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SCIENTIFIC REPORT

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

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Abstract

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA received a request from the European Commission to propose fall-back maximum residue levels (MRLs) for recently revoked Codex MRLs that have been previously implemented in the EU legislation. Overall, MRLs for 12 a.s. are concerned, i.e. chlormequat, diazinon, bifenthrin, fludioxonil, indoxacarb, difenoconazole, famoxadone, azoxystrobin, mandipropamid, emamectin benzoate, flutriafol and afidopyropen. In addition, EFSA was requested to evaluate the toxicological data assessed by JMPR related to pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole. These are active substances have not been assessed previously at EU level. The assessment should allow to take a decision, if the CXLs adopted for these four a.s. can be implemented in the EU MRL legislation.

KEYWORDS

consumer risk assessment, pyrasulfotole, pyrazyflumid, revoked Codex MRLs, spiropidion, tetraniliprole, toxicological evaluation

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SUMMARY

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA was asked to assess whether fall-back maximum residue levels (MRLs) can be established for Codex maximum residue limits (CXLs) revoked in the 54th session of the Codex Committee on Pesticide Residues (CCPR) meeting that were previously implemented in the EU legislation. Overall, CXLs were revoked for 12 a.s., i.e. chlormequat, diazinon, bifenthrin, famoxadone, fludioxonil, indoxacarb, difenoconazole, azoxystrobin, mandipropamid, emamectin benzoate, flutriafol and afidopyropen. Fall-back MRLs should be identified which either reflect authorised EU uses of the respective pesticide or import tolerances that are sufficiently supported by data, provided that they are not higher than the obsolete CXL and they do not pose a risk to consumers. EFSA also checked if the revoked CXLs were replaced by new CXLs. If this was the case, EFSA reported whether the new CXLs were considered acceptable and are therefore to be implemented as fall-back MRL in the EU legislation. In cases, where the EU expressed a reservation on the new CXLs due to ongoing assessments, which may have an implication on the acceptance of the new CXLs as fall-back MRLs, a decision shall be postponed. To ensure that relevant information available at Member State level is considered in the derivation of fall-back MRLs, EFSA performed a Member State consultation, inviting Member States to submit information on national good agricultural practices (GAPs), supporting residue trials and other relevant information (e.g. on import tolerances) not yet assessed previously by EFSA.

If no fall-back MRLs could be identified, the EU MRLs should be lowered to the limit of quantification (LOQ).

Chlormequat: EFSA derived fall-back MRL proposals for mammalian animal products (except milk) and eggs, which were derived from a feeding study submitted in the context of an EU MRL application assessed by EFSA in 2020; the fall-back MRL proposals reflect the EU dietary burden calculated for the different animal species. For poultry products (except eggs) and milk, the new CXLs adopted in 2023 were proposed, as these CXLs were supported by the EU in CCPR54. For wheat, EFSA proposed that the existing EU MRL should be aligned with the new CXL derived by CCPR54.

Diazinon: EFSA recommended the lowering of the existing EU MRLs for the commodities under assessment, in line with a recent assessment of EFSA which identified deficiencies for the toxicological studies available to EFSA.

Bifenthrin: The currently available data were found to be insufficient to confirm the existing toxicological reference values (TRVs) or derive new TRVs. For the risk managers to decide to lower the existing MRLs to the LOQ or to postpone the amendment of EU MRLs, awaiting further data to be provided by a manufacturer, which are expected to be of relevance for the decision on the TRVs.

Fludioxonil: For the new CXLs adopted in 2023 which replace the revoked CXLs, the EU expressed a reservation due to the ongoing periodic re-evaluation of the a.s in the EU. Considering that the EU renewal process and the assessment of endocrine-disrupting properties of fludioxonil is ongoing, EFSA recommended to postpone the modification of the current MRLs.

Indoxacarb: All EU MRLs were recently lowered to the LOQ of 0.01 mg/kg, following a specific assessment of EFSA. EFSA recommended that these EU MRLs set at the LOQ shall continue to apply.

Difenoconazole: The decision whether the new CXLs replacing the revoked CXLs are acceptable shall be postponed, as a number of EU assessments are ongoing for this a.s. (renewal of the approval, MRL review, MRL application) and the outcome of the ongoing assessments is expected to have an impact on the identification of fall-back MRLs.

Famoxadone: The new CXL derived by CCPR54 for tomatoes replacing the previous CXL was considered acceptable by the EU. Hence, it was recommended to be implemented in the EU MRL legislation. For the new CXLs adopted in 2023 for cucumbers and courgettes which also replace revoked CXLs, the EU expressed a reservation. As no alternative fall-back MRL could be identified, the existing MRLs for these commodities should be lowered to the LOQ.

Azoxystrobin: The new CXLs derived by CCPR54 for papayas and for root and tuber vegetables (except potatoes), replacing the previous CXL, were considered acceptable by the EU. Hence, they are recommended to be implemented in the EU MRL legislation.

Mandipropamid: The new CXLs replacing the CXLs for sweet peppers, cucumbers, courgettes and melons were supported by the EU in CCPR54. Hence, they could be used as a fall-back MRL in the EU. For onions, the EU expressed a reservation for the new CXL replacing the revoked CXL, due to an ongoing evaluation of the toxicological profile of a metabolite expected in onions and in root and tuber vegetables. Hence, a decision if the new CXL is acceptable should be postponed. For spring onions, the outcome of the ongoing assessment is also relevant. Therefore, EFSA proposed postponing the decision on a fall-back MRL for spring onions, noting that for spring onions no new CXL was adopted.

Emamectin benzoate: The revoked CXLs for animal products were all replaced by new CXLs. The EU expressed a reservation for the new CXL for milk of different species. Hence, for milks, the EU MRL shall be kept at the LOQ of 0.002 mg/kg. For the remaining commodities, the new CXLs were supported by the EU. These CXLs should therefore be taken over in the EU, after having recalculated the CXLs to match with the EU residue definition.

Flutriafol: The revoked CXLs were replaced by new CXLs, which were sufficiently supported by data and for which no intake concerns were identified. As the EU supported the new CXLs, they are recommended to be implemented in the EU MRL legislation.

Afidopyropen: The revoked CXLs were all replaced by new CXLs for which the EU expressed a reservation, due to the lack of available toxicological data at EU level and pending the outcome of the review by the EU. For the commodities, where the new CXL and the existing EU MRL are set at the LOQ, the EU MRL shall be maintained. For the products where the new CXL is set at levels greater than the LOQ (i.e. for poultry products, including eggs), a decision on implementing the new CXLs shall be postponed, awaiting the outcome of an EU toxicological evaluation of the a.s.

The second part of the current report was prepared to address the request of the European Commission to evaluate the toxicological data assessed by JMPR in 2021 related to the active substances pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole; none of these a.s. has been assessed previously at EU level and therefore agreed toxicological reference values are not established for these a.s. and the relevant metabolites expected in food after using these pesticides on food crops or in food of animal origin via transfer from feed items. The purpose of the evaluation is to provide advice whether the EU reservations on these four substances presented in the CCPR meetings could be lifted and consequently decide whether CXLs established by CCPR53 and CCPR54 could be taken over in EU legislation, provided that the EU did not identify other points which would not impede an implementation in Regulation (EC) No 396/2005.

EFSA scrutinised the JMPR report and monograph for the four substances whether the toxicological data set is in line with the EU standards (Reg (EU) No 283/2013 and relevant Guidance documents) and whether they are sufficient to conclude on the JMPR set TRVs.

EFSA acknowledges the comprehensiveness of the provided information, supported by detailed tabulated summary results from many studies. However, the level of details in the JMPR monograph is not fully comparable to that usually available in the reports drafted for the EU peer review, and EFSA does not have access to the original background studies. The level of details required should allow to assess the relevance and reliability of the studies and undertake an independent review of the results and conclusions; such detailed information has shown to be necessary for the assessment of some data in this mandate. Additional drawbacks were identified where the reasoning behind a conclusion was not detailed (e.g. lack of an overview of the immunotoxicity-related findings).

Critical issues were identified when data were not available (e.g. read-across and quantitative structure–activity relationship (QSAR) analysis used in metabolites assessments) or not sufficiently detailed, particularly for key studies, e.g. where summaries were too concise (genotoxicity studies).

The results of genotoxicity studies are not presented in a sufficiently detailed way that would allow a critical review. This was considered critical for an independent interpretation, in particular when the studies presented equivocal results; on this basis, the genotoxicity potential of the four substances could not be concluded upon. Considering the genotoxicity a critical endpoint in deriving TRVs, EFSA is not in a position to conclude on the acceptable daily intake (ADI) and the acute reference dose (ARfD) derived by JMPR for pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole and does not recommend to use these ADI/ARfD values for EU risk assessments.

BACKGROUND

On 8 February 2023, the European Commission sent a mandate to EFSA, requesting EFSA to give advice and comments on the recommendations of the 2022 Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and on the proposed Codex MRLs in order to support the Commission in its preparation of the EU coordinated positions for the 54th session of the Codex Committee on Pesticide Residues (CCPR54) in 2023. The advice has been provided in scientific report of EFSA (EFSA, 2023b) which was the basis to derive the EU positions in CCPR54.

In the CCPR meeting held in June 2023 (CCPR54), a number of CXLs were proposed to be revoked. Since some of these CXLs have been previously implemented in the EU MRL legislation, the EU MRLs should be modified. EFSA was therefore requested by the European Commission to assess the consequences of the revocations on the EU legislation, and where necessary, suggest modifications of those EU MRLs, which were based on revoked CXLs.

In addition, this mandate requested EFSA to evaluate the toxicological reference values for four active substances assessed in JMPR in 2021, i.e. for pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole.[1] As these substances have never been evaluated in the EU before, the toxicological studies are not accessible to EU Member States and EFSA. In line with the EU policy on EU positions in the CCPR meetings, an EU reservation was introduced for these a.s. in CCPR53, as the information available at the time of the CCPR meeting (i.e. summary of the toxicological assessment reported in the JMPR report 2021) is considered not sufficiently detailed to assess whether the toxicological reference values are acceptable to the EU. However, the reservation could be lifted based on a more detailed assessment of the toxicological data.

Since in the meantime, the 2021 JMPR monograph (FAO and WHO, 2023c), containing a more detailed assessment of the toxicological studies is publicly available, EFSA should perform an assessment in view of the possibility to lift the EU reservation for the four a.s.

Terms of Reference

The European Commission requested EFSA to

1. identify fall-back MRLs, for CXLs that were previously transposed into EU legislation and that JMPR, in its 2022 meeting, proposes to withdraw, 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.
2. assess the information available in the JMPR monograph as regards pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole, in addition to the relevant 2021 JMPR reports.

The requested assessment of fall-back MRLs for revoked CXLs and the assessment of CXLs for pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole should be adopted not later than 1 year after the publication of the JMPR monograph 2021. Hence, the deadline for the report was 1 February 2024 but subsequently, an extension of this deadline to 1 March 2024 was agreed with the European Commission.

1 | ASSESSMENT OF FALL-BACK MRLS FOR REVOKED CXLS

Based on the recommendations of JMPR presented in the 2022 JMPR report (FAO and WHO, 2023a), CCPR decided in its 54th meeting held from 26 June to 1 July 2023 (CCPR 54) to revoke a total of 178 CXLs, covering 18 different a.s. (see Appendix A).[2] As some of these CXLs were previously implemented in the EU legislation, the corresponding EU MRLs need to be re-evaluated and, where necessary, modified, reflecting the new situation for these revoked Codex MRLs.

Most of the revocations were due to the lack of information provided by the manufacturer of the active substances, not defending the CXLs in the periodic review process. In addition, some of the existing CXLs were revoked because alternative MRL proposals were derived by JMPR, reflecting additional or alternative uses. In these cases, new CXLs replaced the revoked CXLs.

For the following a.s., none of the revoked CXLs have been implemented in the EU legislation[3]: dimethoate (27), fenazaquin (297), methidathion (51), omethoate (55), quinclorac (287) and spiromesifen (294). Hence, no further action is required at EU level.

For the remaining 12 active substances, the revoked CXLs have been partially[4] or completely implemented in EU legislation and therefore require a detailed assessment.

[1] Tetraniliprole was evaluated for its toxicological properties in JMPR (2021); in JMPR (2022), the FAO Panel of JMPR assessed the substance and presented Codex MRL proposals and residue definitions.

[2] Report of the 54th Session of the Codex Committee on Pesticide Residues, Appendix III.

[3] The number after the name of the a.s. refers to the Codex code for the a.s.

[4] A CXL is considered to be partially implemented if the Codex food code for the CXL refers to a commodity group and the EU MRLs was not identical with the CXL for all commodities covered by the Codex code (e.g. CXL for fruiting vegetables other than cucurbits 5 mg/kg; EU MRL for tomatoes: 5 mg/kg, EU MRL for sweet peppers, aubergines and okra: 0.01 mg/kg).

For revoked CXLs that have been previously implemented in the EU MRL legislation, alternative, fall-back MRLs should be identified, either reflecting authorised EU uses of the respective pesticide or import tolerances that are sufficiently supported by data, provided that they are not higher than the revoked CXL and they do not pose a risk to consumers.

If no fall-back MRLs can be identified, the EU MRLs should be lowered to an LOQ that is appropriate for the pesticide/commodity combination.

1.1 | Methodology to identify fall-back MRLs

The following methodology for identifying fall-back MRLs for Codex MRLs revoked in CCPR54 was applied:

In order to identify fall-back MRLs, EFSA followed an assessment scheme consisting of 21 steps as outlined below. The decision tree reflecting the assessment scheme can be found in Appendix B.

- **Step 1:** Among the 178 revoked CXLs, 13 CXLs for feed and for processed products have been eliminated from the analysis; they are not relevant for the current assessment, since under Regulation (EC) No 396/2005 MRLs are set only for unprocessed raw agricultural products used for food purpose, but not for products used exclusively for feed or for processed products (case 1 in the decision tree).
- **Step 2:** For the remaining 165 CXLs, it was necessary to identify the food codes in the EU food classification (Annex I of Regulation (EC) No 396/2005) which correspond with the relevant Codex codes. The mapping of the Codex food codes with the EU codes followed the approach outlined below:

    a. Codex food codes that refer to a single food commodity in the EU legislation were mapped directly with the EU food code (e.g. Codex code VC 0424, cucumber is mapped with the EU commodity code 232010, cucumbers). If the Codex code refers to a EU code listed in Part B of the EU food classification (e.g. VD 0524, Chick-pea (dry), corresponding to EU code 0300030-003) was mapped with the code for the main product listed in part A of Annex I (i.e. 300030, peas (dry)).
    b. Codex food codes which refer to commodity groups (e.g. VO 0050, Fruiting vegetables other than cucurbits) were mapped with the individual food commodities covered by the EU food codes reported in Annex I, part A of regulation (EC) No 396/2005 (in the given example, the corresponding codes are 231010 (Tomatoes), 231020 (Sweet peppers/bell peppers), 231030 (Aubergines/eggplants), 231040 (Okra/lady's fingers)).
    c. Codex codes for meat of mammalian species and poultry (e.g. MM 0095 or PM 0110) that were flagged in Codex as referring to 'fat' were mapped with the EU codes referring to fat of the respective species.
    d. Codex food codes for meat (all mammalian species and poultry) not flagged with the suffix 'fat' cannot be mapped with a corresponding food commodity of Annex I of Regulation (EC) No 396/2005, since according to the current legislation, EU MRL are set for muscle (but not for meat, which is a mixture of muscle and fat).[5] However, it is current EU practice that in these cases, a MRL for muscle is derived from the feeding studies evaluated by JMPR which is the corresponding MRL to the CXL for meat. Hence, for these cases, the decision whether a CXL is reflected in the EU legislation requires an additional scrutiny.

    With the mapping of the 165 Codex codes with the EU codes according to step 2a–2d, a total of 521 corresponding pesticide/commodity combinations were identified. The full list of EU codes and commodity names mapped with the revoked CXLs is made publicly available as supporting document to this report.
- **Step 3:** As a next step, EFSA checked whether the residue definitions for enforcement established by JMPR and at EU level for the relevant food commodities are identical or comparable; residues are considered comparable if the wording differs, but the difference has no relevance for the levels. If this is the case, the assessment continues with step 5. If the residue definitions were not comparable, the assessment continues with step 4.
- **Step 4:** EFSA checked whether the CXLs have been converted to match with the EU residue definition. In such cases, usually, a conversion factor is applied to the CXL and the result is rounded to the closest or the next higher MRL class. For those EU MRLs that were found to correspond to a CXL (equivalent EU MRL after conversion to the EU residue definition), the assessment continued with step 5. For CXLs that could not be recalculated to match with the EU residue definition, it is concluded that due to incompatibility of the residue definitions, the CXLs have not been implemented in the EU; therefore, no further assessment is required to identify a fall-back MRL (case 4 in the decision tree).
- **Step 5:** The individual EU MRLs for the pesticide/commodity combinations identified in step 2a, to 2d were compared with the revoked CXLs. In total, 243 EU MRLs were found to correspond to the CXLs. For these cases, the assessment continued with step 6. For those pesticide/commodity combinations where the EU MRL was not identical/comparable with the revoked CXL, EFSA concluded that the EU MRL does not reflect a CXL. Hence, the revocation of the CXL does not have an impact on the EU MRLs. In these cases, no fall-back MRLs need to be derived (case 5 in decision tree).

[5]Annex I of Regulation (EC) No 396/2005 was modified in 2013 (Regulation (EU) No 212/2013). Before the entry into force of this regulation, MRLs were set for meat; after entry into force, MRLs were set for muscle (meat without trimmable fat).

- **Step 6 and 7:** EFSA checked, whether the revoked CXL and the corresponding EU MRL were set at the LOQ. If this was the case, and the revoked CXL was not replaced by a new CXL set at a level higher than the LOQ (step 7), EFSA concluded that there is no need to identify a fall-back MRLs and the EU MRL set at the LOQ shall continue to apply (case 7). If the revoked CXL was replaced by a new CXL greater than the LOQ, the assessment continued with step 13. If the revoked CXL and the corresponding EU MRL were not set at the LOQ, the assessment continued with step 8.
- **Step 8 and 9:** Robust TRVs are an indispensable precondition to perform a reliable risk assessment to ensure that fall-back MRLs do not pose an unacceptable risk to European consumers. Hence, if at EU level TRVs are not established covering the a.s. and the metabolites included in the residue definition for risk assessment, and TRVs from other sources are not available that could be used for an EU risk assessment, the MRLs need to be lowered to the LOQ (case 9A). If the assessment of the toxicological profile of the a.s. and its metabolites is ongoing at EU level (step 9), the derivation of fall-back MRLs shall be postponed, until a decision on the appropriate TRV to be used for the EU risk assessment has been taken (case 9B).
- **Step 10:** For all cases where the EU MRLs were identical/equivalent (after correction for the residue definition) with the CXLs, EFSA checked if the revoked CXLs were replaced by new CXLs. For the non-replaced CXLs, the assessment continued as described in step 11 (for animal products) and step 12 (for plant products). For those cases where the revoked CXLs were replaced by a new CXL, the assessment continued with step 13.
- **Step 11:** Identification of fall-back MRLs for animal products:

    - For animal products, EFSA investigated whether the use of the relevant pesticide is authorised in EU Member States on crops that can be used for feed purpose. The fall-back MRLs for animal products should reflect the EU uses, taking into account the results of the dietary burden calculation and the relevant feeding studies. To identify these cases, EFSA screened previous EFSA assessments. In addition, Member States were consulted, asking them for relevant information on the authorised uses and the supporting data to update the previously calculated dietary burden and the resulting MRLs reflecting new uses that have not been previously assessed by EFSA (e.g. in the context of an MRL review). The fall-back MRL should, however, not be higher than the existing EU MRL (case 11A).
    - If applicable, MRLs set under Regulation (EU) No 37/2010,[6] which could serve as a fall-back MRL, were identified (case 11B).
    - Previously assessed import tolerances for animal products (lower than the existing EU MRL) could also be used as possible fall-back MRL. EFSA therefore investigated, if EFSA previously assessed the setting of an import tolerance for animal products (case 11C).[7]
    - If no fall-back MRL could be identified (case 11A, 11B or 11C), EFSA proposed the lowering of the EU MRL to the LOQ (case 11D).

- **Step 12:** Identification of fall-back MRLs for plant products:

    - EFSA investigated whether authorised EU uses require an MRL between the LOQ and the revoked CXL. To identify these cases, EFSA screened previous EFSA assessments. Member States were consulted, asking them for relevant information on the authorised uses and the supporting data that have not been previously assessed by EFSA (e.g. in the context of an MRL review) (case 12A).
    - EFSA also checked whether previously assessed import tolerance applications or uses in third countries assessed under Article 12 of the MRL Regulation could be used as a basis to derive a fall-back MRL. In addition, Member States were consulted whether import tolerance applications were assessed at national level that justify to establish an EU MRL at a level between the LOQ and the current EU MRL (case 12B).
    - If no fall-back MRLs (reflecting either EU uses or import tolerances) could be identified (case 11A or 11B), EFSA proposed to lower the MRL to the LOQ (case 12C).

- **Step 13**: For revoked CXLs that were replaced by new CXLs, the subsequent identification of fall-back MRLs took into account the EU position presented in CCPR54 on the new CXLs. If no reservation was made on the new CXL, the assessment continues with step 14. If the EU expressed a reservation, the assessment continues with step 16.
- **Step 14**: For cases where the new CXL is equal or higher than the revoked CXL and the EU did not express a reservation/concern in the CCPR meeting, the new (higher) CXL will be implemented in the EU or if the new CXL is equal to the existing EU MRL, the EU MRL will be maintained. Hence, it is not necessary to identify an alternative fall-back MRL (case 14). If the new CXL is lower than the revoked CXL, the assessment continued with step 15 (revoked CXLs referring to animal products) or step 16 (revoked CXLs referring to plant products).
- **Step 15:** Identification of fall-back MRLs for animal products:

[6]Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010.

[7]If the a.s. is no longer approved in the EU, previously assessed import tolerances for animal products require a full reassessment according to the current standards, taking into account all relevant uses approved in third countries. As this information is not available to EFSA, this assessment cannot be performed in the context of the current assessment. Hence, EFSA did not consider these import tolerances as possible fall-back MRLs.

- By analogy to case 11A, EFSA investigated whether the use of the relevant pesticide is authorised in EU Member States on crops that can be used for feed purpose. The fall-back MRLs for animal products should reflect the EU uses, taking into account the results of the dietary burden calculation and the relevant feeding studies. To identify these cases, EFSA screened previous EFSA assessments. In addition, Member States were consulted, asking them for relevant information on the authorised uses for feed products and the supporting data that have not been previously assessed by EFSA (e.g. in the context of an MRL review). The fall-back MRL should, however, not be higher than the existing EU MRL (case 15A).
- By analogy to case 11B, MRLs set under Regulation (EU) No 37/2010, which could serve as a fall-back MRL, were identified (case 15B).
- By analogy to case 11C, previously assessed import tolerances for animal products (lower than or equal to the existing EU MRL) could also be used as possible fall-back MRL. EFSA therefore investigated, if EFSA previously assessed the setting of an import tolerance for animal products (case 15C).
- If no fall-back MRL could be identified (case 15A, 15B or 15C) or if the fall-back MRL was lower than the new CXL, EFSA proposed to implement the new CXL (case 15D).

- **Step 16:** Identification of fall-back MRLs for plant products:

  - EFSA investigated whether authorised EU uses require an MRL between the existing MRL and the new CXL. To identify these cases, EFSA screened previous EFSA assessments. Member States were consulted, asking them for relevant information on the authorised uses and the supporting data that have not been previously assessed by EFSA (e.g. in the context of an MRL review) (case 16A).
  - EFSA also checked whether previously assessed import tolerance applications or uses in third countries assessed under Article 12 of the MRL Regulation could be used as a basis to derive a fall-back MRL. In addition, Member States were consulted whether import tolerance applications were assessed at national level that justify maintaining the respective EU MRL at a level between the existing MRL and the new CXL (case 16B).
  - If no fall-back MRLs (reflecting either EU uses or import tolerances) could be identified (case 16A or 16B), or if the fall-back MRL was lower than the new CXL, EFSA proposed to set the fall-back MRL at the level of the new Codex MRLs (case 16C).

- **Step 17**: If the EU expressed a reservation on the new CXLs, the reason for the reservation triggers the next step of the assessment. If the reservation was referring to ongoing assessments at EU level, the assessment continues with step 18. If the EU reservation was based on any other reasons, the assessment continues with step 19.
- **Step 18**: If the existing EU MRL is demonstrated to be safe for consumers, the existing MRL can be maintained and a decision whether the new CXL can be implemented in the EU to replace the existing CXL can be postponed until the EU assessment is completed (case 18). However, if the existing EU MRL has the potential to cause a consumer health risk, the assessment follows step 19.
- **Step 19**: For revoked CXL that were replaced with a new CXL, for which the EU expressed a reservation, EFSA checked, whether the new CXL and the corresponding EU MRL were set at the LOQ. If this was the case, EFSA concluded that there is no need to identify a fall-back MRL and the EU MRL set at the LOQ shall continue to apply (case 19). If the new CXL was higher than the LOQ, the assessment continued with step 20 (revoked CXLs referring to animal products) or step 21 (revoked CXLs referring to plant products).

- **Step 20**: Identification of fall-back MRLs for animal products:

  - Case 20A: Identical to case 11A
  - Case 20B: Identical to case 11B
  - Case 20C: Identical to case 11C
  - Case 20C: Identical to case 11D

- **Step 21:** Identification of fall-back MRLs for plant products:

  - Case 21A: Identical to case 11A
  - Case 21B: Identical to case 11B
  - Case 21C: Identical to case 11C

To ensure that information on national authorisations or information related to import tolerances that have not been previously assessed by EFSA are incorporated in the assessments to identify fall-back MRLs, EFSA consulted Member States, requesting to share relevant information and data. The Member State consultation was launched on 11 December 2023. The original deadline for submission of additional information (5 January 2024) was extended until 19 January 2024 upon request of some Member States to ensure a comprehensive screening for relevant data and the assessment.

As some of the revoked CXLs could not be clearly attributed to the cases of the decision scheme, EFSA derived proposals for fall-back MRLs based on specific considerations, providing further explanations on the rationale behind (special cases).

The **Member States consultation report** (EFSA, 2024a) is considered as main supporting document to this scientific report and, thus, made publicly available.

1.2 | Chlormequat (15)

In total, 13 CXLs were revoked (see Appendix A), which were assessed according to the assessment approach outlined above. Among the revoked CXLs, three CXLs refer to feed (barley, hay and/or straw; wheat, hay and/or straw) and to processed products (wheat bran). No further discussion is required for these CXLs, since they have not been implemented in the EU legislation (case 1 in the decision tree).

The remaining 10 revoked CXLs were mapped with the corresponding EU food codes (in total, 45 EU food codes were identified as corresponding commodities) (step 2).

Since the residue definition for MRL enforcement set at JMPR and at EU level is not directly comparable, the assessment continued with step 4: EFSA recalculated the CXLs set for the residue definition (i.e. sum of chlormequat cation) to the EU residue definition (i.e. chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride), using a molecular weight correction factor of 1.29. The result of the recalculation was then rounded up to the next MRL class (step 4).

In total, 41 existing EU MRLs were found to be equivalent to the revoked CXLs, taking into account the EU residue definition (step 5).

One additional CXL is considered to fall in this category (EU MRL equivalent to revoked CXL), i.e. the MRL for wheat (CXL 2 mg/kg, recalculated to EU residue definition and rounded to the next MRL class: 3 mg/kg). EFSA noted that the EU MRL for chlormequat in wheat was raised from 4 to 7 mg/kg with Regulation (EC) No 2019/552,[8] which is the legal act implementing the CXLs adopted in 2018. Since the EU did not make a reservation in the CCPR meeting in 2018, the new CXL for wheat (2 mg/kg) would not have triggered a modification of the EU MRL of 4 mg/kg. EFSA assumed that the EU MRL was erroneously set at the level of the CXL for wheat bran instead of wheat grain. Hence, in the subsequent assessment, the MRL for wheat is considered to reflect a revoked CXL.

For three commodities, EFSA concluded that the EU MRLs were not based on previously established CXLs; hence, no further action is required for these cases (i.e. barley, sheep muscle and sheep kidney, case 5 of the decision tree).

The revoked CXLs, which were previously implemented in the EU, were all replaced by new CXLs established in CCPR54. In CCPR54, the EU expressed a reservation on all of them, except on the new CXLs for poultry meat/muscle and poultry fat. The new CXLs for poultry meat and poultry fat were set at the same level as the revoked CXLs. Hence, for these two poultry matrices, the existing EU MRLs shall continue to apply, as they are equivalent to the new CXLs (Case 14).

For the remaining animal commodities, EU MRLs have been calculated in a previous output of EFSA which reflect the EU dietary burden for livestock (EFSA, 2020). These MRLs could serve as a fall-back MRL. However, some Member States have informed EFSA on the authorisation of new uses in crops that can serve for feed purpose (Austria, 2024; Italy, 2024; Netherlands, 2024). EFSA therefore scrutinised the impact of the new uses on the dietary burden and the need to derive alternative MRLs (case 20A). The list of GAPs reported to EFSA as well as the supporting residue trials, dietary burden calculations and the assessment of MRLs and risk assessment values (highest residue (HR)/supervised trials median residue (STMR) values for animal products) derived from the available feeding studies are presented in Appendix C.

For wheat, EFSA proposed to consider the implementation of the new CXL, as the EU did not express a reservation. Further considerations on the situation on wheat can be found in the table below.

In the table below, fall-back MRLs are summarised, including the rationale and the background of the different options of possible fall-back MRLs derived in accordance with the assessment schema (Table 1).

[8]Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6–49.

TABLE 1 Summary table for chlormequat.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL/ recalculated CXL[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) **Enforcement residue definition (Codex):** Chlormequat cation					
500090	Wheat	7	4[c]/6	6 For risk management discussion	**Special case** (not covered by the assessment schema): The EU MRL was probably erroneously set at the level of the CXL for wheat bran (instead for wheat grain) In CCPR 54, the EU made a reservation on the new CXL for wheat grain, replacing the previous CXL (see footnote (c)). Based on the information reported in the JMPR evaluation (FAO and WHO, 2023b), risk managers could consider to lift the reservation, as the new Codex MRL is sufficiently supported by data. Hence, the new CXL, recalculated to the EU residue definition, could replace the previous EU MRL
1011010	Muscle, pig	0.3	0.2[d]	0.02	**Case 20A**: EU MRLs were derived by updating the most recent assessment performed in the context of an MRL application (EFSA, 2020), including the information on new residue trials relevant for feed reported to EFSA in the framework of the Member State consultation The EU MRL proposals were derived from the new feeding study submitted in the context of the MRL application assessed by EFSA (2020), they reflect the EU dietary burden calculated for the different animal species For deriving the appropriate MRL for edible offals (other than liver and kidney), a risk management decision is required (e.g. by extrapolating the MRL for kidney or liver), since the feeding study do not provide results on the relevant matrices Details on the assessment can be found in Appendix C and in the evaluation reports provided by Italy (2024), Netherlands (2024) and Austria (2024)
1011020	Fat, pig	0.15	0.1[d]	0.01*	
1011030	Liver, pig	1.5	0.5[d]	0.05	
1011040	Kidney, pig	1.5	0.5[d]	0.2	
1011050	Edible offals (other than liver and kidney), pig	1.5	0.5[d]	For risk management discussion	
1012010	Muscle, bovine	0.3	0.2[d]	0.2	
1012020	Fat, bovine	0.15	0.1[d]	0.05	
1012030	Liver, bovine	1.5	0.5[d]	0.4	
1012040	Kidney, bovine	1.5	0.5[d]	1	
1012050	Edible offals (other than liver and kidney), bovine	1.5	0.5[d]	For risk management discussion	
1013020	Fat, sheep	0.15	0.1[d]	0.09	
1013030	Liver, sheep	1.5	0.5[d]	0.7	
1013050	Edible offals (other than liver and kidney), sheep	1.5	0.5[d]	For risk management discussion	
1014010	Muscle, goat	0.3	0.2[d]	0.4	**Special case**: EFSA proposed to extrapolate the MRLs derived for the sheep matrices to the relevant goat matrices; For goat muscle and goat kidney, the existing EU MRL of 0.4 and 2 mg/kg, respectively, is proposed. For the remaining goat matrices, see the values reported above in this table under code 1013020 and 1013030 Further risk management discussion recommended
1014020	Fat, goat	0.15	0.1[d]	0.09	
1014030	Liver, goat	1.5	0.5[d]	0.7	
1014040	Kidney, goat	1.5	0.5[d]	2	
1014050	Edible offals (other than liver and kidney), goat	1.5	0.5[d]	For risk management discussion	
1015010	Muscle, equine	0.3	0.2[d]	0.2	**Special case**: EFSA proposed to extrapolate the MRLs derived for bovine matrices in accordance with case 20A to equine matrices Further risk management discussion on the proposed extrapolations is recommended
1015020	Fat, equine	0.15	0.1[d]	0.05	
1015030	Liver, equine	1.5	0.5[d]	0.4	
1015040	Kidney, equine	1.5	0.5[d]	1	
1015050	Edible offals (other than liver and kidney), equine	1.5	0.5[d]	For risk management discussion	
1016010	Muscle, poultry	0.05	0.04/0.05	0.05	**Case 14:** The new CXL could be taken over in the EU legislation, as the EU supported the new CXL for poultry muscle and poultry fat It is noted that the MRLs derived from the EU assessment (see Appendix C) are lower than the new CXLs (0.015 mg/kg for poultry muscle and 0.01 mg/kg for poultry fat)
1016020	Fat, poultry	0.05	0.04/0.05	0.05	

TABLE 1 (Continued)

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL/ recalculated CXL[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1016030	Liver, poultry	0.15	0.2[d]	0.015	**Case 20A**: The MRL proposals were derived by updating the most recent assessment performed in the context of an MRL application (EFSA, 2020), including the information on new residue trials relevant for feed reported to EFSA in the framework of the Member State consultation Details on the assessment can be found in Appendix C and in the evaluation reports provided by Italy (2024), Netherlands (2024) and Austria (2024)
1016040	Kidney, poultry	0.15	0.2[d]		
1016050	Edible offals (other than liver and kidney), poultry	0.15	0.2[d]		
1017010	Muscle, other farmed terrestrial animals	0.3	0.2[d]	0.2	**Special case**: EFSA proposed to extrapolate the MRLs derived for bovine matrices to matrices of other farmed terrestrial animals Further risk management discussion recommended
1017020	Fat, other farmed terrestrial animals	0.15	0.1[d]	0.05	
1017030	Liver, other farmed terrestrial animals	1.5	0.5[d]	0.4	
1017040	Kidney, other farmed terrestrial animals	1.5	0.5[d]	1	
1017050	Edible offals (other than liver and kidney), other farmed terrestrial animals	1.5	0.5[d]	For risk management discussion	
1020010	Milk, Cattle	0.5	0.2/0.3	0.3	**Case 15C:** The new CXL could be taken over in the EU legislation, as the EU supported the new CXL for milk
1020020	Milk, Sheep	0.5	0.2/0.3		
1020030	Milk, Goat	0.5	0.2/0.3		
1020040	Milk, Horse	0.5	0.2/0.3		
1030010	Eggs, chicken	0.15	0.2/0.3[d]	0.03	**Case 20A**: The MRL proposals were derived by updating the most recent assessment performed in the context of an MRL application (EFSA, 2020), including the information on new residue trials relevant for feed reported to EFSA in the framework of the Member State consultation. Details on the assessment can be found in Appendix C and in the evaluation reports provided by Italy (2024), the Netherlands (2024) and Austria (2024)
1030020	Eggs, duck	0.15	0.2/0.3[d]		
1030030	Eggs, geese	0.15	0.2/0.3[d]		
1030040	Eggs, quail	0.15	0.2/0.3[d]		

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

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]For CXLs where the EU did not express a reservation during CCPR54 or where reservation could be lifted after examination of the information in the JMPR evaluations (FAO and WHO, 2023b): CXL recalculated to EU residue definition for enforcement (rounded to the next highest MRL class). Conversion factor to recalculate from Codex residue definition to EU residue definition for enforcement: 1.29.

[c]EU reservation in CCPR54 because clarifications on the critical good agricultural practice (cGAP) were needed in JMPR report (para 77 of CCPR report REP23/PR54).

[d]EU reservation in CCPR54 because the result of the feeding study was rounded up to a higher MRL than necessary (para 77 of CCPR report REP23/PR54).

1.3 | Diazinon (22)

In the framework of the periodic review of diazinon, JMPR recommended the revocation of all existing CXLs (in total 52 CXLs) as JMPR was unable to conclude on the residue definitions for risk assessment (plant and animal products) as well on the residue definition for enforcement applicable to animal products (FAO and WHO, 2023). CCPR54 revoked all CXLs for diazinon.

Three of the revoked CXLs refer to feed and processed products (case 1 in decision tree).

The Codex food codes for the 49 CXLs related to unprocessed food products were mapped with the EU food codes (step 2). In total, 84 corresponding EU commodities were identified.

The residue definitions established at Codex and EU level were found to be identical (step 3). Hence, EU and the Codex MRLs are directly comparable.

In total, 42 EU MRLs set for the corresponding EU commodities identified in step 2 were identical with the revoked CXL (step 5).

The revoked CXLs were not replaced by new CXLs (step 6).

Step 8: In a targeted review of diazinon MRLs (EFSA, 2023), EFSA, supported by Member State experts, concluded that the existing toxicological reference values derived at EU level in the past (ADI 0.0002 mg/kg body weight (bw) per day, ARfD of 0.025 mg/kg bw [EFSA, 2006]) cannot be confirmed since the genotoxicity potential of diazinon is inconclusive, in

particular regarding its clastogenic and aneugenic potential. Accordingly, EFSA concluded that the ADI and ARfD values derived in 2006 in the EU do not comply with the current scientific standards. The toxicological reference values derived by JMPR are not appropriate alternatives (ADI 0.003 mg/kg bw per day, ARfD 0.003 mg/kg bw [FAO and WHO, 2016]), since according to the EU experts the data package assessed by JMPR suffered from the same limitations outlined above for the EU assessment. In the targeted MRL review for diazinon (EFSA, 2023), EFSA proposed the lowering of the existing EU MRLs for diazinon for plant products due to the lack of reliable toxicological reference values. The lowering of the existing EU MRLs is in line with case 9A described in the decision scheme.

For animal products, the origin of the EU MRLs is ambiguous as veterinary MRLs under Regulation (EU) No 37/2010 are set at the same levels. EFSA therefore recommends risk managers to consult the European Medicine Agency (EMA), asking for additional information whether the veterinary MRLs are reflecting currently authorised veterinary uses in livestock. If this is the case, EMA should be invited to share the risk assessment, including the toxicological studies used to derive the TRV performed for the veterinary MRLs with pesticide risk assessors. Depending on the available scientific data and the authorisation status of diazinon for veterinary uses, EFSA recommends a risk management discussion on the lowering of the existing EU MRLs to the LOQ (case 9A) or maintaining/lowering the EU MRLs at/to the level of the existing veterinary MRLs (fall-back MRL) (Case 11B).

In the following table, EFSA summarised the recommendations for those commodities where the existing EU MRLs are likely to be based on previously established CXLs that were revoked by CCPR54.

The proposals presented in the table below are aligned with the proposals derived by EFSA in the targeted MRL review (EFSA, 2023).

It should be noted that the assessment under the previous EFSA assessment was wider, reviewing all existing EU MRLs, while under the current mandate EFSA was asked to assess only the EU MRLs previously implemented in the EU. The recommendations on the lowering of the existing EU MRLs derived in the targeted review for these additional commodities (i.e. pineapples, muscle from swine, bovine, sheep, goat, fat from swine, bovine, sheep, goat, poultry muscle and poultry edible offals other than liver and kidney and milk (except milk of cattle, sheep and goat) are not affected by the current assessment (Table 2).

TABLE 2 Summary table for diazinon.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Diazinon[(F)] **Enforcement residue definition (Codex):** Diazinon[(F)]					
120010	Almonds	0.05	–	LOQ	**Case 9A**: Considering the deficiencies identified for the toxicological studies available to EFSA, and the conclusion not to confirm the previously derived TRV (EFSA, 2023), the lowering of the existing EU MRLs is proposed The recommendations to lower the existing MRLs to the LOQ are aligned with the recommendations derived in EFSA (2023)
154020	Cranberries	0.2	–	LOQ	
211000	Potatoes	0.01*	–	LOQ	
213080	Radishes	0.1	–	LOQ	
220020	Onions	0.05	–	LOQ	
231020	Sweet peppers/bell peppers	0.05	–	LOQ	
234000	Sweet corn	0.02	–	LOQ	
243010	Chinese cabbages/ pe-tsai	0.05	–	LOQ	
244000	Kohlrabies	0.2	–	LOQ	
700000	Hops	0.5	–	LOQ	
810010	Anise/aniseed	5	–	LOQ	
810020	Black caraway/black cumin	5	–	LOQ	
810030	Celery	5	–	LOQ	
810040	Coriander	5	–	LOQ	
810050	Cumin	5	–	LOQ	
810060	Dill	5	–	LOQ	
810070	Fennel	5	–	LOQ	
810080	Fenugreek	5	–	LOQ	
810090	Nutmeg	5	–	LOQ	
820010	Allspice/pimento	0.1*	–	LOQ	
820020	Sichuan pepper	0.1*	–	LOQ	

TABLE 2 (Continued)

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
820040	Cardamom	0.1*	–	LOQ	
820050	Juniper berry	0.1*	–	LOQ	
820060	Peppercorn (black, green and white)	0.1*	–	LOQ	
820070	Vanilla	0.1*	–	LOQ	
820080	Tamarind	0.1*	–	LOQ	
840010	Liquorice	0.5	–	LOQ	
840030	Turmeric/curcuma	0.5	–	LOQ	
900010	Sugar beet	0.1	–	LOQ	
1011030	Liver, pig	0.03	–	LOQ or 0.02 For further risk management discussion	**Case 9A:** Considering the deficiencies identified for the toxicological studies available to EFSA, and the conclusion not to confirm the previously derived TRV (EFSA, 2023), the lowering of the existing EU MRLs to the LOQ should be considered Alternative risk management option: **Case 11B**: The veterinary MRL of 0.02 mg/kg currently set in Reg. (EU) 37/2010 might be considered as an alternative MRL. Risk managers should discuss whether the lowering of the MRL to the veterinary MRL is acceptable, provided the veterinary MRL is reflecting a current veterinary use and the MRL is demonstrated to be safe for consumers. Additional data need to be provided to confirm the indicative risk assessment that has been performed in the recent assessment of EFSA (2023)
1011040	Kidney, pig	0.03	–	LOQ or 0.02 For risk management discussion	
1012030	Liver, bovine	0.03	–	LOQ or 0.02 For risk management discussion	
1012040	Kidney, bovine	0.03	–	LOQ or 0.02 For risk management discussion	
1013030	Liver, sheep	0.03	–	LOQ or 0.02 For risk management discussion	
1013040	Kidney, sheep	0.03	–	LOQ or 0.02 For risk management discussion	
1014030	Liver, goat	0.03	–	LOQ or 0.02 For risk management discussion	
1014040	Kidney, goat	0.03	–	LOQ or 0.02 For risk management discussion	
1020010	Milk, Cattle	0.02	–	LOQ or 0.02 Further risk management discussion	The origin of the existing EU MRLs is ambiguous: These MRLs might reflect the revoked CXL or the veterinary MRL set in Reg. (EU) 37/2010 **Case 9A:** Considering the deficiencies identified for the toxicological studies available to EFSA, and the conclusion not to confirm the previously derived TRV (EFSA, 2023), the lowering of the existing EU MRLs to the LOQ should be considered. For cattle milk a lower LOQ than the default LOQ might be required, as the default LOQ of 0.01 mg/kg was found to be not sufficiently protective for consumers (EFSA, 2023) Alternative risk management option: **Case 11B:** The veterinary MRL of 0.02 mg/kg currently set in Reg. (EU) 37/2010 might be considered as an alternative MRL. Risk managers should discuss whether the existing MRL can be maintained, provided the veterinary MRL is reflecting a current veterinary use and the MRL is demonstrated to be safe for consumers. Additional data need to be provided to confirm the indicative risk assessment has been performed in the recent assessment of EFSA (2023)
1020020	Milk, Sheep	0.02	–	LOQ or 0.02 Further risk management discussion	
1020030	Milk, Goat	0.02	–	LOQ or 0.02 Further risk management discussion	

Abbreviations: CXL, codex maximum residue limit; MRL, maximum residue level; TRV, toxicological reference values.

(F)The residue is fat soluble.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

1.4 | Bifenthrin (178)

Three CXLs were revoked in CCPR54 (see Appendix A); two of them refer to unprocessed food commodities which were previously implemented in the EU legislation (i.e. peppers, subgroup and eggplants) (step 5). The EU and the Codex residue definitions for MRL enforcement are identical (step 3).

The toxicological reference values for bifenthrin have been recently assessed in the EU (EFSA, 2023). In this assessment, EFSA concluded that the existing toxicological reference values derived in 2009 are not confirmed as the toxicological data did not comply with the current standards (case 9A). However, after the publication of the EFSA assessment, a manufacturer communicated to risk managers that additional data will be provided for being assessed by EFSA. As the new data may have an impact on the conclusions derived in the previous assessment of EFSA, the EU assessment could be considered as still ongoing (case 9B of decision schema).

Based on the existing ARfD, the existing EU MRLs for sweet peppers and eggplants/aubergines do not pose an acute consumer health risk. If risk managers consider the EU assessment of the toxicological reference values is still ongoing (case 9B), the existing EU MRLs could be maintained. However, if risk managers consider the assessment is completed and no safe alternative MRLs can be derived due to the lack of a robust EU toxicological reference values, the MRLs should be lowered to the LOQ (case 12CC).

It is also noted that the revoked CXLs for peppers (subgroup) and eggplants (aubergines) were replaced by new CXLs (step 10). The EU expressed a reservation on the new CXLs due to ongoing assessments at EU level (steps 13 and 17). A decision on the implementation of the new CXLs also depends on the conclusion taken on the TRV. Hence, the decision on whether the new CXL can be implemented in the EU is possible, if reliable TRV are derived and the risk assessment does not identify an unacceptable risk for consumers. Hence, a decision needs to be postponed.

In the summary table below, the recommendations for bifenthrin are outlined (Table 3).

TABLE 3 Summary table for bifenthrin.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Bifenthrin (sum of isomers)(F) **Enforcement residue definition (Codex):** Bifenthrin (sum of isomers)(F)					
231030	Aubergines/ eggplants	0.3	0.4[b]	For risk management discussion	**Case 9A**: The modification of the existing EU MRLs could be postponed, if risk managers consider the assessment of TRV is still ongoing, taking into account the communication/commitment of a manufacturer to provide additional toxicological studies. If at the end of such an assessment, EU TRV are derived, the decision on the implementation of the new CXLs can be taken The exposure estimated for the existing EU MRL was below the TRV derived in the EU in 2009 (EFSA, 2023) Alternative risk management option: **Case 9B:** Lowering of the existing MRL to the LOQ, considering that the existing toxicological reference values derived in 2009 were not confirmed as the toxicological data did not comply with the current standards (EFSA, 2023)
231020	Sweet peppers/ bell peppers	0.5	0.4[b]		

Abbreviations: CXL, codex maximum residue limit; MRL, maximum residue level; TRV, toxicological reference values.

(F)The residue is fat soluble.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXLs in CCPR54 because of an ongoing review in the EU.

1.5 | Fludioxonil (211)

In total, 12 CXLs were revoked; all of them refer to unprocessed food products (step 1).

The revoked CXLs were mapped with the corresponding EU food codes (in total, 40 EU food codes were identified as corresponding commodities) (step 2). As the revoked CXL for meat (from mammals other than marine mammals) was flagged with the suffix '(fat)', according to step 2b, the commodity should be mapped with the corresponding EU commodities, i.e. fat (pigs, bovine, sheep, goat, equine and other farmed animals). However, in 2019, when the CXL for meat (fat) was established, EFSA derived the corresponding MRLs for muscle (i.e. 0.02 mg/kg [EFSA, 2019]) which were taken over in the EU legislation. The EU MRLs for muscle established under Regulation (EU) 2020/856,[9] which is the regulation implementing the CXLs established in 2019, are therefore linked to the CXL established in 2019 for meat (from mammals other than marine mammals) and should be assessed under the current review.

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

The residue definition for MRL enforcement set at JMPR and at EU level are comparable. Hence, the direct comparison of the levels of EU and Codex MRLs is possible (step 3).

For 36 of the cases identified in step 2, the existing EU MRLs were found to be equal to the revoked CXLs, and therefore, these cases need to be assessed in view of identifying alternative MRLs since the EU MRLs might be based on the previous CXLs.

For four of the EU food commodities mapped with Codex food codes for the revoked CXLs, the EU MRLs were set at different levels (i.e. beans (with pods), peas (with pods), peas (dry) and lentils (dry)), and therefore, no further assessment is required under the current mandate (case 5).

All of the revoked CXLs implemented in the EU legislation were replaced with new CXLs. As the EU expressed a reservation on the new CXLs due to the ongoing periodic re-evaluation in the EU, a decision on the possible implementation of the new CXLs or a replacement by other MRLs should be postponed, noting that for existing EU MRLs for the commodities concerned, no intake concerns were identified (case 18).

In the following table, EFSA summarises recommendations for fludioxonil (Table 4).

TABLE 4 Summary table for fludioxonil.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): **Plant products:** Fludioxonil **Animal products:** Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil(F) **Enforcement residue definition (Codex):** **Plant products:** Fludioxonil **Animal products:** Sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, expressed as fludioxonil(F)					
163030	Mangoes	2	7[b]	Postpone decision on modification of existing EU MRLs	**Case 18**: For the new CXLs adopted in 2023 (replacing the revoked CXLs), the EU expressed a reservation due to the ongoing periodic re-evaluation of the a.s in the EU. The process is not yet completed. A decision whether the new CXLs can be implemented in the EU or whether the existing EU MRLs need to be modified should therefore be postponed, awaiting the outcome of the EU renewal process and the assessment of endocrine disrupting properties of fludioxonil. The existing EU MRLs are unlikely to pose a risk for consumers (EFSA, 2021)
300010	Beans	0.5	0.3[b]		
1011010	Muscle, pig	0.02	0.02[b,c]		
1011020	Fat, pig	0.02	0.02[b]		
1011030	Liver, pig	0.1	0.15[b]		
1011040	Kidney, pig	0.1	0.15[b]		
1011050	Edible offals (other than liver and kidney), pig	0.1	0.15[b]		
1012010	Muscle, bovine	0.02	0.02[b,c]		
1012020	Fat, bovine	0.02	0.02[b]		
1012030	Liver, bovine	0.1	0.15[b]		
1012040	Kidney, bovine	0.1	0.15[b]		
1012050	Edible offals (other than liver and kidney), bovine	0.1	0.15[b]		
1013010	Muscle, sheep	0.02	0.02[b,c]		
1013020	Fat, sheep	0.02	0.02[b]		
1013030	Liver, sheep	0.1	0.15[b]		
1013040	Kidney, sheep	0.1	0.15[b]		
1013050	Edible offals (other than liver and kidney), sheep	0.1	0.15[b]		
1014010	Muscle, goat	0.02	0.02[b,c]		
1014020	Fat, goat	0.02	0.02[b]		
1014030	Liver, goat	0.1	0.15[b]		
1014040	Kidney, goat	0.1	0.15[b]		
1014050	Edible offals (other than liver and kidney), goat	0.1	0.15[b]		
1015020	Muscle, equine	0.02	0.02[b,c]		
1015020	Fat, equine	0.02	0.02[b]		
1015030	Liver, equine	0.1	0.15[b]		
1015040	Kidney, equine	0.1	0.15[b]		
1015050	Edible offals (other than liver and kidney), equine	0.1	0.15[b]		

(Continues)

TABLE 4 (Continued)

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1017010	Muscle, other farmed terrestrial animals	0.02	0.02[b,c]		
1017020	Fat, other farmed terrestrial animals	0.02	0.02[b]		
1017030	Liver, other farmed terrestrial animals	0.1	0.15[b]		
1017040	Kidney, other farmed terrestrial animals	0.1	0.15[b]		
1017050	Edible offals (other than liver and kidney), other farmed terrestrial animals	0.1	0.15[b]		
1020010	Milk, Cattle	0.04	0.07[b]		
1020020	Milk, Sheep	0.04	0.07[b]		
1020030	Milk, Goat	0.04	0.07[b]		
1020040	Milk, Horse	0.04	0.07[b]		

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

[(F)]The residue is fat soluble.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXLs in CCPR54 because of an ongoing periodic re-evaluation in the EU.

[c]The new CXL is no longer flagged with the suffix (fat). Hence, the CXL therefore refers to meat, which is a mixture of 80% muscle and 20% fat. However, as the residue concentration in fat were similar to muscle, the different matrix description at EU and Codex level does not have an impact on the MRL level.

1.6 | Indoxacarb (216)

In total, five CXLs were revoked, which were assessed according to the assessment approach outlined in Section 1. Among these revoked CXLs, two CXLs refer to feed (maize fodder, dry) and to processed products (milk fats). No further discussion is required for these CXLs, since they are not covered by the MRL EU legislation (case 1).

The food codes for the remaining three revoked CXLs were mapped with the corresponding EU food codes; in total, 42 EU food codes were identified as corresponding commodities (step 2). As the revoked CXL for meat (from mammals other than marine mammals) was flagged with the suffix '(fat)', according to step 2b, the commodity was mapped with the corresponding EU commodities, i.e. fat (pigs, bovine, sheep, goat, equine and other farmed animals).[10]

Since the residue definitions for MRL enforcement set at JMPR and at EU level are identical, a direct comparison of the levels of EU and Codex MRLs is possible (steps 3 and 5).

For 37 of the cases identified in step 2, the existing EU MRLs were found to be equivalent to the revoked CXLs.[11] However, it is noted that the EU MRLs for indoxacarb for all commodities, including the commodities related to the revoked CXLs, were recently lowered to the LOQ of 0.01 mg/kg,[12] following a targeted review of the MRLs for indoxacarb in view of the lowered ADI and ARfD derived at EU level. In this assessment, EFSA concluded that insufficient data are available to conclude on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature (EFSA, 2022a).

In CCPR54, the EU expressed a reservation on the new CXLs, because of the uncertainties on the toxicity and genotoxicity metabolites and degradation for metabolites (IN-P0036, KT413, IN-MP819, IN-TMG00 and IN-MK638) (case 13). In addition, the EU submitted a concern form requesting that JMPR prioritise the periodic review of indoxacarb, based on concerns with the existing toxicological reference values last evaluated in 2005 and insufficient data on metabolites that may present a health concern (CCPR, 2023).

In the context of the current assessment, EFSA recommends that the recently agreed EU MRLs (lowered to the LOQ) should continue to apply.

The following table summarises the recommendations for indoxacarb (Table 5).

[10]It is noted that according to the results of feeding studies in lactating cows and laying hens assessed by JMPR (2009), no residues were found in muscle when the test animals were dosed with feeding levels equal to the calculated dietary burden. In the regulation implementing the CXLs (Regulation (EU) 2015/845), the MRL for muscle of mammalian species was erroneously set at the same level as the MRL for fat, while an MRL of 0.04 mg/kg would have been sufficient.

[11]The revoked CXL for meat (from mammals other than marine mammals) were not considered; the CXL for fat was mapped with the corresponding EU MRLs for fat of pigs, bovine, sheep, goat, equine and other farmed terrestrial animals.

[12]Regulation not yet published; document PLAN/2023/242 voted in the Standing Committee on Plants, Animals, Food and Feed, Section Phytopharmaceuticals- Pesticide Residues held on 19 September 2023.

TABLE 5 Summary table for indoxacarb.

Code[a]	Commodity	Existing EU MRL/new EU MRL[b] (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Indoxacarb (sum of indoxacarb and its R enantiomer)[(F)] **Enforcement residue definition (Codex):** Sum of indoxacarb and its R enantiomer[(F)]					
1011020	Fat, pig	2/0.01*	2[c]	0.01*	**Special case:** The recently lowered EU MRLs set at the LOQ of 0.01 mg/kg shall continue to apply
1011030	Liver, pig	0.05/0.01*	0.05[c]	0.01*	
1011040	Kidney, pig	0.05/0.01*	0.05[c]	0.01*	
1011050	Edible offals (other than liver and kidney), pig	0.05/0.01*	0.05[c]	0.01*	
1012020	Fat, bovine	2/0.01*	2[c]	0.01*	
1012030	Liver, bovine	0.05/0.01*	0.05[c]	0.01*	
1012040	Kidney, bovine	0.05/0.01*	0.05[c]	0.01*	
1012050	Edible offals (other than liver and kidney), bovine	0.05/0.01*	0.05[c]	0.01*	
1013020	Fat, sheep	2/0.01*	2[c]	0.01*	
1013030	Liver, sheep	0.05/0.01*	0.05[c]	0.01*	
1013040	Kidney, sheep	0.05/0.01*	0.05[c]	0.01*	
1013050	Edible offals (other than liver and kidney), sheep	0.05/0.01*	0.05[c]	0.01*	
1014020	Fat, goat	2/0.01*	2[c]	0.01*	
1014030	Liver, goat	0.05/0.01*	0.05[c]	0.01*	
1014040	Kidney, goat	0.05/0.01*	0.05[c]	0.01*	
1014050	Edible offals (other than liver and kidney), goat	0.05/0.01*	0.05[c]	0.01*	
1015020	Fat, equine	2/0.01*	2[c]	0.01*	
1015030	Liver, equine	0.05/0.01*	0.05[c]	0.01*	
1015040	Kidney, equine	0.05/0.01*	0.05[c]	0.01	
1015050	Edible offals (other than liver and kidney), equine	0.05/0.01*	0.05[c]	0.01*	
1017020	Fat, other farmed terrestrial animals	2/0.01*	2[c]	0.01*	
1017030	Liver, other farmed terrestrial animals	0.05/0.01*	0.05[c]	0.01*	
1017040	Kidney, other farmed terrestrial animals	0.05/0.01*	0.05[c]	0.01*	
1017050	Edible offals (other than liver and kidney), other farmed terrestrial animals	0.05/0.01*	0.05[c]	0.01*	
1020010	Milk, Cattle	0.1/0.01*	0.2[c]	0.01*	
1020020	Milk, Sheep	0.1/0.01*	0.2[c]	0.01*	
1020030	Milk, Goat	0.1/0.01*	0.2[c]	0.01*	
1020040	Milk, Horse	0.1/0.01*	0.2[c]	0.01*	

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

[(F)]The residue is fat soluble.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]New EU MRLs voted in September 2023 (Regulation not yet published. New MRLs will become applicable 6 months after the entry into force of the new Regulation).

[c]EU reservation on new CXLs in CCPR54 due to uncertainties on the toxicity and genotoxicity metabolites and degradation for metabolites (IN-P0036, KT413, IN-MP819, IN-TMG00, and IN-MK638).

1.7 | Difenoconazole (224)

Two CXLs referring to unprocessed food products were revoked (i.e. CXL for tea and fruiting vegetables (other than cucurbits)) (step 1). As the residue definitions for enforcement derived by JMPR and in the EU are identical (step 2), the MRLs can be directly compared. Among the commodities covered by the Codex code for fruiting vegetables other than cucurbits, two EU MRLs are set at the same level as the revoked CXL (i.e. aubergines and okra) (step 5). The revoked CXL for tea has not been implemented in the EU legislation, and therefore, not further action is required for tea (case 5).

In CCPR54, the revoked CXL for fruiting vegetables other than cucurbits was replaced by a new CXL for which the EU expressed a reservation due to ongoing assessments at EU level (renewal of the approval of the a.s., review of the existing EU MRLs). Hence, a decision whether the new CXL (replacing the existing CXLs) can be implemented in the EU legislation, shall be postponed, as the existing EU MRLs do not pose an acute consumer health risk (case 18).[13]

In the summary table below, the recommendations for difenoconazole are outlined (Table 6).

TABLE 6 Summary table for difenoconazole.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU, for plant products): Difenoconazole **Enforcement residue definition (Codex):** Difenoconazole					
231030	Aubergines/eggplants	0.6	0.6[b]	Postpone decision on modification of existing EU MRLs	**Case 18**: The decision whether the new CXLs is acceptable shall be postponed. Currently, no modification is necessary, as the existing EU MRL is unlikely to pose a risk for consumers
231040	Okra/lady's fingers	0.6	0.6[b]		

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

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXLs in CCPR54 because of an ongoing periodic review in the EU.

1.8 | Famoxadone (208)

Three CXLs were revoked in CCPR54 (see Appendix A); all three have been previously implemented in the EU legislation (i.e. cucumber, summer squash (courgettes), tomatoes)) (step 5). The EU and the Codex residue definitions for MRL enforcement are identical (step 3).

Toxicological reference values for famoxadone have been derived in 2021 which can be used for the assessment of the safety of EU MRLs (step 8).

In CCPR54, the revoked CXLs were replaced by new CXLs (step 10). The EU expressed a reservation on the new CXLs for cucumber and summer squash (courgette) as the residue trials were not representative of the assessed GAP and the EU suggested that JMPR consider deriving a separate MRL for cucumbers and summer squashes based on available residue trials (steps 13 and 17). Hence, fall-back MRLs need to be derived for cucumbers and courgettes.

The new CXL for tomatoes (set at the same level as the revoked CXL) was found to be acceptable (steps 13 and 14), and therefore, the existing MRL can be maintained in the EU legislation (case 14). The risk assessment for famoxadone presented in the report of EFSA to provide scientific support for preparing an EU position for the 2023 CCPR meeting is still valid (EFSA, 2023b).

In the summary table below, the recommendations for famoxadone are outlined (Table 7).

TABLE 7 Summary table for famoxadone.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Famoxadone[(F)] **Enforcement residue definition (Codex):** Famoxadone[(F)]					
232010	Cucumbers	0.2	0.6[b]	LOQ	**Case 21C**: Famoxadone is no longer approved in the EU. Hence, the previously assessed EU uses (EFSA, 2012a) are no longer relevant for MRL setting The new CXL was not supported by the EU As no import tolerances are reported/supported by data, the existing MRL should be lowered to the LOQ
232030	Courgettes	0.2	0.6[b]	LOQ	
231010	Tomatoes	2	2	2	**Case 14**: The revoked CXL was replaced by a new CXL, which was sufficiently supported by data. No intake concern was identified (EFSA, 2023b). As the EU supported the new CXL, it can be implemented in the EU. A modification of the existing EU MRL is not required, as the new CXL is set at the same level as the EU MRL

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

[(F)]The residue is fat soluble.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXL in CCPR54 because residue trials were not representative of the present GAP; the EU suggested that JMPR consider deriving separate MRLs for cucumbers and summer squashes based on available residue trials.

[13]See risk assessment for difenoconazole presented in EFSA (2023b). The acute risk assessment for the commodities under assessment is still valid.

1.9 | Azoxystrobin (229)

Three CXLs for food products were revoked in CCPR54 (step 1). The residue definitions for MRL enforcement set at JMPR and at EU level are identical (step 2). All three revoked CXLs have been previously implemented in the EU legislation (step 5). As the revoked CXLs were replaced by new CXLs for which the EU did not make a reservation during the CCPR meeting, the new CXLs can be implemented in EU legislation (case 14).

The risk assessment for azoxystrobin presented in the report of EFSA to provide scientific support for preparing an EU position for the 2023 CCPR meeting is still valid (EFSA, 2023b).

In the summary table below, the EU food commodities concerned are listed, containing the existing EU MRL and the new MRLs reflecting the new CXLs (Table 8).

TABLE 8 Summary table for azoxystrobin.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Azoxystrobin **Enforcement residue definition (Codex):** Azoxystrobin					
163040	Papayas	0.3	4	4	**Case 14**: The new CXL derived by CCPR54 for papayas, replacing the previous CXL, was considered acceptable by the EU. No intake concerns were identified
212010	Cassava roots/manioc	1	1	1	**Case 14**: The new CXL derived by CCPR54 for root and tuber vegetables (except potatoes), replacing the previous CXL, was considered acceptable by the EU. No intake concerns were identified. Hence, the existing EU MRLs (identical with the new CXL) shall be maintained
212020	Sweet potatoes	1		1	
212030	Yams	1		1	
212040	Arrowroots	1		1	
213010	Beetroots	1		1	
213020	Carrots	1		1	
213030	Celeriacs/turnip-rooted celeries	1		1	
213040	Horseradishes	1		1	
213050	Jerusalem artichokes	1		1	
213060	Parsnips	1		1	
213070	Parsley roots/Hamburg roots parsley	1		1	
213,090	Salsifies	1		1	
213100	Swedes/rutabagas	1		1	
213110	Turnips	1		1	

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

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

1.10 | Mandipropamid (231)

In total, eight CXLs were revoked; one of the revoked CXLs refers to a processed product (Peppers chilli, dried). No further discussion is required for this CXL, since it is not covered by the EU legislation (step 1).

The Codex food codes for the remaining seven revoked CXLs were mapped with the corresponding EU food codes; in total, seven EU food codes were identified as corresponding commodities (step 2).

As the residue definitions for MRL enforcement set at JMPR and at EU level are comparable, a direct comparison of the levels of EU and Codex MRLs is possible (step 5).

The EU MRL for tomatoes is not identical with the revoked CXL; this MRL is therefore not further assessed, as it is not based on a previously valid CXL. For the remaining six cases identified in step 5 (i.e. onions, spring onions, sweet peppers, cucumbers, courgettes and melons), the existing EU MRLs were found to be most likely based on the revoked CXLs.

The revoked CXLs for onions, sweet peppers, cucumbers, courgettes and melons were replaced by new CXLs (step 10).

The EU expressed a reservation on the new CXL for onions due to an ongoing EU assessment (step 17).[14] Hence, a decision on the fall-back MRL for onions should be postponed, awaiting the outcome of the ongoing assessment. The new CXLs for sweet peppers, cucumbers, courgettes and melons established in CCPR54 were supported by the EU (step 14). As

[14]The EU residue definition for risk assessment for root crops also covers metabolite SYN 500003, which was shown to be more acutely toxic than mandipropamid; however, due to data gaps, it was not possible to derive reference values for the consumer risk assessment (EFSA, 2012b). New data were provided by the applicant which are assessed in the framework of renewal of the approval for the a.s. The assessment is still ongoing.

the current EU MRL for cucumber and courgettes is set at the same level as the new CXLs, no modification of the EU MRL is required (case 14). For melons, some Member States reported national authorisations. However, the new CXL is higher than the MRL required for these EU uses (i.e. 0.3 mg/kg). Therefore, the new CXL of 0.4 mg/kg is an appropriate fall-back MRL, which also covers the authorised EU uses.

In the following table, the recommendations for fall-back MRLs for mandipropamid are summarised (Table 9).

TABLE 9 Summary table for mandipropamid.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Mandipropamid (any ratio of constituent isomers) **Enforcement residue definition (Codex):** Mandipropamid					
220020	Onions	0.1	0.05[b]	Further risk management discussion recommended	**Case 18**: The decision whether the new CXL replacing the revoked CXL shall be implemented at EU level or whether an alternative fall-back MRL shall be established should be postponed, awaiting the outcome of the assessment of the residue definition for risk assessment for root and tuber vegetables For mandipropamid, an acute risk assessment was not necessary (no ARfD established). For the metabolite proposed for being included in the residue definition for risk assessment for root crops (SYN 500003), currently no ARfD is available[c] EFSA therefore recommends that risk managers discuss whether the existing EU MRL shall be maintained until a decision on the toxicological profile of metabolite SYN 500003 can be taken
220040	Spring onions/ green onions and Welsh onions	7	No new CXL adopted	Further risk management discussion recommended	**Special case**: A decision on the appropriate fall-back MRL for spring onions shall be linked to the decision on the fall-back MRL for onions. For both commodities, the toxicological profile of metabolite SYN 500003 needs to be addressed, before fall-back MRLs can be identified
231020	Sweet peppers/bell peppers	1	0.7	0.7	**Case 16C**: The new CXL was supported by the EU in CCPR54. Hence, it could be used as a fall-back MRL in the EU No uses in third countries were reported to EFSA that would require a higher MRL
232010	Cucumbers	0.2	0.2	0.2	**Case 14**: The new CXL was supported by the EU; as it is set at the same level as the existing EU MRL based on the revoked CXL, no modification of the EU MRL is required
232030	Courgettes	0.2	0.2	0.2	
233010	Melons	0.5	0.4	0.4	Case 16 C: The new CXL was supported by the EU in CCPR54. In 2018, in the framework of the MRL review, an MRL proposal of 0.3 mg/kg was derived which reflects an EU indoor use of mandipropamid (EFSA, 2018). Some Member States confirm the authorisation of the indoor use in melons. As the new CXL is higher than the MRL required for the EU uses, the new CXL would be an appropriate fall-back MRL, covering the authorised EU uses

Abbreviations: ARfD, acute reference dose; CXL, codex maximum residue limit; MRL, maximum residue level.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXLs in CCPR54 because of an ongoing periodic review in the EU.

[c]The toxicological profile of metabolite SYN 500003 will be performed in the context of the renewal of the active. New data were provided but are not yet assessed.

1.11 | Emamectin benzoate (247)

In total, four CXLs were revoked by CCPR54 (see Appendix A). They all refer to unprocessed food products (step 1).

The Codex food codes for the revoked CXLs were mapped with the EU food codes. In total, 34 corresponding EU commodities were identified (step 2).

As the residue definitions for MRL enforcement derived in the EU and at Codex level are different, a direct comparison of the EU MRLs with the Codex MRLs is not possible (step 3). However, the Codex MRLs, which are expressed as emamectin B1a benzoate, can be recalculated to the EU residue definition (Emamectin B1a (free base)) by applying a molecular weight correction factor of 0.88 (step 4) before they are compared with the EU MRLs. For all commodities concerned, the EU MRLs were found to be equivalent to the revoked CXLs (step 5).

For emamectin, toxicological reference values are established in the EU which can be used to assess the safety of EU MRLs (step 8).

The revoked CXLs identified in step 5 were replaced by new CXLs; most of the new CXLs which are proposed to be set at the same level or a slightly higher level than the revoked CXL were supported by the EU in CCPR54, and therefore shall be implemented in the EU MRL legislation (case 14). However, for the new CXLs for milks, the EU introduced a reservation, as the CXLs were found to be set at a level higher than necessary (step 19). Hence, for milks, the existing EU MRL which is set at the LOQ shall be maintained (case 20D).

In the following table, EFSA summarised the recommendations on fall-back MRLs for emamectin (Table 10).

TABLE 10 Summary table for emamectin.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL/ recalculated CXL[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Emamectin B1a and its salts, expressed as emamectin B1a (free base)[(F)] **Enforcement residue definition (Codex):** Emamectin B1a benzoate[(F),c]					
1011020	Fat, pig	0.02	0.02/0.02	0.02	**Case 14**: The new CXLs derived by CCPR54, replacing the previous CXL, were considered acceptable by the EU. (The new CXLs were recalculated to match with the EU residue definition and rounded to the next MRL class. This recalculation gave the same MRL value.) No intake concerns were identified (EFSA, 2023b)
1012020	Fat, bovine	0.02	0.02/0.02	0.02	
1013020	Fat, sheep	0.02	0.02/0.02	0.02	
1014020	Fat, goat	0.02	0.02/0.02	0.02	
1015020	Fat, equine	0.02	0.02/0.02	0.02	
1017020	Fat, other farmed terrestrial animals	0.02	0.02/0.02	0.02	
1020010	Milk, Cattle	0.002*	0.003[d]	0.002*	**Case 20D**: The existing EU MRL set at LOQ shall continue to apply The new CXL was not considered to be an alternative fall-back MRL option as the EU expressed a reservation
1020020	Milk, Sheep	0.002*	0.003[d]		
1020030	Milk, Goat	0.002*	0.003[d]		
1020040	Milk, Horse	0.002*	0.003[d]		
1011010	Muscle, pig	0.004	0.005/0.005	0.005	**Case 14**: The new CXLs derived by CCPR54, replacing the previous CXL, were considered acceptable by the EU (The new CXLs were recalculated to match with the EU residue definition; and rounded to the next MRL class. The value reflects the residues expected in muscle). No intake concerns were identified (EFSA, 2023b)
1012010	Muscle, bovine	0.004	0.005/0.005	0.005	
1013010	Muscle, sheep	0.004	0.005/0.005	0.005	
1014010	Muscle, goat	0.004	0.005/0.005	0.005	
1015010	Muscle, equine	0.004	0.005/0.005	0.005	
1017010	Muscle, other farmed terrestrial animals	0.004	0.005/0.005	0.005	
1011030	Liver, pig	0.08	0.1/0.09	0.09	**Case 14**: The new CXLs derived by CCPR54, replacing the previous CXL, were recalculated to match with the EU residue definition. The new CXLs were considered acceptable by the EU. No intake concerns were identified (EFSA, 2023b)
1011040	Kidney, pig	0.08	0.1/0.09	0.09	
1011050	Edible offals (other than liver and kidney), pig	0.08	0.1/0.09	0.09	
1012030	Liver, bovine	0.08	0.1/0.09	0.09	
1012040	Kidney, bovine	0.08	0.1/0.09	0.09	
1012050	Edible offals (other than liver and kidney), bovine	0.08	0.1/0.09	0.09	
1013030	Liver, sheep	0.08	0.1/0.09	0.09	
1013040	Kidney, sheep	0.08	0.1/0.09	0.09	
1013050	Edible offals (other than liver and kidney), sheep	0.08	0.1/0.09	0.09	
1014030	Liver, goat	0.08	0.1/0.09	0.09	
1014040	Kidney, goat	0.08	0.1/0.09	0.09	
1014050	Edible offals (other than liver and kidney), goat	0.08	0.1/0.09	0.09	
1015030	Liver, equine	0.08	0.1/0.09	0.09	
1015040	Kidney, equine	0.08	0.1/0.09	0.09	
1015050	Edible offals (other than liver and kidney), equine	0.08	0.1/0.09	0.09	
1017030	Liver, other farmed terrestrial animals	0.08	0.1/0.09	0.09	
1017040	Kidney, other farmed terrestrial animals	0.08	0.1/0.09	0.09	
1017050	Edible offals (other than liver and kidney), other farmed terrestrial animals	0.08	0.1/0.09	0.09	

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

[(F)]The residue is fat soluble.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]For CXLs where the EU did not express a reservation during CCPR54: CXL recalculated to EU residue definition for enforcement (rounded to the next highest MRL class). Conversion factor to recalculate from Codex residue definition to EU residue definition for enforcement: 0.88.

[c]Conversion factor to recalculate from Codex residue definition to EU residue definition for enforcement: 0.88.

[d]Reservation because the proposed CXL for milk (0.003 mg/kg; the recalculation of the CXL to the EU residue definition results in the same level (i.e. 0.003 mg/kg), was considered to be too high, not reflecting the results of the feeding study and therefore violating the ALARA principle.

1.12 | Flutriafol (248)

In total, eight CXLs were revoked (see Appendix A). They all refer to unprocessed food products (step 1).

The Codex food codes for the revoked CXLs were mapped with the EU food codes (step 2). As the Codex MRLs for meat from mammals other than marine mammals are flagged with the suffix (fat), they were mapped with the EU codes for fat of the different mammalian species (step 2c). In total, 43 corresponding EU commodities were identified.

As the residue definitions are identical, a direct comparison of the EU MRLs with the Codex MRLs is possible (step 3).

For 12 of the commodities identified in step 2, the existing EU MRLs were found to be equivalent to the revoked CXLs (step 5).

Although flutriafol is no longer approved in the EU, the toxicological reference values established in 2011[15] is still applicable and can be used to assess the safety of EU MRLs (step 8).

The revoked CXLs identified in step 5 were replaced by new CXLs which were supported by the EU in CCPR54 (step 13). For all of these cases, the new CXL was set at a higher or at the same level as the revoked CXL, and therefore, the new CXLs shall be implemented in the EU or the existing EU MRLs shall continue to be applied (case 14).

In the following table, EFSA summarised the recommendation on fall-back MRLs for flutriafol (Table 11).

TABLE 11 Summary table for flutriafol.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Flutriafol **Enforcement residue definition (Codex):** Flutriafol(F)					
1020010	Milk, Cattle	0.01*	0.01	0.01	**Case 14**: The revoked CXLs were replaced by new CXLs, which were sufficiently supported by data. According to JMPR report 2022, in poultry muscle, residues of < 0.0024 mg/kg are expected at the maximum dietary burden. Hence, the current EU MRL of 0.01* mg/kg would be sufficient to cover the Codex MRL. As the Codex MRL is flagged with the suffix (fat), which means that the MRL refers to fat, the CXL should be taken over for poultry fat No intake concerns were identified (EFSA, 2023b). As the EU supported the new CXLs, they can be implemented in the EU MRL legislation
1020020	Milk, Sheep	0.01*	0.01	0.01	
1020030	Milk, Goat	0.01*	0.01	0.01	
1020040	Milk, Horse	0.01*	0.01	0.01	
1030010	Eggs, chicken	0.01*	0.01	0.01	
1030020	Eggs, duck	0.01*	0.01	0.01	
1030030	Eggs, geese	0.01*	0.01	0.01	
1030040	Eggs, quail	0.01*	0.01	0.01	
1016010	Muscle, poultry	0.01*	0.03 (fat)	0.01*	
1016020	Fat, poultry	0.01*	0.03 (fat)	0.03	
1016030	Liver, poultry	0.03	0.03	0.03	
1016040	Kidney, poultry	0.03	0.03	0.03	
1016050	Edible offals (other than liver and kidney), poultry	0.03	0.03	0.03	

Abbreviation: CXL, codex maximum residue limit; MRL, maximum residue level.

(F)The residue is fat soluble.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

1.13 | Afidopyropen (312)

In total, eight CXLs were revoked, all of them related to unprocessed food commodities.

These Codex food codes of the revoked CXLs were mapped with the corresponding EU food codes; in total, 43 EU food codes were identified as corresponding commodities (step 2).

At EU level, default MRLs according to Art. 18(1)(b) and the default residue definition (i.e. parent compound only) are applicable. The Codex residue definition covers only parent compound and therefore the residue definitions can be considered comparable (step 3), noting that the Codex residue definition is flagged as fat soluble.

For 21 food EU commodity codes, the existing EU MRLs set at the limit of quantification (LOQ) were found to be identical to the revoked CXLs (steps 5 and 6). In 13 of these cases, the revoked CXLs were replaced by new CXLs, equally set at the LOQ. Hence, for these commodities, the EU MRL at the LOQ shall continue to apply (case 7). For eight commodities, the new CXLs were set at higher levels. However, as the EU expressed a reservation due to the lack of available toxicological data at EU level and pending the outcome of the review by the EU, a decision on the modification of the MRLs for should be postponed (case 18).

[15]Commission Implementing Directive 2011/42/EU of 11 April 2011 amending Council Directive 91/414/EEC to include flutriafol as active substance and amending Commission Decision 2008/934/EC. OJ L 97, 12.4.2011, p. 42–45.

The remaining 21 revoked CXLs (all of them set at levels greater than the LOQ, except the one for milk which was set at the level of 0.001*mg/kg) have not been implemented in the EU legislation and therefore are not subject to the current assessment (case 4).

In the following table, EFSA summarises the assessment for afidopyropen (Table 12).

TABLE 12 Summary table for afidopyropen.

Code[a]	Commodity	Existing EU MRL (mg/kg)	New CXL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition (EU): Afidopyropen (default MRLs) **Enforcement residue definition (Codex):** Afidopyropen[(F)]					
1011010	Muscle, pig	0.01*	0.01*[b]	0.01*	**Case 7:** The EU MRLs are set at the default level of 0.01 mg/kg. The revoked CXLs and the new CXLs are also set at the level of 0.01 mg/kg. It is noted that the EU expressed a reservation on the new CXL (see footnote (b)) EFSA concludes that there is no need to modify the current EU MRLs set at the LOQ of 0.01 mg/kg
1011020	Fat, pig	0.01*	0.01*[b]	0.01*	
1012010	Muscle, bovine	0.01*	0.01*[b]	0.01*	
1012020	Fat, bovine	0.01*	0.01*[b]	0.01*	
1013010	Muscle, sheep	0.01*	0.01*[b]	0.01*	
1013020	Fat, sheep	0.01*	0.01*[b]	0.01*	
1014010	Muscle, goat	0.01*	0.01*[b]	0.01*	
1014020	Fat, goat	0.01*	0.01*[b]	0.01*	
1015010	Muscle, equine	0.01*	0.01*[b]	0.01*	
1015020	Fat, equine	0.01*	0.01*[b]	0.01*	
1016010	Muscle, poultry	0.01*	0.01*[b]	0.01*	
1016020	Fat, poultry	0.01*	0.015[b]	Postpone decision on modification of existing EU MRLs	**Case 18**: The decision whether the new CXLs replacing the revoked CXLs can be implemented in the EU legislation should be postponed, if risk managers decide to request an EU assessment of the toxicological profile of afidopyropen similar to the assessment performed for the four a.s. presented in Section 2 of the current report. The existing EU MRL at the LOQ is not posing a risk for consumers
1016030	Liver, poultry	0.01*	0.02[b]		
1016040	Kidney, poultry	0.01*	0.02[b]		
1016050	Edible offals (other than liver and kidney), poultry	0.01*	0.02[b]		
1017010	Muscle, other farmed terrestrial animals	0.01*	0.01*[b]	0.01*	**Case 7**: The EU MRLs are set at the default level of 0.01 mg/kg. The revoked CXLs and the new CXLs are also set at the level of 0.01 mg/kg Hence, there is no need to modify the EU MRLs
1017020	Fat, other farmed terrestrial animals	0.01*	0.01*[b]	0.01*	
1030010	Eggs, chicken	0.01*	0.03[b]	Postpone decision on modification of existing EU MRLs	**Case 18**: The decision whether the new CXLs replacing the revoked CXLs can be implemented in the EU legislation should be postponed, if risk managers decide to request an EU assessment of the toxicological profile of afidopyropen similar to the assessment performed for the four a.s. presented in Section 2 of the current report. The existing EU MRL at the LOQ is not posing a risk for consumers.
1030020	Eggs, duck	0.01*	0.03[b]		
1030030	Eggs, geese	0.01*	0.03[b]		
1030040	Eggs, quail	0.01*	0.03[b]		

MRL: maximum residue level; CXL: codex maximum residue limit.

[(F)]The residue is fat soluble.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]EU reservation on new CXLs in CCPR54 due to the lack of available toxicological data at EU level and pending the outcome of the review by the EU.

2 | TOXICOLOGICAL ASSESSMENT OF A.S. FOR WHICH PREVIOUSLY NO EU EVALUATION WAS PERFORMED

As per term of reference 2, EFSA has been mandated by the European Commission to assess the information available in the JMPR monograph (FAO and WHO, 2023c) as regards the substances pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole in addition to the relevant 2021 JMPR report (FAO and WHO, 2022). The purpose of this EFSA assessment is to provide advice whether the EU reservations on these four substances could be lifted based on the detailed assessment of the toxicological data reported in the JMPR Monographs.

2.1 | Methodology for reviewing toxicological assessment and the risk assessment of CXLs established for the a.s. under assessment

To address this point of the Terms of Reference, EFSA scrutinised the available toxicological information provided in the JMPR monograph (FAO and WHO, 2023c) and verified (1) whether the data set is in line with the EU legal requirements set by Regulation (EU) No 283/2013[16] and guidance documents in place and (2) whether it is sufficient to confirm the JMPR set TRVs.

The lack of fulfilment of the EU Regulation on data requirements was detailed and whether it may impact the derivation of TRVs.

EFSA acknowledges the comprehensiveness of the provided information, supported by detailed tabulated summary results from many studies. However, it is noted that the level of details in the JMPR monograph is not fully comparable to that usually available in the reports drafted for the EU peer review, and the original background studies are not available to EFSA. The level of details required should allow to assess the relevance and reliability of the studies and undertake an independent review of the results and conclusions; such detailed information has shown to be necessary for the assessment of some data in this mandate. Additional drawbacks were identified where the reasoning behind a conclusion was not detailed (e.g. lack of an overview of the immunotoxicity-related findings).

Critical issues were identified when data were not available (e.g. read-across and QSAR analysis used in metabolites assessments) or not sufficiently detailed, particularly for key studies, e.g. where summaries were too concise (genotoxicity studies).

Based on the above scrutiny, EFSA verified whether the data are sufficient to confirm the JMPR established TRVs.

On 21 December 2023, EFSA consulted Member States, requesting to submit comments on the draft report by 15 January 2024. The **Member States consultation report** (EFSA, 2024b) is considered as main supporting document to this scientific report and, thus, made publicly available.

In addition, EFSA updated the regulatory background information and the exposure/risk assessment presented in the EFSA report supporting CCPR preparation of 2022 (EFSA, 2022b).

2.2 | Pyrasulfutole (321)

In the table below, the regulatory background information is summarised (Table 13).

TABLE 13 Regulatory background information.

		Comments, references
JMPR assessment	JMPR meeting September 2021	FAO and WHO (2022, 2023c)
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status	Not approved	A.s. not authorised in the EU No application for approval under Regulation (EC) No 1107/2009[a] submitted in the EU
EFSA conclusion available	No	
EFSA MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (CMR cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Pyrasulfotole is an herbicide acting by inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (4-HPPD) in susceptible plants EFSA notes that a mode of action (MoA) shared with other a.s. assessed by EFSA and approved in the EU, such as isoxaflutole, mesotrione, tembotrione or clomazone EU MRLs above the LOQ have been established for pyrasulfotole in Annex IIIA of Regulation (EC) No 839/2008[b] for oats, bovine liver and bovine kidney. These MRLs were included in the EU MRL legislation, based on previously established national MRLs that were notified by Member States, using national toxicological reference values for the risk assessment In 2022, CCPR53 adopted CXLs for barley, oats, rye, wheat/triticale, sorghum and for animal products (mammalian and poultry). In addition, CXLs were adopted for feed items	

[a]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.

[b]Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1–216.

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

2.2.1 | Review of the toxicological assessment of compounds relevant for hazard characterisation

In its assessment, JMPR derived the following residue definitions and toxicological reference values (Tables 14, 15) (FAO and WHO, 2022, 2023c).

TABLE 14 Residue definitions derived by JMPR.

	Commodity group	JMPR evaluation
RD enf	Plant products	Sum of pyrasulfotole and desmethyl-pyrasulfotole, expressed as pyrasulfotole
	Animal products	Sum of pyrasulfotole and desmethyl-pyrasulfotole, expressed as pyrasulfotole The residue is not fat soluble
RD RA	Plant products	Sum of pyrasulfotole and desmethyl-pyrasulfotole and its conjugates, expressed as pyrasulfotole
	Animal products	Sum of pyrasulfotole and desmethyl-pyrasulfotole, expressed as pyrasulfotole
Rationale for residue definitions	The residue definitions are based on metabolism studies with wheat, rotational crops and livestock In cereals, pyrasulfotole was extensively metabolised and not detected in grains; **pyrasulfotole-benzoic acid** (**MTFM-BA**) was the main compound (24%–98% TRR) in all wheat matrices (forage, hay, straw and grains). **Glucose conjugates of desmethyl-pyrasulfotole** were identified in wheat forage, hay and straw; **desmethyl-pyrasulfotole** was predominant residue in field trials **MTFM-BA** was identified as the only metabolite in rotational crops occurring at levels higher than 0.01 mg/kg. It is noted that this metabolite is a common soil metabolite of isoxaflutole; in the two dossiers, the DT_{50} values calculated for this metabolite differed significantly As only one primary crop metabolism study is available, the residue definition in plant commodities shall be restricted to cereals only In livestock metabolism studies, **pyrasulfotole** was the predominant compound in animal matrices, milk and eggs; **desmethyl-pyrasulfotole** was the major metabolite identified in milk (12% TRR) Livestock feeding studies were available in lactating cows (pyrasulfotole) and laying hens. Metabolite **MTFM-BA** was the main compound the livestock is exposed to Considering that **MTFM-BA** is a **common metabolite** with isoxaflutole and that it is a (minor) rat metabolite and of no toxicological concern according to toxicity studies, JMPR decided that this metabolite should not be included in the residue definitions for plant and animal matrices Validated analytical enforcement methods are available to control residues of pyrasulfotole, desmethyl-pyrasulfotole (free and conjugated) and MTFM-BA in plant and animal matrices. The method involves hydrolysis step to release conjugates The storage stability of desmethyl-pyrasulfotole is limited to 3 months in high water content commodities (relevant for forage) and dry feed	

TABLE 15 Toxicological reference values (TRV) derived by JMPR.

	Value	Comments
ADI	0.01 mg/kg bw per day	JMPR (2021). Two-year toxicity and carcinogenicity study (rat), UF 100; based on the NOAEL of 1 mg/kg bw per day for effects on the eyes and increased plasma cholesterol observed at 10 mg/kg bw per day The JMPR noted a margin of 56,000 fold between the ADI and the LOAEL for urinary tract carcinoma and papilloma in mice The JMPR also noted that a parental LOAEL of 2.5 mg/kg bw per day was identified in the two-generation reproductive toxicity study in rats (lowest dose tested); however, the effects seen at this LOAEL (increased thyroid weight and histopathological changes – pigment deposition and colloid alteration) were considered of equivocal toxicological significance, therefore decided to base the ADI on the NOAEL from the 2-year rat study
ARfD	Unnecessary	JMPR (2021) –
Metabolites included in JMPR RD for RA	• **Desmethyl-pyrasulfotole** (AE 1073910) and its conjugates According to JMPR, the ADI of pyrasulfotole applies also to desmethyl-pyrasulfotole and pyrasulfotole-desmethyl-*O*-glucoside, expressed as pyrasulfotole • **Pyrasulfotole-benzoic acid** (MTFM-BA) (main metabolite for plant, livestock and rotational crops, not included in the RD derived by JMPR). MTFM-BA is a common metabolite to isoxaflutole (in the isoxaflutole dossier, this metabolite is referred to as RPA 203328). Under the EU peer review of isoxaflutole (EFSA, 2016a), the metabolite was concluded unlikely to be genotoxic and an ADI of 0.8 mg/kg bw per day was derived; the setting of an ARfD was considered unnecessary	

EFSA reviewed the toxicological data assessed by JMPR and described in the JMPR monograph (FAO and WHO, 2023c) and derived the following conclusions:

- The JMPR monograph presents details on the results from the pivotal studies on the relevant endpoints, such as toxicokinetic and metabolism studies, short-term toxicity in rats and dogs, long-term toxicity and carcinogenicity, reproductive and developmental toxicity studies, as well as neurotoxicity and mechanistical research carried out by the applicant. The critical studies are reported to comply with good laboratory practice (GLP) and the more recent versions of the OECD test guidelines.
- It is noted that an assessment of the validity of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies is not reported.
- A critical issue is identified for genotoxicity assessment of pyrasulfotole. Only an overview summary table of genotoxicity studies is provided for pyrasulfotole. Given the critical nature of the genotoxicity endpoint, a detailed, independent review of the data is needed to reach a conclusion on the genotoxicity profile of the a.s.
- Another critical issue is identified as regards metabolites assessment, that is based solely on read across with no QSAR analysis, or toxicological studies (genotoxicity or general toxicity) provided (see also below).

Furthermore, as regards the completeness of the data submitted to the JMPR, a number of data required by the EU Regulation on data requirements were not available:

- The toxicokinetic data (absorption, distribution and excretion) available to the JMPR do not fully comply with the EU data requirements as investigations were not conducted upon repeated dosing.
- An interspecies comparative in vitro metabolism study is not available and needs to be performed on animal species used in pivotal studies and human material to assess the relevance of the toxicological animal data, including the toxicological reference values to humans.
- Acute toxicity studies upon dermal or inhalation exposures, including skin and eyes irritation and skin sensitisation endpoints were not investigated, which represents data gaps when compared to the EU data requirements; however, these data are not considered relevant to the current assessment.
- No data are available on phototoxicity or photomutagenicity, and no rationale for waiving such investigations is provided.
- Specific immunotoxicity tests were not performed and the information on the immune system is too concise in the monograph to assess whether such a study would be required.
- The assessment of the endocrine-disrupting properties of pyrasulfotole was not conducted in line with the EU requirements and overall, no conclusion can be drawn on the ED potential of the a.s. (ECHA and EFSA, 2018). Of note, the data set includes in vivo studies relevant to address potential adverse effects linked to endocrine-mediated MoAs. Some effects were noted in these studies, such as a delay in balanopreputial separation in a two-generation reproductive toxicity study conducted according to most recent protocol (OECD, 2001), and thyroid effects (i.e. increased thyroid weight and/or histopathological changes (pigment deposition and colloid alteration with or without diffuse follicular hypertrophy/hyperplasia) in one species (rat) in studies of different durations (i.e. 90-day, 2-year, rat and 2-generation reproductive toxicity studies). These findings would need to be further integrated into lines of evidence and MoA for the thyroid-modality (T-modality) to conclude on the endocrine disruption potential of the a.s. Overall, no conclusion can be drawn on the ED potential of pyrasulfotole.
- Toxicological studies are available on the metabolite pyrasulfotole-benzoic acid (MTFM-BA) that is a common metabolite to isoxaflutole (also referred as RPA 203328). The monograph reports the same studies on this metabolite as those assessed by the peer review in 2016 under the isoxaflutole review (EFSA, 2016a).
- With regard to the metabolites desmethyl-pyrasulfotole and its conjugates, and pyrasulfotole-hydroxymethyl, identified as minor rat metabolites, additional data would be needed to enable a conclusion whether they are covered by the toxicity profile of the parent pyrasulfotole, such as QSAR analysis, or comparison of the physico-chemical properties of these compounds as a first step (EFSA PPR Panel, 2016).
- No details on the search of the scientific peer-reviewed open literature on the active substance (and its relevant metabolites), dealing with side effects on health according to the EU guidance document (EFSA, 2011) have been provided.

With regard to the interpretation of the studies reported in the monograph, although tabulated results are available, additional tables would be helpful to confirm the outcome concluded by the JMPR experts. In addition, details on historical control data (HCD) are not available.

Based on the available information on pyrasulfotole and the relevant metabolites expected to occur in food and feed, EFSA concludes that:

- It is not possible to conclude on the genotoxicity potential of pyrasulfotole due to the conciseness of the provided summary (no comprehensive tabulated summaries of the studies are available).
- The interpretation and conclusion of some general toxicity studies (treatment relationship and adversity of the findings) would need further details.
- The metabolites desmethyl-pyrasulfotole (and its conjugates) and pyrasulfotole-hydroxymethyl assessments are solely based on systemic availability in toxicological studies and read-across, with no studies (genotoxicity or general toxicity), this needing further elaboration.

As regards the compliance with the EU standards, the provided toxicological data set is not fully aligned with regard to:

- Toxicokinetics;
- Immunotoxicity;
- ED assessment.

In addition, no information is available on the validation of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies, a comparative interspecies in vitro metabolism study, a phototoxicity assessment and details on the search for published literature on the a.s. and its relevant metabolites.

Based on the above, in particular due to the concise reporting of the genotoxicity studies on pyrasulfotole, EFSA is not in the position to conclude on the ADI derived by the JMPR for this substance or confirm that an ARfD is not required.

2.2.2 | Updated consumer risk assessment

Considering the toxicological assessment performed by EFSA, the dietary exposure assessment/risk assessment presented in the EFSA report 2022 has been updated, including the relevant input values for the CXLs adopted in CCPR53 in the exposure calculation (see Table 16).

TABLE 16 Summary of the dietary exposure assessment.

Acute exposure assessment	Chronic exposure assessment	Results of JMPR risk assessment
RA assumptions: A short-term dietary exposure calculation was performed using PRIMo rev. 3.1, including all food commodities for which the Codex MRLs were higher than the EU MRLs. The input values were derived from the JMPR assessment A full risk assessment could not be performed, as the data were found insufficient to derive an EU ARfD	**RA assumptions:** A long-term dietary exposure calculation was performed using PRIMo rev. 3.1, including all food commodities (existing EU MRLs or Codex MRLs if higher than existing EU MRLs) A full risk assessment could not be performed, as the data were found insufficient to derive an EU ADI	**Specific comments:** JMPR derived an ADI of 0.01 mg/kg. The setting of an ARfD was considered unnecessary
Results: Among the commodities for which CXLs were established, the highest short-term exposure was calculated for bovine edible offals (2.2 µg/kg bw), swine edible offal (0.9 µg/kg bw and cattle milk (0.62 µg/kg bw)	**Results:** The overall chronic exposure accounted for 1.1 µg/kg bw per day (NL toddler). Among the commodities under consideration, cattle milk was identified as the main contributor	**Results:** Long-term exposure: Max 2% of the JMPR ADI

2.2.3 | Overall conclusions

TABLE 17 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	JMPR derived an ADI, which also applies to the metabolites included in the RD (i.e. desmethyl pyrasulfotole and its conjugates); the setting of an ARfD was considered unnecessary EFSA reviewed the toxicological data and is not in the position to conclude on the ADI derived by the JMPR or confirm that an ARfD is not necessary
Residue definitions	In the EU, an RD for RA has not formally been established. For MRL enforcement, the RD covers the parent pyrasulfotole only. JMPR RD for enforcement is wider than the EU RD, i.e. sum of pyrasulfotole and its conjugates, expressed as pyrasulfotole. The same RD is applicable to plant and animal products for MRL enforcement and risk assessment
Codex MRL proposals	In 2022, EFSA considered the Codex MRL proposals were sufficiently supported by data. In CCPR53, the Codex MRLs were adopted For the following commodities, the CXLs are higher than the EU MRLs: barley, sorghum, animal tissues of mammalian species and poultry (except liver of bovine), eggs, milks For oats and bovine liver, the existing EU MRLs are higher than the CXLs
Dietary risk assessment	The EU risk assessment cannot be finalised, since EFSA could not conclude on the toxicological reference values
Recommendation to Risk Managers	EFSA recommends to reconsider the existing EU MRLs set at levels above the LOQ, considering that the TRV could not be derived As the TRV were not supported by EU experts, the risk assessment could not be finalised. The implementation of the CXLs for barley, sorghum, animal tissues of mammalian species and poultry (except liver of bovine), eggs, milks in the EU is therefore not recommended

2.3 | Pyraziflumid (322)

In the table below, the regulatory background information is summarised.

TABLE 18 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2021	FAO and WHO (2022, 2023c)
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status	Not approved	Not authorised in the EU
EFSA conclusion available	No	
EFSA MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (CMR cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Pyraziflumid is a SDHI (succinate dehydrogenase inhibitor) fungicide whose MoA is shared by several EU approved a.s. such as benzovindiflupyr, bixafen, boscalid, cyflumetofen, fluopyram, flutolanil, fluxapyroxad, isofetamid, penflufen, penthiopyrad or sedaxane In 2021, JMPR concluded that since no analytical method for the measurement of pyraziflumid and its metabolites in animal commodities was available, no MRLs could be recommended for animal commodities In CCPR53, CXLs were adopted for apples, grapes, pears and persimmon In the EU, the default MRL of 0.01 mg/kg is applicable for all plant and animal products (Art. 18(1)(b))	

2.3.1 | Review of the toxicological assessment of compounds relevant for hazard characterisation

In its assessment, JMPR derived the following residue definitions and toxicological reference values (Tables 19, 20) (FAO and WHO, 2022, 2023c).

TABLE 19 Residue definitions derived by JMPR.

	Commodity group	JMPR evaluation
RD enf	Plant products	Pyraziflumid
	Animal products	Pyraziflumid and its pyraziflumid-4′-OH metabolite (free), expressed as pyraziflumid The residue is fat soluble
RD RA	Plant products	Pyraziflumid
	Animal products	Pyraziflumid and its pyraziflumid-4′-OH metabolite (free and conjugated), expressed as pyraziflumid
Rationale for residue definitions	Plant metabolism studies in tomatoes, lettuce and paddy rice demonstrated that parent compound is the predominant residue accounting for 99%–100% TRR in tomato fruit, lettuce heads and lettuce leaves at 0–14 DALA; 28 DALA the parent was identified to account for 77%–96% of TRR in rice grain, hulls and straw Pyraziflumid-4′-OH was observed as a significant metabolite in goat muscle (up to 15% TRR), goat fat (up to 20% TRR), hen muscle (up to 20% TRR), egg yolk (up to 15% TRR) and was the major component in goat liver (up to 50% TRR) and hen liver (up to 39% TRR). Pyraziflumid-4′-OH glucuronide was observed in goat kidney, skim milk and egg white	

TABLE 20 Toxicological reference values (TRV) derived by JMPR.

	Value	Comments
ADI	0.02 mg/kg bw per day	JMPR (2021) Two-year toxicity and carcinogenicity study (rat); UF of 100; based on the NOAEL of 2.2 mg/kg bw per day for macroscopic and histopathological signs of liver and thyroid toxicity seen in both sexes, and indications of minor kidney toxicity in females, observed at 4.3 mg/kg bw per day The JMPR noted a margin between the ADI and the LOAEL for the observed thyroid tumours and hepatocellular adenomas in rats of 2300

TABLE 20 (Continued)

	Value	Comments
ARfD	2 mg/kg bw	JMPR (2021) Acute neurotoxicity study (rat); UF of 300; based on the LOAEL of 500 mg/kg bw for reduced in locomotor activity and an increased UF (3x) for the use of a LOAEL instead of a NOAEL
Metabolites included in JMPR RD for RA	• pyraziflumid-4′-OH (free) The toxicological reference values of pyraziflumid (ADI and ARfD) apply to the metabolite pyraziflumid-4′-OH (BC-01) and its glucuronide conjugate, expressed as pyraziflumid Pyraziflumid amide (metabolite observed in goat kidney, kidney of hens and hen muscle and eggs) was not included in the RD. For this metabolite, genotoxicity could not be excluded on the basis of QSAR analysis. Since no toxicological studies were available for this metabolite, JMPR recommended to compare the exposure with the TTC for genotoxic substances (0.0025 µg/kg bw per day [0.15 µg/person per day])	

EFSA reviewed the toxicological data assessed by JMPR and described in the JMPR monograph (FAO and WHO, 2023c) and derived the following conclusions:

The JMPR monograph presents details on the results from the pivotal studies on the relevant endpoints, such as toxicokinetic and metabolism studies, short-term toxicity in rats and dogs, long-term, carcinogenicity, reproductive toxicity as well as acute neurotoxicity studies in rats. The critical studies are reported to comply with GLP and the more recent versions of the OECD test guidelines.

It is noted that an assessment of the validity of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies is not reported.

A critical issue is identified for genotoxicity assessment of pyraziflumid. Only an overview summary table of genotoxicity studies is provided for pyraziflumid. Given the critical nature of the genotoxicity endpoint, a detailed, independent review of the data is needed to enable a conclusion on the genotoxicity profile of the a.s.

Another critical issue is identified with regard to one metabolite assessment (pyraziflumid amide) that presents a genotoxicity concern based on limited QSAR analysis, with no studies (genotoxicity or general toxicity) provided (see also below).

Furthermore, with regard to the completeness of the data submitted to the JMPR, a number of data required by the EU Regulation on data requirements were not available:

- The toxicokinetic data (absorption, distribution and excretion) available to the JMPR do not fully comply with the EU data requirements as investigations were not conducted upon repeated dosing.
- No data are available on phototoxicity or photomutagenicity, and no rationale for waiving such investigations is provided.
- Specific immunotoxicity tests were not performed and the information on the immune system is too concise in the monograph to assess whether such a study would be required.
- The assessment of the endocrine-disrupting properties of pyraziflumid was not conducted in line with the EU requirement and overall, no conclusion can be drawn on the ED potential of the a.s. (ECHA and EFSA, 2018). Of note, the data set includes a two-generation reproductive toxicity study conducted according to most recent protocol (OECD, 2001) which is relevant to address potential adverse effects linked to an endocrine-mediated mode of action. Thyroid and liver are target organs of pyraziflumid in rats, but not in mice or dogs. Mechanistic studies (1- to 15-week studies) investigated serum thyroid hormone levels and hepatic enzymes activities indicating increased levels of TSH but no changes in T4 or T3; increased levels of total liver microsomal P450 content; and increased EROD, PROD and T4 UDP-GT activity. An in vitro study indicates that pyraziflumid does not directly inhibit TPO activity in rats. The information needs to be integrated into lines of evidence and MoA for the T-modality to conclude on the endocrine disruption potential of the a.s. Overall, no conclusion can be drawn on the ED potential of pyraziflumid.
- No toxicological studies are available on the metabolites included in the residue definition (pyraziflumid 4′-OH and its glucuronide conjugate) and pyraziflumid amide. Pyraziflumid 4′-OH (and its glucuronide conjugate) assessment is based on its systemic availability in toxicity studies since largely excreted through bile, their toxicity being covered by the TRVs established for the parent compound. Regarding pyraziflumid amide, the JMPR raised concerns over its genotoxic potential (pyraziflumid amide may bind to DNA and may induce chromosomal aberrations) based on QSAR analysis (not presented); this represents a critical concern for the metabolite. Data gaps are identified to clarify the genotoxicity potential of the latter metabolite as a first step and then, in case the concern over its genotoxic potential is lifted, to investigate its general toxicity compared to that of the parent upon repeated-dose exposure (EFSA PPR Panel, 2016).
- No details on the search of the scientific peer-reviewed open literature on the active substance (and its relevant metabolites), dealing with side effects on health, have been provided (EFSA, 2011).

With regard to the interpretation of the studies reported in the monograph, although some tabulated results were reported in the monograph, additional tables are needed to confirm the negative outcome concluded by the JMPR experts. In addition, details on historical control data (HCD) are not available.

Based on the available information on pyraziflumid and the relevant metabolites expected to occur in food and feed, EFSA concludes that:

- It is not possible to conclude on the genotoxicity potential of pyraziflumid due to the conciseness of the provided summary (no comprehensive tabulated summaries of the studies are available).
- The interpretation and conclusion of some general toxicity studies (treatment relationship and adversity of the findings) would need further details.
- A genotoxicity concern is raised on the metabolite pyraziflumid amide based on limited QSAR analysis and no studies (genotoxicity or general toxicity), genotoxicity studies should be requested as a first step to clarify this concern.

As regards the compliance with the EU standards, the provided toxicological data set is not fully aligned with regard to

- Toxicokinetics
- Immunotoxicity
- ED assessment

In addition, no data is available on the validation of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies, a phototoxicity assessment and details on the search for published literature on the a.s. and its relevant metabolites.

Based on the above, in particular due to the inconclusive genotoxicity potential of pyraziflumid, EFSA is not in the position to conclude on the ADI and the ARfD derived by the JMPR for this substance.

2.3.2 | Updated consumer risk assessment

Considering the toxicological assessment performed by EFSA, the dietary exposure assessment/risk assessment presented in the EFSA report 2022 has been updated, including the relevant input values for the CXLs adopted in CCPR53 in the exposure calculation (see **Table 21**).

TABLE 21 Summary of the dietary exposure assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary exposure calculation was performed using PRIMo rev. 3.1, including only those food commodities for which the Codex MRLs were adopted. The input values were derived from the JMPR assessment A full risk assessment could not be performed, as the data were found insufficient to derive an EU ARfD	**RA assumptions:** A long-term dietary exposure calculation was performed using PRIMo rev. 3.1, including those food commodities for which the Codex MRLs were adopted. For the remaining commodities, the default EU MRL of 0.01 mg/kg was used as input value A full risk assessment could not be performed, as the data were found insufficient to derive an EU ADI	**Specific comments:** In its risk assessment, JMPR used the ADI and ARfD of 0.02 mg/kg bw per day and 2 mg/kg bw, respectively. The risk assessment of JMPR covered not only the commodities, for which CXLs were adopted, but also the animal products, for which due to the lack of analytical methods CCPR decided not to establish CXLs
Results: Among the commodities for which CXLs were established, the highest short-term exposure was calculated pears (101 µg/kg bw), apples 79 µg/kg bw) and table grapes (71 µg/kg bw)	**Results:** The overall chronic exposure accounted for 8.39 µg/kg bw per day (NL toddler) Among the commodities under consideration, apples were identified as the main contributor	**Results:** Long-term exposure: Max 8% of the JMPR ADI Short-term exposure: Highest result for grapes and pears: 3% of ARfD

2.3.3 | Overall conclusions

TABLE 22 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU In the EU, the default MRLs under Art. 18(1)(b) is applicable for all plant and animal products
Toxicological assessment	JMPR derived an ADI and an ARfD, which also apply to one metabolite and its glucuronide conjugate included in the RD; for an additional metabolite for which genotoxicity could not be excluded (QSAR), JMPR used a TTC approach (0.0025 µg/kg bw per day) EFSA reviewed the toxicological data and is not in the position to conclude on the ADI and ARfD derived by the JMPR
Residue definitions	RDs are not formally established in the EU; the default residue definitions are therefore applicable The RD derived by JMPR for plant products covers the parent compound only and is therefore comparable with the EU RD. For animal products, the JMPR RD is wider than the EU RD as it also comprises a metabolite

TABLE 22 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Codex MRL proposals	The Codex MRLs adopted by CCPR53 (apples, pears, persimmon, grapes) were considered by EFSA to be sufficiently supported by data. In CCPR53, the Codex MRLs were adopted The existing EU MRLs for these commodities are lower than the CXLs
Dietary risk assessment	The EU risk assessment cannot be finalised, since EFSA could not conclude on the toxicological reference values
Recommendation to Risk Managers	As the TRV were not supported by EU experts, the risk assessment could not be finalised. The implementation of the CXLs in the EU is therefore not recommended

2.4 | Spiropidion (323)

In the table below, the regulatory background information is summarised.

TABLE 23 Background information.

		Comments, references
JMPR assessment	JMPR meeting September 2021	FAO and WHO (2022, 2023c)
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status	Not approved	Not authorised in the EU
EFSA conclusion available	No	
EFSA MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (CMR cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Spiropidion is a pro-insecticide incorporating a novel tetramic acid derivative The pesticidal mode of action (MoA) is by inhibiting the enzyme acetyl-CoA carboxylase In CCPR53, CXLs were adopted for cucumbers, melons, peppers, potatoes, pumpkins, soya beans, tomatoes, watermelons, winter squash and animal products In the EU, the default MRL of 0.01 mg/kg is applicable for all plant and animal products (Art. 18(1)(b))	

2.4.1 | Review of the toxicological assessment of compounds relevant for hazard characterisation

In its assessment, JMPR derived the following residue definitions and toxicological reference values (Tables 24, 25) (FAO and WHO, 2022, 2023c).

TABLE 24 Residue definitions derived by JMPR.

	Commodity group	JMPR evaluation
RD enf	Plant products	Sum of spiropidion and spiropidion-enol (SYN547305) expressed as spiropidion
	Animal products	Spiropidion-enol (SYN547305) expressed as spiropidion
RD RA	Plant products	Sum of spiropidion, spiropidion-enol (SYN547305), 3-(4-chloro-2,6-dimethyl-phenyl)-4-hydroxy-8-methoxy-1,8-diazaspiro[4.5]dec-3-en-2-one (SYN547435) and 3-(4-chloro-2,6-dimethyl-phenyl)-4-hydroxy-1-methyl-1,8-diazaspiro[4.5]dec-3-en-2-one (SYN548430), expressed as spiropidion
	Animal products	Free and conjugated spiropidion-enol (SYN547305) expressed as spiropidion
Rationale for residue definitions	JMPR assessed metabolism studies in tomatoes, potatoes and cotton seed In addition, animal metabolism studies in lactating goats, laying hens and rats were available Analytical methods for plant and animal matrices are available to enforce the proposed CXLs Storage stability data were provided demonstrating that the residue trials are valid in view of storage stability The residue definitions for risk assessment comprise metabolites for which toxicological information was available to conclude that the metabolites are covered by the ADI/ARfD However, additional metabolites for which no toxicological studies were available were not included in the residue definitions, but exposure was compared to the TTC for Cramer Class III compounds	

TABLE 25 Toxicological reference values (TRV) derived by JMPR.

	Value	Comments
ADI	0.02	JMPR (2021) 2-year toxicity and carcinogenicity study in rats, UF 100; based on the NOAEL of 2.4 mg/kg bw per day for an equivocal increase in testicular interstitial cell adenomas observed at 4.7 mg/kg bw per day
ARfD	0.3	JMPR (2021) 28-day toxicity study in dogs, UF 100; based on the NOAEL of 30 mg/kg bw for mortality and clinical signs observed at 65–> 100 mg/kg bw per day. This NOAEL is supported by the NOAEL of 30 mg/kg bw for an initial body weight loss (GDs 6–9) in dams, observed at 100 mg/kg bw per day in a rat developmental toxicity study
Metabolites included in JMPR RD for RA		• Spiropidion-enol (SYN547305) • 3-(4-chloro-2,6-dimethyl-phenyl)-4-hydroxy-8-methoxy-1,8-diazaspiro[4.5]dec-3-en-2-one (SYN547435) • 3-(4-chloro-2,6-dimethyl-phenyl)-4-hydroxy-1-methyl-1,8-diazaspiro[4.5]dec-3-en-2-one (SYN548430) The toxicological reference values of spiropidion apply to the metabolites spiropidion-enol (SYN547305 free and conjugate), SYN548430, SYN 547435 (and SYN548939), expressed as spiropidion • SYN550820 (identified in cotton metabolism study in foliage and gin trash) • SYN550839 (identified in cotton metabolism study in foliage and gin trash) • Dehydrogenated spiropidion-enol (identified in tomato metabolism study in fruit) • SYN549098 (identified in confined rotational crop study in mature lettuce) For the four above-mentioned metabolites, no toxicological studies were available; based on structural considerations, genotoxicity was considered unlikely. JMPR proposed to calculate the dietary exposure and compare it to the TTC for Cramer Class III compounds, individually

EFSA reviewed the toxicological data assessed by JMPR and described in the JMPR monograph (FAO and WHO, 2023c).

The JMPR monograph presents details on the results from the pivotal studies on the relevant endpoints, such as toxicokinetic and metabolism studies, short-term toxicity in mice, rats and dogs, long-term and carcinogenicity, reproductive, developmental and acute neurotoxicity studies carried out by the applicant. Most of the studies are reported to comply with GLP and the more recent versions of the OECD test guidelines.

It is noted that an assessment of the validity of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies is not reported.

A critical issue is identified for genotoxicity assessment of spiropidion. Only an overview summary table of genotoxicity studies is provided for spiropidion, and results interpretation is based on many assumptions. Given the critical nature of the genotoxicity endpoint, an independent review of the data is needed to enable a conclusion on the genotoxicity profile of spiropidion.

Another critical issue is identified as regards metabolites assessment, that is based on read across and limited QSAR analysis, with no studies (genotoxicity or general toxicity) provided (see also below).

Furthermore, with regard to the completeness of the data submitted to the JMPR, a number of data required by the EU Regulation on data requirements were not available:

- Specific immunotoxicity tests were not performed and the potential for immunotoxicity of spiropidion was not fully addressed in the monograph, considering that findings on the immune system were identified in the available toxicity studies.
- The assessment of the endocrine-disrupting properties of spiropidion was not conducted in line with the EU requirements and overall, no conclusion can be drawn on the ED potential of the a.s. (ECHA and EFSA, 2018). Of note, the data set includes in vivo studies relevant to address potential adverse effects linked to endocrine-mediated MoAs. Some effects were noted in these studies, such as increase incidence in Leydig cell adenomas in a carcinogenicity study in the mouse, and follicular cell hypertrophy in the thyroid in rats across various studies. While the chemical induction of Leydig cell tumours in rodents is generally considered of limited relevance to humans, the MoA is most frequently via increasing LH stimulation, which is relevant for humans. It is reported that, in the toxicity database, there was no evidence of hypothalamus–pituitary–gonadal axis perturbation; however, no description of such database is provided, and overall, the information needs to be integrated into lines of evidence to conclude on EAS modalities. Some mechanistic studies investigated UDP-GT induction (ex vivo) and TPO inhibition (in vitro); spiropidion was reported to be an inducer of hepatic UDP-GT activity in both male and female rats while spiropidion and metabolite SYN547305 are not inhibitors of rat TPO activity. However, the information needs to be integrated in lines of evidence and MoA to conclude on the endocrine disruption potential of the a.s.
- The assessment of the dietary metabolites was essentially based on their chemical structure and read across vs. the parent compound; their genotoxic potential was assessed based on QSAR analyses, and no information on the QSAR tools used is detailed. Such an assessment is not in line with EFSA assessment of metabolites. More models should be used, since the different models do have different reliability of each prediction (EFSA PPR Panel, 2016).
- No details on the search of the scientific peer-reviewed open literature on the active substance (and its relevant metabolites), dealing with side effects on health, have been provided (EFSA, 2011).

With regard to the interpretation of the studies reported in the monograph, although some tabulated results were reported in the monograph, additional table is needed to confirm the outcome concluded by the JMPR experts. This is the case for the presence of spiropidion and/or its metabolite(s) in plasma samples of some control animals from 28-day and 90-day studies in mice, rats and dogs, and in the 1-year dog study. JMPR concluded that such contaminations did not invalidate neither TK data nor studies interpretation (low number of contaminated samples, concentrations marginally above the LOQ), further details are needed to conclude on the impact of this on the study results. In addition, details on HCDs are not available.

Based on the available information on spiropidion and the relevant metabolites expected to occur in food and feed, EFSA concludes that:

- It is not possible to conclude on the genotoxicity potential of spiropidion due to the conciseness of the provided summary (no comprehensive tabulated summaries of the studies are available).
- The interpretation and conclusion of some general toxicity studies (treatment relationship and adversity of findings) would need further details.
- Metabolites assessment is solely based on read across and limited QSAR analysis, with no studies (genotoxicity or general toxicity), this needing further elaboration.

As regards the compliance with the EU standards, the provided toxicological data set is not fully aligned with regard to

- Immunotoxicity
- ED assessment

In addition, no information is available on the validation of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies and details on the search for published literature on the a.s. and its relevant metabolites.

Based on the above, in particular due to the inconclusive genotoxicity potential of spiropidion, EFSA is not in the position to conclude on the ADI derived by the JMPR for this substance or confirm that an ARfD is not required.

2.4.2 | Updated consumer risk assessment

Considering the toxicological assessment performed by EFSA, the dietary exposure assessment/risk assessment presented in the EFSA report 2022 has been updated, including the relevant input values for the CXLs adopted in CCPR53 in the exposure calculation (see Table 26).

TABLE 26 Summary of the dietary exposure assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary exposure calculation was performed using PRIMo rev. 3.1, including only those food commodities for which the Codex MRLs were adopted A full risk assessment could not be performed, as the data were found insufficient to derive an EU ARfD	**RA assumptions:** A long-term dietary exposure calculation was performed using PRIMo rev. 3.1, including the food commodities for which the Codex MRLs were adopted. For the remaining commodities, the default EU MRL of 0.01 mg/kg was used as input value A full risk assessment could not be performed, as the data were found insufficient to derive an EU ADI	**Specific comments:** In its risk assessment, JMPR used the ADI and ARfD of 0.02 mg/kg bw per day and 0.3 mg/kg bw, respectively. For dehydrogenated spiropidion-enol (identified in tomato fruit metabolism study) and SYN549098 (confined rotational crop study in lettuce and in fruit), JMPR used the TTC approach. For two additional metabolites (SYN550839 and SYN550820), no exposure calculations were performed because the metabolites are not relevant for the crops for which Codex MRLs were derived The risk assessment of JMPR covered not only the commodities, for which CXLs were adopted, but also the animal products, for which due to the lack of analytical methods CCPR decided not to establish CXLs
Results: Among the commodities for which CXLs were established, the highest short-term exposure was calculated potatoes (151 μg/kg bw), melons (138 μg/kg bw) and watermelons (111 μg/kg bw)	**Results:** The overall chronic exposure accounted for 3.55 μg/kg bw per day (GEMS/Food G11) Among the commodities under consideration, soybeans were identified as the main contributor	**Results:** Long-term exposure: Max 10% of the JMPR ADI Short-term exposure: Highest result for watermelons: 60% of ARfD Dehydrogenated spiropidion-enol: JMPR estimated a dietary exposure for the dehydrogenated spiropidion-enol metabolite of 0.07 μg/kg bw per day, based on the residues of this metabolite identified in tomato metabolism studies. No details on the calculations were provided SYN549098 (free and conjugated): JMPR estimated a dietary exposure of 0.025 μg/kg bw per day, based on residue levels found in leafy vegetables grown in rotation with spiropidion-treated crops

2.4.3 | Overall conclusions

TABLE 27 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	JMPR derived an ADI and an ARfD, which also apply to one metabolite included in the RD EFSA reviewed the toxicological data and is not in the position to conclude on the ADI and ARfD derived by the JMPR.
Residue definitions	JMPR RD for enforcement is wider than EU RD. RD for RA has not formally been established in the EU
Codex MRL proposals	Codex MRL proposals sufficiently supported by data The following CXLs are higher than the EU MRLs: cucumbers, melons, peppers, potatoes, pumpkins, soya beans, tomatoes, watermelons, winter squash and animal products
Dietary risk assessment	The EU risk assessment cannot be finalised, since EFSA could not conclude on the toxicological reference values
Recommendation to Risk Managers	As the TRV were not supported by EU experts, the risk assessment could not be finalised. The implementation of the CXLs in the EU is therefore not recommended

2.5 | Tetraniliprole (324)

In the table below, the regulatory background information is summarised.

TABLE 28 Toxicological reference values (TRV) derived by JMPR.

		Comments, references
JMPR assessment	JMPR meeting September 2021 and JMPR meeting 2022	Evaluation of toxicology in 2021 (FAO and WHO, 2022, 2023c) Assessment of residue definition and MRL proposals in 2022 (FAO and WHO, 2023a)
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status	Not approved	Not authorised in the EU
EFSA conclusion available	No	
EFSA MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (CMR cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Tetraniliprole is an anthranilic diamide-class insecticide, with a proposed pesticidal mode of action (MOA) involving the activation of ryanodine receptor channels, leading to internal calcium store depletion that impairs regulation of muscle contraction; in the JMPR report mammalian ryanodine receptors are indicated to be substantially less sensitive to the effects of anthranilic diamides than insect ryanodine receptors In CCPR54, CXLs were adopted for cabbage, head, cherries, flowerhead brassicas, fruiting vegetables, other than cucurbits, (except okra, martynia and roselle) leaves of brassica, lemons and limes, maize, oranges, peaches, plums, pome fruits, pummelos/grapefruit, rice husked, small fruit vine climbing, soya bean, sweet corn, tree nuts, tuberous and corm vegetables and for animal products In the EU, the default MRL of 0.01 mg/kg is applicable for all plant and animal products (Art. 18(1)(b))	

2.5.1 | Review of the toxicological assessment of compounds relevant for hazard characterisation

In its assessment, JMPR derived the following residue definitions and toxicological reference values (Tables 29, 30) (FAO and WHO, 2022, 2023a).

TABLE 29 Residue definitions derived by JMPR.

	Commodity group	JMPR evaluation
RD enf	Plant products	Tetraniliprole
	Animal products	Tetraniliprole The residue is not fat soluble
RD RA	Plant products	Tetraniliprole + tetraniliprole-N-methyl- quinazolinone, expressed as tetraniliprole
	Animal products	Tetraniliprole + tetraniliprole-N-methyl- quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole
Rationale for residue definitions	In the plant metabolism studies involving foliar applications (apples, potato, lettuce, paddy rice), soil drench application (tomato), granular in planting hole applications (rice) and seed treatments (potato and maize), in confined rotational crop metabolism studies and in processing studies, tetraniliprole was the major component (apple, tomato, lettuce, tomato, potato) of the radioactive residue As tetraniliprole is considered suitable as a marker compound, the residue for compliance with the MRL was defined as tetraniliprole Metabolite tetraniliprole-N-methyl-quinazolinone (BSC-CQ63359) was the only compound identified in relevant amounts in plant matrices (up to 20% TRR in tomato, rice grain and potatoes, but generally at levels ≤ 0.01 mg eq/kg in food commodities). In the supervised field trials, it was only found occasionally above the LOQ of 0.01 mg/kg, with tetraniliprole being present at levels about an order of magnitude higher Tetraniliprole is not stable under baking/brewing/boiling (pH 5, 100°C, 60 min) and sterilisation (pH 6, 120°C, 20 min) conditions. Under these conditions, 65%–68% and 1.1%–1.5% AR was recovered as parent and 27%–30% AR and 94% AR as tetraniliprole-N-methyl-quinazolinone (BSC-CQ63359), respectively. Processing under heating indicated conversion of parent tetraniliprole into tetraniliprole-N-methyl- quinazolinone (BSC-CQ63359), e.g. mustard greens (up to 20% TRR), broccoli (up to 29% TRR), tomato paste (23%–48% TRR) and soya bean meal (up to 81% TRR) JMPR derived a residue definition for dietary risk assessment for plant commodities as tetraniliprole and tetraniliprole-N-methyl-quinazolinone (BSC-CQ63359), expressed as tetraniliprole Metabolism in animals was assessed in goat and poultry studies. Tetraniliprole was a major component in all goat tissues (24%–71% TRR), poultry fat (26%–55% TRR) and eggs (4.2%–14% TRR), but it contributes little to the overall residue in poultry muscle (3.7%–10% TRR) and liver (1.6%–4.2% TRR). Metabolite tetraniliprole-despyridyl-N-methyl-quinazolinone was a major compound in eggs and fat (63%TRR, 0.029 mg eq/kg) and was also found in liver (12%TRR, 0.065 mg eq/kg) and muscle (8.6% TRR, 0.001 mg eq/kg). Parent tetraniliprole was also the major component in all cattle tissues and milk. Therefore, the JMPR decided to define the residue for compliance with the MRL as tetraniliprole. Tetraniliprole was metabolised into numerous components in livestock metabolism studies, of which 17 were accounted for > 10% TRR and/or > 0.01 mg eq/kg The metabolites were considered in three categories, either covered by the toxicity of the parent, suitable for assessment by the TTC approach following Cramer Class III or by the TTC approach for genotoxic compounds JMPR proposed the residue definition for dietary risk assessment for animal commodities as follows: sum of tetraniliprole, tetraniliprole-N-methyl-quinazolinone (BSC-CQ63359) and tetraniliprole-benzylalcohol (BCS-CZ91631), expressed as tetraniliprole EFSA did not agree on the residue definition for animal products. In particular, for poultry, parent tetraniliprole seems to be not a good marker substance, and therefore, the residue definition for enforcement is considered not appropriate In addition, tetraniliprole-despyridyl-N-methyl-quinazolinone was found to be a major compound in eggs (36% TRR, 0.030 mg eq/kg) and fat (63% TRR, 0.029 mg eq/kg); it was also found in liver (12% TRR, 0.065 mg eq/kg) and muscle (8.6% TRR, 0.001 mg eq/kg) In the toxicological evaluation of 2021 JMPR, this metabolite (tetraniliprole-despyridyl-N-methyl-quinazolinone) was reported to give alerts for genotoxicity using OECD QSAR ToolBox, Version 4.5 In 2022, JMPR compared the exposure for this metabolite with the TTC Cramer class III threshold (see below JMPR risk assessment)	

TABLE 30 Toxicological reference values (TRV) derived by JMPR.

	Value	Comments
ADI	2 mg/kg bw per day	JMPR (2021) 2-year toxicity and carcinogenicity and 2-generation reproductive toxicity studies in rats, UF 100; based on the NOAEL of 221 mg/kg bw per day for decreased body weight, increased diffuse squamous cell hyperplasia in the cervix and vagina and increased severity of corpora lutea depletion observed at 1052 mg/kg bw per day in the 2-year rat study and the NOAEL of 196 mg/kg bw per day for decreased pup body weights resulting in delayed completion of vaginal opening observed at 896 mg/kg bw per day in the 2-generation reproductive toxicity study in rats
ARfD	Unnecessary	JMPR (2021) –

(Continues)

TABLE 30 (Continued)

	Value	Comments
Metabolites included in JMPR RD for RA	Metabolites included in JMPR RD for RA: • Tetraniliprole-N-methyl- quinazolinone (BCS-CQ63359) • Tetraniliprole-benzylalcohol (BCS-CZ91631) The ADI applies to these metabolites; JMPR also concluded that no ARfD is required for these two metabolites JMPR assessed a number of additional metabolites which were not included in the RD for RA • Tetraniliprole-desmethyl-amide (BCS-CN42374): Based on its structural similarity to the parent, tetraniliprole-desmethyl-amide was predicted to be no more toxic than the parent • Tetraniliprole-hydroxy-N-methyl (BCS-CZ91629): This metabolite was considered to be covered by the parent as it is a major metabolite in the rat For a number of metabolites found in livestock metabolism studies, JMPR concluded that they do not show any alerts for genotoxicity in QSAR analysis. However, they were considered insufficiently similar to the parent to read across their toxicity, and hence, the Cramer class III threshold of toxicological concern (TTC) of 1.5 µg/kg bw per day should be applied; the following metabolites fall in this category (see below JMPR risk assessment): • T-quinazolinone (goat) (BCS-CZ73507), • T-pyrazole-5-carboxylic acid (goat and poultry) (BCS-CL73217) • T-N-methyl-quinazolinone-benzylalcohol (goat) • T-despyridyl-N-methyl-quinazolinone (poultry)[a] • T-pyridinyl-pyrazole-5-carboxylic acid (goat) • T-pyrazole-5-N-methyl-amide (goat and poultry) (BCS-CZ84317); • T-pyrazole-5-amide (poultry and goat liver only) • T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (goat) The following metabolites were assessed using TTC approach for genotoxic compounds: • T-despyridyl (poultry) • Tetrazole-conjugates (poultry) • T-despyridyl-N-methyl-quinazolinone-hydroxy/T-despyridyl-hydroxy (poultry) • T-deschloro-desmethyl-amide (poultry) • T-despyridyl-quinazolinone (poultry) • T-pyrazole-5-N-methyl-amide-hydroxy (poultry) • T-deschloro-desmethyl-amide

[a]It is noted that in JMPR, 2021, **T-despyridyl-N-methyl-quinazolinone** (poultry) was reported to fall in the category with genotoxic alerts. Hence, the JMPR report should be corrected, unless additional information was provided to JMPR.

Metabolites included in EU RD for RA: not relevant as no EU RDs are established.

EFSA reviewed the toxicological data assessed by JMPR and described in the JMPR monograph (FAO and WHO, 2023c).

The JMPR monograph presents details on the results from the pivotal studies on the relevant endpoints, such as toxicokinetic and metabolism studies, short-term toxicity in rats and dogs, long-term and carcinogenicity, reproductive and developmental toxicity studies, as well as neurotoxicity and mechanistical research carried out by the applicant. The critical studies are reported to comply with GLP and the more recent versions of the OECD test guidelines.

It is noted that an assessment of the validity of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies is not reported.

A critical issue is identified for genotoxicity assessment of tetraniliprole. Only an overview summary table of genotoxicity studies is provided. Given the critical nature of the genotoxicity endpoint, an independent review of the data is needed to enable a conclusion on the genotoxicity profile of tetraniliprole.

Another critical issue is identified as regards the assessment of some metabolites, that is based on read across and limited QSAR analysis, with no studies (genotoxicity or general toxicity) provided (see also below).

Furthermore, with regard to the completeness of the data available to the JMPR, data gaps were identified when compared with the EU data requirements:

- The assessment of the endocrine-disrupting properties of tetraniliprole was not conducted in line with the EU requirements and overall, no conclusion can be drawn on the ED potential of the a.s. (ECHA and EFSA, 2018). Of note, the data set includes in vivo studies relevant to address potential adverse effects linked to endocrine-mediated MoAs. Some effects were noted in these studies, such as decreased pup body weights and delayed vaginal opening. Special investigations were presented, including an uterotrophic assay, negative but of unclear reliability; a steroidogenesis assay in H295R cell line, with changes in oestradiol, cortisol, testosterone and progesterone secretion with tetraniliprole and its metabolite BCS CQ63359. However, the information needs to be integrated into lines of evidence and MoA to conclude on the endocrine disruption potential of the a.s.
- The assessment of the dietary metabolites was essentially based on their chemical structure and read across vs. the parent compound; their genotoxic potential was assessed based on QSAR analyses, and no information on the QSAR tools used is detailed. Such an assessment is not in line with EFSA assessment of metabolites. More models should be used, since the different models do have different reliability of each prediction (EFSA PPR Panel, 2016).
- No details on the search of the scientific peer-reviewed open literature on the active substance (and its relevant metabolites), dealing with side effects on health, have been provided (EFSA, 2011).

With regard to the interpretation of the studies reported in the monograph, although some tabulated results were reported in the monograph, additional table are needed to confirm the outcome concluded by the JMPR experts; these include for instance the information on plasma levels in some short-term studies (missing or informing of possible contamination of control samples). In addition, details on HCDs are not available.

Based on the available information on tetraniliprole and the relevant metabolites expected to occur in food and feed, EFSA concludes that:

- It is not possible to conclude on the genotoxicity potential of tetraniliprole due to the conciseness of the provided summary (no comprehensive tabulated summaries of the studies are available).
- The interpretation and conclusion of some general toxicity studies (treatment relationship and adversity of findings) would need further details.
- Metabolites assessment is solely based on read across and limited QSAR analysis, with no studies (genotoxicity or general toxicity), this needing further elaboration.

As regards the compliance with the EU standards, the provided toxicological data set is not fully aligned with regard to ED assessment.

In addition, no information is available for the validation of the analytical methods used in feed, body fluids and tissues and any additional matrices used in support of the toxicity studies and details on the search for published literature on the a.s. and its relevant metabolites.

Based on the above, in particular due to the inconclusive genotoxicity potential of tetraniliprole, EFSA is not in the position to conclude on the ADI derived by the JMPR for this substance or confirm that an ARfD is not required.

2.5.2 | Updated consumer risk assessment

Considering the toxicological assessment performed by EFSA, the dietary exposure assessment/risk assessment presented in the EFSA report 2022 has been updated, including the relevant input values for the CXLs adopted in CCPR54 in the exposure calculation (see Table 31).

TABLE 31 Summary of the dietary exposure assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary exposure calculation was performed using PRIMo rev. 3.1, including only those food commodities for which the Codex MRLs were adopted A full risk assessment could not be performed, as the data were found insufficient to derive an EU ARfD For animal products, the information on the HR for animal products was not reported in the JMPR report, as according to JMPR an acute risk assessment was not required. For these commodities, the risk assessment was therefore performed with the MRL	**RA assumptions:** A long-term dietary exposure calculation was performed using PRIMo rev. 3.1, including the food commodities for which the Codex MRLs were adopted. For the remaining commodities, the default MRL was used as input value for the chronic exposure calculation A full risk assessment could not be performed, as the data were found insufficient to derive an EU ADI	**Specific comments:** In 2021, JMPR concluded that, for several metabolites, the TTC Cramer Class III could be applied (no indication for genotoxicity) For the 2022 meeting of JMPR, additional information was provided For three metabolites (T-quinazolinone, T-pyridinyl-pyrazole-5-carboxylic acid and T-pyrazole-5-N-methyl-amide), the 2022 JMPR confirmed that the TTC Cramer Class III could be applied (no indication for genotoxicity) The exposure based on the residue levels found in animal commodities from the goat and laying hen metabolism studies, resulted in the following maximum long-term exposures (T = tetraniliprole). It is noted that the exposure levels were not corrected for the dose levels used in the goat study (slightly under dosed) but were corrected for the dose levels used in the laying hen study (36 times over dosed)
Results: Among the commodities for which CXLs were established, the highest short-term exposure was calculated kales (321 µg/kg bw), table grapes (67 µg/kg bw) and head cabbage (49 µg/kg bw)	**Results:** The overall chronic exposure accounted for 10.81 µg/kg bw per day (Dutch toddler) Among the commodities under consideration, milk was identified as the main contributor	**Results:** Long-term exposure: Max 0% of the JMPR ADI (17 GEMS/Food Consumption Cluster Diets) Short-term exposure: Not relevant (JMPR did not derive an ARfD) TTC consideration of metabolites TTC Cramer Class III (< 0.0025 µg/kg bw corrected for dietary burden) T-quinazolinone (goat, T-pyrazole-5-carboxylic acid (goat and poultry T-N-methyl-quinazolinone-benzylalcohol (goat)

(Continues)

TABLE 31 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
		T-pyridinyl-pyrazole-5-carboxylic acid (goat **T-despyridyl-N-methyl-quinazolinone (poultry)***) T-pyrazole-5-N-methyl-amide (goat and poultry) T-pyrazole-5-amide (poultry and goat liver only) T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (goat) *In the 2021 JMPR report, this metabolite was reported to fall in the category with genotoxic alerts. **The estimated exposure for this metabolite exceeded the TTC for genotoxic compounds** For the following metabolites for which genotoxicity cannot be excluded, the estimated exposure was below the TTC for genotoxic compound: T-despyridyl (poultry) Tetrazole-conjugates (poultry) T-despyridyl-N-methyl-quinazolinone-hydroxy/ T-despyridyl-hydroxy (poultry) T-deschloro-desmethyl-amide (poultry) T-despyridyl-quinazolinone (poultry) T-pyrazole-5-N-methyl-amide-hydroxy (poultry) T-deschloro-desmethyl-amide

2.5.3 | Overall conclusions

TABLE 32 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	JMPR derived an ADI, which also applies to one metabolite included in the RD; ARfD unnecessary EFSA reviewed the toxicological data and is not in the position to conclude on the ADI derived by the JMPR or confirm that an ARfD is not necessary
Residue definitions	JMPR RD for enforcement is wider than EU RD. RD for RA has not formally been established in the EU In CCPR54, the EU expressed a reservation on the residue definition for enforcement for animal-derived commodities
Codex MRL proposals	Codex MRL proposals sufficiently supported by data. The Codex MRL proposals were adopted in CCPR54 The following CXLs are higher than the existing EU MRLs: cabbage, head; cherries, flowerhead brassicas, fruiting vegetables, other than cucurbits, leaves of brassica, lemons and limes, maize, oranges, peaches, plums, pome fruits, pummelos/grapefruit, small fruit vine climbing, soya bean, tree nuts, tuberous and corm vegetables and for animal products (mammalians)
Dietary risk assessment	The EU risk assessment cannot be finalised, since EFSA could not conclude on the toxicological reference values
Recommendation to Risk Managers	As the TRV were not supported by EU experts, the risk assessment could not be finalised. The implementation of the CXLs in the EU is therefore not recommended

2.6 | Remarks and recommendations

EFSA scrutinised the available toxicological information provided in the JMPR monograph (FAO and WHO, 2023c) to confirm whether they are sufficient to confirm the JMPR TRVs on pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole, which were never assessed in the EU, verifying their alignment with the EU legal requirements.

EFSA acknowledges the comprehensiveness of the provided information, supported by detailed tabulated summary results from many studies. However, it is noted that the level of details in the Monographs is not fully comparable to that usually available in the reports drafted for in the EU peer review, and the original background studies are not available to EFSA. The level of details required should allow to assess the relevance and reliability of the studies and undertake an independent review of the results and conclusions; such detailed information has shown to be necessary for the interpretation and assessment of some data in this mandate. Additional drawbacks were identified where the reasoning behind a conclusion was not detailed (e.g. lack of an overview of the immunotoxicity-related findings).

Critical issues were identified when data were not available (e.g. read-across and QSAR analysis used in metabolites assessments) or not sufficiently detailed, particularly for key studies, e.g. where summaries were too concise (genotoxicity studies).

The results of genotoxicity studies are not presented in a sufficiently detailed way that would allow a critical review. This was considered critical for an independent interpretation, in particular when the studies presented equivocal results; on this basis, the genotoxicity potential of the four substances could not be concluded upon. Considering the genotoxicity

a critical endpoint in deriving TRVs, EFSA is not in a position to confirm the TRVs established by the JMPR for the four active substances.

The toxicological profile of some metabolites was solely based on read-across and QSAR analyses that are not presented in the monograph. Therefore, no conclusion could be reached on these metabolites with regard to their genotoxicity and general toxicity compared with the respective parent compounds.

EFSA would welcome bilateral discussions with the JMPR to propose ways forward, proposals could include the submission of pivotal studies and analysis to EFSA in similar cases, or agreement on the key information needed for an independent interpretation of the data and overall dossier. This was also highlighted by MSs during the commenting on this output.

ABBREVIATIONS

4-HPPD	4-hydroxyphenylpyruvate dioxygenase
ADI	acceptable daily intake
ARfD	acute reference dose
ALARA	as low as reasonable
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DM	dry matter
DMS	document management system
DNA	deoxyribonucleic acid
dw	dry weight
EAS	oestrogen, androgen and steroidogenesis modalities
ECHA	European Chemical Agency
ED	endocrine disruptor
EMS	evaluating Member State
EROD	ethoxyresorufin O-deethylase
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GD	gestation day
GLP	Good Laboratory Practice
ha	hectare
HCD	historical control data
hL	hectolitre
HR	highest residue
IARC	International Agency on Research on Cancer
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LH	luteinizing hormone
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification (determination)
LP	large portion
MoA	mode of action
MRL	maximum residue limit
MS	Member States
MW	Molecular weight
n. a	not applicable
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
ppm	parts per million (10^{-6})
PRIMo	(EFSA) Pesticide Residues Intake Model
PROD	pentoxyresorufin O-dealkylase
QSAR	quantitative structure–activity relationship
RA	risk assessment
RAC	raw agricultural commodity
RD-RA	residue definition for risk assessment
RD-ENF	residue definition for enforcement practice

RMS	rapporteur Member State
SDHI	succinate dehydrogenase inhibitor
SEU	Southern European Union
STMR	supervised trials median residue
T3	triiodothyronine
T4	thyroxine
T-modality	thyroid-modality
TPO	thyroid peroxidase
TTC	threshold of toxicological concern
TRR	total radioactive residues
TSH	thyroid stimulating hormone (thyrotropin)
UDP-GT	uridine diphosphate-glucuronyl transferase
vB	very bioaccumulative
vP	very persistent
VF	variation factor
WHO	World Health Organisation
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 NUMBERS

EFSA-Q-2023-00188; EFSA-Q-2023-00189; EFSA-Q-2023-00190; EFSA-Q-2023-00191; EFSA-Q-2023-00902.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

List of CXLs revoked by CCPR54

Codex identifier	Active substance	Code	Commodity name	Revoked CXL[a] (mg/kg)	CXL was implemented in EU legislation[b]
15	Chlormequat	AS 0640	Barley, hay and/or straw	50 (dw)	
		AS 0654	Wheat, hay and/or straw	80 (dw)	
		CM 0654	Wheat bran, unprocessed	7	
		GC 0640	Barley	2	
		GC 0654	Wheat	2	Y
		MF 0100	Mammalian fats (except milk fats)	0.1	Y
		ML 0106	Milks	0.3	Y
		MM 0095	Meat (from mammals other than marine mammals)	0.2 (no results for muscle reported)	Y
		MO 0105	Edible offal (mammalian)	1	Y
		PE 0112	Eggs	0.1	Y
		PF 0111	Poultry fats	0.04 (*)	Y
		PM 0110	Poultry meat	0.04 (*) (muscle: < LOQ)	Y
		PO 0111	Poultry, edible offal of	0.1	Y
22	Diazinon	AM 0660	Almond hulls	5	
		DF 0014	Prunes	2	
		DH 1100	Hops, dry	0.5	Y
		FB 0021	Currants, black, red, white	0.2	
		FB 0264	Blackberries	0.1	
		FB 0265	Cranberry	0.2	Y
		FB 0272	Raspberries, red, black	0.2	
		FB 0275	Strawberry	0.1	
		FB 4079	Boysenberry	0.1	
		FI 0341	Kiwifruit	0.2	
		FI 0353	Pineapple	0.1	
		FP 0009	Pome fruits (group)	0.3	
		FS 0013	Cherries (subgroup)	1	
		FS 0014	Plums (including fresh prunes) (subgroup)	1	
		FS 0247	Peach	0.2	
		GC 0645	Maize	0.02 (*)	
		HS 0190	Spices, seeds	5	Y
		HS 0191	Spices, fruits and berries	0.1 (*)	Y
		HS 0193	Spices, roots and rhizomes	0.5	Y
		HS 0444	Peppers chilli, dried	0.5	
		ML 0106	Milks	0.02 F	Y
		MM 0097	Meat of cattle, pigs & sheep	2 (fat) (muscle: 0.03)	
		MM 0814	Goat meat	2 (fat) (muscle: 0.03)	
		MO 0098	Kidney of cattle, goats, pigs and sheep	0.03	Y
		MO 0099	Liver of cattle, goats, pigs & sheep	0.03	Y
		PE 0840	Chicken eggs	0.02 (*)	Y
		PM 0840	Chicken meat	0.02 (*) (muscle: < 0.01)	
		PO 0840	Chicken, edible offal of	0.02 (*)	
		TN 0660	Almonds	0.05	Y
		TN 0678	Walnuts	0.01 (*)	
		VA 0385	Onion, bulb	0.05	Y
		VA 0389	Spring onion	1	

(Continued)

Codex identifier	Active substance	Code	Commodity name	Revoked CXL[a] (mg/kg)	CXL was implemented in EU legislation[b]
		VB 0041	Cabbages, head	0.5	
		VB 0400	Broccoli	0.5	
		VB 0405	Kohlrabi	0.2	Y
		VC 0424	Cucumber	0.1	
		VC 0431	Squash, summer	0.05	
		VC 4199	Cantaloupe	0.2	
		VL 0467	Chinese cabbage (type pe-tsai)	0.05	Y
		VL 0480	Kale (including among others: Collards, curly kale, Scotch kale, thousand-headed kale; not including Marrow-stem kele)	0.05	
		VL 0482	Lettuce, head	0.5	
		VL 0483	Lettuce, leaf	0.5	
		VL 0502	Spinach	0.5	
		VO 0445	Peppers, sweet (including pimento or pimiento)	0.05	Y
		VO 0447	Sweet corn (corn-on-the-cob)	0.02	Y
		VO 0448	Tomato	0.5	
		VP 0526	Common bean (pods and/or immature seeds)	0.2	
		VP 0529	Garden pea, shelled (succulent seeds)	0.2	
		VR 0494	Radish	0.1	Y
		VR 0577	Carrot	0.5	
		VR 0589	Potato	0.01 (*)	Y
		VR 0596	Sugar beet	0.1	Y
27	Dimethoate	AS 0654	Wheat, hay and/or straw	1	
		FC 0001	Citrus fruits (group)	5 (excluding kumquats)	
		FI 0345	Mango	1 Po	
		FP 0230	Pear	1	
		FS 0013	Cherries (subgroup)	2	
		FT 0305	Table olives	0.5	
		GC 0640	Barley	2	
		GC 0654	Wheat	0.05	
		HS 0190	Spices, seeds	5	
		HS 0191	Spices, fruits and berries	0.5	
		HS 0193	Spices, roots and rhizomes	0.1 (*)	
		HS 0444	Peppers chilli, dried	3	
		MF 0100	Mammalian fats (except milk fats)	0.05 (*)	
		ML 0107	Milk of cattle, goats & sheep	0.05 (*)	
		MM 0096	Meat of cattle, goats, horses, pigs & horses	0.05 (*) (muscle: < LOQ)	
		MO 0812	Cattle, edible offal of	0.05 (*)	
		MO 0822	Sheep, edible offal of	0.05 (*)	
		PE 0112	Eggs	0.05 (*)	
		PF 0111	Poultry fats	0.05 (*)	
		PM 0110	Poultry meat	0.05 (*) (muscle: < LOQ)	
		PO 0111	Poultry, edible offal of	0.05 (*)	
		VB 0402	Brussels sprouts	0.2	
		VB 0403	Cabbage, Savoy	0.05 (*)	
		VB 0404	Cauliflower	0.2	

(Continues)

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Codex identifier	Active substance	Code	Commodity name	Revoked CXL[a] (mg/kg)	CXL was implemented in EU legislation[b]
		VL 0482	Lettuce, head	0.3	
		VL 0506	Turnip greens	1	
		VO 0445	Peppers, sweet (including pimento or pimiento)	0.5	
		VP 0063	Peas (pods and succulent = immature seeds)	1	
		VR 0506	Turnip, Garden	0.1	
		VR 0589	Potato	0.05	
		VR 0596	Sugar beet	0.05	
		VS 0620	Artichoke, globe	0.05	
		VS 0621	Asparagus	0.05 (*)	
		VS 0624	Celery	0.5	
51	Methidathion	DT 1114	Tea, green, black (black, fermented and dried)	0.5	
		FB 0269	Grapes	1	
		FC 0003	Mandarins (including mandarin-like hybrids) (subgroup)	5	
		FP 0226	Apple	0.5	
		FP 0230	Pear	1	
		FS 0013	Cherries (subgroup)	0.2	
55	Omethoate	HS 0191	Spices, fruits and berries	0.01	
		HS 0193	Spices, roots and rhizomes	0.05	
178	Bifenthrin	HS 0444	Peppers chilli, dried	5	
		VO 0051	Peppers (subgroup)	0.5	Y
		VO 0440	Eggplant	0.3	Y
208	Famoxadone	VC 0424	Cucumber	0.2	Y
		VC 0431	Squash, summer	0.2	Y
		VO 0448	Tomato	2	Y
211	Fludioxonil	FI 0345	Mango	2	Y
		MF 0100	Mammalian fats (except milk fats)	0.02	Y
		ML 0106	Milks	0.04	Y
		MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat) (muscle: 0.012)	Y
		MO 0105	Edible offal (mammalian)	0.1	Y
		VD 0071	Beans (dry)	0.5	Y
		VD 0072	Peas (dry)	0.07	
		VD 0524	Chick-pea (dry)	0.3	
		VD 0533	Lentil (dry)	0.3	
		VP 0061	Beans with pods (Phaseolus spp.) immature pods and succulent seeds)	0.6 (green pods and immature seeds)	
		VP 0063	Peas (pods and succulent = immature seeds)	0.3	
		VP 4453	Snap bean (young pods)	0.6	
216	Indoxacarb	AS 0645	Maize fodder (dry)	25	
		FM 0183	Milk fats	2	
		ML 0106	Milks	0.1	Y
		MM 0095	Meat (from mammals other than marine mammals)	2 (fat) (muscle: 0.031)	Y (fat)
		MO 0105	Edible offal (mammalian)	0.05	Y

(Continued)

Codex identifier	Active substance	Code	Commodity name	Revoked CXL[a] (mg/kg)	CXL was implemented in EU legislation[b]
224	Difenoconazole	DT 1114	Tea, green, black (black, fermented and dried)	20	
		VO 0050	Fruiting vegetables, other than cucurbits (group)	0.6 (except chilli peppers)	Y
229	Azoxystrobin	FI 0345	Mango	0.7	
		FI 0350	Papaya	0.3	Y
		VR 0075	Root and tuber vegetables (group)	1 (except potato)	Y
231	Mandipropamid	HS 0444	Peppers chilli, dried	10	
		VA 0385	Onion, bulb	0.1	Y
		VA 0389	Spring onion	7	Y
		VC 0046	Melons, except watermelon	0.5	Y
		VC 0424	Cucumber	0.2	Y
		VC 0431	Squash, summer	0.2	Y
		VO 0051	Peppers (subgroup)	1	Y
		VO 0448	Tomato	0.3	
247	Emamectin benzoate	MF 0100	Mammalian fats (except milk fats)	0.02	Y
		ML 0106	Milks	0.002	Y
		MM 0095	Meat (from mammals other than marine mammals)	0.004 (muscle: 0.004)	Y
		MO 0105	Edible offal (mammalian)	0.08	Y
248	Flutriafol	MF 0100	Mammalian fats (except milk fats)	0.02	
		ML 0106	Milks	0.01 (*)	Y
		MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat) (muscle: 0.066)	
		MO 0105	Edible offal (mammalian)	1	
		PE 0112	Eggs	0.01 (*)	Y
		PF 0111	Poultry fats	0.02	
		PM 0110	Poultry meat	0.01 (*) (muscle: < 0.0027)	Y
		PO 0111	Poultry, edible offal of	0.03	Y
287	Quinclorac	FB 0265	Cranberry	1.5	
		SO 0495	Rape seed	0.15	
294	Spiromesifen	MF 0100	Mammalian fats (except milk fats)	0.15	
		ML 0106	Milks	0.015	
		MM 0095	Meat (from mammals other than marine mammals)	0.15 F (muscle: < 0.01)	
		MO 0105	Edible offal (mammalian)	0.3	
		PE 0112	Eggs	0.02	
		PF 0111	Poultry fats	0.02	
		PM 0110	Poultry meat	0.02 (muscle: < LOQ)	
		PO 0111	Poultry, edible offal of	0.05	
297	Fenazaquin	FM 0183	Milk fats	0.02 (*)	
		MF 0100	Mammalian fats (except milk fats)	0.02 (*)	
		ML 0106	Milks	0.02 (*)	
		MM 0095	Meat (from mammals other than marine mammals)	0.02 (*) (fat) (muscle: < 0.02)	
		MO 0105	Edible offal (mammalian)	0.02 (*)	

(Continues)

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Codex identifier	Active substance	Code	Commodity name	Revoked CXL[a] (mg/kg)	CXL was implemented in EU legislation[b]
312	Afidopyropen	MF 0100	Mammalian fats (except milk fats)	0.01 (*)	Y
		ML 0106	Milks	0.001 (*)	
		MM 0095	Meat (from mammals other than marine mammals)	0.01 (*) (muscle: < 0.01)	Y
		MO 0105	Edible offal (mammalian)	0.2	
		PE 0112	Eggs	0.01 (*)	Y
		PF 0111	Poultry fats	0.01 (*)	Y
		PM 0110	Poultry meat	0.01 (*) (muscle: < 0.01)	Y
		PO 0111	Poultry, edible offal of	0.01 (*)	Y

Abbreviation: MRL, maximum residue level.

[a]Revoked CXLs for meat: according to the EU food classification, EU MRLs are set for muscle, and not for meat. Hence, the Codex MRLs for meat cannot be directly compared with the EU MRLs for muscle. EFSA therefore retrieved from the feeding studies assessed by JMPR assessments the highest residue concentration expected in muscle; this value for muscle is reported in brackets. If the EU MRL was compared to the residue level reported in the JMPR assessment (considering eventual differences due to rounding of the results of the feeding study to the next MRL class), the EU MRL could be considered as corresponding to a revoked CXL.

[b]CXL flagged with 'Y' as being implemented in the EU legislation, if the EU MRL for the corresponding commodity is set at the same/equivalent level as the revoked CXL. If a Codex food code covers more than one food code in the EU legislation (group MRLs), the revoked CXL is flagged with 'Y' if at least one of the corresponding EU codes is equivalent to the revoked CXL.

APPENDIX B

Assessment scheme to identify fall-back MRLs for CXLs revoked by CCPR54, which were previously implemented in the EU MRL legislation

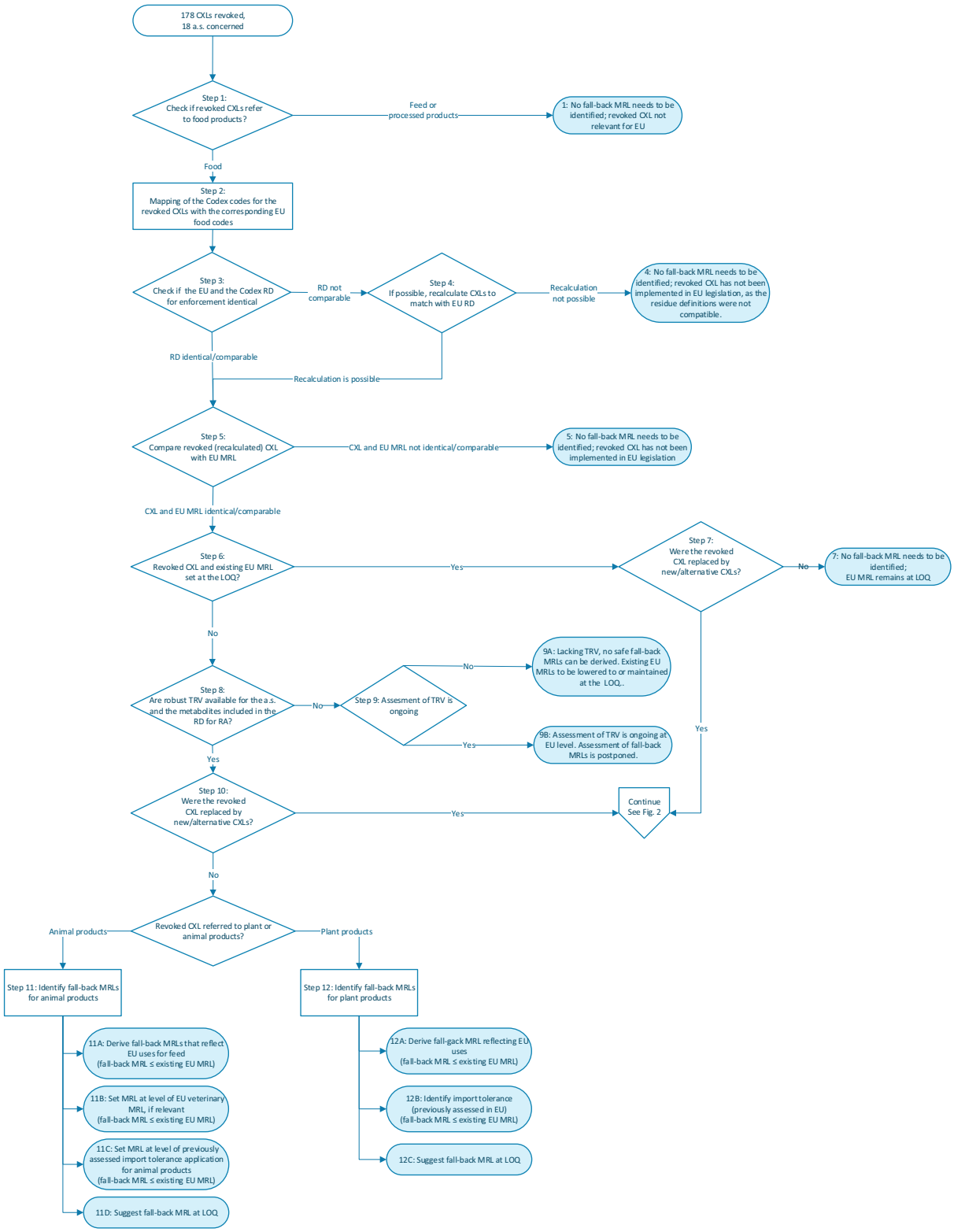

FIGURE B.1 Assessment scheme, part 1.

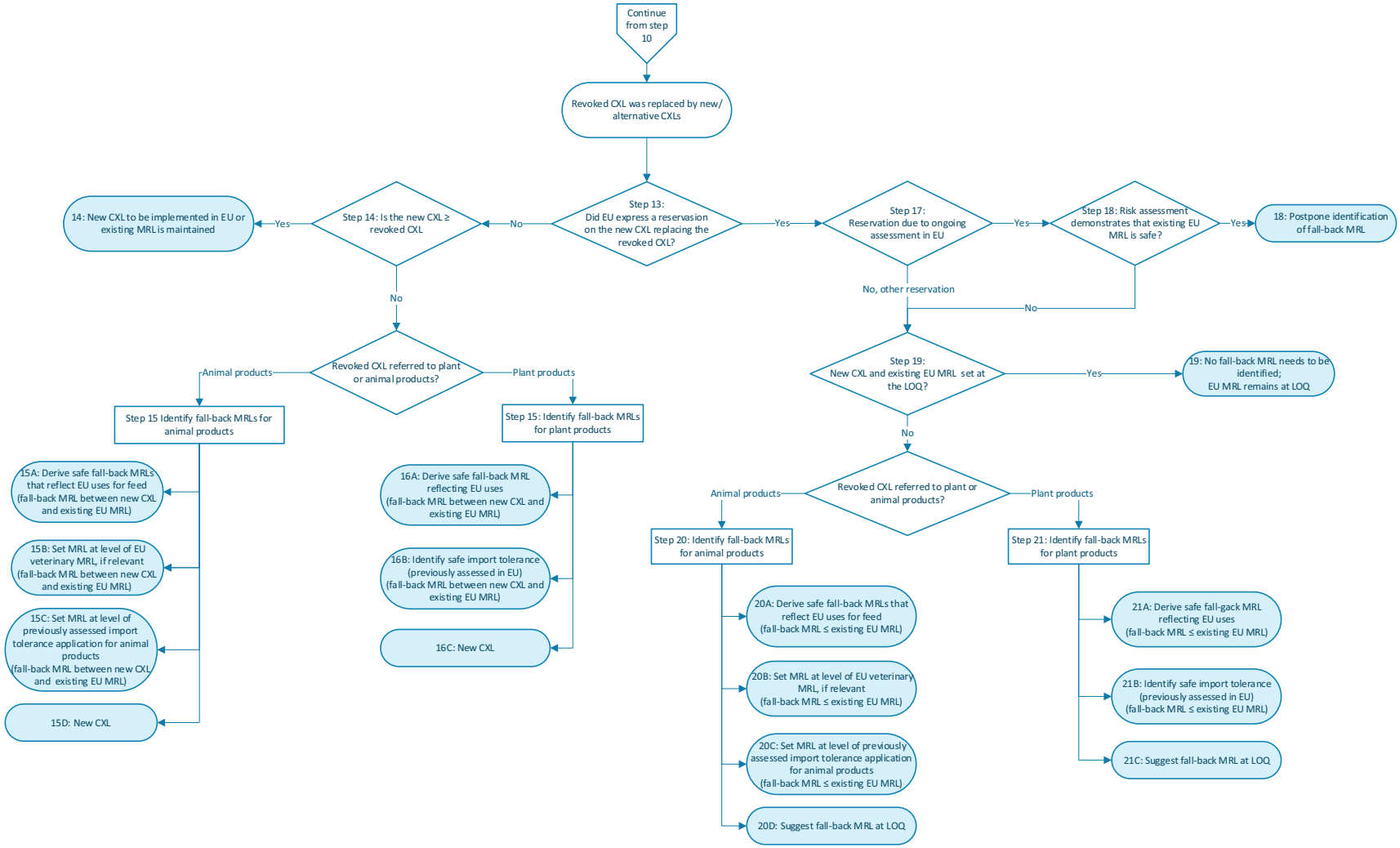

FIGURE B.2 Assessment scheme, part 2.

APPENDIX C

Supporting information on Chlormequat

In the framework of the Member State Consultation, Austria, the Netherlands and Italy informed EFSA that new uses of chlormequat were authorised for products that can be also sued for feed purpose and therefore have the potential to impact the dietary burden of livestock. The reported GAPs are listed in the table below. The critical GAPs for the different feed commodities are flagged as CGAP (see remarks).

TABLE C.1 Overview good agricultural practices (GAPs) for chlormequat chloride, reported to EFSA in the framework of the Member State Consultation.

				Application				Application rate per treatment		
Crop and/or situation	Region	F, G or I[a]	Pests or Group of pests controlled	Method kind	Growth stage of crop[b]	Max number	Interval between application (min)	Max. rate per appl. kg as/ha	PHI (days)[c]	Remarks
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	1		1.00	n.a.	Winter barley
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	2	7	0.75	n.a.	Winter barley
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	2	7	0.70	n.a.	Winter barley
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	1		1.00	n.a.	Spring barley
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	2	7	0.75	n.a.	Spring barley
Barley	NEU (AT)	F	Plant growth regulator	Foliar spray	20–39	2	7	0.70	n.a.	Spring barley
Barley	NEU (NL)	F	Plant growth regulator	Foliar spray	20–39	1		1.5	n.a.	Split application possible **cGAP NEU**
Barley	SEU (IT)	F	Plant growth regulator	Foliar spray	26–30	1		1.844	n.a.	cGAP SEU
Oat	NEU (NL)	F	Plant growth regulator	Foliar spray	20–39	1		1.5	n.a.	Split application possible **cGAP NEU**
Oat	SEU (IT)	F	Plant growth regulator	Foliar spray	39–39	1		1.38	n.a.	cGAP SEU
Rye	NEU (NL)	F	Plant growth regulator	Foliar spray	20–39	1		1.5	n.a.	Split application possible cGAP NEU
Rye	SEU (IT)	F	Plant growth regulator	Foliar spray	29–31	1		1.38	n.a.	cGAP SEU
Wheat	NEU (NL)	F	Plant growth regulator	Foliar spray	20–39	1		1.5	n.a.	Split application possible cGAP NEU
Wheat	SEU (IT)	F	Plant growth regulator	Foliar spray	26–31	1		1.38	n.a.	
Wheat	SEU (IT)	F	Plant growth regulator	Foliar spray	26–31	1		1.6	n.a.	Triticum durum cGAP SEU

[a]Outdoor or field use (F), greenhouse application (G) or indoor application (I).

[b]Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

[c]PHI – minimum preharvest interval.

In support of the critical GAPs, residue trials were provided by Member States (Austria, 2024; Italy, 2024; Netherlands, 2024). All trials were demonstrated to be valid with respect to the storage stability and the analytical methods used to analyse.

In the table below, the results of the valid residue trials on wheat, barley, oats and rye grain and straw as well as the results of statistical assessment (median residue, highest residue, MRL proposal) reflecting the critical GAPs reported.

TABLE C.2 Overview of the available residue trials data.

Commodity	Region[a]	Outdoor/ indoor	Individual trial results (mg/kg)		Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)	Median CF[d]	Comments
			Enforcement	Risk assessment					
Enforcement residue definition: Sum of chlormequat and its salts, expressed as chlormequat chloride									
Barley grain	NEU	Outdoor	cGAP NEU 1 × 1.5 kg as/ha, BBCH 39 0.06, 0.08, 0.16, 0.22, 0.31, 0.40, 2 × 0.41, 0.47, 0.49, 0.64, 0.84, 0.90, 0.99, 1.00, 1.50 (16 trials)	0.06, 0.08, 0.16, 0.22, 0.31, 0.40, 2 × 0.41, 0.47, 0.49, 0.64, 0.84, 0.90, 0.99, 1.00, 1.50 (16 trials)	0.44	1.50	3.00	1	Report numbers: 2004/1015956, S09-00600, S11-00718, S16-01534
Barley grain	SEU	Outdoor	cGAP SEU 1 × 1.844 kg as/ha, BBCH 30 < 0.05, 0.08, 0.11, 0.13, 0.16, 0.18, 0.38, 2 × 0.40, 0.70, 0.76, 0.77, 0.78, 0.85, 1.20, 1.40 (16 trials)	< 0.05, 0.08, 0.11, 0.13, 0.16, 0.18, 0.38, 2 × 0.40, 0.70, 0.76, 0.77, 0.78, 0.85, 1.20, 1.40 (16 trials)	0.40	1.40	3.00	1	Report numbers: S10-00222, S11-00718, S16-01534
Oat grain	NEU	Outdoor	cGAP NEU 1 × 1.5 kg as/ha, BBCH 39 0.33, 0.79, 0.88, 0.89, 0.90, 1.00, 1.40, 1.50, 1.60, 1.70, 1.80, 1.90, 2.0, 2.30, 2.40, 2 × 2.50, 2.60, 2.70, 3.40, 4.10, 4.20, 4.30, 7.40 (24 trials)	0.33, 0.79, 0.88, 0.89, 0.90, 1.00, 1.40, 1.50, 1.60, 1.70, 1.80, 1.90, 2.0, 2.30, 2.40, 2 × 2.50, 2.60, 2.70, 3.40, 4.10, 4.20, 4.30, 7.40 (24 trials)	1.95	7.40	9.00	1	Report numbers: S09-00600, S09-03288, S16-01535, S16-01536, S18-00128, S18-00129
Oat grain	SEU	Outdoor	cGAP SEU 1 × 1.38 kg as/ha, BBCH 39 0.28, 3 × 0.56, 0.70, 0.87, 2 × 1.10, 1.50, 1.70, 2.00, 2 × 2.70, 2.80, 6.70 (15 trials)	0.28, 3 × 0.56, 0.70, 0.87, 2 × 1.10, 1.50, 1.70, 2.00, 2 × 2.70, 2.80, 6.70 (15 trials)	1.10	6.70	9.00	1	Report numbers: S09-03288, S11-00716, S16-01536, S18-00129
Rye grain	NEU	Outdoor	cGAP NEU 1 × 1.5 kg as/ha, BBCH 39 2 × < 0.05, 2 × 0.06, 0.20, 0.21, 0.24, 0.30, 0.31, 0.32, 0.34, 0.38, 0.42, 0.44, 0.45, 2 × 0.46, 0.49, 0.59, 0.67, 0.79, 0.82, 0.94, 1.00, 2.60 (25 trials)	2 × < 0.05, 2 × 0.06, 0.20, 0.21, 0.24, 0.30, 0.31, 0.32, 0.34, 0.38, 0.42, 0.44, 0.45, 2 × 0.46, 0.49, 0.59, 0.67, 0.79, 0.82, 0.94, 1.00, 2.60 (25 trials)	0.42	2.60	3.00	1	Report numbers: S09-00600, S09-03289, S16-01537, S16-01538
Rye grain	SEU	Outdoor	cGAP SEU 1 × 1.38 kg as/ha, BBCH 31 < 0.05, 0.27, 0.51, 0.59, 0.65, 0.84, 0.89, 1.00, 1.10, 2 × 1.20, 1.40, 1.80, 1.90, 2.30, 2.80 (16 trials)	< 0.05, 0.27, 0.51, 0.59, 0.65, 0.84, 0.89, 1.00, 1.10, 2 × 1.20, 1.40, 1.80, 1.90, 2.30, 2.80 (16 trials)	1.05	2.80	5.00	1	Report numbers: S09-03289, S11-00717, S16-01538

TABLE C.2 (Continued)

Commodity	Region[a]	Outdoor/ indoor	Individual trial results (mg/kg)		Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)	Median CF[d]	Comments
			Enforcement	Risk assessment					
Wheat grain	NEU	Outdoor	cGAP NEU: 1 × 1.5 kg as/ha BBCH 39 < 0.05, 2 × 0.11, 0.13, 0.14, 0.20, 0.20, 0.30, 0.33, 0.45, 0.47, 0.62, 0.73, 0.76, 0.88, 0.94, 0.96, 1.30 (18 trials) New trials Trials reported in EFSA (2014)	< 0.05, 2 × 0.11, 0.13, 0.14, 0.20, 0.20, 0.30, 0.33, 0.45, 0.47, 0.62, 0.73, 0.76, 0.88, 0.94, 0.96, 1.30 (18 trials)	0.39	1.30	2.00	1	Report numbers: 2004/1015956, 2005/1014176, BAS-0716, S09-00600, S16-01533
Wheat grain	SEU	Outdoor	cGAP SEU 1 × 1.6 kg as/ha, BBCH 31 3 × < 0.05, 2 × 0.07, 0.08, 0.10, 0.14, 0.17, 0.19, 0.20, 0.32, 0.55, 2 × 0.56, 0.60, 0.61, 0.62, 0.63, 0.73, 1.20 (21 trials) Trials reported in IT report	3 × < 0.05, 2 × 0.07, 0.08, 0.10, 0.14, 0.17, 0.19, 0.20, 0.32, 0.55, 2 × 0.56, 0.60, 0.61, 0.62, 0.63, 0.73, 1.20 (21 trials)	0.20	1.20	2.00	1	Report numbers: 2004/1015956, 2005/1014176, BAS-0716, BAS-0717, S08-00267, S16-01533
Barley straw	NEU	Outdoor	cGAP: see barley grain 0.64, 2.60, 2 × 3.40, 3.50, 4.10, 4.70, 5.23, 5.40, 6.00, 6.70, 7.10, 7.27, 8.10, 9.12, 34.00 (16 trials)	0.64, 2.60, 2 × 3.40, 3.50, 4.10, 4.70, 5.23, 5.40, 6.00, 6.70, 7.10, 7.27, 8.10, 9.12, 34.00 (16 trials)	5.32	34.00	n.a.	n.a.	Report numbers: 2004/1015956, S09-00600, S11-00718, S16-01534
Barley straw	SEU	Outdoor	cGAP: see barley grain < 0.50, 0.80, 1.40, 2 × 1.60, 2.00, 2.40, 2.80, 3.00, 3.30, 5.90, 7.60, 8.20, 9.40, 22.00, 39.00 (16 trials)	< 0.50, 0.80, 1.40, 2 × 1.60, 2.00, 2.40, 2.80, 3.00, 3.30, 5.90, 7.60, 8.20, 9.40, 22.00, 39.00 (16 trials)	2.90	39.00	n.a.	n.a.	Report numbers: S10-00222, S11-00718, S16-01534
Oat straw	NEU	Outdoor	cGAP: see oat grain 0.57, 0.64, 0.73, 0.75, 0.90, 3 × 1.10, 1.40, 2.40, 2.50, 2.60, 2.80, 2.90, 3.00, 3.60, 3.80, 4.10, 4.70, 2 × 6.00, 6.10, 6.50, 11.00 (24 trials)	0.57, 0.64, 0.73, 0.75, 0.90, 3 × 1.10, 1.40, 2.40, 2.50, 2.60, 2.80, 2.90, 3.00, 3.60, 3.80, 4.10, 4.70, 2 × 6.00, 6.10, 6.50, 11.00 (24 trials)	2.70	11.00	n.a.	n.a.	Report numbers: S09-00600, S09-03288, S16-01535, S16-01536, S18-00128, S18-00129
Oat straw	SEU	Outdoor	cGAP: see oat grain 0.25, < 0.50, 0.50, 0.56, 0.65, 0.92, 1.10, 1.20, 2 × 2.30, 3.10, 4.50, 5.60, 6.60, 8.30 (15 trials)	0.25, < 0.50, 0.50, 0.56, 0.65, 0.92, 1.10, 1.20, 2 × 2.30, 3.10, 4.50, 5.60, 6.60, 8.30 (15 trials)	1.20	8.30	n.a.	n.a.	Report numbers: S09-03288, S11-00716, S16-01536, S18-00129
Rye straw	NEU	Outdoor	cGAP: see rye grain 0.35, 0.75, 1.10, 1.30, 2 × 1.40, 1.60, 2.00, 3.30, 2 × 3.50, 4.30, 4.80, 5.00, 5.20, 2 × 6.10, 6.50, 7.10, 7.80, 10.00, 2 × 11.00, 18.00, 23.00 (25 trials)	0.35, 0.75, 1.10, 1.30, 2 × 1.40, 1.60, 2.00, 3.30, 2 × 3.50, 4.30, 4.80, 5.00, 5.20, 2 × 6.10, 6.50, 7.10, 7.80, 10.00, 2 × 11.00, 18.00, 23.00 (25 trials)	4.80	23.00	n.a.	n.a.	Report numbers: S09-00600, S09-03289, S16-01537, S16-01538

(Continues)

TABLE C.2 (Continued)

Commodity	Region[a]	Outdoor/ indoor	Individual trial results (mg/kg)		Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)	Median CF[d]	Comments
			Enforcement	Risk assessment					
Rye straw	SEU	Outdoor	cGAP: see rye grain 0.19, 0.72, 1.30, 1.40, 1.60, 1.70, 2.60, 3×3.10, 3.30, 3.40, 4.00, 4.70, 5.10, 6.30 (16 trials)	0.19, 0.72, 1.30, 1.40, 1.60, 1.70, 2.60, 3×3.10, 3.30, 3.40, 4.00, 4.70, 5.10, 6.30 (16 trials)	3.10	6.30	n.a.	n.a.	Report numbers: S09-03289, S11-00717, S16-01538
	NEU	Outdoor	cGAP: see wheat grain 0.69, 1.40, 2×1.90, 2.50, 2.60, 3.11, 5.30, 6.20, 7.90, 8.10, 9.40, 9.50, 13.00, 13.39, 18.80, 24.00, 31.30 (18 trials)	0.69, 1.40, 2×1.90, 2.50, 2.60, 3.11, 5.30, 6.20, 7.90, 8.10, 9.40, 9.50, 13.00, 13.39, 18.80, 24.00, 31.30 (18 trials)	7.05	31.30	n.a.	n.a.	Report numbers: 2004/1015956, 2005/1014176, BAS-0716, S09-00600, S16-01533
Wheat straw	SEU	Outdoor	cGAP: see wheat grain 4×<0.50, 0.61, <0.70, 0.77, 1.30, 2×, 2.50, 2.72, 4.10, 6.08, 6.50, 7.40, 8.30, 8.40, 9.00, 14.50, 15.00, 16.00 (21 trials)	4×<0.50, 0.61, <0.70, 0.77, 1.30, 2×, 2.50, 2.72, 4.10, 6.08, 6.50, 7.40, 8.30, 8.40, 9.00, 14.50, 15.00, 16.00 (21 trials)	2.72	16.00	n.a.	n.a.	Report numbers: 2004/1015956, 2005/1014176, BAS-0716, BAS-0717, S08-00267, S16-01533

Abbreviation: n.a., not applicable.

[a]NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

[b]Median value of the individual trial results according to the enforcement residue definition.

[c]Highest value of the individual trial results according to the enforcement residue definition.

[d]The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

It is noted that for the cereal grains under assessment, the results of the residue trials submitted by Member States lead to MRLs that are lower than the existing EU MRLs (see Table C.3). Similarly, the risk assessment values for cereal grain derived from the studies reported in Table C.2 were lower than the risk assessment values derived in previous assessments. However, as regards cereal straw, the new trials in wheat straw resulted in a higher HR compared to the results assessed previously, while the new trials for other cereals straws resulted in end points as the previous ones.

TABLE C.3 List of existing MRLs and risk assessment values for cereal grains and straw derived in previous assessments.

Commodity	Existing MRL	STMR	HR	Comments
Enforcement residue definition: Sum of chlormequat and its salts, expressed as chlormequat chloride				
Barley grain	7	1.24	4.28	MRL application, assessed by EFSA proposal derived in EFSA (2020), MRL established in Regulation (EU) 2020/1565[a]
Oats grain	15	3.1	7.4	MRL is derived from a GAP evaluated at EU level in the context of the MRL review (EFSA, 2016b; MRL established in Regulation (EU) 2017/693)[b]
Rye grain	8	1.42 (1.1 × CF of 1.29)	4.39 (3.4 × CF of 1.29)	Codex MRL of 6 mg/kg was derived by JMPR (FAO and WHO, 2017) adopted in 2018 by CAC 41, after recalculation to match with the EU residue definition, it was taken over in Regulation (EU) 2019/552[c] The Codex MRL of 6 mg/kg (corresponding the EU MRL of 8 mg/kg) is still in place
Wheat grain	7	0.75 (0.58 × CF of 1.29)	1.68 (1.3 CF of 1.29)	Codex MRL of 2 mg/kg was adopted in 2018 by CAC 41; the value of 7 mg/kg was erroneously taken over in Regulation (EU) 2019/552 In CCPR54, the CXL of 2 mg/kg for wheat was revoked and replaced by a new CXL of 4 mg/kg. The STMR/HR values reported in this line reflect the results reported in JMPR report 2017 for the CXL of 2 mg/kg. Considering that the CXL has been revoked, the STMR/HR are considered obsolete. See also comments on wheat MRL in Section 1.2
	6 (new Codex MRL)	1.1 (0.855 × CF of 1.29)	3.74 (2.9 × CF of 1.29)	For the new Codex MRL of 4 mg/kg derived by CCPR54 (recalculated to EU residue definition: 6 mg/kg) the following STMR and HR values were reported in the JMPR report 2022 (FAO and WHO, 2023a), which were recalculated with the CF of 1.29 to match with the EU residue definition: • STMR: 0.885 mg/kg • HR: 2.9 mg/kg
Barley straw	–	18.0	55.0	Derived in EFSA (2020) (MRL application for barley)
Oats straw	–	4.4	11	Derived in EFSA (2016b) (MRL review) from 8 trials in NEU for the NEU GAP (1 × 1.4 kg/ha, BBCH 32–39); the residue trials assessed in EFSA (2016b) were also submitted in the context of the Member State consultation and are part of the trials reported in Table C.2
Rye straw	–	4.8	7.8	Derived in EFSA (2016b) (MRL review) from 9 trials in NEU for the NEU GAP (1 × 1.4 kg/ha, BBCH 32); the residue trials assessed in EFSA (2016b) were also submitted in the context of the Member State consultation and are part of the trials reported in Table C.2
Wheat straw	–	13.4	28.7	EFSA (2016b), NEU GAP (1 × 1.5 kg as./ha), based on 7 trials. It could not be verified that the trials assessed by EFSA were also reflected in the data presented in the context of the Member State consultation. However, considering that the new data set reported in Table C.2 is more comprehensive, EFSA used the HR and STMR derived in Table C.2 for the calculation of the dietary burden
Barley grain	7	1.24	4.28	MRL application, assessed by EFSA proposal derived in EFSA (2020), MRL established in Regulation (EU) 2020/1565
Oats grain	15	3.1	7.4	MRL is derived from a GAP evaluated at EU level in the context of the MRL review (EFSA, 2016b; MRL established in Regulation (EU) 2017/693)
Rye grain	8	1.42 (1.1 × CF of 1.29)	4.39 (3.4 × CF of 1.29)	Codex MRL of 6 mg/kg was derived by JMPR (FAO and WHO, 2017) adopted in 2018 by CAC 41, after recalculation to match with the EU residue definition, it was taken over in Regulation (EU) 2019/552 The Codex MRL of 6 mg/kg (corresponding the EU MRL of 8 mg/kg) is still in place

(Continues)

TABLE C.3 (Continued)

Commodity	Existing MRL	STMR	HR	Comments
Wheat grain	7	0.75 (0.58 × CF of 1.29)	1.68 (1.3 CF of 1.29)	Codex MRL of 2 mg/kg was adopted in 2018 by CAC 41; the value of 7 mg/kg was erroneously taken over in Regulation (EU) 2019/552 In CCPR54, the CXL of 2 mg/kg for wheat was revoked and replaced by a new CXL of 4 mg/kg. The STMR/HR values reported in this line reflect the results reported in JMPR report 2017 for the CXL of 2 mg/kg. Considering that the CXL has been revoked, the STMR/HR are considered obsolete. See also comments on wheat MRL in Section 1.2
	6 (new Codex MRL)	1.1 (0.855 × CF of 1.29)	3.74 (2.9 × CF of 1.29)	For the new Codex MRL of 4 mg/kg derived by CCPR54 (recalculated to EU residue definition: 6 mg/kg), the following STMR and HR values were reported in the JMPR report 2022 (FAO and WHO, 2023a), which were recalculated with the CF of 1.29 to match with the EU residue definition: • STMR: 0.885 mg/kg • HR: 2.9 mg/kg
Barley straw	–	18.0	55.0	Derived in EFSA (2020) (MRL application for barley)
Oats straw	–	4.4	11	Derived in EFSA (2016b) (MRL review) from 8 trials in NEU for the NEU GAP (1 × 1.4 kg/ha, BBCH 32–39); the residue trials assessed in EFSA (2016b) were also submitted in the context of the Member State consultation and are part of the trials reported in Table C.2
Rye straw	–	4.8	7.8	Derived in EFSA (2016b) (MRL review) from 9 trials in NEU for the NEU GAP (1 × 1.4 kg/ha, BBCH 32); the residue trials assessed in EFSA (2016b) were also submitted in the context of the Member State consultation and are part of the trials reported in Table C.2
Wheat straw	–	13.4	28.7	EFSA (2016b), NEU GAP (1 × 1.5 kg as./ha), based on 7 trials. It could not be verified that the trials assessed by EFSA were also reflected in the data presented in the context of the Member State consultation. However, considering that the new data set reported in Table C.2 is more comprehensive, EFSA used the HR and STMR derived in Table C.2 for the calculation of the dietary burden

[a]Commission Regulation (EU) 2020/1565 of 27 October 2020 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products. OJ L 358, 28.10.2020, p. 3–29.

[b]Commission Regulation (EU) 2017/693 of 7 April 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bitertanol, chlormequat and tebufenpyrad in or on certain products. OJ L 101, 13.4.2017, p. 1–34.

[c]Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6–49.

For the dietary burden calculation using the current animal model (Animal model 2017[17]), processing factors for cereal by-products derived from processing studies were identified that were used to replace the default processing factors (see Table C.4).

TABLE C.4 Overview of the relevant processing factors (required for dietary burden calculations).

Processed commodity	Number of trials	Median PF (best estimate)	Median CF	Comments
Enforcement and risk assessment residue definition: Sum of chlormequat and its salts, expressed as chlormequat chloride				
Brewer's grain, dried	3	0.24	1	Processing studies for spent grain (Report No. S16-01534, Italy, 2024; Netherlands, 2024) Considering the water solubility of chlormequat, the residue level in spent grain are expected to be lower compared to the residues in the starting product (barley grain). Hence, the results are plausible
Wheat gluten meal	3	0.15	1	Processing studies for gluten feed meal (Report No. S16-01533, Italy, 2024; Netherlands, 2024)
Wheat milled by-products	3	1.73	1	Processing studies on total bran (Report No. S16-01533, Italy, 2024; Netherlands, 2024)

[17]https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

By comparing the results of the new uses reported to EFSA (see cGAPs reported in Table C.1) and the results of previously assessed uses of chlormequat in cereals/cereal by-products, EFSA derived the following input values for the dietary burden calculation (Table C.5).

TABLE C.5 Input values for the dietary burden calculation.

	Median dietary burden		Maximum dietary burden	
Commodity	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
Barley grain	1.24	STMR (EFSA, 2020; see Table C.3)	1.24	STMR (EFSA, 2020; see Table C.3)
Oat grain	3.10	STMR (EFSA, 2016b; see Table C.3)	3.10	STMR (EFSA, 2016b; see Table C.3)
Rye grain	1.42	1.1 (STMR JMPR 2017) × 1.29 (CF) (EFSA, 2020; see Table C.3)	1.42	1.1 (STMR JMPR 2017) × 1.29 (CF) (EFSA, 2020; see Table C.3)
Wheat grain	1.1	0.855 (STMR JMPR 2022) × 1.29 (CF), see Table C.3	1.1	0.855 (STMR JMPR 2022) × 1.29 (CF), see Table C.3
Brewers grain	0.30	1.24 (STMR barley grain) × 0.24 (PF spent grain, see Table C.4)	0.30	1.24 (STMR barley grain) × 0.24 (PF spent grain, see Table C.4)
Distiller's grain	0.26	1.1 (STMR wheat) × 3.3 (default PF)	0.26	1.1 (STMR wheat) × 3.3 (default PF)
Wheat gluten meal	0.17	1.1 (STMR wheat) × 0.15 (PF wheat gluten meal, see Table C.4)	0.17	1.1 (STMR wheat) × 0.15 (PF wheat gluten meal, see Table C.4)
Wheat milled by-products	1.9	1.1 (STMR wheat) × 1.73 (PF all bran, see Table C.4)	1.9	1.1 (STMR wheat) × 1.73 (PF all bran, see Table C.4)
Barley straw	18	EFSA, 2020 (see Table C.3)	55	EFSA, 2020 (see Table C.3)
Oat straw	2.7	STMR oat straw, derived by pooling the NEU residue trials assessed by EFSA (2016b) and 16 new NEU trials (see Table C.2)	11	STMR oat straw, derived by pooling the NEU residue trials assessed by EFSA (2016b) and 17 new NEU trials (see Table C.2)
Rye straw	4.8	STMR rye straw, pooling the NEU residue trials assessed by EFSA (2016b) and 17 new NEU trials (see Table C.2)	23	HR rye straw, pooling the residue trials assessed by EFSA (2016b) and 17 new NEU trials (see Table C.2)
Wheat straw	7.05	STMR wheat straw (see Table C.2)[a]	31.3	HR wheat straw (see Table C.2)[a]
Triticale straw	7.05	See wheat straw	31.3	See wheat straw

Abbreviations: CF, conversion factor; HR, highest residue; PF, processing factor; STMR, supervised trials median residue.

[a]The residue trials assessed in the MRL review (EFSA, 2020) reflect a similar GAP as the GAP reported in Table C.1. However, as it cannot be verified whether the residue trials on straw were identical with residue trials submitted in the framework of the Member State Consultation of the current assessment, EFSA did not pool the trials with the trials reported in Table C.2. The trials provided in the Member State consultation were considered to be more robust, and were therefore selected for the calculation of the dietary burden.

The results of the dietary burden calculation is presented in Table C.6. In the last column, the dietary burden calculated in the most recent EFSA assessment (EFSA, 2020) is reported.

TABLE C.6 Results of the dietary burden calculation for chlormequat chloride (reference to animal model).

Relevant groups (subgroups)	Dietary burden expressed in							Trigger (0.004 mg/kg bw) exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM						Max burden
	Median	Maximum	Median	Maximum	Most critical diet[a]	Most critical commodity[b]			mg/kg bw
Cattle (all diets)	0.312	0.792	8.11	20.58	Dairy cattle	Barley	Straw	Yes	21.27
Cattle (dairy only)	0.312	0.792	8.11	20.58	Dairy cattle	Barley	Straw	Yes	21.27
Sheep (all diets)	0.575	1.635	13.53	38.47	Lamb	Barley	Straw	Yes	38.86
Sheep (ewe only)	0.451	1.282	13.53	38.47	Ram/Ewe	Barley	Straw	Yes	38.86
Swine (all diets)	0.093	0.093	3.09	3.09	Swine (finishing)	Oat	Grain	Yes	3.97
Poultry (all diets)	0.266	0.440	3.88	6.43	Poultry layer	Wheat	Dtraw	Yes	10.8
Poultry (layer only)	0.266	0.440	3.88	6.43	Poultry layer	Wheat	Straw	Yes	10.8

Abbreviation: bw, body weight; DM, dry matter.

[a]When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

[b]The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

The dietary burden calculations for cattle, sheep, swine and poultry demonstrate that – compared to the previous EFSA assessment – the expected overall dietary burden does not change significantly. In fact, the results of the updated calculations gave a slightly lower result.

Feeding studies with lactating cows were previously assessed in the framework of the EU pesticides peer review (EFSA, 2009) and the most recent MRL application (EFSA, 2020). The most recent additional feeding study was performed with a lower LOQ and generally produced more critical risk assessment values; hence, this study was selected to derive MRL proposals and risk assessment values for products of animal origin (EFSA, 2020).

Based on the re-evaluation of the residue situation for livestock, the following MRL proposals and risk **assessment values are derived for animal products** (Table C.7).

TABLE C.7 MRL proposals for animal products.

	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		
Animal commodity	**Mean**	**Highest**	**$STMR_{Mo}$ (mg/kg)**	**HR_{Mo} (mg/kg)**	**MRL proposal (mg/kg)**
Cattle (all) – Closest feeding level (0.9 mg/kg bw; 1.1 N rate, dairy cattle [highest diet])[a]					
Muscle	0.15	0.16	0.05	0.16	0.2
Fat	0.02	0.04	0.01	0.04	0.05
Liver	0.34	0.38	0.17	0.34	0.4
Kidney	0.96	1.12	0.51	1.02	1
Cattle (dairy only) – Closest feeding level (0.9 mg/kg bw; 1.1 N rate, dairy cattle)[a]					
Milk[b]	0.17	0.18	0.07	0.15	0.15
Sheep (all)[a] – Closest feeding level (0.9 mg/kg bw; 0.6 N rate, Lamb [highest diet])[a]					
Muscle	0.15	0.16	0.10	0.35	0.4
Fat	0.02	0.04	0.03	0.09	0.09
Liver	0.34	0.38	0.26	0.68	0.7
Kidney	0.96	1.12	0.77	2.03	2
Sheep (dairy only)[c] – Closest feeding level (0.9 mg/kg bw; 0.7 N rate, Ewe)[a]					
Milk[b]	0.17	0.18	0.10	0.24	0.3
Swine (all) – Closest feeding level (0.3 mg/kg bw; 3.2 N rate, finishing [highest diet])[a]					
Muscle	0.05	0.06	0.02	0.02	0.02
Fat	0.01	0.02	0.00	0.01	0.01*
Liver	0.14	0.16	0.04	0.05	0.05
Kidney	0.40	0.56	0.12	0.17	0.2
Poultry (all) – Closest feeding level (0.306 mg/kg bw; 0.7 N rate, layer [highest diet])[a]					
Muscle	0.01	0.01	0.01	0.01	0.015
Fat	0.01	0.01	0.01	0.01	0.01*
Liver	0.01	0.01	0.01	0.01	0.015
Poultry (layer only) – Closest feeding level (0.306 mg/kg bw; 0.7 N rate, Layer)[a]					
Eggs[d]	0.01	0.01	0.01	0.02	0.02

Abbreviations: bw, body weight; HR, highest residue; STMR, supervised trials median residue.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Closest feeding level and N dose rate related to the maximum dietary burden.

[b]For milk, mean was derived from the pooled, daily samples.

[c]Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

[d]For eggs, mean and highest residues were derived from the pooled, daily samples.

Overall, EFSA concludes that the MRLs for animal products derived in EFSA (2020) are still valid.