%	Celeries	3%	Lettuces		37%
36%	FR child 3 15 yr	4.32	8%	Milk: Cattle	5%	Eggs: Chicken	3%	Oranges	0.0%	36%
35%	GEMS/Food G11	4.23	7%	Celeries	4%	Wine grapes	3%	Milk: Cattle		35%
33%	UK infant	3.99	14%	Milk: Cattle	5%	Eggs: Chicken	2%	Bananas		33%
33%	FR toddler 2 3 yr	3.99	10%	Milk: Cattle	4%	Apples	3%	Beans (with pods)	0.0%	33%
32%	SE general	3.85	5%	Lettuces	4%	Milk: Cattle	3%	Eggs: Chicken		32%
31%	GEMS/Food G06	3.77	5%	Table grapes	4%	Tomatoes	2%	Wheat		31%
31%	GEMS/Food G08	3.70	4%	Wine grapes	2%	Lettuces	2%	Milk: Cattle		31%
31%	GEMS/Food G10	3.66	4%	Lettuces	2%	Milk: Cattle	2%	Tomatoes		31%
30%	GEMS/Food G15	3.58	4%	Wine grapes	2%	Milk: Cattle	2%	Celeries		30%
29%	UK toddler	3.46	7%	Milk: Cattle	3%	Eggs: Chicken	2%	Oranges		29%
28%	ES child	3.36	5%	Lettuces	4%	Milk: Cattle	3%	Eggs: Chicken		28%
27%	RO general	3.30	6%	Wine grapes	4%	Milk: Cattle	2%	Eggs: Chicken		27%
27%	DE women 14-50 yr	3.28	4%	Milk: Cattle	3%	Wine grapes	3%	Apples	0.0%	27%
27%	DK child	3.25	4%	Milk: Cattle	3%	Eggs: Chicken	3%	Apples		27%
26%	DE general	3.11	4%	Milk: Cattle	3%	Wine grapes	3%	Apples	0.0%	26%
23%	ES adult	2.75	7%	Lettuces	2%	Eggs: Chicken	2%	Milk: Cattle		23%
22%	PT general	2.65	10%	Wine grapes	1%	Table grapes	1%	Potatoes		22%
22%	NL general	2.65	3%	Milk: Cattle	2%	Wine grapes	2%	Apples		22%
22%	FR adult	2.64	9%	Wine grapes	2%	Eggs: Chicken	2%	Milk: Cattle	0.0%	22%
18%	FR infant	2.17	6%	Milk: Cattle	2%	Apples	2%	Beans (with pods)	0.0%	18%
17%	IT toddler	2.01	4%	Lettuces	2%	Wheat	2%	Tomatoes		17%
16%	FI 3 yr	1.94	2%	Bananas	2%	Raspberries (red and yellow)	1%	Strawberries		16%
16%	UK vegetarian	1.93	3%	Wine grapes	2%	Lettuces	1%	Eggs: Chicken		16%
16%	IT adult	1.92	5%	Lettuces	1%	Tomatoes	1%	Wheat		16%
16%	DK adult	1.89	4%	Wine grapes	2%	Milk: Cattle	1%	Eggs: Chicken		16%
15%	UK adult	1.78	4%	Wine grapes	1%	Lettuces	1%	Eggs: Chicken	0.0%	15%
12%	FI 6 yr	1.50	1%	Raspberries (red and yellow)	1%	Bananas	1%	Lettuces		12%
10%	LT adult	1.24	2%	Apples	1%	Milk: Cattle	1%	Eggs: Chicken		10%
9%	PL general	1.12	2%	Apples	2%	Table grapes	1%	Tomatoes		9%
9%	FI adult	1.09	2%	Lettuces	1%	Wine grapes	0.7%	Tomatoes		9%
5%	IE child	0.57	1%	Milk: Cattle	0.6%	Eggs: Chicken	0.4%	Apples		5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluopyram 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.

Thiamethoxam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Thiamethoxam

LOQs (mg/kg) range from: 0.01 to: 0.07

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:	2007	Year of evaluation:	2007

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)	5%	NL toddler	1.34	2%	Milk: Cattle	0.4%	Apples	0.3%	Tomatoes	5%	0.3%
	3%	DE child	0.74	0.8%	Milk: Cattle	0.5%	Apples	0.3%	Tomatoes	2%	0.4%
	3%	NL child	0.73	0.9%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Apples	3%	0.2%
	3%	GEMS/Food G06	0.72	1%	Tomatoes	0.3%	Wheat	0.1%	Sweet peppers/bell peppers	1%	1%
	3%	UK infant	0.66	1%	Milk: Cattle	0.1%	Potatoes	0.1%	Tomatoes	2%	0.1%
	3%	FR child 3 15 yr	0.65	0.9%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	2%	0.3%
	2%	FR toddler 2 3 yr	0.62	1%	Milk: Cattle	0.1%	Tomatoes	0.1%	Apples	2%	0.2%
	2%	GEMS/Food G11	0.61	0.3%	Milk: Cattle	0.3%	Tomatoes	0.2%	Celeries	2%	0.7%
	2%	RO general	0.58	0.6%	Tomatoes	0.4%	Milk: Cattle	0.2%	Wheat	1%	0.8%
	2%	GEMS/Food G15	0.56	0.4%	Tomatoes	0.3%	Milk: Cattle	0.2%	Wheat	2%	0.6%
	2%	GEMS/Food G08	0.54	0.4%	Tomatoes	0.2%	Milk: Cattle	0.2%	Wheat	2%	0.6%
	2%	GEMS/Food G07	0.54	0.3%	Tomatoes	0.2%	Milk: Cattle	0.2%	Wheat	2%	0.5%
	2%	GEMS/Food G10	0.53	0.4%	Tomatoes	0.2%	Milk: Cattle	0.2%	Wheat	1%	0.6%
	2%	UK toddler	0.52	0.8%	Milk: Cattle	0.2%	Tomatoes	0.2%	Wheat	2%	0.2%
	2%	DK child	0.51	0.5%	Milk: Cattle	0.2%	Rye	0.2%	Swine: Muscle/meat	2%	0.2%
	2%	SE general	0.50	0.5%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Tomatoes	2%	0.3%
	2%	IE adult	0.49	0.2%	Rhubarbs	0.2%	Milk: Cattle	0.1%	Sweet potatoes	1%	0.6%
	2%	ES child	0.48	0.5%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	2%	0.3%
	2%	DE women 14-50 yr	0.45	0.5%	Milk: Cattle	0.2%	Tomatoes	0.2%	Sugar beet roots	1%	0.3%
	2%	DE general	0.44	0.5%	Milk: Cattle	0.2%	Tomatoes	0.2%	Sugar beet roots	1%	0.2%
	2%	FI adult	0.39	1%	Coffee beans	0.2%	Tomatoes	0.0%	Potatoes	1%	0.2%
	1%	NL general	0.36	0.3%	Milk: Cattle	0.1%	Tomatoes	0.1%	Sugar beet roots	1%	0.2%
	1%	FR infant	0.33	0.6%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	1%	0.1%
	1%	ES adult	0.30	0.2%	Tomatoes	0.2%	Milk: Cattle	0.1%	Wheat	0.8%	0.3%
	1%	IT toddler	0.30	0.4%	Tomatoes	0.3%	Wheat	0.1%	Florence fennels	0.6%	0.6%
	1%	PT general	0.28	0.3%	Tomatoes	0.2%	Potatoes	0.2%	Wheat	0.8%	0.3%
	1%	FR adult	0.28	0.2%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wine grapes	0.9%	0.2%
	0.9%	IT adult	0.24	0.4%	Tomatoes	0.2%	Wheat	0.1%	Florence fennels	0.4%	0.5%
	0.9%	DK adult	0.23	0.2%	Milk: Cattle	0.2%	Tomatoes	0.1%	Swine: Muscle/meat	0.7%	0.2%
	0.9%	LT adult	0.23	0.2%	Tomatoes	0.2%	Milk: Cattle	0.1%	Potatoes	0.7%	0.2%
	0.9%	FI 3 yr	0.22	0.2%	Potatoes	0.2%	Tomatoes	0.1%	Bananas	0.6%	0.2%
	0.8%	UK vegetarian	0.21	0.2%	Tomatoes	0.1%	Milk: Cattle	0.1%	Wheat	0.5%	0.3%
	0.7%	UK adult	0.19	0.1%	Tomatoes	0.1%	Milk: Cattle	0.1%	Wheat	0.6%	0.2%
	0.7%	FI 6 yr	0.18	0.1%	Potatoes	0.1%	Tomatoes	0.0%	Wheat	0.5%	0.2%
	0.6%	PL general	0.17	0.3%	Tomatoes	0.1%	Potatoes	0.1%	Apples	0.3%	0.3%
	0.4%	IE child	0.09	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.0%

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 Unio

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)
3%	Celeries	0.8 / 0.4	15
3%	Rhubarbs	0.8 / 0.4	15
1%	Florence fennels	0.8 / 0.4	6.5
1.0%	Sweet peppers/bell peppers	0.7 / 0.08	4.8
0.9%	Tomatoes	0.7 / 0.08	4.7
0.4%	Aubergines/egg plants	0.7 / 0.08	2.0

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)
1%	Florence fennels	0.8 / 0.4	7.5
1%	Celeries	0.8 / 0.4	6.4
0.8%	Cardoons	0.8 / 0.4	4.2
0.7%	Rhubarbs	0.8 / 0.4	3.7
0.4%	Aubergines/egg plants	0.7 / 0.08	2.2
0.3%	Sweet peppers/bell peppers	0.7 / 0.08	1.3
0.3%	Tomatoes	0.7 / 0.08	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)
4%	Florence fennels / boiled	0.8 / 0.4	18
3%	Rhubarbs / sauce/puree	0.8 / 0.4	15
0.3%	Tomatoes / juice	0.7 / 0.08	1.5
0.2%	Tomatoes / sauce/puree	0.7 / 0.08	0.76

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%	Celeries / boiled	0.8 / 0.4	14
2%	Florence fennels / boiled	0.8 / 0.4	7.8
1%	Rhubarbs / sauce/puree	0.8 / 0.4	5.8
1.0%	Cardoons / boiled	0.8 / 0.4	4.9
0.2%	Okra, lady's fingers / boiled	0.7 / 0.47	0.76
0.1%	Tomatoes / sauce/puree	0.7 / 0.08	0.66

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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Acetamiprid

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

Toxicological reference values

ADI (mg/kg bw/day):	0.025	ARfD (mg/kg bw):	0.025
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:

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)
16%	NL toddler	4.08	5%	Milk: Cattle	3%	Apples	1%	Pears	0.2%	16%
11%	DE child	2.72	3%	Apples	2%	Milk: Cattle	0.7%	Cherries (sweet)	0.3%	11%
9%	NL child	2.14	2%	Milk: Cattle	2%	Apples	0.6%	Currants (red, black and white)	0.2%	9%
7%	GEMS/Food G08	1.86	3%	Olives for oil production	0.6%	Tomatoes	0.4%	Milk: Cattle	0.2%	7%
7%	ES child	1.79	2%	Olives for oil production	1.0%	Milk: Cattle	0.8%	Lettuces	0.2%	7%
7%	GEMS/Food G06	1.74	2%	Tomatoes	1%	Olives for oil production	0.4%	Table grapes	0.1%	7%
6%	UK infant	1.57	3%	Milk: Cattle	0.6%	Bovine: Edible offals (other than liver and ki	0.4%	Apples	0.3%	6%
6%	GEMS/Food G10	1.48	1%	Olives for oil production	0.7%	Tomatoes	0.6%	Lettuces	0.2%	6%
6%	GEMS/Food G07	1.47	0.9%	Olives for oil production	0.6%	Tomatoes	0.5%	Wine grapes	0.3%	6%
6%	FR child 3 15 yr	1.39	2%	Milk: Cattle	0.5%	Apples	0.4%	Tomatoes	0.2%	6%
5%	FR toddler 2 3 yr	1.37	2%	Milk: Cattle	0.9%	Apples	0.2%	Tomatoes	0.2%	5%
5%	GEMS/Food G15	1.31	0.6%	Tomatoes	0.6%	Olives for oil production	0.6%	Milk: Cattle	0.2%	5%
5%	ES adult	1.28	1%	Olives for oil production	1%	Lettuces	0.4%	Tomatoes	0.1%	5%
5%	SE general	1.26	1.0%	Milk: Cattle	0.8%	Lettuces	0.4%	Tomatoes	0.2%	5%
5%	GEMS/Food G11	1.25	0.8%	Olives for oil production	0.6%	Milk: Cattle	0.5%	Tomatoes	0.2%	5%
5%	IE adult	1.21	0.5%	Wine grapes	0.4%	Sheep: Edible offals (other than liver and ki	0.3%	Milk: Cattle	0.1%	5%
5%	DE women 14-50 yr	1.19	1.0%	Milk: Cattle	0.7%	Apples	0.4%	Tomatoes	0.1%	5%
5%	RO general	1.19	1%	Tomatoes	0.9%	Milk: Cattle	0.6%	Wine grapes	0.3%	5%
5%	UK toddler	1.17	2%	Milk: Cattle	0.5%	Apples	0.3%	Currants (red, black and white)	0.3%	5%
5%	DE general	1.13	1.0%	Milk: Cattle	0.7%	Apples	0.3%	Tomatoes	0.1%	5%
4%	DK child	1.03	1%	Milk: Cattle	0.7%	Apples	0.4%	Cucumbers	0.2%	4%
4%	PT general	0.97	0.9%	Wine grapes	0.8%	Olives for oil production	0.5%	Tomatoes	0.2%	4%
3%	NL general	0.83	0.7%	Milk: Cattle	0.4%	Apples	0.2%	Tomatoes	0.2%	3%
3%	FR adult	0.80	0.8%	Wine grapes	0.4%	Milk: Cattle	0.2%	Tomatoes	0.1%	3%
3%	FR infant	0.76	1%	Milk: Cattle	0.5%	Apples	0.2%	Spinaches	0.1%	3%
3%	IT toddler	0.75	0.7%	Tomatoes	0.6%	Lettuces	0.3%	Wheat	0.0%	3%
3%	FI 3 yr	0.72	0.5%	Raspberries (red and yellow)	0.3%	Tomatoes	0.3%	Bananas	0.2%	3%
3%	IT adult	0.71	0.7%	Lettuces	0.6%	Tomatoes	0.2%	Apples	0.0%	3%
2%	DK adult	0.58	0.4%	Milk: Cattle	0.3%	Wine grapes	0.3%	Tomatoes	0.1%	2%
2%	FI 6 yr	0.53	0.3%	Raspberries (red and yellow)	0.2%	Tomatoes	0.2%	Cucumbers	0.2%	2%
2%	UK vegetarian	0.52	0.3%	Tomatoes	0.3%	Wine grapes	0.3%	Lettuces	0.1%	2%
2%	LT adult	0.50	0.5%	Apples	0.3%	Tomatoes	0.3%	Milk: Cattle	0.2%	2%
2%	PL general	0.48	0.6%	Apples	0.5%	Tomatoes	0.2%	Cherries (sweet)	0.1%	2%
2%	UK adult	0.47	0.4%	Wine grapes	0.2%	Milk: Cattle	0.2%	Lettuces	0.1%	2%
1%	FI adult	0.37	0.3%	Tomatoes	0.3%	Lettuces	0.2%	Apples	0.0%	1%
0.8%	IE child	0.20	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Currants (red, black and white)	0.1%	0.8%

Conclusion:

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

The long-term intake of residues of Acetamiprid is unlikely to present a public health concern.

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

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

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
116%	Pears	0.4 / 0.21	29
114%	Lettuces	1.5 / 0.75	29
91%	Apples	0.4 / 0.21	23
80%	Apricots	0.8 / 0.57	20
73%	Table grapes	0.5 / 0.25	18
67%	Melons	0.2 / 0.11	17
65%	Tomatoes	0.5 / 0.28	16
63%	Quinces	0.8 / 0.64	16
55%	Sweet peppers/bell peppers	0.4 / 0.23	14
54%	Watermelons	0.2 / 0.11	13
52%	Cucumbers	0.4 / 0.2	13
51%	Cauliflowers	0.4 / 0.22	13
44%	Head cabbages	0.4 / 0.25	11
43%	Cherries (sweet)	1.5 / 0.88	11
43%	Blackberries	2 / 1	11
42%	Bananas	0.4 / 0.11	10
42%	Broccoli	0.4 / 0.25	10
40%	Escaroles/broad-leaved endives	0.4 / 0.25	10
38%	Peaches	0.2 / 0.1	9.5
37%	Courgettes	0.4 / 0.2	9.3
37%	Raspberries (red and yellow)	2 / 1	9.2
35%	Medlar	0.8 / 0.64	8.9
35%	Granate apples/pomegranates	0.3 / 0.16	8.8
33%	Asparagus	0.8 / 0.43	8.3
32%	Currants (red, black and white)	2 / 1	7.9
29%	Bovine: Edible offals (other than liver and kidney)	1 / 1	7.3
29%	Bovine: Liver	1 / 0.89	7.2
28%	Spinaches	0.6 / 0.31	7.0
24%	Blueberries	2 / 1	6.0
24%	Gooseberries (green, red and yellow)	2 / 1	5.9
21%	Lamb's lettuce/corn salads	3 / 1.9	5.3
20%	Roman rocket/rucola	3 / 1.9	5.1
19%	Chards/beet leaves	0.6 / 0.31	4.8
19%	Aubergines/egg plants	0.4 / 0.19	4.8
18%	Cranberries	2 / 1	4.5
18%	Globe artichokes	0.7 / 0.25	4.4
18%	Table olives	3 / 1.3	4.4
16%	Strawberries	0.5 / 0.25	4.1
15%	Beans (with pods)	0.6 / 0.32	3.7
14%	Other farmed animals: Muscle/meat	0.5 / 0.5	3.5
13%	Bovine: Kidney	1 / 0.89	3.4
13%	Swine: Muscle/meat	0.5 / 0.27	3.3
12%	Swine: Edible offals (other than liver and kidney)	1 / 1	3.0
12%	Pumpkins	0.2 / 0.11	2.9
11%	Oranges	0.9 / 0.02	2.9
10%	Peas (with pods)	0.6 / 0.32	2.6
10%	Milk: Cattle	0.2 / 0.02	2.5
10%	Chervil	3 / 1.9	2.5
9%	Wine grapes	0.5 / 0.25	2.3
8%	Parsley	3 / 1.9	2.1
8%	Bovine: Muscle/meat	0.5 / 0.27	1.9
7%	Dewberries	2 / 1	1.8
7%	Grapefruits	0.9 / 0.02	1.7
6%	Equine: Muscle/meat	0.5 / 0.27	1.6
6%	Chives	3 / 1.9	1.6
6%	Potatoes	0.01 / 0.01	1.5
6%	Peas (without pods)	0.3 / 0.18	1.5
6%	Sheep: Muscle/meat	0.5 / 0.27	1.5
6%	Sage	3 / 1.9	1.4
6%	Beans (without pods)	0.3 / 0.18	1.4
6%	Basil and edible flowers	3 / 1.9	1.4
5%	Mandarins	0.9 / 0.02	1.3
5%	Plums	0.04 / 0.03	1.3
5%	Swine: Kidney	1 / 0.89	1.1
4%	Swine: Liver	1 / 0.89	1.1
4%	Gherkins	0.6 / 0.37	1.0
4%	Olives for oil production	3 / 0.8	1.0
4%	Celery leaves	3 / 1.9	0.91
3%	Lemons	0.9 / 0.02	0.74
3%	Coconuts	0.07 / 0.05	0.72
2%	Cress and other sprouts and shoots	3 / 1.9	0.56
2%	Milk: Goat	0.2 / 0.02	0.48
2%	Honey and other apiculture products	2 / 0.13	0.47
2%	Onions	0.02 / 0.02	0.45
2%	Sweet corn	0.01 / 0.01	0.43
2%	Limes	0.9 / 0.02	0.43
1%	Beans	0.15 / 0.02	0.37

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%	Head cabbages	0.4 / 0.25	11
40%	Red mustards	3 / 1.9	10
39%	Quinces	0.8 / 0.64	9.7
36%	Blueberries	2 / 1	9.1
36%	Lettuces	1.5 / 0.75	9.1
35%	Cherries (sweet)	1.5 / 0.88	8.8
34%	Table grapes	0.5 / 0.25	8.5
33%	Blackberries	2 / 1	8.2
26%	Currants (red, black and white)	2 / 1	6.6
26%	Pears	0.4 / 0.21	6.4
25%	Apricots	0.8 / 0.57	6.2
24%	Broccoli	0.4 / 0.25	6.0
24%	Wine grapes	0.5 / 0.25	5.9
24%	Apples	0.4 / 0.21	5.9
23%	Chards/beet leaves	0.6 / 0.31	5.9
22%	Cucumbers	0.4 / 0.2	5.6
22%	Raspberries (red and yellow)	2 / 1	5.4
21%	Aubergines/egg plants	0.4 / 0.19	5.1
20%	Cauliflowers	0.4 / 0.22	5.1
20%	Escaroles/broad-leaved endives	0.4 / 0.25	5.0
19%	Courgettes	0.4 / 0.2	4.7
18%	Gooseberries (green, red and yellow)	2 / 1	4.5
18%	Watermelons	0.2 / 0.11	4.5
18%	Tomatoes	0.5 / 0.28	4.4
18%	Medlar	0.8 / 0.64	4.4
17%	Melons	0.2 / 0.11	4.3
15%	Sweet peppers/bell peppers	0.4 / 0.23	3.8
14%	Lamb's lettuce/corn salads	3 / 1.9	3.6
14%	Bovine: Liver	1 / 0.89	3.6
13%	Bovine: Edible offals (other than liver and kidney)	1 / 1	3.3
13%	Asparagus	0.8 / 0.43	3.3
13%	Globe artichokes	0.7 / 0.25	3.2
11%	Granate apples/pomegranates	0.3 / 0.16	2.8
11%	Other farmed animals: Muscle/meat	0.5 / 0.5	2.8
10%	Swine: Edible offals (other than liver and kidney)	1 / 1	2.6
10%	Sheep: Liver	1 / 0.89	2.5
10%	Beans (with pods)	0.6 / 0.32	2.5
9%	Strawberries	0.5 / 0.25	2.3
9%	Bananas	0.4 / 0.11	2.3
9%	Parsley	3 / 1.9	2.3
9%	Roman rocket/rucola	3 / 1.9	2.2
9%	Gherkins	0.6 / 0.37	2.2
9%	Rose hips	2 / 1	2.2
8%	Swine: Kidney	1 / 0.89	2.0
7%	Bovine: Kidney	1 / 0.89	1.9
7%	Peaches	0.2 / 0.1	1.9
6%	Pumpkins	0.2 / 0.11	1.6
6%	Bovine: Muscle	0.5 / 0.27	1.5
6%	Dewberries	2 / 1	1.4
5%	Swine: Muscle/meat	0.5 / 0.27	1.3
5%	Table olives	3 / 1.3	1.3
5%	Equine: Muscle/meat	0.5 / 0.27	1.3
5%	Sheep: Muscle/meat	0.5 / 0.27	1.3
5%	Swine: Liver	1 / 0.89	1.3
5%	Spinaches	0.6 / 0.31	1.2
5%	Cranberries	2 / 1	1.1
4%	Peas (with pods)	0.6 / 0.32	1.1
4%	Peas (without pods)	0.3 / 0.18	0.96
3%	Milk: Cattle	0.2 / 0.02	0.77
3%	Cress and other sprouts and shoots	3 / 1.9	0.72
3%	Beans (without pods)	0.3 / 0.18	0.71
3%	Sheep: Edible offals (other than liver and kidney)	1 / 1	0.68
3%	Oranges	0.9 / 0.02	0.66
2%	Olives for oil production	3 / 0.8	0.62
2%	Celery leaves	3 / 1.9	0.62
2%	Purslanes	0.6 / 0.31	0.59
2%	Plums	0.04 / 0.03	0.53
2%	Poultry: Liver	0.1 / 0.1	0.47
2%	Coconuts	0.07 / 0.05	0.43
2%	Goat: Muscle	0.5 / 0.27	0.42
2%	Mandarins	0.9 / 0.02	0.39
2%	Grapefruits	0.9 / 0.02	0.39
2%	Sage	3 / 1.9	0.38
1%	Milk: Goat	0.2 / 0.02	0.37
1%	Swine: Fat tissue	0.3 / 0.16	0.32
1%	Chives	3 / 1.9	0.32
1%	Milk: Sheep	0.2 / 0.02	0.30

1%	Poultry: Muscle/meat	0.02 / 0.02	0.34
1%	Bovine: Fat tissue	0.3 / 0.16	0.33
1%	Pistachios	0.07 / 0.05	0.29
1%	Swine: Fat tissue	0.3 / 0.16	0.27
1%	Brussels sprouts	0.05 / 0.03	0.25
1.0%	Eggs: Chicken	0.02 / 0.02	0.25
0.8%	Chestnuts	0.07 / 0.05	0.21
0.7%	Walnuts	0.07 / 0.05	0.17
0.7%	Hazelnuts/cobnuts	0.07 / 0.05	0.16
0.6%	Almonds	0.07 / 0.05	0.14
0.6%	Wheat	0.1 / 0.01	0.14
0.6%	Pecans	0.07 / 0.05	0.14
0.5%	Lentils	0.15 / 0.02	0.13
0.5%	Peas	0.15 / 0.02	0.13
0.5%	Cashew nuts	0.07 / 0.05	0.13
0.5%	Figs	0.03 / 0.01	0.12
0.5%	Thyme	3 / 1.9	0.11
0.4%	Poultry: Liver	0.1 / 0.1	0.11
0.3%	Milk: Sheep	0.2 / 0.02	0.07
0.2%	Rosemary	3 / 1.9	0.06
0.2%	Barley	0.05 / 0.01	0.06
0.2%	Brazil nuts	0.07 / 0.05	0.04
0.2%	Rapeseeds/canola seeds	0.4 / 0.03	0.04
0.1%	Garlic	0.02 / 0.01	0.04
0.1%	Mustard seeds	0.15 / 0.03	0.03
0.1%	Macadamia	0.07 / 0.05	0.03
0.09%	Soyabeans	0.01 / 0.01	0.02
0.08%	Laurel/bay leaves	3 / 1.9	0.02
0.07%	Pine nut kernels	0.07 / 0.05	0.02
0.04%	Oat	0.05 / 0.01	0.01
0.04%	Linseeds	0.06 / 0.01	0.01
0.02%	Peppercorn (black, green and white)	0.1 / 0.1	0.00
0.01%	Poultry: Fat tissue	0.02 / 0.02	0.00
0.00%	Cardamom	0.1 / 0.1	0.00

Expand/collapse list

1%	Potatoes	0.01 / 0.01	0.30
1%	Onions	0.02 / 0.02	0.30
0.9%	Poultry: Muscle	0.02 / 0.02	0.23
0.9%	Basil and edible flowers	3 / 1.9	0.23
0.9%	Chestnuts	0.07 / 0.05	0.23
0.8%	Lemons	0.9 / 0.02	0.19
0.8%	Rosemary	3 / 1.9	0.19
0.8%	Rosemary	3 / 1.9	0.19
0.8%	Rosemary	3 / 1.9	0.19
0.8%	Rosemary	3 / 1.9	0.19
0.7%	Brussels sprouts	0.05 / 0.03	0.18
0.7%	Honey and other apiculture products	2 / 0.13	0.18
0.6%	Sweet corn	0.01 / 0.01	0.16
0.6%	Bovine: Fat tissue	0.3 / 0.16	0.16
0.6%	Chervil	3 / 1.9	0.15
0.6%	Limes	0.9 / 0.02	0.15
0.5%	Pistachios	0.07 / 0.05	0.13
0.5%	Beans	0.15 / 0.02	0.13
0.5%	Lentils	0.15 / 0.02	0.12
0.5%	Pecans	0.07 / 0.05	0.11
0.4%	Figs	0.03 / 0.01	0.11
0.4%	Walnuts	0.07 / 0.05	0.11
0.4%	Macadamia	0.07 / 0.05	0.11
0.4%	Sheep: Kidney	1 / 0.89	0.09
0.3%	Eggs: Chicken	0.02 / 0.02	0.09
0.3%	Cashew nuts	0.07 / 0.05	0.09
0.3%	Wheat	0.1 / 0.01	0.08
0.3%	Almonds	0.07 / 0.05	0.07
0.3%	Peas	0.15 / 0.02	0.07
0.2%	Hazelnuts/cobnuts	0.07 / 0.05	0.06
0.2%	Soyabeans	0.01 / 0.01	0.06
0.2%	Pine nut kernels	0.07 / 0.05	0.05
0.2%	Barley	0.05 / 0.01	0.05
0.1%	Brazil nuts	0.07 / 0.05	0.03
0.1%	Eggs: Quail	0.02 / 0.02	0.03
0.08%	Poppy seeds	0.3 / 0.03	0.02
0.08%	Poppy seeds	0.3 / 0.03	0.02
0.06%	Rapeseeds/canola seeds	0.4 / 0.03	0.02
0.04%	Cardamom	0.1 / 0.1	0.01
0.04%	Eggs: Goose	0.02 / 0.02	0.01
0.03%	Garlic	0.02 / 0.01	0.01
0.03%	Oat	0.05 / 0.01	0.01
0.02%	Poultry: Fat tissue	0.02 / 0.02	0.01
0.02%	Linseeds	0.06 / 0.01	0.00
0.01%	Peppercorn (black, green and white)	0.1 / 0.1	0.00

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)
79%	Broccoli / boiled	0.4 / 0.25	20
73%	Currants (red, black and white) / juice	2 / 0.64	18
66%	Escaroles/broad-leaved endives / boiled	0.4 / 0.25	17
61%	Cauliflowers / boiled	0.4 / 0.22	15
41%	Elderberries / juice	2 / 0.64	10
40%	Oranges / juice	0.9 / 0.19	10
39%	Pumpkins / boiled	0.2 / 0.11	9.8
39%	Chards/beet leaves / boiled	0.6 / 0.31	9.6
34%	Gherkins / pickled	0.6 / 0.37	8.5
30%	Raspberries / juice	2 / 0.64	7.5
28%	Courgettes / boiled	0.4 / 0.2	7.1
17%	Spinaches / frozen; boiled	0.6 / 0.31	4.3
16%	Beans (with pods) / boiled	0.6 / 0.32	4.0
16%	Wine grapes / juice	0.5 / 0.09	3.9
15%	Apples / juice	0.4 / 0.07	3.8

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)
37%	Cauliflowers / boiled	0.4 / 0.22	9.2
33%	Currants (red, black and white) / juice	2 / 0.64	8.2
24%	Pumpkins / boiled	0.2 / 0.11	6.1
24%	Broccoli / boiled	0.4 / 0.25	6.0
24%	Elderberries / juice	2 / 0.64	5.9
20%	Escaroles/broad-leaved endives / boiled	0.4 / 0.25	5.1
18%	Courgettes / boiled	0.4 / 0.2	4.6
16%	Chards/beet leaves / boiled	0.6 / 0.31	3.9
11%	Oranges / juice	0.9 / 0.19	2.9
10%	Spinaches / frozen; boiled	0.6 / 0.31	2.6
9%	Wine grapes / wine	0.5 / 0.25	2.4
9%	Apples / juice	0.4 / 0.07	2.3
8%	Grapefruits / juice	0.9 / 0.19	2.1
7%	Wine grapes / juice	0.5 / 0.09	1.9
6%	Table grapes / raisins	0.5 / 1.18	1.4

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.

Acetamiprid – new TRVs

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Acetamiprid

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

	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)	44%	NL toddler	2.21	24%	Milk: Cattle	5%	Apples	3%	Rose hips	1%	44%
	27%	DE child	1.35	8%	Milk: Cattle	5%	Apples	2%	Honey and other apiculture products	1%	27%
	25%	GEMS/Food G08	1.23	13%	Olives for oil production	2%	Milk: Cattle	0.8%	Wheat	1%	25%
	24%	ES child	1.20	12%	Olives for oil production	5%	Milk: Cattle	0.9%	Wheat	1%	24%
	22%	NL child	1.10	10%	Milk: Cattle	3%	Apples	0.9%	Rose hips	1%	22%
	22%	UK infant	1.10	15%	Milk: Cattle	0.8%	Honey and other apiculture products	0.7%	Apples	1%	22%
	20%	FR toddler 2 3 yr	1.02	12%	Milk: Cattle	1%	Apples	0.9%	Beans (with pods)	0.9%	20%
	20%	FR child 3 15 yr	1.00	9%	Milk: Cattle	2%	Olives for oil production	0.9%	Wheat	1%	20%
	18%	GEMS/Food G10	0.89	6%	Olives for oil production	2%	Milk: Cattle	1%	Cress and other sprouts and shoots	1%	18%
	17%	GEMS/Food G06	0.86	6%	Olives for oil production	1%	Wheat	1.0%	Milk: Cattle	0.6%	17%
	17%	GEMS/Food G07	0.83	5%	Olives for oil production	3%	Milk: Cattle	0.8%	Wheat	1%	17%
	15%	GEMS/Food G15	0.77	3%	Olives for oil production	3%	Milk: Cattle	1%	Rose hips	1%	15%
	15%	GEMS/Food G11	0.76	4%	Olives for oil production	3%	Milk: Cattle	0.8%	Lamb's lettuce/corn salads	1%	15%
	15%	UK toddler	0.73	8%	Milk: Cattle	0.8%	Wheat	0.8%	Apples	1%	15%
	14%	ES adult	0.70	7%	Olives for oil production	2%	Milk: Cattle	0.5%	Wheat	0.6%	14%
	14%	IE adult	0.68	2%	Sheep: Edible offals (other than liver and kidney)	2%	Milk: Cattle	2%	Other farmed animals: Muscle/meat	0.8%	14%
	13%	DE women 14-50 yr	0.66	5%	Milk: Cattle	1%	Olives for oil production	1%	Apples	0.5%	13%
	13%	SE general	0.66	5%	Milk: Cattle	2%	Bovine: Muscle/meat	0.8%	Potatoes	1%	13%
	13%	DE general	0.65	5%	Milk: Cattle	1%	Olives for oil production	1%	Apples	0.5%	13%
	12%	RO general	0.61	5%	Milk: Cattle	1%	Wheat	0.7%	Potatoes	1%	12%
	12%	DK child	0.59	5%	Milk: Cattle	1%	Apples	0.9%	Swine: Muscle/meat	1%	12%
	11%	FR infant	0.55	7%	Milk: Cattle	0.7%	Apples	0.6%	Beans (with pods)	0.5%	11%
	9%	PT general	0.47	4%	Olives for oil production	1%	Potatoes	1.0%	Wine grapes	1%	9%
	9%	NL general	0.46	3%	Milk: Cattle	0.6%	Apples	0.5%	Potatoes	0.8%	9%
	9%	FR adult	0.44	2%	Milk: Cattle	1%	Olives for oil production	0.9%	Wine grapes	0.5%	9%
	5%	DK adult	0.27	2%	Milk: Cattle	0.4%	Apples	0.4%	Wine grapes	0.5%	5%
	5%	FI 3 yr	0.27	0.9%	Potatoes	0.7%	Strawberries	0.6%	Raspberries (red and yellow)	1.0%	5%
	5%	LT adult	0.25	2%	Milk: Cattle	0.8%	Apples	0.6%	Potatoes	0.9%	5%
	5%	IT toddler	0.23	1%	Wheat	0.4%	Apples	0.4%	Cherries (sweet)	0.2%	5%
	4%	UK vegetarian	0.21	1%	Milk: Cattle	0.4%	Wheat	0.3%	Wine grapes	0.4%	4%
	4%	UK adult	0.20	1%	Milk: Cattle	0.4%	Wine grapes	0.3%	Wheat	0.6%	4%
	4%	IT adult	0.20	0.8%	Wheat	0.3%	Apples	0.3%	Cherries (sweet)	0.1%	4%
	4%	FI 6 yr	0.19	0.8%	Potatoes	0.6%	Strawberries	0.5%	Raspberries (red and yellow)	0.8%	4%
	3%	PL general	0.16	0.9%	Apples	0.7%	Potatoes	0.4%	Cherries (sweet)	0.7%	3%
	3%	IE child	0.13	1%	Milk: Cattle	0.2%	Wheat	0.1%	Apples	0.3%	3%
	2%	FI adult	0.09	0.3%	Strawberries	0.3%	Apples	0.2%	Potatoes	0.2%	2%

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

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

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

Show results 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)
88%	Globe artichokes	0.7 / 0.25	4.4
81%	Cherries (sweet)	0.8 / 0.33	4.0
80%	Pears	0.07 / 0.03	4.0
80%	Peaches	0.08 / 0.04	4.0
73%	Beans (with pods)	0.6 / 0.32	3.7
69%	Other farmed animals: Muscle/meat	0.5 / 0.5	3.5
67%	Bovine: Kidney	1 / 0.89	3.4
65%	Swine: Muscle/meat	0.5 / 0.27	3.3
63%	Apples	0.07 / 0.03	3.1
62%	Blackberries	0.6 / 0.29	3.1
61%	Sweet peppers/bell peppers	0.09 / 0.05	3.0
60%	Swine: Edible offals (other than liver and kidney)	1 / 1	3.0
59%	Strawberries	0.5 / 0.18	2.9
58%	Table grapes	0.08 / 0.04	2.9
57%	Oranges	0.9 / 0.02	2.9
55%	Medlar	0.3 / 0.2	2.8
54%	Raspberries (red and yellow)	0.6 / 0.29	2.7
52%	Peas (with pods)	0.6 / 0.32	2.6
50%	Milk: Cattle	0.2 / 0.02	2.5
49%	Chervil	3 / 1.9	2.5
47%	Tomatoes	0.06 / 0.04	2.3
46%	Cauliflowers	0.06 / 0.04	2.3
45%	Aubergines/egg plants	0.2 / 0.09	2.3
42%	Lamb's lettuce/corn salads	1.5 / 0.75	2.1
42%	Parsley	3 / 1.9	2.1
41%	Blueberries	0.7 / 0.34	2.0
40%	Roman rocket/rucola	1.5 / 0.75	2.0
40%	Gooseberries (green, red and yellow)	0.7 / 0.34	2.0
39%	Cucumbers	0.05 / 0.03	2.0
39%	Bovine: Muscle/meat	0.5 / 0.27	1.9
35%	Dewberries	2 / 1	1.8
35%	Quinces	0.15 / 0.07	1.7
34%	Grapefruits	0.9 / 0.02	1.7
33%	Melons	0.08 / 0.01	1.7
33%	Broccoli	0.06 / 0.04	1.7
32%	Equine: Muscle/meat	0.5 / 0.27	1.6
32%	Table olives	0.9 / 0.48	1.6
31%	Chives	3 / 1.9	1.6
31%	Potatoes	0.01 / 0.01	1.5
30%	Cranberries	0.7 / 0.34	1.5
30%	Peas (without pods)	0.3 / 0.18	1.5
29%	Apricots	0.08 / 0.04	1.5
29%	Sheep: Muscle/meat	0.5 / 0.27	1.5
29%	Sage	3 / 1.9	1.4
28%	Beans (without pods)	0.3 / 0.18	1.4
28%	Courgettes	0.05 / 0.03	1.4
28%	Basil and edible flowers	3 / 1.9	1.4
27%	Watermelons	0.08 / 0.01	1.3
26%	Mandarins	0.9 / 0.02	1.3
25%	Plums	0.04 / 0.03	1.3
23%	Swine: Kidney	1 / 0.89	1.1
22%	Swine: Liver	1 / 0.89	1.1
21%	Gherkins	0.6 / 0.37	1.0
20%	Olives for oil production	3 / 0.8	1.0
19%	Head cabbages	0.03 / 0.02	0.93
18%	Celery leaves	3 / 1.9	0.91
15%	Lemons	0.9 / 0.02	0.74
14%	Coconuts	0.07 / 0.05	0.72
11%	Cress and other sprouts and shoots	3 / 1.9	0.56
10%	Milk: Goat	0.2 / 0.02	0.48
9%	Honey and other apiculture products	2 / 0.13	0.47
9%	Onions	0.02 / 0.02	0.45
9%	Sweet corn	0.01 / 0.01	0.43
9%	Limes	0.9 / 0.02	0.43
7%	Wine grapes	0.08 / 0.04	0.37
7%	Beans	0.15 / 0.02	0.37
7%	Poultry: Muscle/meat	0.02 / 0.02	0.34
7%	Bovine: Fat tissue	0.3 / 0.16	0.33
6%	Pumpkins	0.08 / 0.01	0.29
6%	Bovine: Edible offals (other than liver and kidney)	0.05 / 0.04	0.29
6%	Pistachios	0.07 / 0.05	0.29
5%	Swine: Fat tissue	0.3 / 0.16	0.27
5%	Brussels sprouts	0.05 / 0.03	0.25
5%	Eggs: Chicken	0.02 / 0.02	0.25
5%	Bovine: Liver	0.03 / 0.03	0.24
4%	Chestnuts	0.07 / 0.05	0.21
4%	Asparagus	0.01 / 0.01	0.19

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)
66%	Cherries (sweet)	0.8 / 0.33	3.3
65%	Globe artichokes	0.7 / 0.25	3.2
62%	Blueberries	0.7 / 0.34	3.1
56%	Other farmed animals: Muscle/meat	0.5 / 0.5	2.8
52%	Swine: Edible offals (other than liver and kidney)	1 / 1	2.6
52%	Red mustards	0.9 / 0.49	2.6
50%	Sheep: Liver	1 / 0.89	2.5
49%	Beans (with pods)	0.6 / 0.32	2.5
49%	Aubergines/egg plants	0.2 / 0.09	2.4
48%	Blackberries	0.6 / 0.29	2.4
46%	Parsley	3 / 1.9	2.3
45%	Gherkins	0.6 / 0.37	2.2
44%	Rose hips	2 / 1	2.2
39%	Swine: Kidney	1 / 0.89	2.0
37%	Bovine: Kidney	1 / 0.89	1.9
34%	Strawberries	0.5 / 0.18	1.7
31%	Raspberries (red and yellow)	0.6 / 0.29	1.6
31%	Bovine: Muscle	0.5 / 0.27	1.5
31%	Gooseberries (green, red and yellow)	0.7 / 0.34	1.5
29%	Dewberries	2 / 1	1.4
28%	Lamb's lettuce/corn salads	1.5 / 0.75	1.4
27%	Medlar	0.3 / 0.2	1.4
27%	Table grapes	0.08 / 0.04	1.4
26%	Swine: Muscle/meat	0.5 / 0.27	1.3
26%	Equine: Muscle/meat	0.5 / 0.27	1.3
26%	Sheep: Muscle/meat	0.5 / 0.27	1.3
25%	Swine: Liver	1 / 0.89	1.3
22%	Peas (with pods)	0.6 / 0.32	1.1
22%	Quinces	0.15 / 0.07	1.1
19%	Peas (without pods)	0.3 / 0.18	0.96
19%	Broccoli	0.06 / 0.04	0.95
19%	Wine grapes	0.08 / 0.04	0.95
19%	Cauliflowers	0.06 / 0.04	0.93
18%	Roman rocket/rucola	1.5 / 0.75	0.89
18%	Pears	0.07 / 0.03	0.89
18%	Head cabbages	0.03 / 0.02	0.88
17%	Cucumbers	0.05 / 0.03	0.83
17%	Sweet peppers/bell peppers	0.09 / 0.05	0.83
16%	Apples	0.07 / 0.03	0.81
16%	Peaches	0.08 / 0.04	0.79
15%	Milk: Cattle	0.2 / 0.02	0.77
14%	Cress and other sprouts and shoots	3 / 1.9	0.72
14%	Beans (without pods)	0.3 / 0.18	0.71
14%	Courgettes	0.05 / 0.03	0.70
14%	Sheep: Edible offals (other than liver and kidney)	1 / 1	0.68
13%	Oranges	0.9 / 0.02	0.66
13%	Tomatoes	0.06 / 0.04	0.63
12%	Olives for oil production	3 / 0.8	0.62
12%	Celery leaves	3 / 1.9	0.62
12%	Purslanes	0.6 / 0.31	0.59
11%	Plums	0.04 / 0.03	0.53
10%	Table olives	0.9 / 0.48	0.48
9%	Poultry: Liver	0.1 / 0.1	0.47
9%	Apricots	0.08 / 0.04	0.46
9%	Watermelons	0.08 / 0.01	0.45
9%	Melons	0.08 / 0.01	0.43
9%	Coconuts	0.07 / 0.05	0.43
8%	Goat: Muscle	0.5 / 0.27	0.42
8%	Mandarins	0.9 / 0.02	0.39
8%	Cranberries	0.7 / 0.34	0.39
8%	Grapefruits	0.9 / 0.02	0.39
8%	Sage	3 / 1.9	0.38
7%	Milk: Goat	0.2 / 0.02	0.37
6%	Swine: Fat tissue	0.3 / 0.16	0.32
6%	Chives	3 / 1.9	0.32
6%	Milk: Sheep	0.2 / 0.02	0.30
6%	Potatoes	0.01 / 0.01	0.30
6%	Onions	0.02 / 0.02	0.30
5%	Poultry: Muscle	0.02 / 0.02	0.23
5%	Basil and edible flowers	3 / 1.9	0.23
5%	Chestnuts	0.07 / 0.05	0.23
4%	Lemons	0.9 / 0.02	0.19
4%	Rosemary	3 / 1.9	0.19
4%	Rosemary	3 / 1.9	0.19
4%	Rosemary	3 / 1.9	0.19
4%	Rosemary	3 / 1.9	0.19
4%	Brussels sprouts	0.05 / 0.03	0.18

3%	Walnuts	0.07 / 0.05	0.17
3%	Hazelnuts/cobnuts	0.07 / 0.05	0.16
3%	Almonds	0.07 / 0.05	0.14
3%	Wheat	0.1 / 0.01	0.14
3%	Pecans	0.07 / 0.05	0.14
3%	Lentils	0.15 / 0.02	0.13
3%	Peas	0.15 / 0.02	0.13
3%	Cashew nuts	0.07 / 0.05	0.13
2%	Figs	0.03 / 0.01	0.12
2%	Thyme	3 / 1.9	0.11
2%	Poultry: Liver	0.1 / 0.1	0.11
1%	Milk: Sheep	0.2 / 0.02	0.07
1%	Rosemary	3 / 1.9	0.06
1%	Barley	0.05 / 0.01	0.06
0.9%	Brazil nuts	0.07 / 0.05	0.04
0.8%	Rapeseeds/canola seeds	0.4 / 0.03	0.04
0.7%	Garlic	0.02 / 0.01	0.04
0.6%	Mustard seeds	0.15 / 0.03	0.03
0.5%	Macadamia	0.07 / 0.05	0.03
0.5%	Soyabeans	0.01 / 0.01	0.02
0.4%	Laurel/bay leaves	3 / 1.9	0.02
0.3%	Pine nut kernels	0.07 / 0.05	0.02
0.2%	Oat	0.05 / 0.01	0.01
0.2%	Linseeds	0.06 / 0.01	0.01
0.09%	Peppercorn (black, green and white)	0.1 / 0.1	0.00
0.04%	Poultry: Fat tissue	0.02 / 0.02	0.00
0.02%	Cardamom	0.1 / 0.1	0.00

4%	Honey and other apiculture products	2 / 0.13	0.18
3%	Pumpkins	0.08 / 0.01	0.16
3%	Sweet corn	0.01 / 0.01	0.16
3%	Bovine: Fat tissue	0.3 / 0.16	0.16
3%	Chervil	3 / 1.9	0.15
3%	Limes	0.9 / 0.02	0.15
3%	Pistachios	0.07 / 0.05	0.13
3%	Bovine: Edible offals (other than liver and kidney)	0.05 / 0.04	0.13
3%	Beans	0.15 / 0.02	0.13
2%	Lentils	0.15 / 0.02	0.12
2%	Bovine: Liver	0.03 / 0.03	0.12
2%	Pecans	0.07 / 0.05	0.11
2%	Figs	0.03 / 0.01	0.11
2%	Walnuts	0.07 / 0.05	0.11
2%	Macadamia	0.07 / 0.05	0.11
2%	Sheep: Kidney	1 / 0.89	0.09
2%	Eggs: Chicken	0.02 / 0.02	0.09
2%	Cashew nuts	0.07 / 0.05	0.09
2%	Wheat	0.1 / 0.01	0.08
2%	Asparagus	0.01 / 0.01	0.08
1%	Almonds	0.07 / 0.05	0.07
1%	Peas	0.15 / 0.02	0.07
1%	Hazelnuts/cobnuts	0.07 / 0.05	0.06
1%	Soyabeans	0.01 / 0.01	0.06
1%	Pine nut kernels	0.07 / 0.05	0.05
1.0%	Barley	0.05 / 0.01	0.05
0.7%	Brazil nuts	0.07 / 0.05	0.03
0.6%	Eggs: Quail	0.02 / 0.02	0.03
0.4%	Poppy seeds	0.3 / 0.03	0.02
0.4%	Poppy seeds	0.3 / 0.03	0.02
0.3%	Rapeseeds/canola seeds	0.4 / 0.03	0.02
0.2%	Cardamom	0.1 / 0.1	0.01
0.2%	Eggs: Goose	0.02 / 0.02	0.01
0.1%	Garlic	0.02 / 0.01	0.01
0.1%	Oat	0.05 / 0.01	0.01
0.1%	Poultry: Fat tissue	0.02 / 0.02	0.01
0.10%	Linseeds	0.06 / 0.01	0.00
0.06%	Peppercorn (black, green and white)	0.1 / 0.1	0.00

Expand/collapse list

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

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
200%	Oranges / juice	0.9 / 0.19	10
170%	Gherkins / pickled	0.6 / 0.37	8.5
80%	Beans (with pods) / boiled	0.6 / 0.32	4.0
63%	Broccoli / boiled	0.06 / 0.04	3.2
56%	Cauliflowers / boiled	0.06 / 0.04	2.8
54%	Elderberries / juice	0.5 / 0.17	2.7
41%	Raspberries / juice	0.6 / 0.18	2.0
39%	Rose hips / jam	2 / 0.64	1.9
29%	Olives for oil production / oils	3 / 1.6	1.5
24%	Apples / juice	0.07 / 0.02	1.2
24%	Cranberries / juice	0.7 / 0.2	1.2
22%	Peaches / canned	0.08 / 0.04	1.1
21%	Courgettes / boiled	0.05 / 0.03	1.1
20%	Pumpkins / boiled	0.08 / 0.01	0.98
19%	Potatoes / fried	0.01 / 0.01	0.93

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)
57%	Oranges / juice	0.9 / 0.19	2.9
41%	Grapefruits / juice	0.9 / 0.19	2.1
33%	Cauliflowers / boiled	0.06 / 0.04	1.7
31%	Elderberries / juice	0.5 / 0.17	1.6
26%	Purslanes / boiled	0.6 / 0.31	1.3
22%	Peas (with pods) / boiled	0.6 / 0.32	1.1
19%	Broccoli / boiled	0.06 / 0.04	0.96
19%	Beans (without pods) / boiled	0.3 / 0.18	0.93
16%	Rose hips / jam	2 / 0.64	0.80
15%	Apples / juice	0.07 / 0.02	0.73
14%	Courgettes / boiled	0.05 / 0.03	0.69
12%	Pumpkins / boiled	0.08 / 0.01	0.61
11%	Peas (without pods) / boiled	0.3 / 0.18	0.56
8%	Wine grapes / juice	0.08 / 0.02	0.42
8%	Wine grapes / wine	0.08 / 0.04	0.38

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Acetamiprid is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Dinotefuran

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

Toxicological reference values

ADI (mg/kg bw/day):	0.22	ARfD (mg/kg bw):	1.75
Source of ADI:	JMPR	Source of ARfD:	ECHA
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:

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%	GEMS/Food G06	6.67	2%	Rice	0.2%	Tomatoes	0.1%	Table grapes	0.1%	0.3%
	3%	NL toddler	5.66	1%	Milk: Cattle	0.9%	Rice	0.2%	Table grapes	0.3%	0.1%
	2%	GEMS/Food G10	5.19	2%	Rice	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	0.1%
	2%	UK infant	3.94	0.9%	Rice	0.7%	Milk: Cattle	0.0%	Tomatoes	0.1%	0.0%
	2%	PT general	3.63	1%	Rice	0.2%	Wine grapes	0.1%	Tomatoes	0.1%	0.1%
	2%	FR toddler 2 3 yr	3.57	0.9%	Rice	0.5%	Milk: Cattle	0.0%	Tomatoes	0.1%	0.0%
	1%	UK toddler	3.17	0.9%	Rice	0.4%	Milk: Cattle	0.0%	Tomatoes	0.1%	0.0%
	1%	FR child 3 15 yr	3.09	0.7%	Rice	0.4%	Milk: Cattle	0.1%	Tomatoes	0.1%	0.1%
	1%	DE child	2.74	0.4%	Rice	0.4%	Milk: Cattle	0.1%	Table grapes	0.2%	0.1%
	1%	ES child	2.62	0.7%	Rice	0.2%	Milk: Cattle	0.1%	Tomatoes	0.1%	0.1%
	1%	GEMS/Food G07	2.47	0.5%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	0.1%
	1%	SE general	2.40	0.6%	Rice	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	0.1%
	1%	RO general	2.38	0.4%	Rice	0.2%	Milk: Cattle	0.2%	Wine grapes	0.1%	0.2%
	1%	NL child	2.34	0.4%	Milk: Cattle	0.3%	Rice	0.1%	Table grapes	0.2%	0.0%
	1%	GEMS/Food G15	2.28	0.5%	Rice	0.1%	Milk: Cattle	0.1%	Wine grapes	0.1%	0.1%
	1%	GEMS/Food G08	2.21	0.4%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	0.1%
	1%	GEMS/Food G11	2.21	0.4%	Rice	0.1%	Milk: Cattle	0.1%	Wine grapes	0.1%	0.1%
	1%	FI 3 yr	2.20	0.8%	Rice	0.0%	Tomatoes	0.0%	Table grapes	0.1%	0.0%
	0.9%	DK child	2.01	0.4%	Rice	0.2%	Milk: Cattle	0.0%	Tomatoes	0.1%	0.1%
	0.9%	IE adult	1.91	0.3%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	0.1%
	0.8%	UK vegetarian	1.86	0.6%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.0%	0.0%
	0.8%	UK adult	1.78	0.5%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.0%	0.0%
	0.8%	FI 6 yr	1.67	0.6%	Rice	0.0%	Tomatoes	0.0%	Potatoes	0.1%	0.0%
	0.7%	FR adult	1.52	0.2%	Rice	0.2%	Wine grapes	0.1%	Milk: Cattle	0.0%	0.0%
	0.7%	ES adult	1.49	0.4%	Rice	0.1%	Milk: Cattle	0.1%	Tomatoes	0.0%	0.1%
	0.6%	NL general	1.29	0.2%	Rice	0.2%	Milk: Cattle	0.1%	Wine grapes	0.1%	0.0%
	0.5%	IE child	1.20	0.4%	Rice	0.1%	Milk: Cattle	0.0%	Table grapes	0.0%	0.0%
	0.5%	IT toddler	1.16	0.3%	Rice	0.1%	Tomatoes	0.0%	Peaches	0.1%	0.1%
	0.5%	DE women 14-50 yr	1.15	0.2%	Milk: Cattle	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	0.1%
	0.5%	DE general	1.11	0.2%	Milk: Cattle	0.1%	Wine grapes	0.0%	Tomatoes	0.1%	0.1%
	0.5%	LT adult	1.11	0.3%	Rice	0.1%	Milk: Cattle	0.0%	Tomatoes	0.0%	0.0%
	0.5%	FR infant	1.07	0.3%	Milk: Cattle	0.1%	Rice	0.0%	Potatoes	0.0%	0.0%
	0.5%	IT adult	1.04	0.3%	Rice	0.1%	Tomatoes	0.0%	Peaches	0.0%	0.1%
	0.4%	DK adult	0.98	0.1%	Rice	0.1%	Wine grapes	0.1%	Milk: Cattle	0.0%	0.0%
	0.3%	FI adult	0.73	0.2%	Rice	0.0%	Tomatoes	0.0%	Wine grapes	0.1%	0.0%
	0.1%	PL general	0.33	0.1%	Tomatoes	0.0%	Table grapes	0.0%	Potatoes	0.0%	0.1%

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 of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sweet peppers/bell peppers	0.5 / 0.55	33	0.9%	Aubergines/egg plants	0.5 / 0.55	15
2%	Tomatoes	0.6 / 0.55	32	0.5%	Sweet peppers/bell peppers	0.5 / 0.55	9.0
0.8%	Aubergines/egg plants	0.5 / 0.55	14	0.5%	Tomatoes	0.6 / 0.55	8.7
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Tomatoes / juice	0.6 / 0.15	2.9	0.1%	Tomatoes / sauce/puree	0.6 / 0.15	1.2
0.1%	Tomatoes / sauce/puree	0.6 / 0.15	1.4	0.05%	Okra, lady's fingers / boiled	0.5 / 0.55	0.89
Expand/collapse list							

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.

Cyantraniliprole

European Food Safety Authority

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:	EC	Source of ARfD:	EC
Year of evaluation:	2016	Year of evaluation:	2016

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)	20%	FR adult	1.97	13%	Wine grapes	6%	Tea (dried leaves of Camellia sinensis)	0.6%	Table grapes		20%
	16%	PT general	1.56	14%	Wine grapes	2%	Table grapes	0.1%	Soyabeans		16%
	15%	IE adult	1.53	7%	Wine grapes	5%	Tea (dried leaves of Camellia sinensis)	1%	Table grapes		15%
	13%	GEMS/Food G07	1.29	8%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	2%	Table grapes		13%
	11%	NL toddler	1.13	9%	Table grapes	2%	Raspberries (red and yellow)	0.4%	Tea (dried leaves of Camellia sinens		11%
	11%	GEMS/Food G11	1.10	6%	Wine grapes	2%	Table grapes	2%	Tea (dried leaves of Camellia sinens		11%
	11%	RO general	1.08	9%	Wine grapes	1%	Table grapes	0.3%	Eggs: Chicken		11%
	10%	GEMS/Food G08	0.98	6%	Wine grapes	2%	Table grapes	1%	Tea (dried leaves of Camellia sinens		10%
	9%	DE child	0.94	8%	Table grapes	0.6%	Raspberries (red and yellow)	0.5%	Eggs: Chicken		9%
	9%	GEMS/Food G15	0.91	6%	Wine grapes	2%	Table grapes	0.6%	Tea (dried leaves of Camellia sinens		9%
	9%	GEMS/Food G06	0.90	6%	Table grapes	2%	Tea (dried leaves of Camellia sinensis)	0.4%	Soyabeans		9%
	9%	UK adult	0.89	6%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	0.3%	Table grapes		9%
	8%	NL child	0.84	6%	Table grapes	1%	Raspberries (red and yellow)	0.7%	Tea (dried leaves of Camellia sinens		8%
	8%	DE women 14-50 yr	0.80	5%	Wine grapes	2%	Table grapes	1%	Tea (dried leaves of Camellia sinens		8%
	8%	DE general	0.77	5%	Wine grapes	1%	Table grapes	1%	Tea (dried leaves of Camellia sinens		8%
	7%	UK vegetarian	0.74	5%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	0.4%	Table grapes		7%
	7%	DK adult	0.70	5%	Wine grapes	1.0%	Table grapes	0.4%	Tea (dried leaves of Camellia sinens		7%
	7%	NL general	0.67	3%	Wine grapes	1%	Tea (dried leaves of Camellia sinensis)	1%	Table grapes		7%
	7%	GEMS/Food G10	0.66	2%	Wine grapes	2%	Table grapes	1%	Tea (dried leaves of Camellia sinens		7%
	6%	FR child 3 15 yr	0.59	2%	Wine grapes	2%	Table grapes	1.0%	Tea (dried leaves of Camellia sinens		6%
	5%	UK toddler	0.47	1%	Table grapes	1%	Tea (dried leaves of Camellia sinensis)	1%	Raspberries (red and yellow)		5%
	4%	UK infant	0.36	2%	Tea (dried leaves of Camellia sinensis)	0.6%	Eggs: Chicken	0.2%	Dewberries		4%
	3%	FI 3 yr	0.32	2%	Raspberries (red and yellow)	1%	Table grapes	0.0%	Peas		3%
	3%	ES adult	0.29	2%	Wine grapes	0.2%	Table grapes	0.2%	Eggs: Chicken		3%
	3%	FI adult	0.26	2%	Wine grapes	0.4%	Table grapes	0.4%	Raspberries (red and yellow)		3%
	2%	FI 6 yr	0.24	1%	Raspberries (red and yellow)	1.0%	Table grapes	0.0%	Beans		2%
	2%	FR toddler 2 3 yr	0.21	1%	Wine grapes	0.3%	Eggs: Chicken	0.2%	Raspberries (red and yellow)		2%
	2%	PL general	0.19	2%	Table grapes	0.1%	Raspberries (red and yellow)	0.0%	Beans		2%
	1%	DK child	0.14	1%	Table grapes	0.4%	Eggs: Chicken	0.0%	Raspberries (red and yellow)		1%
	1.0%	SE general	0.10	0.4%	Eggs: Chicken	0.3%	Dewberries	0.1%	Blackberries		1.0%
	0.8%	IT adult	0.08	0.7%	Table grapes	0.0%	Beans	0.0%	Lentils		0.8%
	0.7%	ES child	0.07	0.3%	Eggs: Chicken	0.2%	Table grapes	0.1%	Lentils		0.7%
	0.6%	IT toddler	0.06	0.6%	Table grapes	0.0%	Beans	0.0%	Raspberries (red and yellow)		0.6%
	0.5%	IE child	0.05	0.3%	Table grapes	0.1%	Tea (dried leaves of Camellia sinensis)	0.1%	Eggs: Chicken		0.5%
	0.4%	FR infant	0.04	0.2%	Wine grapes	0.1%	Raspberries (red and yellow)	0.1%	Eggs: Chicken		0.4%
	0.3%	LT adult	0.03	0.2%	Eggs: Chicken	0.1%	Raspberries (red and yellow)	0.1%	Table grapes		0.3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Cyantraniliprole 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Imazapyx

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

Toxicological reference values

ADI (mg/kg bw/day):	2.5	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:

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)
	0.13%	GEMS/Food G11	3.30	0.1%	Soyabeans	0.01%	Wheat	0.0%	Milk: Cattle	0.0%	0.0%
	0.12%	GEMS/Food G10	3.02	0.1%	Soyabeans	0.0%	Wheat	0.0%	Poultry: Muscle/meat	0.0%	0.0%
	0.09%	GEMS/Food G08	2.16	0.1%	Soyabeans	0.0%	Wheat	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.08%	GEMS/Food G07	2.05	0.0%	Soyabeans	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	0.0%
	0.08%	NL toddler	2.05	0.0%	Milk: Cattle	0.0%	Maize/corn	0.0%	Wheat	0.1%	0.0%
	0.08%	GEMS/Food G15	2.03	0.0%	Soyabeans	0.0%	Wheat	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.07%	GEMS/Food G06	1.81	0.0%	Soyabeans	0.0%	Wheat	0.0%	Maize/corn	0.0%	0.0%
	0.05%	NL child	1.22	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	0.0%
	0.04%	FR child 3 15 yr	1.07	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.04%	DE child	1.00	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Apples	0.0%	0.0%
	0.04%	FR toddler 2 3 yr	0.92	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.04%	UK infant	0.90	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.04%	DK child	0.88	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.03%	ES child	0.86	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.03%	RO general	0.86	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.03%	UK toddler	0.80	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.03%	SE general	0.77	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.0%	Milk: Cattle	0.0%	0.0%
	0.03%	PT general	0.71	0.0%	Wheat	0.0%	Soyabeans	0.0%	Potatoes	0.0%	0.0%
	0.03%	IT toddler	0.63	0.0%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.0%	0.0%
	0.02%	NL general	0.60	0.0%	Wheat	0.0%	Soyabeans	0.0%	Milk: Cattle	0.0%	0.0%
	0.02%	DE women 14-50 yr	0.59	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	0.0%
	0.02%	IE adult	0.58	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	0.0%
	0.02%	DE general	0.57	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.02%	ES adult	0.47	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	0.0%
	0.02%	FR adult	0.44	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.02%	IT adult	0.41	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.0%	0.0%
	0.02%	FR infant	0.39	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%
	0.01%	DK adult	0.32	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.01%	LT adult	0.30	0.0%	Wheat	0.0%	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	0.0%
	0.01%	UK adult	0.30	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.0%	Milk: Cattle	0.0%	0.0%
	0.01%	UK vegetarian	0.29	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	0.0%
	0.01%	FI 3 yr	0.26	0.0%	Wheat	0.0%	Potatoes	0.0%	Bananas	0.0%	0.0%
	0.01%	FI 6 yr	0.20	0.0%	Wheat	0.0%	Potatoes	0.0%	Bananas	0.0%	0.0%
	0.01%	IE child	0.18	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.0%
	0.01%	FI adult	0.16	0.0%	Coffee beans	0.0%	Wheat	0.0%	Soyabeans	0.0%	0.0%
	0.00%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Imazapyr 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Cyflumetofen

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

Toxicological reference values

ADI (mg/kg bw/day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
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 : ---

	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)	2%	NL toddler	3.99	0.8%	Apples	0.4%	Milk: Cattle	0.3%	Pears	0.6%	0.0%
	2%	DE child	3.45	1.0%	Apples	0.3%	Oranges	0.2%	Table grapes	0.2%	0.1%
	1%	NL child	2.19	0.4%	Apples	0.1%	Milk: Cattle	0.1%	Table grapes	0.3%	0.0%
	1.0%	GEMS/Food G06	1.62	0.3%	Tomatoes	0.1%	Table grapes	0.1%	Oranges	0.2%	0.0%
	0.9%	FR child 3 15 yr	1.58	0.3%	Oranges	0.1%	Milk: Cattle	0.1%	Apples	0.3%	0.0%
	0.8%	FR toddler 2 3 yr	1.44	0.2%	Apples	0.2%	Milk: Cattle	0.1%	Oranges	0.3%	0.0%
	0.8%	DE women 14-50 yr	1.40	0.2%	Apples	0.2%	Oranges	0.1%	Wine grapes	0.2%	0.0%
	0.8%	RO general	1.33	0.2%	Wine grapes	0.2%	Tomatoes	0.1%	Apples	0.2%	0.0%
	0.8%	DE general	1.33	0.2%	Apples	0.1%	Oranges	0.1%	Wine grapes	0.2%	0.0%
	0.8%	GEMS/Food G07	1.30	0.2%	Wine grapes	0.1%	Oranges	0.1%	Tomatoes	0.2%	0.0%
	0.7%	GEMS/Food G11	1.25	0.1%	Apples	0.1%	Wine grapes	0.1%	Tomatoes	0.2%	0.0%
	0.7%	IE adult	1.23	0.1%	Wine grapes	0.1%	Oranges	0.1%	Grapefruits	0.1%	0.0%
	0.7%	GEMS/Food G08	1.16	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Apples	0.2%	0.0%
	0.7%	GEMS/Food G15	1.16	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Apples	0.2%	0.0%
	0.7%	PT general	1.15	0.3%	Wine grapes	0.1%	Tomatoes	0.1%	Apples	0.1%	0.0%
	0.7%	UK toddler	1.15	0.2%	Oranges	0.1%	Apples	0.1%	Milk: Cattle	0.2%	0.0%
	0.7%	UK infant	1.11	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Oranges	0.3%	0.0%
	0.6%	GEMS/Food G10	1.10	0.1%	Tomatoes	0.1%	Oranges	0.1%	Apples	0.2%	0.0%
	0.6%	DK child	1.08	0.2%	Apples	0.1%	Cucumbers	0.1%	Milk: Cattle	0.2%	0.1%
	0.6%	ES child	1.07	0.2%	Oranges	0.1%	Tomatoes	0.1%	Apples	0.2%	0.0%
	0.6%	FR adult	0.98	0.3%	Wine grapes	0.1%	Apples	0.0%	Oranges	0.1%	0.0%
	0.6%	SE general	0.94	0.1%	Apples	0.1%	Milk: Cattle	0.1%	Tomatoes	0.2%	0.0%
	0.5%	NL general	0.91	0.1%	Apples	0.1%	Oranges	0.1%	Wine grapes	0.1%	0.0%
	0.5%	ES adult	0.77	0.1%	Oranges	0.1%	Tomatoes	0.1%	Apples	0.1%	0.0%
	0.4%	IT toddler	0.73	0.1%	Tomatoes	0.1%	Apples	0.0%	Wheat	0.1%	0.0%
	0.4%	DK adult	0.67	0.1%	Wine grapes	0.1%	Apples	0.0%	Tomatoes	0.1%	0.0%
	0.4%	UK vegetarian	0.67	0.1%	Wine grapes	0.1%	Oranges	0.1%	Tomatoes	0.1%	0.0%
	0.4%	FR infant	0.67	0.1%	Apples	0.1%	Milk: Cattle	0.0%	Courgettes	0.2%	
	0.4%	FI adult	0.66	0.1%	Coffee beans	0.1%	Tomatoes	0.0%	Apples	0.0%	0.2%
	0.4%	FI 3 yr	0.65	0.1%	Apples	0.1%	Tomatoes	0.1%	Cucumbers	0.1%	0.1%
	0.4%	UK adult	0.62	0.1%	Wine grapes	0.0%	Oranges	0.0%	Tomatoes	0.1%	0.0%
	0.4%	PL general	0.61	0.2%	Apples	0.1%	Tomatoes	0.0%	Table grapes	0.0%	0.0%
	0.4%	IT adult	0.60	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges	0.0%	0.0%
	0.3%	LT adult	0.56	0.1%	Apples	0.1%	Tomatoes	0.0%	Milk: Cattle	0.1%	0.0%
	0.3%	FI 6 yr	0.50	0.0%	Apples	0.0%	Tomatoes	0.0%	Cucumbers	0.1%	0.0%
	0.1%	IE child	0.16	0.0%	Apples	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	0.0%

Conclusion:

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

The long-term intake of residues of Cyflumetofen 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Oxathiapiprolin

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

Toxicological reference values

ADI (mg/kg bw/day):	0.14	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
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 : ---

	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	4.46	2%	Spinaches	0.4%	Milk: Cattle	0.2%	Escaroles/broad-leaved endives	0.8%	2%
	1%	NL child	2.02	0.6%	Spinaches	0.2%	Milk: Cattle	0.1%	Escaroles/broad-leaved endives	0.4%	1%
	1%	SE general	2.00	0.4%	Chinese cabbages/pe-tsai	0.4%	Lettuces	0.2%	Spinaches	0.2%	1%
	1%	DE child	1.99	0.5%	Spinaches	0.1%	Milk: Cattle	0.1%	Table grapes	0.4%	1%
	1%	GEMS/Food G10	1.79	0.3%	Chinese cabbages/pe-tsai	0.3%	Lettuces	0.1%	Spinaches	0.2%	1%
	1%	IT adult	1.67	0.4%	Lettuces	0.2%	Spinaches	0.2%	Other spinach and similar	0.1%	1%
	1%	ES adult	1.58	0.5%	Lettuces	0.2%	Chards/beet leaves	0.2%	Spinaches	0.1%	1%
	1%	ES child	1.58	0.4%	Lettuces	0.2%	Spinaches	0.2%	Chards/beet leaves	0.2%	0.9%
	1%	FR infant	1.50	0.6%	Spinaches	0.1%	Milk: Cattle	0.1%	Leeks	0.2%	0.9%
	1%	IE adult	1.43	0.3%	Spinaches	0.1%	Wine grapes	0.1%	Lettuces	0.2%	0.9%
	1%	GEMS/Food G11	1.42	0.2%	Spinaches	0.1%	Leeks	0.1%	Wine grapes	0.2%	0.8%
	1%	FR toddler 2 3 yr	1.41	0.4%	Spinaches	0.2%	Milk: Cattle	0.1%	Leeks	0.4%	0.6%
	1.0%	NL general	1.38	0.4%	Spinaches	0.1%	Escaroles/broad-leaved endives	0.1%	Lettuces	0.2%	0.8%
	1.0%	IT toddler	1.36	0.3%	Lettuces	0.1%	Chards/beet leaves	0.1%	Spinaches	0.1%	0.9%
	1.0%	FR child 3 15 yr	1.34	0.3%	Spinaches	0.2%	Milk: Cattle	0.1%	Other lettuce and other salad plants	0.3%	0.6%
	0.9%	GEMS/Food G06	1.31	0.1%	Spinaches	0.1%	Tomatoes	0.1%	Lettuces	0.2%	0.8%
	0.9%	GEMS/Food G07	1.27	0.2%	Lettuces	0.1%	Wine grapes	0.1%	Spinaches	0.2%	0.7%
	0.9%	GEMS/Food G08	1.21	0.2%	Lettuces	0.1%	Wine grapes	0.1%	Spinaches	0.2%	0.7%
	0.7%	FR adult	1.05	0.2%	Wine grapes	0.1%	Other lettuce and other salad plants	0.1%	Spinaches	0.1%	0.6%
	0.7%	DE women 14-50 yr	1.01	0.1%	Spinaches	0.1%	Lettuces	0.1%	Milk: Cattle	0.2%	0.5%
	0.7%	GEMS/Food G15	0.97	0.1%	Lettuces	0.1%	Wine grapes	0.1%	Head cabbages	0.2%	0.5%
	0.7%	DE general	0.96	0.1%	Spinaches	0.1%	Lettuces	0.1%	Milk: Cattle	0.2%	0.5%
	0.6%	RO general	0.88	0.1%	Wine grapes	0.1%	Head cabbages	0.1%	Milk: Cattle	0.2%	0.4%
	0.5%	PT general	0.76	0.2%	Wine grapes	0.1%	Lettuces	0.1%	Kales	0.1%	0.5%
	0.5%	DK child	0.75	0.1%	Lettuces	0.1%	Milk: Cattle	0.0%	Rye	0.2%	0.3%
	0.5%	FI adult	0.73	0.2%	Coffee beans	0.1%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.2%	0.3%
	0.5%	UK infant	0.71	0.3%	Milk: Cattle	0.0%	Spinaches	0.0%	Potatoes	0.4%	0.1%
	0.5%	UK toddler	0.66	0.1%	Milk: Cattle	0.1%	Spinaches	0.0%	Wheat	0.3%	0.2%
	0.5%	UK vegetarian	0.66	0.1%	Lettuces	0.1%	Spinaches	0.1%	Wine grapes	0.1%	0.4%
	0.5%	FI 3 yr	0.63	0.2%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	Potatoes	0.1%	0.4%
	0.4%	FI 6 yr	0.62	0.1%	Spinaches	0.1%	Lettuces	0.1%	Chinese cabbages/pe-tsai	0.1%	0.4%
	0.4%	UK adult	0.55	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches	0.1%	0.3%
	0.4%	DK adult	0.52	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Milk: Cattle	0.1%	0.3%
	0.3%	PL general	0.35	0.0%	Chinese cabbages/pe-tsai	0.0%	Head cabbages	0.0%	Table grapes	0.0%	0.2%
	0.2%	LT adult	0.33	0.1%	Lettuces	0.0%	Head cabbages	0.0%	Milk: Cattle	0.1%	0.2%
	0.1%	IE child	0.13	0.0%	Milk: Cattle	0.0%	Spinaches	0.0%	Wheat	0.0%	0.0%

Conclusion:

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

The long-term intake of residues of Oxathiapiprolin 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Tetraniliprole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	2	ARfD (mg/kg bw):	not necessay
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2021	Year of evaluation:	2021

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.01%	FR toddler 2 3 yr	0.15	0.01%	Mandarins						0.0%
	0.01%	NL child	0.12	0.01%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	IE adult	0.10	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	SE general	0.08	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	NL toddler	0.08	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	DE child	0.08	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FI 3 yr	0.07	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FI 6 yr	0.06	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G06	0.06	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	UK toddler	0.05	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G08	0.05	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	IT toddler	0.04	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G07	0.04	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G10	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	NL general	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	ES child	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G11	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FR child 3 15 yr	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	IT adult	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	GEMS/Food G15	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FR infant	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	ES adult	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FI adult	0.03	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	DK adult	0.02	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	DE women 14-50 yr	0.02	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	DK child	0.02	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	PT general	0.02	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	DE general	0.02	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	FR adult	0.01	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.00%	UK adult	0.01	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.0%	RO general	0.01	0.00%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.0%	UK vegetarian	0.01	0.0%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.0%	PL general	0.01	0.0%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.0%	LT adult	0.00	0.0%	Mandarins		FRUIT AND TREE NUTS				0.0%
	0.0%	IE child	0.00	0.0%	Mandarins		FRUIT AND TREE NUTS				0.0%
		UK infant			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Tetraniliprole 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Isoflucypram (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
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)
3%	NL toddler	1.28	1%	Milk: Cattle	0.3%	Apples	0.2%	Wheat	3%	0.2%
2%	NL child	0.69	0.6%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Wheat	2%	0.2%
2%	DE child	0.65	0.5%	Milk: Cattle	0.3%	Apples	0.2%	Wheat	1%	0.2%
2%	UK infant	0.63	1.0%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	0.1%
1%	FR child 3 15 yr	0.58	0.6%	Milk: Cattle	0.2%	Wheat	0.1%	Sugar beet roots	1%	0.2%
1%	FR toddler 2 3 yr	0.57	0.7%	Milk: Cattle	0.2%	Wheat	0.1%	Apples	1%	0.2%
1%	UK toddler	0.48	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.2%
1%	DK child	0.45	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Rye	0.9%	0.2%
1%	GEMS/Food G06	0.45	0.4%	Wheat	0.1%	Tomatoes	0.1%	Milk: Cattle	0.8%	0.4%
1%	GEMS/Food G11	0.44	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	0.9%	0.2%
1%	RO general	0.43	0.3%	Milk: Cattle	0.3%	Wheat	0.1%	Potatoes	0.8%	0.3%
1%	GEMS/Food G15	0.42	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Potatoes	0.8%	0.3%
1%	GEMS/Food G07	0.42	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Potatoes	0.8%	0.2%
1%	GEMS/Food G08	0.41	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Potatoes	0.8%	0.2%
1%	SE general	0.41	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Bovine: Muscle/meat	0.9%	0.2%
1%	GEMS/Food G10	0.40	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Soyabeans	0.8%	0.2%
1.0%	ES child	0.40	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	0.8%	0.2%
0.9%	DE women 14-50 yr	0.37	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Wheat	0.8%	0.1%
0.9%	DE general	0.36	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Wheat	0.8%	0.1%
0.9%	IE adult	0.35	0.1%	Wheat	0.1%	Milk: Cattle	0.1%	Sweet potatoes	0.8%	0.1%
0.8%	NL general	0.31	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Sugar beet roots	0.7%	0.1%
0.7%	FR infant	0.30	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.7%	0.0%
0.6%	PT general	0.25	0.2%	Wheat	0.1%	Potatoes	0.1%	Wine grapes	0.4%	0.2%
0.6%	IT toddler	0.23	0.3%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.2%	0.3%
0.6%	ES adult	0.23	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Oranges	0.4%	0.1%
0.5%	FR adult	0.22	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Wine grapes	0.4%	0.1%
0.4%	FI 3 yr	0.18	0.1%	Potatoes	0.1%	Wheat	0.0%	Bananas	0.4%	0.1%
0.4%	DK adult	0.18	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.4%	0.1%
0.4%	LT adult	0.17	0.1%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	0.4%	0.1%
0.4%	UK vegetarian	0.17	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.3%	0.1%
0.4%	IT adult	0.16	0.2%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.2%	0.2%
0.4%	UK adult	0.15	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.3%	0.1%
0.4%	FI 6 yr	0.14	0.1%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.3%	0.1%
0.3%	FI adult	0.13	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	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	0.09	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.2%	0.1%

Conclusion:

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

The long-term intake of residues of Isoflucypram (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): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Wheat	0.05 / 0.02	0.29	0.2%	Wheat	0.05 / 0.02	0.17
0.1%	Barley	0.1 / 0.02	0.11	0.10%	Barley	0.1 / 0.02	0.10
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Wheat / milling (flour)	0.05 / 0.02	0.24	0.1%	Barley / beer	0.1 / 0	0.14
0.1%	Wheat / milling (wholemeal)-baking	0.05 / 0.02	0.11	0.09%	Wheat / bread/pizza	0.05 / 0.02	0.09
0.1%	Barley / cooked	0.1 / 0.02	0.07	0.08%	Wheat / pasta	0.05 / 0.02	0.08
0.0%	Barley / milling (flour)	0.1 / 0.02	0.04	0.07%	Wheat / bread (wholemeal)	0.05 / 0.02	0.07
Expand/collapse list							

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,4-Dimethylnaphthalene (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
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:

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)	83%	NL toddler	82.69	64%	Potatoes	13%	Milk: Cattle	1%	Apples	0.0%	0.1%
	81%	PT general	81.39	80%	Potatoes	0.4%	Wheat	0.2%	Wine grapes		
	72%	FI 3 yr	71.84	71%	Potatoes	0.1%	Bananas	0.1%	Wheat	0.0%	
	67%	SE general	67.11	62%	Potatoes	3%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.0%	
	63%	GEMS/Food G11	63.08	59%	Potatoes	2%	Milk: Cattle	0.4%	Soyabeans		0.2%
	62%	GEMS/Food G08	62.47	59%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		0.2%
	61%	RO general	60.70	56%	Potatoes	2%	Milk: Cattle	0.5%	Wheat	0.0%	0.2%
	61%	GEMS/Food G07	60.64	56%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		0.3%
	61%	NL child	60.62	52%	Potatoes	5%	Milk: Cattle	0.8%	Sugar beet roots	0.0%	0.1%
	59%	UK infant	59.44	49%	Potatoes	8%	Milk: Cattle	0.4%	Eggs: Chicken	0.0%	0.1%
	59%	FI 6 yr	59.14	58%	Potatoes	0.1%	Wheat	0.1%	Bananas	0.0%	
	59%	UK toddler	58.99	52%	Potatoes	4%	Milk: Cattle	0.4%	Wheat	0.0%	0.1%
	58%	GEMS/Food G15	57.67	53%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		0.2%
	52%	PL general	52.07	51%	Potatoes	0.2%	Apples	0.1%	Tomatoes		
	49%	LT adult	49.39	48%	Potatoes	0.8%	Milk: Cattle	0.2%	Apples		0.1%
	48%	GEMS/Food G10	48.47	44%	Potatoes	1%	Milk: Cattle	0.4%	Poultry: Muscle/meat		0.4%
	47%	DE child	47.22	39%	Potatoes	4%	Milk: Cattle	1%	Apples	0.0%	0.2%
	42%	DK child	41.84	36%	Potatoes	3%	Milk: Cattle	0.5%	Rye		0.1%
	40%	NL general	39.99	36%	Potatoes	2%	Milk: Cattle	0.3%	Sugar beet roots	0.0%	0.1%
	39%	IE adult	38.60	34%	Potatoes	0.9%	Milk: Cattle	0.5%	Sheep: Liver		0.1%
	37%	FR toddler 2 3 yr	36.66	28%	Potatoes	6%	Milk: Cattle	0.3%	Apples	0.0%	0.1%
	34%	GEMS/Food G06	33.88	30%	Potatoes	0.7%	Wheat	0.5%	Milk: Cattle		0.2%
	33%	FR infant	33.25	29%	Potatoes	4%	Milk: Cattle	0.2%	Apples	0.0%	0.0%
	33%	ES child	32.63	28%	Potatoes	3%	Milk: Cattle	0.4%	Wheat	0.0%	0.3%
	31%	FR child 3 15 yr	30.76	23%	Potatoes	5%	Milk: Cattle	0.4%	Wheat	0.0%	0.2%
	23%	DE general	23.04	18%	Potatoes	3%	Milk: Cattle	0.4%	Sugar beet roots	0.0%	0.1%
	23%	UK adult	22.61	21%	Potatoes	0.6%	Milk: Cattle	0.2%	Wheat	0.0%	0.1%
	22%	UK vegetarian	22.23	21%	Potatoes	0.7%	Milk: Cattle	0.2%	Wheat		0.0%
	21%	DK adult	21.23	19%	Potatoes	1%	Milk: Cattle	0.1%	Wheat		0.1%
	21%	DE women 14-50 yr	21.21	16%	Potatoes	3%	Milk: Cattle	0.4%	Sugar beet roots	0.0%	0.1%
	19%	FI adult	18.84	18%	Potatoes	0.5%	Coffee beans	0.1%	Rye		
	17%	ES adult	16.55	14%	Potatoes	1%	Milk: Cattle	0.2%	Wheat	0.0%	0.2%
	15%	IT toddler	14.91	13%	Potatoes	0.6%	Wheat	0.1%	Other cereals		
	14%	FR adult	13.52	11%	Potatoes	0.9%	Milk: Cattle	0.2%	Wine grapes	0.0%	0.1%
	10%	IE child	10.36	9%	Potatoes	0.8%	Milk: Cattle	0.1%	Wheat	0.0%	0.0%
	10%	IT adult	10.09	9%	Potatoes	0.4%	Wheat	0.1%	Tomatoes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,4-Dimethylnaphthalene (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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Florylpicoxamid (F)

LOQs (mg/kg) range from: 0.01 to: 0.02

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:	2023	Year of evaluation:	2023

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
2%	NL toddler	2.42	0.8%	Milk: Cattle	0.6%	Table grapes	0.1%	Tomatoes	0.4%	2%
2%	DE child	1.60	0.5%	Table grapes	0.3%	Milk: Cattle	0.1%	Strawberries	0.3%	1%
2%	GEMS/Food G06	1.59	0.4%	Tomatoes	0.4%	Table grapes	0.2%	Wheat	0.2%	1%
2%	RO general	1.56	0.6%	Wine grapes	0.2%	Tomatoes	0.2%	Milk: Cattle	0.1%	1%
1%	NL child	1.49	0.4%	Table grapes	0.3%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	1%
1%	PT general	1.41	0.9%	Wine grapes	0.1%	Tomatoes	0.1%	Table grapes	0.1%	1%
1%	GEMS/Food G07	1.35	0.6%	Wine grapes	0.1%	Tomatoes	0.1%	Table grapes	0.2%	1%
1%	GEMS/Food G15	1.28	0.4%	Wine grapes	0.1%	Tomatoes	0.1%	Table grapes	0.2%	1%
1%	FR adult	1.28	0.9%	Wine grapes	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	1%
1%	FR child 3 15 yr	1.25	0.3%	Milk: Cattle	0.1%	Wine grapes	0.1%	Table grapes	0.1%	1%
1%	GEMS/Food G08	1.23	0.4%	Wine grapes	0.1%	Tomatoes	0.1%	Table grapes	0.2%	1%
1%	GEMS/Food G11	1.21	0.4%	Wine grapes	0.2%	Table grapes	0.1%	Tomatoes	0.2%	1.0%
1%	IE adult	1.18	0.5%	Wine grapes	0.1%	Table grapes	0.1%	Melons	0.2%	1.0%
1%	DE women 14-50 yr	1.06	0.3%	Wine grapes	0.2%	Milk: Cattle	0.1%	Table grapes	0.1%	1.0%
1%	DE general	1.01	0.3%	Wine grapes	0.2%	Milk: Cattle	0.1%	Table grapes	0.1%	0.9%
1%	GEMS/Food G10	1.00	0.2%	Tomatoes	0.2%	Wine grapes	0.1%	Table grapes	0.2%	0.8%
1.0%	FR toddler 2 3 yr	0.96	0.4%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.1%	0.8%
0.9%	UK infant	0.94	0.5%	Milk: Cattle	0.1%	Strawberries	0.1%	Wheat	0.1%	0.8%
0.9%	DK child	0.89	0.2%	Milk: Cattle	0.1%	Cucumbers	0.1%	Wheat	0.1%	0.7%
0.9%	UK toddler	0.87	0.3%	Milk: Cattle	0.1%	Table grapes	0.1%	Wheat	0.1%	0.8%
0.8%	NL general	0.80	0.2%	Wine grapes	0.1%	Milk: Cattle	0.1%	Table grapes	0.1%	0.7%
0.8%	DK adult	0.77	0.4%	Wine grapes	0.1%	Milk: Cattle	0.1%	Table grapes	0.0%	0.7%
0.8%	SE general	0.76	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Tomatoes	0.1%	0.6%
0.7%	ES child	0.72	0.2%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wheat	0.1%	0.6%
0.7%	UK adult	0.68	0.4%	Wine grapes	0.1%	Tomatoes	0.0%	Milk: Cattle	0.0%	0.6%
0.6%	UK vegetarian	0.63	0.3%	Wine grapes	0.1%	Tomatoes	0.0%	Wheat	0.1%	0.6%
0.6%	ES adult	0.61	0.2%	Wine grapes	0.1%	Tomatoes	0.1%	Milk: Cattle	0.1%	0.5%
0.5%	FI 3 yr	0.52	0.1%	Strawberries	0.1%	Table grapes	0.1%	Tomatoes	0.1%	0.4%
0.5%	IT toddler	0.51	0.2%	Tomatoes	0.1%	Wheat	0.0%	Table grapes	0.1%	0.4%
0.5%	FR infant	0.49	0.2%	Milk: Cattle	0.0%	Strawberries	0.0%	Sugar beet roots	0.1%	0.4%
0.4%	IT adult	0.41	0.1%	Tomatoes	0.1%	Wheat	0.0%	Table grapes	0.1%	0.4%
0.4%	FI 6 yr	0.41	0.1%	Strawberries	0.1%	Table grapes	0.1%	Tomatoes	0.1%	0.3%
0.4%	FI adult	0.40	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Coffee beans	0.1%	0.3%
0.3%	PL general	0.34	0.1%	Table grapes	0.1%	Tomatoes	0.0%	Potatoes	0.1%	0.3%
0.3%	LT adult	0.33	0.1%	Tomatoes	0.1%	Milk: Cattle	0.0%	Potatoes	0.1%	0.3%
0.2%	IE child	0.15	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Table grapes	0.0%	0.1%

Conclusion:

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

The long-term intake of residues of Florylpicoxamid (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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Isocycloseram (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.08
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2023	Year of evaluation:	2023

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)	13%	NL toddler	2.67	6%	Apples	2%	Pears	0.7%	Oranges	2%	12%
	12%	DE child	2.32	7%	Apples	1%	Oranges	0.7%	Cherries (sweet)	0.9%	11%
	7%	NL child	1.42	3%	Apples	0.6%	Pears	0.5%	Oranges	1%	6%
	5%	GEMS/Food G06	1.08	2%	Tomatoes	0.5%	Apples	0.4%	Wheat	1%	4%
	4%	FR child 3 15 yr	0.88	1%	Oranges	0.9%	Apples	0.4%	Tomatoes	1.0%	4%
	4%	FR toddler 2 3 yr	0.86	2%	Apples	0.5%	Oranges	0.3%	Mandarins	0.8%	4%
	4%	DE women 14-50 yr	0.80	1%	Apples	0.6%	Oranges	0.4%	Tomatoes	0.7%	3%
	4%	RO general	0.79	1.0%	Tomatoes	0.7%	Apples	0.3%	Head cabbages	0.9%	3%
	4%	GEMS/Food G11	0.79	0.8%	Apples	0.5%	Tomatoes	0.4%	Soyabeans	1.0%	3%
	4%	GEMS/Food G15	0.78	0.6%	Tomatoes	0.6%	Apples	0.3%	Sweet peppers/bell peppers	1.0%	3%
	4%	GEMS/Food G08	0.75	0.6%	Apples	0.6%	Tomatoes	0.2%	Soyabeans	1%	3%
	4%	GEMS/Food G10	0.75	0.7%	Tomatoes	0.4%	Apples	0.4%	Soyabeans	1.0%	3%
	4%	GEMS/Food G07	0.74	0.5%	Tomatoes	0.5%	Apples	0.4%	Oranges	1%	3%
	4%	IE adult	0.74	0.4%	Apples	0.3%	Oranges	0.2%	Pears	1.0%	3%
	4%	DE general	0.73	1%	Apples	0.5%	Oranges	0.3%	Tomatoes	0.6%	3%
	4%	DK child	0.73	1%	Apples	0.4%	Pears	0.3%	Rye	0.9%	3%
	3%	ES child	0.69	0.7%	Oranges	0.6%	Apples	0.5%	Tomatoes	0.7%	3%
	3%	UK toddler	0.68	0.9%	Apples	0.6%	Oranges	0.3%	Tomatoes	0.9%	3%
	3%	UK infant	0.64	0.8%	Apples	0.4%	Oranges	0.4%	Milk: Cattle	0.8%	3%
	3%	SE general	0.64	0.6%	Apples	0.4%	Tomatoes	0.2%	Oranges	0.8%	3%
	3%	IT toddler	0.55	0.7%	Tomatoes	0.5%	Apples	0.3%	Wheat	0.6%	2%
	3%	NL general	0.54	0.8%	Apples	0.3%	Oranges	0.2%	Tomatoes	0.7%	2%
	3%	PT general	0.53	0.6%	Apples	0.4%	Tomatoes	0.3%	Potatoes	0.8%	2%
	2%	ES adult	0.48	0.4%	Oranges	0.4%	Apples	0.4%	Tomatoes	0.5%	2%
	2%	PL general	0.47	1%	Apples	0.4%	Tomatoes	0.2%	Potatoes	0.3%	2%
	2%	IT adult	0.45	0.6%	Tomatoes	0.4%	Apples	0.2%	Wheat	0.4%	2%
	2%	FI 3 yr	0.43	0.5%	Apples	0.3%	Tomatoes	0.2%	Potatoes	0.6%	2%
	2%	FR infant	0.41	0.9%	Apples	0.2%	Milk: Cattle	0.1%	Broccoli	0.4%	2%
	2%	LT adult	0.41	1.0%	Apples	0.3%	Tomatoes	0.2%	Potatoes	0.4%	2%
	2%	FR adult	0.37	0.4%	Apples	0.2%	Tomatoes	0.2%	Oranges	0.5%	1%
	2%	UK vegetarian	0.34	0.3%	Tomatoes	0.3%	Apples	0.3%	Oranges	0.4%	1%
	2%	DK adult	0.34	0.5%	Apples	0.3%	Tomatoes	0.2%	Pears	0.3%	1%
	2%	FI 6 yr	0.32	0.3%	Apples	0.2%	Tomatoes	0.2%	Potatoes	0.5%	1%
	1%	FI adult	0.29	0.3%	Apples	0.3%	Coffee beans	0.3%	Tomatoes	0.2%	1%
	1%	UK adult	0.27	0.2%	Tomatoes	0.2%	Apples	0.2%	Oranges	0.4%	1%
	0.6%	IE child	0.11	0.2%	Apples	0.1%	Broccoli	0.1%	Wheat	0.2%	0.4%

Conclusion:

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

The long-term intake of residues of Isocycloseram (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)
66%	Head cabbages	4 / 1.2	53
47%	Pears	0.4 / 0.27	37
36%	Oranges	0.4 / 0.22	29
36%	Apples	0.4 / 0.27	29
31%	Tomatoes	0.5 / 0.43	25
27%	Peaches	0.3 / 0.23	22
24%	Broccoli	0.7 / 0.46	19
23%	Cauliflowers	0.5 / 0.32	19
19%	Mandarins	0.4 / 0.25	15
17%	Plums	0.4 / 0.32	13
16%	Kaki/Japanese persimmons	0.4 / 0.27	13
15%	Melons	0.15 / 0.08	12
15%	Grapefruits	0.3 / 0.15	12
13%	Sweet peppers/bell peppers	0.3 / 0.18	11
11%	Lemons	0.5 / 0.25	8.6

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)
63%	Head cabbages	4 / 1.2	50
14%	Broccoli	0.7 / 0.46	11
10%	Pears	0.4 / 0.27	8.2
9%	Apples	0.4 / 0.27	7.6
9%	Cauliflowers	0.5 / 0.32	7.4
9%	Tomatoes	0.5 / 0.43	6.8
8%	Oranges	0.4 / 0.22	6.7
8%	Cherries (sweet)	1 / 0.62	6.2
7%	Kaki/Japanese persimmons	0.4 / 0.27	5.9
7%	Plums	0.4 / 0.32	5.7
6%	Aubergines/egg plants	0.3 / 0.18	4.9
6%	Brussels sprouts	2 / 0.81	4.9
6%	Mandarins	0.4 / 0.25	4.5
5%	Peaches	0.3 / 0.23	4.3
5%	Quinces	0.4 / 0.27	4.1

Expand/collapse list

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Broccoli / boiled	0.7 / 0.46	36
28%	Cauliflowers / boiled	0.5 / 0.32	22
10%	Brussels sprouts / boiled	2 / 0.81	8.2
7%	Peaches / canned	0.3 / 0.23	6.0
7%	Apples / juice	0.4 / 0.11	5.7
4%	Pears / juice	0.4 / 0.11	3.4
4%	Oranges / juice	0.4 / 0.06	3.4
3%	Courgettes / boiled	0.09 / 0.06	2.2
2%	Tomatoes / juice	0.5 / 0.1	1.9
2%	Peaches / juice	0.3 / 0.1	1.6
1%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
1%	Tomatoes / sauce/puree	0.5 / 0.1	0.95
1%	Potatoes / fried	0.01 / 0.01	0.93
1%	Pumpkins / boiled	0.01 / 0.01	0.89
1%	Witloofs / boiled	0.01 / 0.01	0.89

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)
17%	Cauliflowers / boiled	0.5 / 0.32	13
14%	Broccoli / boiled	0.7 / 0.46	11
4%	Apples / juice	0.4 / 0.11	3.5
2%	Peaches / canned	0.3 / 0.23	1.9
2%	Courgettes / boiled	0.09 / 0.06	1.4
1%	Oranges / juice	0.4 / 0.06	0.97
1%	Tomatoes / sauce/puree	0.5 / 0.1	0.82
0.9%	Grapefruits / juice	0.3 / 0.06	0.70
0.7%	Pumpkins / boiled	0.01 / 0.01	0.55
0.5%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.5%	Beetroots / boiled	0.01 / 0.01	0.39
0.5%	Head cabbages / canned	4 / 0.04	0.36
0.4%	Celeries / boiled	0.01 / 0.01	0.34
0.3%	Parsnips / boiled	0.01 / 0.01	0.21
0.3%	Kohlrabies / boiled	0.01 / 0.01	0.21

Expand/collapse list

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Isotianil

LOQs (mg/kg) range from: 0.01 to: 0.02

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	not necessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2023	Year of evaluation:	2023

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	4%	NL toddler	1.87	2%	Milk: Cattle	0.2%	Apples	0.1%	Maize/corn	4%	3%
	2%	UK infant	1.01	2%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	2%
	2%	NL child	0.93	1.0%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	2%	1%
	2%	FR toddler 2 3 yr	0.87	1%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	2%	1%
	2%	DE child	0.83	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Oranges	2%	1%
	2%	FR child 3 15 yr	0.81	0.9%	Milk: Cattle	0.1%	Wheat	0.1%	Oranges	2%	1%
	1%	UK toddler	0.68	0.8%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	1.0%
	1%	DK child	0.58	0.5%	Milk: Cattle	0.1%	Rye	0.1%	Swine: Muscle/meat	1%	0.7%
	1%	SE general	0.54	0.5%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.1%	Potatoes	1%	0.7%
	1%	ES child	0.53	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Bovine: Muscle/meat	1.0%	0.7%
	1%	RO general	0.52	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	0.6%
	1%	GEMS/Food G11	0.51	0.3%	Milk: Cattle	0.1%	Potatoes	0.1%	Soyabeans	1.0%	0.5%
	1.0%	DE women 14-50 yr	0.49	0.5%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.9%	0.6%
	1.0%	DE general	0.48	0.5%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Apples	0.9%	0.6%
	1.0%	GEMS/Food G15	0.48	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.9%	0.5%
	1.0%	GEMS/Food G07	0.48	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.9%	0.5%
	0.9%	FR infant	0.47	0.7%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.9%	0.7%
	0.9%	GEMS/Food G08	0.46	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Swine: Muscle/meat	0.9%	0.4%
	0.9%	GEMS/Food G10	0.45	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Soyabeans	0.9%	0.4%
	0.8%	GEMS/Food G06	0.42	0.1%	Wheat	0.1%	Milk: Cattle	0.1%	Tomatoes	0.8%	0.2%
	0.8%	NL general	0.39	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Potatoes	0.8%	0.5%
	0.8%	IE adult	0.39	0.2%	Milk: Cattle	0.1%	Sweet potatoes	0.0%	Wheat	0.7%	0.3%
	0.6%	ES adult	0.28	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.5%	0.3%
	0.5%	FR adult	0.26	0.2%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.5%	0.3%
	0.5%	DK adult	0.24	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Potatoes	0.5%	0.3%
	0.4%	LT adult	0.22	0.2%	Milk: Cattle	0.1%	Potatoes	0.0%	Swine: Muscle/meat	0.4%	0.2%
	0.4%	PT general	0.21	0.1%	Potatoes	0.1%	Wheat	0.0%	Wine grapes	0.4%	0.0%
	0.4%	UK vegetarian	0.18	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.2%
	0.4%	UK adult	0.18	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.2%
	0.3%	FI 3 yr	0.17	0.1%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.3%	0.0%
	0.3%	IT toddler	0.17	0.1%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.3%	0.0%
	0.3%	FI 6 yr	0.13	0.1%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.3%	0.0%
	0.3%	FI adult	0.13	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.2%	0.0%
	0.2%	IT adult	0.12	0.1%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.2%	0.0%
	0.2%	IE child	0.12	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.2%
	0.2%	PL general	0.10	0.1%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.2%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Isotianil 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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):	0.2	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)	8%	NL toddler	15.02	2%	Sunflower seeds	2%	Rapeseeds/canola seeds	1%	Milk: Cattle		8%
	7%	RO general	14.34	4%	Sunflower seeds	2%	Wheat	0.8%	Wine grapes		7%
	7%	GEMS/Food G08	13.74	3%	Sunflower seeds	1%	Wheat	0.6%	Rapeseeds/canola seeds		7%
	7%	GEMS/Food G15	13.49	3%	Sunflower seeds	1%	Wheat	0.5%	Wine grapes		7%
	7%	GEMS/Food G07	13.11	2%	Sunflower seeds	1%	Wheat	1.0%	Rapeseeds/canola seeds		7%
	6%	NL child	11.83	2%	Sunflower seeds	1%	Wheat	0.8%	Rapeseeds/canola seeds		6%
	5%	GEMS/Food G06	9.24	2%	Wheat	1%	Sunflower seeds	0.5%	Table grapes		5%
	4%	FR child 3 15 yr	8.73	1%	Sunflower seeds	1%	Wheat	0.6%	Milk: Cattle		4%
	4%	GEMS/Food G10	8.64	1%	Sunflower seeds	1%	Wheat	0.5%	Rapeseeds/canola seeds		4%
	4%	PT general	8.64	2%	Sunflower seeds	1%	Wheat	1%	Wine grapes		4%
	4%	DK child	8.31	2%	Rye	1%	Wheat	0.6%	Swine: Muscle/meat		4%
	4%	IE adult	7.85	1%	Sunflower seeds	0.8%	Linseeds	0.7%	Wheat		4%
	4%	DE child	7.34	1%	Wheat	0.6%	Table grapes	0.6%	Sunflower seeds		4%
	3%	GEMS/Food G11	6.93	1%	Wheat	0.7%	Sunflower seeds	0.5%	Wine grapes		3%
	3%	NL general	6.79	1%	Sunflower seeds	0.6%	Wheat	0.5%	Rapeseeds/canola seeds		3%
	3%	FR toddler 2 3 yr	6.13	0.9%	Wheat	0.8%	Sunflower seeds	0.7%	Milk: Cattle		3%
	3%	FR adult	5.73	1%	Wine grapes	0.7%	Sunflower seeds	0.7%	Wheat		3%
	3%	ES child	5.62	1%	Wheat	0.7%	Sunflower seeds	0.3%	Milk: Cattle		3%
	3%	DE general	5.01	0.6%	Wheat	0.4%	Wine grapes	0.4%	Sunflower seeds		3%
	2%	DE women 14-50 yr	4.90	0.6%	Wheat	0.4%	Sunflower seeds	0.4%	Wine grapes		2%
	2%	IT toddler	4.30	2%	Wheat	0.1%	Sunflower seeds	0.0%	Table grapes		2%
	2%	ES adult	4.18	0.7%	Wheat	0.6%	Sunflower seeds	0.2%	Wine grapes		2%
	2%	UK infant	3.92	1.0%	Milk: Cattle	0.8%	Wheat	0.1%	Oat		2%
	2%	UK toddler	3.84	1%	Wheat	0.5%	Milk: Cattle	0.1%	Table grapes		2%
	1%	SE general	3.00	1.0%	Wheat	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat		1%
	1%	DK adult	2.83	0.4%	Wine grapes	0.3%	Wheat	0.2%	Swine: Muscle/meat		1%
	1%	IT adult	2.73	1%	Wheat	0.1%	Table grapes	0.1%	Sunflower seeds		1%
	1%	LT adult	2.67	0.3%	Rye	0.3%	Wheat	0.3%	Sunflower seeds		1%
	1%	UK adult	2.32	0.5%	Wheat	0.5%	Wine grapes	0.1%	Milk: Cattle		1%
	1%	UK vegetarian	2.31	0.6%	Wheat	0.4%	Wine grapes	0.1%	Milk: Cattle		1%
	1%	FI 3 yr	2.20	0.4%	Wheat	0.2%	Oat	0.2%	Rye		1%
	0.9%	FR infant	1.88	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Sunflower seeds		0.9%
	0.8%	FI 6 yr	1.68	0.3%	Wheat	0.2%	Rye	0.1%	Oat		0.8%
	0.6%	FI adult	1.27	0.2%	Rye	0.1%	Wine grapes	0.1%	Wheat		0.6%
	0.5%	IE child	1.06	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.5%
	0.2%	PL general	0.41	0.1%	Table grapes	0.1%	Sunflower seeds	0.0%	Cultivated fungi		0.2%

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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Tricyclazole

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

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2023	Year of evaluation:	2023

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)	2%	NL toddler	1.24	1%	Milk: Cattle	0.2%	Apples	0.1%	Maize/corn	2%	1%
	1%	NL child	0.66	0.5%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	1%	0.6%
	1%	DE child	0.63	0.4%	Milk: Cattle	0.2%	Apples	0.1%	Wheat	1%	0.5%
	1%	UK infant	0.61	0.8%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	1%	0.9%
	1%	FR toddler 2 3 yr	0.56	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	1%	0.7%
	1%	FR child 3 15 yr	0.55	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Sugar beet roots	1%	0.6%
	0.9%	UK toddler	0.45	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.9%	0.5%
	0.8%	GEMS/Food G11	0.42	0.2%	Milk: Cattle	0.1%	Potatoes	0.1%	Soyabeans	0.8%	0.2%
	0.8%	DK child	0.41	0.3%	Milk: Cattle	0.1%	Rye	0.1%	Wheat	0.8%	0.4%
	0.8%	GEMS/Food G07	0.38	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.2%
	0.8%	GEMS/Food G06	0.38	0.1%	Wheat	0.1%	Tomatoes	0.0%	Milk: Cattle	0.7%	0.1%
	0.8%	GEMS/Food G15	0.38	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.2%
	0.8%	GEMS/Food G08	0.38	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.2%
	0.8%	RO general	0.38	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.3%
	0.8%	ES child	0.38	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Cocoa beans	0.7%	0.4%
	0.7%	SE general	0.37	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Potatoes	0.7%	0.4%
	0.7%	DE women 14-50 yr	0.37	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.7%	0.3%
	0.7%	GEMS/Food G10	0.37	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Soyabeans	0.7%	0.2%
	0.7%	DE general	0.36	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Apples	0.7%	0.3%
	0.7%	FI adult	0.35	0.6%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.7%	0.0%
	0.7%	IE adult	0.33	0.1%	Milk: Cattle	0.1%	Sweet potatoes	0.0%	Wheat	0.7%	0.1%
	0.6%	NL general	0.30	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Potatoes	0.6%	0.2%
	0.6%	FR infant	0.29	0.3%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.6%	0.4%
	0.4%	FR adult	0.22	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.4%	0.1%
	0.4%	PT general	0.21	0.1%	Potatoes	0.1%	Wheat	0.0%	Wine grapes	0.4%	0.0%
	0.4%	ES adult	0.21	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.4%	0.2%
	0.4%	FI 3 yr	0.18	0.1%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.3%	0.0%
	0.3%	DK adult	0.16	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.3%	0.2%
	0.3%	IT toddler	0.16	0.1%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.3%	0.0%
	0.3%	LT adult	0.16	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	Apples	0.3%	0.1%
	0.3%	UK vegetarian	0.15	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.1%
	0.3%	FI 6 yr	0.14	0.1%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.3%	0.0%
	0.3%	UK adult	0.14	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.1%

Conclusion:

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

The long-term intake of residues of Tricyclazole 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)
3%	Bovine: Liver	0.01 / 0.18	1.5
3%	Bovine: Edible offals (other than liver and kidney)	0.01 / 0.18	1.3
2%	Milk: Cattle	0.01 / 0.01	1.2
1%	Swine: Edible offals (other than liver and kidney)	0.01 / 0.18	0.54
0.5%	Milk: Goat	0.01 / 0.01	0.24
0.4%	Swine: Liver	0.01 / 0.18	0.22
0.3%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.3%	Rice	0.3 / 0.01	0.13
0.2%	Eggs: Chicken	0.01 / 0.01	0.12
0.2%	Swine: Muscle/meat	0.01 / 0.01	0.12
0.2%	Bovine: Kidney	0.01 / 0.03	0.09
0.1%	Bovine: Muscle/meat	0.01 / 0.01	0.07
0.1%	Other farmed animals: Muscle/meat	0.01 / 0.01	0.07
0.1%	Equine: Muscle/meat	0.01 / 0.01	0.06
0.1%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.07%	Milk: Sheep	0.01 / 0.01	0.04
0.06%	Swine: Kidney	0.01 / 0.03	0.03
0.04%	Bovine: Fat tissue	0.01 / 0.01	0.02
0.03%	Swine: Fat tissue	0.01 / 0.01	0.02
0.02%	Poultry: Liver	0.01 / 0.01	0.01
0.00%	Poultry: Fat tissue	0.01 / 0.01	0.00

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Bovine: Liver	0.01 / 0.18	0.72
1%	Bovine: Edible offals (other than liver and kidney)	0.01 / 0.18	0.60
1%	Swine: Other products	0.01 / 0.18	0.59
1%	Sheep: Liver	0.01 / 0.18	0.50
0.9%	Swine: Edible offals (other than liver and kidney)	0.01 / 0.18	0.47
0.8%	Milk: Cattle	0.01 / 0.01	0.39
0.7%	Bovine: Other products	0.01 / 0.18	0.36
0.5%	Swine: Liver	0.01 / 0.18	0.25
0.4%	Milk: Goat	0.01 / 0.01	0.18
0.3%	Milk: Sheep	0.01 / 0.01	0.15
0.2%	Sheep: Edible offals (other than liver and kidney)	0.01 / 0.18	0.12
0.2%	Poultry: Muscle	0.01 / 0.01	0.12
0.2%	Rice	0.3 / 0.01	0.09
0.1%	Bovine: Muscle	0.01 / 0.01	0.06
0.1%	Other farmed animals: Muscle/meat	0.01 / 0.01	0.06
0.1%	Swine: Kidney	0.01 / 0.03	0.06
0.1%	Bovine: Kidney	0.01 / 0.03	0.05
0.10%	Swine: Muscle/meat	0.01 / 0.01	0.05
0.10%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.09%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.09%	Poultry: Liver	0.01 / 0.01	0.05
0.09%	Eggs: Chicken	0.01 / 0.01	0.04
0.04%	Swine: Fat tissue	0.01 / 0.01	0.02
0.03%	Goat: Muscle	0.01 / 0.01	0.02
0.03%	Eggs: Quail	0.01 / 0.01	0.01
0.03%	Poultry: Kidney	0.01 / 0.01	0.01
0.02%	Bovine: Fat tissue	0.01 / 0.01	0.01
0.01%	Eggs: Goose	0.01 / 0.01	0.01
0.01%	Poultry: Fat tissue	0.01 / 0.01	0.00
0.01%	Sheep: Kidney	0.01 / 0.03	0.00

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Rice / milling (polishing)	0.3 / 0	0.06

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%	Rice / milling (polishing)	0.3 / 0	0.04

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