EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2023)2217651

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
13 - 14 February 2023

CIRCABC Link:
https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/e8996de9-e82d-44b6-b46f-8161ad9f4604?p=1

SUMMARY REPORT

A.01 Art. 12 and Art. 10 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12 – updated table

The Commission presented the updated table.

2. Confirmatory data Art. 12 follow-up

a) Cases where a Reasoned Opinion (RO) has been published from the European Food Safety Authority (EFSA)

The EFSA RO on the Article 12 confirmatory data assessment for metalaxyl-M was discussed in the past, but a risk management decision was still pending for herbs and edible flowers. The Commission had asked to confirm if the newly proposed indoor Good Agricultural Practices (GAP) had been authorised in any of the Member States. One Member State confirmed having authorised an indoor GAP (identical to the critical GAP for lettuces, but with lower application rate), for which the scaled data lead to the same MRL as the current one. Therefore, the Commission proposed maintaining the existing MRL.

The Commission informed of the ROs for paclobutrazol and tebufenpyrad, for which EFSA reported the need for certain risk management considerations.

For paclobutrazol, all data gaps were addressed and new residue trials were provided to confirm some of the existing MRLs. For quinces, medlars, loquats/Japanese medlars, apricots and peaches, no residue trials analysing the triazole derivative metabolites (TDMs) were available and therefore EFSA could not perform a consumer risk assessment. Nevertheless, as trials analysing TDMs were not requested at the time of the MRL review, the Commission proposed deleting all footnotes concerning data gaps and establishing the existing MRLs as permanent.

For tebufenpyrad, no specific risk management consideration was requested by EFSA. Therefore, the Commission proposed modifying or confirming the existing MRLs as recommended by EFSA.

One Member State commented that the new GAP proposed for metalaxyl-M in herbs and edible flowers may be inappropriate because of the lettuce variety

concerned. That Member State will further investigate this issue and provide its comments.

Member States were invited to submit their comments by 7 March 2023.

b) Missing analytical standards follow up

Following the reminder letters to manufacturers regarding the commercial availability of analytical standards for cyflufenamid (E-isomer), fluroxypyr conjugates and spiroxamine carboxylic acid metabolite M06, a manufacturer confirmed the availability of e-cyflufenamid, now listed on the website of the EU Reference Laboratories. For the other two analytes, the Commission sent out a second and last reminder letter for manufacturers to react by 10 May 2023. In absence of any response, the lack of this information will be considered in the review of MRLs.

3. List of non-approved substances for follow up

The Commission presented the table containing the list of non-approved substances for follow up and reminded that the next mandate to EFSA for a targeted review of non-approved substances' MRLs will include, as previously agreed, carbaryl, dicloran, diquat, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, and saflufenacil. Due to the current EFSA workload, this targeted review will not start before the second half of 2023.

4. Use of footnotes under Article 12 when the MRL is set at the Limit of Quantification (LOQ)

The Commission presented a third version of the draft general principles on setting footnotes for MRLs established at the LOQ. While this question arose for MRLs set under the Article 12 review procedure, it could also be applicable to other situations. The aim is to enhance consistency and harmonisation across measures, although it was acknowledged that special cases may arise. Once agreed, the approach will be integrated into the Commission Working Document SANCO/11485/2012 on drafting measures to amend pesticides MRLs following Article 12 of Reg. (EC) No 396/2005.

Member States were invited to share their comments on the revised proposal and the revised Commission Working Document by 7 March 2023.

5. Statement from EFSA for substances for which no Article 12 review is necessary

Following the publication of EFSA's Statement[1], the Commission presented a table proposing follow up actions. No action is required for chlorsulfuron, epoxiconazole and topramezone, as they are already included in Annex V to Regulation (EC) No 396/2005.

The inclusion of fish oil and sheep fat in Annex IV is proposed to become permanent by removing the relevant footnote in a forthcoming routine MRL proposal (agenda item B.01). *Metarhizium brunneum* strain Ma 43 and straight chain Lepidopteran pheromones, were proposed for inclusion in Annex IV. For plant oils/citronella oil, the approval expired on 30 August 2022 and the application for the renewal of the approval had been withdrawn by the applicant. In addition, in accordance with the five

[1] EFSA Statement on Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. https://www.efsa.europa.eu/en/efsajournal/pub/7723

assessment criteria of the Commission guidance[2] it was proposed to withdraw the substance from Annex IV in which it had been temporarily included previously and to move the substance into Annex V. For rape seed oil, quartz sand and aluminium silicate (aka kaolin), it was proposed to wait for the outcome of the renewal of their approval.

Member States were invited to submit their comments by 7 March 2023.

A.02 Feedback from the section PPP Legislation of this Committee:

1. General issues

The Commission provided an overview of the main outcome of the meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation held in December 2022 and January 2023 and gave an update on the table of active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon, and for which follow-up action was therefore needed.

2. Setting of Toxicological Reference Values derived via an MRL application or MRL review process (outside an assessment for approval or renewal of an active substance)

The Commission explained that it proposed to amend the existing document setting out the procedure for reporting and amending residue definitions for risk assessment to also include a procedure on toxicological reference values (TRVs) that are not set during an approval or renewal process e.g. TRVs set as part of an MRL evaluation/MRL review process. In particular the following additions are proposed:

In case a full Renewal/Review Report (RR) is available for the active substance, the RR is amended with the new TRVs, endorsed by the PAFF Committee Section phytopharmaceuticals Legislation, and the new TRVs are added to the EU Pesticide Database DB.

In case a full Renewal/Review Report (RR) does not exist (e.g. the active substance was never assessed in the EU) or is not complete (e.g. the RR is only focusing on procedural issues), a document setting out the TRVs is presented to the PAFF Section Phytopharmaceuticals Legislation. The PAFF endorses the TRV and the endorsement is captured in the summary report of the meeting. The new TRVs are then added to the EU Pesticide DB.

The update of the EU pesticides DB includes an indication of the EFSA output in which the new values are provided and the date of endorsement in the SCoPAFF, Section Phytopharmaceuticals – Legislation.

One Member State suggested mentioning, along with the reference to the EFSA output, the specific studies that allowed deriving the new TRVs. EFSA clarified that when an EFSA output is mentioned as a source, this implies citing the metadata supporting it (which include the evaluation report and the studies submitted).

Another Member State commented that clarity of the source of the TRVs (approval/renewal review or MRL setting process) should be ensured. The Commission highlighted that, as stated in the procedure, if a full renewal report is available, the TRVs will be included and explained there, avoiding any risk of misunderstanding.

[2] SANCO/11188/2013 Rev. 2 – Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005. https://food.ec.europa.eu/system/files/2016-10/pesticides_mrl_guidelines_sanco-2013-11188.pdf

Another Member State commented that a recent EFSA outcome concluded that carbendazim was not clastogenic but aneugenic, but that this was not captured in the DB update. The Commission explained that specific conclusions of the scientific assessment are not included in the database with the agreed TRVs (ADI and ARfD) since they can be found in the EFSA outcome underpinning them and recalled that the assessment of clastogenicity would also be relevant in the context of the classification of a substance under Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging (CLP) of chemical substances and mixtures.

EFSA observed that discussion will be necessary for TRVs of substances the approvals of which have expired many years ago, as they may not reflect existing scientific development.

Member States were invited to submit comments by 28 February in view of endorsing the updated paper in the March meeting of the SCoPAFF, Section Phytopharmaceuticals – Legislation.

3. Clethodim

The Commission informed on the developments as regards the toxicological risk assessment for clethodim metabolites in the framework of the ongoing process on the renewal of the approval for that substance. This information was also shared in the SCoPAFF – Section Legislation held on 25 - 26 January 2023.

4. TRVs for tricyclazole and thiophanate-methyl

The Commission informed of the discussion held in the SCoPAFF – Legislation meeting of 25 – 26 January 2023, where the TRVs established by EFSA in the context of an MRL application for tricyclazole on rice and in the context of an Article 43 review of carbendazim and thiophanate-methyl were endorsed. At that time, a Member State expressed concerns as regards a study that was used for the evaluation of tricyclazole. EFSA provided additional explanation on the approach used to derive the TRVs, and noted that two Expert meetings were held to discuss this. EFSA asked for information on the particular details raising concerns from that Member State.

Member States were invited to submit comments by 28 February.

A.03 Specific substances:

1. Glufosinate ammonium

There were no news on this point.

2. Glyphosate

The Commission Implementing Regulation (EU) 2022/2364 of 2 December 2022 extending the approval period for glyphosate[3] was published on 5 December 2022.

3. Bacillus thuringiensis

The Commission summarised the proposals for eight *Bacillus thuringiensis* strains presented in the last meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation. They are based on minimum time periods that elapse between the application of a plant protection product containing these active substances and the harvesting of edible crops intended for fresh consumption if residues data reported by the EFSA conclusion showed a density of the active substance above the level of 10^5

[3] EUR-Lex - 32022R2364 - EN - EUR-Lex (europa.eu)

CFU/g. In addition, these proposals concern the generation of more data regarding the decline of spores of the active substance after application, and storage stability data. The vote on the draft Regulations is foreseen to take place at the SCoPAFF, section Phytopharmaceuticals – Legislation on 22-23 March 2023.

The Commission asked Member States to reflect whether, when considering the conditions of use for its renewal of approval, Bt strains could be included into Annex IV to Regulation (EC) No 396/2005, or if an MRL would still be needed.

A Member State highlighted the importance of protecting consumers and that, therefore, the level of 10^5 CFU/g should cover the whole *Bacillus cereus sensu lato* group, in line with what reported in the EFSA opinion[4]. It stated that for consumer protection the difference between *Bacillus cereus* and Bacillus thuringiensis would be irrelevant, but that PCR methods to distinguish the two strains are actually available. That Member State indicated that more data from the applicants on residue decline studies would have been necessary to take an appropriate risk management decision.

Similarly, another Member State indicated that since relevant supporting data had not been provided by the applicants, it would be difficult to take a decision on the way forward under Regulation (EC) No 396/2005. It asked for the timeframe in which such data were required in the context of the restricted approval conditions.

The Commission answered that data were to be expected within 2,5years. It also highlighted that Commission Regulation (EC) No 2073/2005[5] only sets limits for *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants, and that setting MRLs for Bt would seem a stricter approach than what the food hygiene Regulation requires.

4. Trimethyl-sulfonium (Trimesium) cation

The discussion with EFSA on the occurrence of TMS residues is ongoing. EFSA agreed to further investigate its monitoring database and to liaise with the EU Reference Laboratories in this regard.

5. Sodium hydrogen carbonate

The MRLs for the two separate entries in the EU MRL database for the substance sodium hydrogen carbonate, one as basic substance and another one as low risk active substance, have now being aligned. The MRLs are now set in Annex IV for both.

6. Phosphonates/fertilizers

The Commission informed about the reactions of several Member States on a possible amendment to the Fertilising Products Regulation (FPR) regarding the status of phosphonates, and about the discussion that took place at the meeting of the SCoPAFF, Section Phytopharmaceuticals – Legislation on 25 – 26 January 2023. The proposal, supported by two not peer-reviewed studies, was to lift the current restriction provided in the FPR on a maximum concentration of 0.5 % w/w for the product function category 'plant biostimulant'.

Several Member States pointed out that the use of phosphonates as biostimulants may lead to non-compliance with the existing MRL which must be complied with,

[4] Risks for public health related to the presence of Bacillus cereus and other Bacillus spp. Including Bacillus thuringiensis in foodstuffs. EFSA Journal 2016;14(7):4524

[5] Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1)

irrespective if a substance is used as PPP or as biostimulant. The Commission informed that the colleagues in charge of the FPR were informed of those concerns and agreed to keep the proposal on hold and to reach out to the industry to submit new MRL applications (supported by GAPs, not by monitoring data) covering this use.

A Member State noted that, when the new, lower, LOQ for this substance will be implemented by the draft Regulation PLAN/2023/138, MRL compliance issues may emerge for several crops irrespective of the use of this substance as fertiliser. Similar issues are already observed in organic crops, due to the persistence of the substance in the soil. The Member State recommended considering this when deciding to lower the MRL to the LOQ for crops for which no uses are authorised.

Member States were invited to provide further comments by the 7 March 2023.

7. Spiromesifen

The Commission informed of the intention to combine the MRLsreview for spiromesifen according to Article 12 of Regulation (EC) No 396/2005 with the review of its MRLs following the end of all grace periods (maximum date for Member States to grant such periods is 30 March 2025).

A.04 News from and files related to the European Food Safety Authority:

1. Progress under Article 10 of Regulation (EC) No 396/2005

EFSA reported that outputs addressing 5 processes had been adopted since the last meeting. Currently, outputs addressing 52 such processes are at different steps of the procedure. Of these, 15 are under scientific assessment (10 under Regulation (EC) No 396/2005 and 5 under Regulation (EC) No 1107/2009) and 33 under clock-stop as additional data had been requested (26 under Regulation (EC) No 396/2005 and 7 under Regulation (EC) No 1107/2009).

2. Progress under Article 12 of Regulation (EC) No 396/2005

EFSA presented the state of play of the ongoing Article 12 reviews. Since the last meeting, 11 MRL reviews were finalised, 20 are on hold, 10 are currently being assessed at different stages of the procedure, while for 9 substances data is pending. The progress report table is publicly available for interested stakeholders [6].

3. Update on other mandates

Adoptions since the last meeting

The following outputs were adopted by EFSA since the last meeting:

- Scientific Committee Opinion on an Acceptable Daily Intake (ADI) for exposure to copper under Article 29 of Regulation (EC) No 178/2002;
- Risk assessment of MRLs for oxamyl in view of consumer protection under Article 43 of Regulation (EC) No 396/2005;
- Targeted review of MRLs for bifenthrin under Article 43 of Regulation (EC) No 396/2005;
- Revised targeted risk assessment for certain MRLs for nicotine (mandate requested by Department of Agriculture, Food and the Marine (DAFM) of Ireland) under Article 43 of Regulation (EC) No 396/2005;
- Targeted risk assessment and an evaluation of confirmatory data for certain MRLs for thiacloprid under Article 43 of Regulation (EC) No 396/2005.

[6] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf

Ongoing mandates

Eighteen further mandates are currently ongoing relating to several substances or horizontal issues. Details are available on the EFSA website[7].

4. Other issues

Pesticides Steering Network (PSN)/Transparency/IUCLID

EFSA informed that from the first 68 IUCLID post transparency MRL dossiers received, 27 are pending finalisation of the admissibility checks by the Evaluating Member States (EMSs), 39 were declared admissible by the EMSs, and 2 were withdrawn. From the 39 admissible dossiers, 13 passed EFSA's confidentiality assessment and 26 are pending.

To reduce delays of the admissibility check by EMSs, considering EFSA's legal obligation to publish a dossier upon admissibility, and to ensure a smooth and robust process, a teleconference between the EMS and EFSA is strongly recommended prior the declaration of admissibility with the aim of checking the key elements of the dossier and of the admissibility checklist (which will be made available in an Appendix to the Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure[8]) to avoid issues at a later stage. The EMS should contact EFSA to set up this teleconference prior to the declaration of admissibility. EFSA also intends to lean the confidentiality assessment only on a closed list (items that can be claimed confidential according to Regulation (EU) 2019/1381).

EFSA prioritizes the confidentiality assessments considering the submission date of the IUCLID dossiers (oldest to newest), and the progress of the EMS's assessment of dossiers.

EFSA and the European Chemicals Agency (ECHA) drafted a new guidance document: "Supporting information for MS organisations to access EFSA Agency IUCLID". The template is available for IUCLID PSN members via the dedicated Teams space.

Exposure assessment concerning the risks for public health related to the presence of BAC, DDAC and chlorates in/on fish and fish-products (Article 31 of Regulation (EC) No. 178/2002)

In May 2022, EFSA launched a call for collecting monitoring data from both the pesticides and contaminants domains, for the residues of benzalkonium chloride (BAC), didecyldimethylammonium chloride (DDAC) and chlorates. 2.296 entries were received and used as a starting point for EFSA's data analysis. As the data for BAC and DDAC included their different congeners, only data reported as the 'sum of BAC, 'sum of DDAC' will be retained, in line with the residue definitions. No information was available on the source of fish (wild or farmed). Only 'fish meat' will be considered as there is no sufficient number of samples for sub-division into species. Finally, despite the data call being open to all countries, only a few Member States and the United Kingdom submitted data. Thus, the EFSA conclusions will be indicative only, due to the limited geographical representativeness of the data.

[7] https://open.efsa.europa.eu/questions
[8] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2021.EN-6464

Guidance on Rotational Crops (Article 31 of Regulation (EC) No. 178/2002)

The public consultation on the draft EU Guidance Document was launched on 2 February 2023, for comments until 17 March 2023[9]. The document intends to support the practical implementation of the relevant OECD Test Guidelines and Guidance Documents in a harmonised way respecting the EU regulatory framework on data requirements by: i) describing under which circumstances studies investigating the nature and magnitude of residues in rotational/succeeding crops are required, ii) describing the design of rotational crop studies (metabolism studies in rotational crops, rotational crops field studies), iii) providing guidance on the interpretation of the studies in view of performing the consumer risk assessments and developing risk mitigation measures (including options for setting MRLs). EFSA aims to develop a user-friendly document to support risk assessors in their work. A chapter was included on recommendations on points that require further discussions and follow-up work (e.g. development of tools that will allow more robust assessments). Another chapter was added to assess the uncertainties and the conservatism of the proposed approaches, to provide risk managers the relevant information for taking an informed decision on the different risk management options (setting MRLs, defining use restrictions to avoid or reduce residues in rotational crops).

International – EFSA Report on scientific support for preparing the EU position for the 53rd and 54th Sessions of Codex Committee for Pesticide Residues (CCPR)

JMPR held its annual meeting on 12-23 September 2022 and its summary report, published in October 2022, includes 35 substances. A mandate under Article 43 of Regulation (EC) No 396/2005 was sent to EFSA for the yearly report on scientific support for preparing the EU position for the 54th Session of CCPR, which includes an additional request to evaluate the availability of analytical enforcement methods. EFSA is also requested to produce a second report identifying fall-back MRLs for withdrawn Codex MRLs (CXLs) previously implemented in the EU, and perform a detailed assessment of toxicological properties of new substances that have not been assessed in the EU (assessed by JMPR in 2021: pyrasulfotole, pyraziflumid, spiropidion, tetraniliprole), based on information that will be presented in the JMPR monograph on toxicology (not yet published).

EFSA invited Member States to volunteer as Rapporteurs (RMS) for those substances that do not currently have one by 28 February 2023.

Cumulative Risk Assessment (CRA)

For retrospective CRA, EFSA will launch in March a new call for cooperation on the basis of separate modalities – toxicology and exposure assessment, with the intention to conclude multiple Framework Partnership Agreements. For prospective CRA, a mock assessment of tefluthrin/carrots for acute effects started in December 2022, and a mock assessment of fenamidone/lettuce for chronic effects is planned to start in April 2023.

[9] https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011hlL/pc0271

Further assessment of beauvericin (Contaminants panel)

EFSA informed that an ad-hoc EFSA Working Group is considering the possibility to update the 2014 Scientific Opinion[10] with the new data from the External Scientific Report published in 2018[11].

EFSA 2023 Annual Report on Pesticide Residues

EFSA launched its consultation with Member States with a deadline by end of February. The report includes a pilot application of probabilistic risk assessment, therefore EFSA provided an overview of the methodology and of the main conclusions. Some Member States did not meet the minimum number of samples required by the EU multi-annual control programme (MACP), including for organic products and baby food, while the analytical coverage for some substances amenable to single-residue methods was limited. EFSA encouraged Member States to keep monitoring non-approved substances in imported products and to report more consistently on their enforcement action. For organic products the non-compliance rate remained steady (1.8%), while the findings of ethylene oxide accounted for circa 40% of the overall MRL exceedances due to the specific incident that occurred in 2021.

On the EFSA's recommendation for the analytical separation of lambda- and gamma-cyhalothrin, the Commission clarified that the EURLs have already provided an analytical method, which will be captured in the forthcoming Article 12 MRL review of gamma-cyhalothrin.

A Member State requested clarification on the update of the Processing Factors (PFs) and EFSA confirmed that it will be available early 2024.

A.05 Alignment of certain MRLs for pesticides and veterinary medicinal products:

The Commission presented an update of the ongoing work. At meeting of this Committee held on 20 – 21 November 2022, one Member State had noted that some of the active substances are also used as food additives, and enquired whether this should also be considered. The Commission investigated this issue and prepared a table containing substances with a dual use as pesticide and as food additive in accordance with Regulation (EC) No 1333/2008. For food additives, the *quantum satis* principle applies for all substances for which an ADI is not needed; maximum permitted levels are established for those substances for which an ADI is set. The Commission concluded that, according to the collected information, no misalignment exists for substances used both as pesticides and as food additives and that the specific footnotes established in Annex IV of Regulation (EC) No 396/2005 for some of the substances takes account of such dual uses. One Member State mentioned that further harmonisation may be needed for sodium aluminium silicate (E 554).

Member States are invited to submit their comments by 7 March 2023.

A.06 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2022-2023:

1. General overview

The Commission provided an update on the state of play for the remaining substances listed in the overview table.

[10] https://www.efsa.europa.eu/en/efsajournal/pub/3802
[11] https://www.efsa.europa.eu/en/supporting/pub/en-1406

2. Chlormequat, mepiquat and fosetyl-Al in cultivated fungi

The recent (2019-2021) EFSA monitoring data were analysed to assess the need for revising the existing temporary MRLs (tMRLs) for chlormequat and mepiquat in cultivated fungi and oyster mushrooms. A large dataset was available for cultivated fungi for both substances suggesting possible lowering of the existing tMRL. For oyster mushrooms, the available data was less abundant, but also indicating possible lowering of the existing tMRL. A new application for setting a MRL for mepiquat in fungi was recently received by a Member State, which proposed to provide a preliminary update of its assessment at the next meeting. The Commission therefore proposed postponing the decision on the potential lowering of the MRL for mepiquat in cultivated mushrooms.

Monitoring data from EFSA were also collected for fosetyl-Al in cultivated fungi and wheat. Although no tMRLs are in place for this substance, as the MRL for wheat was recently[12] increased from 2mg/kg to 150 mg/kg, data were collected to investigate the current situation and possible MRL exceedances in cultivated fungi due to cross-contamination from wheat straw. No exceedance was identified, but, this was expected as the available data covered the period preceding the entry into force of the new (increased) MRLs. In order to assess the potential need for establishing a tMRL for fosetyl-Al in cultivated fungi more recent data from 2022 onwards will need to be considered.

A Member State pointed out that, due to the dry summers of recent years, the use of growth regulators may have been lower than under normal conditions and therefore their content in straw in recent years may not present a reliable worst case scenario, thus the data may not be suitable for deciding on the lowering of the existing MRLs. That Member State also pointed out that the dataset from the industry significantly differs from that of EFSA and this should be investigated.

Another Member State noted that the industry is still working on new residue trials and suggested waiting for this data before revising the existing MRL.

The Commission agreed to postpone decisions on the revision of the tMRLs for chlormequat and mepiquat in cultivated fungi and oyster mushrooms, pending the collection of new data from EFSA and from the industry.

Member States are invited to submit their comments by 7 March 2023.

1. Chlorpropham

The recent (2021-2022) monitoring data provided by the industry were analysed to assess the need for revising the existing tMRL for chlorpropham in potatoes. Based on the new data, the existing MRL could be lowered to either 0.25 mg/kg (97.5th percentile of the data population) or to 0.2 mg/kg (95th percentile). Nevertheless, as the modification of the tMRL from 0.4 mg/kg to 0.35 mg/kg introduced by Regulation 2023/377 is not yet applicable, it is appropriate to wait for its applicability before further reducing the MRL, and to postpone the discussion on this issue.

Member States are invited to submit their comments by 7 March 2023.

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1807

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The working group is still addressing the comments received from the consultation round last year.

2. OECD Honey Guidelines

A Member State that attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. The main decision tree is being finalised. The working group is focusing on (a) non-target plants and (b) defining critical GAPs for honey. A first draft is expected for comments in June 2023.

3. Codex Alimentarius/JMPR issues

a) Guidelines for general principles for EU coordinated positions for CCPR

The Commission presented an updated draft considering comments received from Member States and EFSA and clarified that the document is to be considered as an internal procedural working document, and will not be published. The various comments received from Member States and the main issues raised were discussed with the Committee.

Furthermore, the Commission informed that in its recent mandate to EFSA for support for the preparation of the EU positions for the CCPR54 it requested EFSA to assess whether analytical methods are available to enforce the proposed draft CXLs. A Member State suggested that the availability of reference standards should also be considered in this assessment.

Another Member State suggested that the EU should introduce reservations for all CXLs proposed for active substances meeting the cut-off criteria, and noted that it will no longer be in a position to support any of them. The Commission clarified that decisions for MRLs are risk-based rather than hazard-based and that it would therefore continue to propose implementation of such CXLs into EU legislation.

EFSA proposed adding a numbering in the document, to facilitate the submission of comments, and to clarify that when a proposed CXL applies to more than one product in Annex I (e.g., grapes, which corresponds to both table and wine grapes in Annex I), if a risk is identified with one of the two, only part of the CXL can be taken over.

The Commission will share a revised document aiming to finalise it in May.

Member States were invited to submit their comments by 7 March 2023.

b) Issues arising from electronic Working Groups (eWGs)

The Commission provided an overview of each eWG, inviting Member States to contribute on each topic directly on the site of the respective forum of the eWG or during the discussions on the EU harmonised positions. The eWG on the Revision of the Classification of Food and Feed had proposed some changes to the classification, including the part of the commodity to which the MRL applies for ‘Group 006 Assorted tropical and sub-tropical fruits - inedible peel’ and ‘Group 023 Oilseeds and oilfruits’.

Member States are invited to submit their comments on the eWG on the Revision of the Classification of Food and Feed by 17 February 2023, on the Management of

unsupported compounds without public health concern scheduled for periodic review by JMPR by 21 February 2023 and on the other eWGs by 7 March 2023.

c) New EFSA mandate for CCPR54

The mandate requesting EFSA support for the preparation of the EU positions for the upcoming CCPR54 had been sent. It requests EFSA to provide scientific advice on the recommendations of the 2022 Joint FAO/WHO Meeting on Pesticides Residues (JMPR), and to deliver its outcome by March 2023. In addition, it requests EFSA to assess the toxicological information on pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole provided in the JMPR 2022 monograph (as soon as this will be published) and to identify fall-back MRLs for CXLs (transposed into EU legislation) that were withdrawn by Codex in 2022. These additional assessments should be provided in a separate outcome, one year after the publication of the JMPR monograph.

A Member State informed that it had assessed an application for ethiprole, based on which TRVs were derived, and submitted it to EFSA for its assessment, and noted that the provided data may be used to assess CXLs in the future.

EFSA indicated possible issues with meeting the deadline for delivering its outcomes, as the JMPR 2022 report is not yet available.

d) Others

The Commission confirmed with the RMS that it would prepare a concern form for phosmet for submission ahead of the CCPR meeting in June 2023. The concern form will be shared by 14 March 2023.

A.08 State of play on Cumulative Risk Assessment (CRA):

The Commission announced that it plans to organize another Working group with risk managers from the Member States in which EFSA will also provide a training on CRA. The date will soon be communicated and Member States will be asked to appoint their representatives for participation.

A.09 Feedback from the WG on genotoxic carcinogens held on 19 January 2023:

The Commission informed that Member States' competent authorities in the field of pesticides residues and contaminants met on 19 January 2023 to discuss and progress towards an agreement on harmonized risk management approaches/enforcement actions in cases of incidents involving food products containing genotoxic and carcinogenic substances. The aim is to be prepared to react quickly with a common EU approach if such a food safety incident would happen in the future.

The Commission noted that Member States broadly supported the initiative and the principle of a harmonized approach, but that views remain divergent on some technical points. The Commission reminded that Member States had been invited to send their comments by 7 February 2023, coordinating their positions between the pesticide and the contaminants areas, and that Member States that had not yet done so are still invited to send their comments. The Commission will consider all the elements brought forward in reflections about possible next steps, on which Member States will be kept informed.

A.10 Notifications under Article 18(4) to Reg. (EC) No 396/2005:

No issues were raised under this agenda item.

A.11 Designation of Member States for maximum residue levels (MRL) applications:

Two Member States were approached by an applicant willing to submit an import tolerance application for setting MRLs for aminocyclopyrachlor in meat and milk based on GAPs in the United States. While aminocyclopyrachlor was never assessed in the EU, and therefore has not an established EMS, another Member State is currently evaluating another import tolerance application from the US for this active substance in products of animal origin. That same Member State has also acted as rapporteur for this active substance in the preparation of the EU positions for CCPR47 in 2015. Therefore, the Committee agreed that that this Member State would act as an EMS in this case, in view of the expertise on this active substance.

A.12 Update of the Technical Guideline on the Evaluation of Extraction Efficiency (SANTE/2017/10632 Rev. 4):

A Member State that volunteered to update the document, presented a section of Questions and Answers included as Annex II in Revision 5 of the document, which will be tabled for endorsement in the next meeting.

Member States are invited to submit their comments by 7 March 2023.

A.13 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830 Rev. 2) for endorsement by Member States:

The Committee endorsed the Guidance Document SANTE/2020/12830, Revision 2.

A.14 Forthcoming draft Regulations (indicative only):

1. Deltamethrin, metalaxyl-M, thiabendazole and trifloxystrobin

The Commission informed of a new draft Regulation reviewing the MRLs for deltamethrin, metalaxyl-M, thiabendazole and trifloxystrobin, considering the latest EFSA conclusions on the confirmatory data of those substances, as well as the assessment of new MRLs requests according to Article 6 of Regulation (EC) No 396/2005. The new draft Regulation will take into account the feedback provided by the EU Reference Laboratories (EURLs) in terms of residue definition and LOQs in different food matrices.

2. Quinoxyfen, lufenuron

There are no concrete plans for the timing of such a forthcoming Regulation, however both substances are considered by the Commission under the new approach considering environmental issues of global concern under the Farm to Fork Strategy.

3. Bifenthrin, haloxyfop, profoxydim, difenacoum, desmedipham

The Commission informed of its plan to draft one or more Regulations reviewing the MRLs for bifenthrin, haloxyfop, profoxydim, difenacoum, and desmedipham, all of them substances that are no longer approved in the EU. The draft Regulations will take into account the forthcoming EFSA targeted MRL review for bifenthrin (which is still under finalisation in EFSA) and the targeted review of haloxyfop MRLs (published). The Commission proposed to apply harmonised general principles for the application

of the EU data requirements, the EFSA Pesticide Residue Intake Model (PRIMo) and the confirmatory data that were assessed in some of those EFSA targeted reviews[13]. The Commission shared with the Committee several letters received from applicants and stakeholder associations interested in the MRL reviews for bifenthrin and haloxyfop. The new draft Regulation will also take into account the feedback provided by the EURLs in terms of residue definition and LOQs in different food matrices.

4. Oxamyl and etridiazole

The Commission informed that EFSA had adopted its Statement following the mandate under Article 43 to perform a risk assessment of MRLs for oxamyl with the new TRVs in view of consumer protection, including investigating the need and feasibility of lower LOQs. EFSA still identified acute and chronic risks for many commodities even with LOQs lower than 0.01* mg/kg.

Member States were invited to send their comments on the setting of LOQs for oxamyl by 7 March 2023 and were reminded to coordinate their positions with their other representatives for the vote on the non-renewal of oxamyl at the upcoming meeting of the section Phytopharmaceuticals-Legislation on 21-22 March 2023 of this Committee.

The Commission informed that etridiazole would also be included in the same draft Regulation. No uses, import tolerances or CXLs exist for etridiazole, so that all MRLs will be set at product-specific LOQs in Annex V.

5. Dithianon

The Commission reminded that EFSA published its RO on the Article 12 review of MRLs for dithianon on 9 January 2023. In this review, EFSA considered additional data available on the toxicity of the metabolites 1,4-naphthoquinone and phthalic acid for which data gaps were identified during the assessment of the confirmatory data. However, a data gap remains on the mutagenicity potential of metabolite 1,4-naphthoquinone.

At the meeting of the SCoPAFF section Phytopharmaceuticals-Legislation of 25-26 January 2023, Member States were invited to consult the EFSA RO and to send comments by the deadline of 28 February, coordinating with representatives from the pesticide residue area.

A.15 Prioritisation of Guidance Documents:

The Commission informed of two documents that were shared with Member States on CIRCA BC: a) a document describing the proposed future process of prioritisation of guidance documents and b) a priority list of guidance documents to be prepared in the near future that was still elaborated under an interim procedure. The first document is for endorsement in the forthcoming meeting of the SCoPAFF, section Phytopharmaceuticals, Legislation on 22-23 March 2023, the second was endorsed at the meeting of the same section of the Committee on 13-14 January 2023. As it did not contain new work items for the residues section of the Committee, it was not separately discussed in a previous meeting of this section.

[13] Relevant for the mandate on azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos.

A.16 Draft revised Communications on data requirements (Commission Regulation (EU) No 283/2013 and 284/2013):

The Commission updated on the information received by Member States after the latest consultation on the revised Communications on data requirements. Among those providing feedback to the consultation, there were diverging views on the necessity of including in the Communication the dietary guidelines for pesticide residues in fish. The majority indicated that currently such guidelines should not be included as they are not yet applicable. This had also been clarified earlier on the dedicated Commission web site[14].

A.17 Revision of sampling procedures for pesticides residues:

The Commission is preparing a revision of Directive 2002/63, revamped as an Implementing Act based on Article 34(6) of Regulation (EU) 2017/625. Comments received by the Member States concerned, among others, inclusion of new products, in alignment with Annex I to Regulation (EC) No 396/2005, update of sampling procedures, e.g. sampling of products with very large units, compliance decisions by risk managers, updates of terminology and possible equivalent requirements for food business operators.

A Member State suggested the creation of a dedicated working group for this purpose. Other Member States commented on the urgency for a Better Training Safer Food (BTSF) training on sampling. The Commission will reflect on these suggestions, will provide updates in future communication and will present a draft Regulation during a next meeting.

Member States were invited to submit their comments by 7 March 2023.

A.18 Issues related to Annex 1 of Regulation (EC) No 396/2005:

The Commission shared a proposal to respond to multiple requests for clarification collected in the last years related to the classification of products in Annex I to Regulation (EC) No 396/2005. Those requests related both to products that are not explicitly mentioned and for which classification remains sometimes unclear, and to products which would need to be re-classified, as they would fit batter into another group/subgroup. In addition, the Commission proposed deleting footnote (1) of Annex I relating to some exemptions for animal feed which have frequently been misinterpreted and misused in the past and led to enforcement problems, including at EU borders. Member States were generally positive towards this suggestion. Some of them indicated possible impacts on the feed chain, others highlighted the advantages of such a deletion, such as better and clearer enforcement action by Member States.

Member States were invited to submit their comments by 28 February 2023.

A.19 Other Information points:

1. Update on PRAC measures/objections

The Commission informed that a minor misalignment between one of the recitals and the enacting terms of draft Regulation SANTE/10090/2022 had been identified, while the measure was under scrutiny by the European Council and Parliament. In the meantime it has been corrected and adopted as Commission Regulation (EU) 2023/377.

[14] https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en

The Commission recalled that EFSA has very recently re-assessed the risk for consumers related to the existing MRLs for nicotine in rose hips, teas and capers based on new data. The respective statement was adopted by EFSA but is not yet published. In this statement EFSA concluded that the existing MRL for teas does not pose risks for EU consumers, contrary to the previous EFSA risk assessment in which consumption data of tea for Irish children had been used that were later examined and found to be unreliable. While the MRLs established by Regulation (EU) 2023/377 will not change (they were based on monitoring data on the basis of the As Low As Reasonably Achievable (ALARA) principle), the new risk assessment will allow the Commission to propose transitional arrangements for teas produced before the application date of the modified MRLs included in Regulation (EU) 2023/377. A new draft Regulation will be tabled for vote at the next possible meeting of this Committee, ensuring that transitional arrangements will apply as from the first day of application of Regulation (EU) 2023/377.

2. Brexit

No issue was raised under this point.

3. Future organisation of PAFF meetings

The Commission informed that, following the comments received from Member States at the last meeting of this section of the Committee, it intends to hold the 2023 meetings of the SCoPAFF, section Phytopharmaceuticals, Pesticides Residues in alternating mode (hybrid alternating with fully virtual). As the February 2023 meeting was organised in hybrid mode, the meetings scheduled for 10-11 May 2023 and 20-21 November 2023 will be fully virtual, while the meeting scheduled for 18-19 September 2023 will be organised in hybrid mode again. The Commission also remarked that it had noted the constant decline of representatives physically attending the meeting since September 2022. It reminded Member States that it would be beneficial for the discussions if more representatives would attend the meetings physically.

4. Update on F2F -measure lowering MRLs for clothianidin and thiamethoxam

The Commission shared the letters replying to the comments received from third countries during the WTO/TBT consultation on the draft Regulation lowering the MRLs for clothianidin and thiamethoxam. In addition to these letters, the Commission is currently providing further clarifications to trade partners and third countries in order to ensure that the implementation of the Farm to Fork Policy on pesticide residues is well understood. As this process must be concluded first, a detailed planning for future draft Regulations lowering MRLs for other substances having environmental concerns of global nature is not yet available (see also agenda item A.14.2).

5. Public consultation on the past, present and future of the EU's Horizon research and innovation programmes 2014-2027

The Commission informed that a public consultation on the past, present and future of the EU's Horizon research and innovation programmes 2014-2027 started on 1 December 2022 and is ongoing until 23 February 2023. It invited Member States to participate in the survey (link provided on the slides shared via CIRCABC).

6. Isoxaben - fast track procedure for gherkins

A Member State requested to use the fast-track procedure, foreseen by the Technical Guidelines on the MRL setting procedure (chapter 3.6), to set a MRL for isoxaben in

gherkins based on residue trials for courgettes, which were assessed by EFSA in the framework of the MRL review of the substance (EFSA, 2022[15]).

One Member State took the floor and supported the proposal.

7. Thiacloprid

The Commission informed that the EFSA statement on thiacloprid has been recently adopted.

8. Bupirimate and ethirimol - fast track procedure for aubergines

A Member State requested to use the fast-track procedure, foreseen by the Technical Guidelines on the MRL setting procedure (chapter 3.6), to set a MRL for bupirimate and ethirimol in aubergines based on the residue trials on tomatoes, assessed by EFSA during the MRL review of the substance (EFSA, 2019[16]). According to that review, the critical EU GAP for aubergine was registered at that time in Spain. However, it is no longer authorised in the EU and is now superseded by the Italian/Maltese GAP for aubergine and tomato. This GAP was already assessed by EFSA to set the MRLs for bupirimate and ethirimol in tomato.

The Commission noted that the existing MRL for bupirimate in aubergines is higher than the one that would be obtained applying this fast-track procedure, and that the lowering of MRLs on basis of a fast-track procedure, while the confirmatory assessment is still pending, is not the correct procedure. As the existing MRL for bupirimate in aubergines will not be lowered before the finalisation of the Article 12 confirmatory data assessment, which is still pending, the Commission suggested to consider using the available GAP for tomatoes for setting new MRLs for aubergines in that framework.

9. Copper – next steps

The Commission informed that EFSA had published its scientific opinion on the re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources on 17 January 2023. EFSA's Scientific Committee established an ADI of 0.07 mg/kg bw per day for the adult population and concluded that the current copper exposure presents no health risk for the population, including children. The Commission will discuss with EFSA the need for a possible follow-up mandate to re-assess the MRLs and will keep this Committee informed.

A Member State reported difficulties in enforcing the current levels in Regulation (EC) No 396/2005 on products of animal origin and chia seeds, due to the background levels of copper.

Member States were invited to send any preliminary comments by 7 March 2023.

10. Prosulfocarb

A Member State provided an update for prosulfocarb detections above the LOQ in apples following up on the earlier discussions on this topic by this Committee in February and April 2022. It reported that, despite the introduction of several mitigation measures, prosulfocarb was still found in apples as a consequence of cross-contamination from lawful uses on neighbouring crops and possible spray drift.

[15] EFSA. Reasoned opinion on the review of the existing maximum residue levels for isoxaben according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7062.

[16] EFSA. Reasoned opinion on the review of the existing maximum residue levels for bupirimate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(7):5757

Therefore, the Member State suggested exploring the possibility of applying a tMRL in accordance with Article 16 of Regulation (EC) No 396/2005.

Several other Member States reported cases of cross-contamination of prosulfocarb in various corps and provided information on mitigation measures in place. While such measures do not result into a 'no detection' situation, they contribute in keeping the level as low as possible and MRL exceedances are rare.

The Commission reiterated its position that establishing a tMRL would not be appropriate, as this issue is not related to a specific crop rather to the volatility of the substance, and thus this should be addressed in the frame of the approval of the substance. Given that its renewal process is ongoing, and the Member State that raised the issue acts as co-rapporteur, this should be discussed in the context of the renewal of approval procedure, also involving the Post Approval Issues (PAI) group who dealt with such issues previously. EFSA noted that it may not be possible to solve the issue from the approval side, as this will be focussed on representative crops and not on non-target crops.

Member States were invited to provide comments by 7 March 2023.

11. Possible emergency measure on phosmet/cherries by France

A discussion took place on the letter from France dated 9 February 2023 requesting the Commission to take an emergency measure in accordance with Article 53 of Regulation (EC) No 178/2002 (General Food Law) to ban the placing on the market of cherries from cherry trees treated with phosmet. The matter was presented to the Commission and the Member States to decide whether such an EU wide measure would be justified.

France referred to the high acute toxicity of phosmet and the ARfD exceedances with the existing MRL of 1 mg/kg for cherries. While acknowledging that a draft Regulation lowering MRLs for all crops to the LOQ was tabled for vote (see point B.07), France expressed concerns that by the time of its application in summer 2023, cherries with residues higher than the LOQ could still be imported into the EU. France explained that the request focusses on cherries only as they are produced for 2023 before the application date of the measure lowering MRLs.

The Commission gave its preliminary views and considers that an EU wide emergency measure is unnecessary, as it already took rapid action on phosmet with the regular measure voted at this meeting, lowering MRLs to the LOQ for all products (not only for cherries), and establishing a shortened deferred application date of 3 months instead of the standard 6 months. The health concerns with MRLs for several commodities (not only for cherries) were known from the non-renewal process, while under the subsequent MRL process and within the context of the regulatory procedure with scrutiny the fastest possible action has already been taken.

As no specific views were received on this point, due to the late distribution of the French request which the Commission only received one working day before the meeting, the Commission invited all 26 Member States to send their comments urgently by 16 February 2023.

On the next procedural steps, the Commission explained it would reflect and consider Member States' comments, and subsequently inform them electronically of its decision on an EU wide emergency measure according to Article 53 of Regulation (EC) No 178/2002. The Commission recalled the procedure that if France would unilaterally decide to adopt such a national interim measure, then as per Article 54, the Commission

would have to submit it within 10 working days to this Committee with a view to its extension, amendment or abrogation. A specific follow-up meeting of this Committee may therefore be required.

12. Responding to comments from third countries sent to Rapporteur Member States

The discussion was brought up as part of the draft Regulation lowering MRLs for phosmet (see point B.07). At the beginning of the Article 12 MRL review process, the RMS had received letters from grower associations from third countries highlighting their use of phosmet; however, the letters did not contain any specific data, e.g. to support an import tolerance request, thus there was no data for the RMS and EFSA to consider and assess uses in non-EU countries. EFSA explained that only GAPs already authorized or evaluated by Member States can be considered in the EFSA ROs under Article 12. Import tolerance requests including the required data related to uses in non-EU countries should be submitted under Article 6 of Regulation (EC) No 396/2005, and not during the MRL review process under Article 12. The Commission noted that the process and timelines for submitting non-EU uses are not always clear for non-EU countries and considered it useful to increase efforts to explain its procedures.

Member States were invited to submit their comments by 7 March 2023.

13. Update of the extrapolation guidance (SANTE/2019/12752) as regards France

France requested reviewing Annex II of the technical guidelines on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2018/12752) related to the division of France in two geographical zones.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fish oil, pendimethalin, sheep fat and spirotetramat in or on certain products.

(PLAN/2023/196)

The Commission outlined the draft Regulation and its contents. An MRL application on EU uses of pendimethalin in peas (with pods), beans (with pods) and leeks had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. For spirotetramat, such an application was submitted for herbs and edible flowers. EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers. The draft Regulation also proposes retaining permanently fish oil and sheep fat in Annex IV to Regulation (EC) No 396/2005.

A Member State noted that, for spirotetramat in the category ‘others’ (0256990) of herbs and edible flowers, EFSA did not recommend a MRL value, noting that risk managers may consider the MRL of 10 mg/kg for the whole group as it is safe for consumers. Therefore, that Member State suggested setting that MRL at 10 mg/kg, in line with the MRL that is proposed for sage and laurel, as some crops included in this group have a similarly high oil content. Another Member State agreed with proposal, noting that setting the MRL for ‘others’ based on the representative commodity being most likely to contain the highest residue would be in line with the Commission

Technical Guidelines on extrapolation (SANTE/2019/12752). EFSA and another Member State supported the proposal.

The Commission revised the draft Regulation, taking into account the above conclusions, and presented it for vote in its Revision 2.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for folpet in or on certain products.

(PLAN/2022/2599)

The Commission outlined the draft Regulation and its contents. An MRL application for EU uses of folpet in lettuces had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. EFSA confirmed that the proposed MRL is fully supported by data and safe for consumers. Revision 1 of the draft Regulation was presented for vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole in or on certain products.

(PLAN/2022/1666)

The Commission outlined the draft Regulation and its contents. An MRL application pursuant to Article 6(1) of Regulation (EC) No 396/2005 had been submitted for cyantraniliprole in apricots. In addition, an import tolerances application for cyantraniliprole used in Canada and the United States of America on several crops had been submitted in accordance with Article 6(2) and (4) of that Regulation.

Revision 3 of the draft Regulation includes editorial changes and proposes setting the new MRLs proposed by EFSA for cyantraniliprole in apricots, potatoes, "tropical root and tuber vegetables", "cucurbits with inedible peel", Chinese cabbages/ pe-tsai, other leafy brassica, escaroles/broad-leaved endives, "spinaches and similar leaves" (except spinach), and parsley. Although some information on the magnitude of residues and on the formation of cyantraniliprole degradation products in processed products was not available, EFSA had noted that the consumers' exposure to cyantraniliprole metabolites is expected to be low and that the safety margin is wide. Therefore, the Commission proposed setting the new MRLs proposed by EFSA.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) .../... amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45 and *Purpureocillium lilacinum* strain PL 11.

(PLAN/2022/2573)

The Commission presented an overview of the draft Regulation which includes *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45, *Purpureocillium lilacinum* strain PL 11 to Annex IV of Regulation (EC) No 396/2005. A Member State indicated that it will abstain the voting of the draft Regulation because of including *Purpureocillium lilacinum* strain PL 11 into Annex IV of Regulation (EC) No 396/2005 as leucinostatins should be considered as toxicologically relevant metabolites. It referred to the EFSA conclusion[17] on the peer review supporting its view.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram in or on certain products.

(PLAN/2023/197)

The Commission outlined the draft Regulation in its Revision 2, which proposes transposing into EU legislation the CXLs for bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram, as EFSA concluded that they are safe for consumers and the EU had not reserved its position in the CCPR 2022.

A Member State commented that, as the intention of this draft Regulation is to implement all CXLs for which the EU did not introduce reservations, if a CXL is proposed for a product group, the MRLs of the minor crops belonging to that group should be also modified. As several of such minor crops are not included in Annex I, these are covered be the relevant categories of 'others'. Therefore, that Member State recommended to set the MRL for mandipropamid in Citrus fruits 'others' (0110990) at 0.5 mg/kg and for fenhexamid in Bulb vegetables 'others' (0220990) at 3 mg/kg. Another Member State agreed with the proposal.

The Commission agreed on the proposed modifications and revised the draft Regulation, taking into account the above conclusions, and presented it for vote in its Revision 3.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) …./….. as regards a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

(PLAN/2022/2309)

Following a comment from a Member State questioning the inclusion of clopyralid in the EU MACP due to the upcoming Article 12 review of its MRLs, which will most likely revise its residue definition to include its conjugates, the Commission clarified that this has no impact on the enforcement activity. Even if, according to the same

[17] Peer review of the pesticide risk assessment of the active substance *Purpureocillium lilacinum* strain PL11 (EFSA Journal 2022;20(5):6393) https://doi.org/10.2903/j.efsa.2022.6393

Member State, current enforcement analytical methods underestimate the findings, it is even now more imperative to include the substance in the EU MACP, given that those underestimates resulted into increased findings of the substance in 3 consecutive years. On the concerns for the analytical method for copper, the Commission recalled that the method is included for development in the Working Programme of the EURLs for 2023 and will be available for 2024 when the new EU MACP will apply.

Revision 3 of the draft Regulation was tabled for vote.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) .../... amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for phosmet in or on certain products.

(PLAN/2022/2311)

The Commission presented an overview of the draft Regulation, explaining that the lowering of MRLs is based on exceedances of Toxicological Reference Values (TRVs), which were lowered during the non-renewal process. For some commodities, a LOQ lower than 0.01 mg/kg is needed to ensure consumer protection. As the data gap on the toxicity and genotoxicity of the metabolite phosmet-oxon remains, no MRL can be confirmed to be safe, even in such cases where there is no exceedance of the TRVs. Since there are CXLs for phosmet, a concern form will be lodged to the JMPR ahead of the next CCPR meeting (see also point A.07).

Following the consultation of trading partners under the WTO/SPS procedure, the Commission informed of the comments received from four non-EU countries, requesting to maintain EU MRLs, as phosmet is an important insecticide for the protection of many crops that are exported to the EU, in particular apples, oranges, peaches, cherries, grapes, blueberries, cranberries, and nuts. In addition, they request longer deferred application periods, in the range of 18 months/2 years, as well as transition periods for the products already produced. One country commented that the lowering of MRLs for phosmet is hazard-based and not risk-based. The Committee noted that the lowering of the MRLs is based on the health risks identified by EFSA in its RO on the Article 12 review of the existing MRLs.

Another country commented that, as EFSA's RO indicates the risk assessment as provisional, any measure on MRLs should be put on hold until its finalization. The Commission clarified that the risk assessment is noted by EFSA as provisional in view of the data gap on the toxicity and genotoxicity of the metabolite phosmet-oxon, so that this metabolite could not be included in the risk assessment. However, the concerns identified in the provisional risk assessment would remain even if this data gap was filled. Another country noted during the Article 12 review process many growers' association had sent letters to the RMS on uses of the substance, but that EFSA did not take them into account. The RMS clarified that those letters did not contain specific data, e.g. to support an import tolerance request, thus no data was available for the RMS and EFSA to consider and assess in non-EU countries (see also point A.19.12).

The Netherlands made the following declaration:

"The Netherlands are not in favour of a LOQ lower than 0.01 mg/kg as it requires extraordinary capacity from official control laboratories. A clear food safety concern must be addressed and there are no examples of unsafe foods being placed on the EU

market which justify the MRL setting for phosmet below 0.01 mg/kg, including for milk. Furthermore, peeling factors were not taken into consideration, whereas some commodities are usually consumed without the peel".

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for pyriproxyfen in or on certain products.

(PLAN/2022/2637)

The Commission presented an overview of the draft Regulation reviewing the MRLs for pyriproxyfen under Article 12 of Regulation (EC) No 396/2005 and the modifications made since the last meeting.

For commodities for which no residue trials are available, the MRLs should be lowered to the LOQ. For kumquats, the MRL is aligned with the 2017 CXL for citrus fruits. The Commission shared a letter from industry requesting to maintain the MRL for bananas at 0.7 mg/kg until an import tolerance request could be submitted. A producing country from Latin America also provided a letter of support. The MRL had been proposed to be lowered to the LOQ by EFSA as there is no authorised use in the EU anymore, there is no CXL, and no fall-back GAP was available during the MRL review. The Commission had received detailed information from industry that an import tolerances request was in an advanced stage of preparation, with clear timelines and protocols for ongoing trials and the results of a first trial supporting the existing MRL of 0.7mg/kg already available. The RMS confirmed that the MRL of 0.7 mg/kg would be safe for consumers. In view of the exceptional situation, as concrete data from a first residue trial was submitted with specific plans for further generation of data, along with support from producing countries, Member States agreed that the MRL for bananas could be maintained temporarily at 0.7 mg/kg, pending the submission of an import tolerance request.

Member States were invited to submit their comments by 21 February 2023.

C.02 Exchange of views of the Committee on a draft Commission regulation as regards maximum residue levels for denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron in or on certain products.

(PLAN/2022/2310)

The Commission presented an overview of the draft Regulation reviewing the MRLs for the non-approved substances denatonium benzoate, diuron, methomyl and teflubenzuron, and for etoxazole, renewed on 1 February 2021 with a restriction to ornamental plants in greenhouses, for which the peer review revealed data gaps with regard to the toxicity of metabolites.

Member States were invited to submit their comments by 21 February 2023.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for indoxacarb in or on certain products.

(PLAN/2023/242)

The Commission presented an overview of the draft Regulation lowering the MRLs for indoxacarb. Its approval was not renewed, and any grace periods that may have been

granted by Member States will expire on 19 September 2023. As part of the peer review of the renewal process, the ADI and ARfD were lowered. In its RO, EFSA identified exceedances of the TRVs for a range of commodities (apples, pears, apricots, cherries, peaches, plums, table and wine grapes, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower, lettuces), while some others (basil, milk, eggs and poultry tissues) required further consideration by risk managers.

EFSA noted that the EU MRL for muscle from mammalians should be modified from 2 mg/kg to 0.04 mg/kg, as it is based on a CXL for meat (mammals) flagged with the suffix "(fat)", which means that the CXL of 2 mg/kg is applicable to fat. This value is derived from the 2009 JMPR report, reflecting the dietary burden supporting the CXLs for animal products (mammalians). As the MRL of 2 mg/kg for muscle is based on the residues in fat only, it is overestimated, and considering that the EU MRL is set for muscle and not for meat, EFSA recommended to re-consider it and set it at the most realistic value of 0.04 mg/kg, EFSA confirmed that in its RO the risk assessment was performed with the correct values and is not affected by the erroneously established MRL for muscle.

Member States were invited to submit their comments by 7 March 2023.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for carbetamide, carboxin, and triflumuron in or on certain products.

(PLAN/2022/2308)

The Commission presented an overview of the draft Regulation as regards the MRLs for the non-approved active substances carbetamide, carboxin and triflumuron. The Commission informed that fenbuconazole was removed from the draft Regulation in order to wait for the outcome of EFSA's assessment on the confirmatory data following the Article 12 MRL Review of the substance.

Member States were invited to submit their comments by 21 February 2023.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenazate in or on certain products.

(PLAN/2022/2307)

The Commission gave an overview of the draft Regulation which proposes to lower all MRLs, including those based on CXLs, to the LOQ, following the recent use restrictions for bifenazate to non-edible crops. The Commission informed of a meeting with the applicant who expressed concerns that the Regulation becomes applicable too quickly after the expiry of the grace periods granted by Member States. The Commission clarified that the date of application needs to consider the procedures following voting which can last four to five months, in addition to the 6 months plus 20 days period after publication before the Regulation becomes applicable.

The Commission gave an overview of the grace periods granted by Member States and recalled that Regulation (EU) 2022/698 of 3 May 2022 renewing the approval for bifenazate applies from 1 July 2022 which means that Member States had time to revise their existing authorisations of PPPs containing bifenazate for the sale, the distribution and for the disposal, storage, and use of existing stocks of the PPPs concerned. In addition, the Commission had asked Member States to consider granting shorter grace

periods in view of the schedule for the MRL review. The Commission clarified that the draft Regulation currently does not provide a transitional period for products placed on the market before its application date and that it was notified as such to trading partners via the WTO/SPS procedure. Member States were asked to comment whether such a period could be granted.

Member States were invited to submit their comments by 7 March 2023.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for carbendazim and thiophanate-methyl.

(PLAN/2022/2853)

The Commission presented an overview of the draft Regulation addressing carbendazim, thiophanate-methyl and also benomyl. The measure intends lowering the existing MRLs for carbendazim in grapefruits, oranges, papayas and mangoes and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes to the LOQ, as EFSA identified acute risk for consumers with the current MRL for these products. It takes into consideration the Toxicological Reference Values (TRVs) derived by EFSA in its RO of 2021[18] and modifies the residue definition for carbendazim, separating it from benomyl. For the latter, it proposes to set all MRLs to the LOQ and move the substance to Annex V to Regulation (EC) No 396/2005. The Commission intends to table this measure for voting in September 2023.

A Member State noted that the Article 12 review for those substances[19] also identified risks for consumers for some crops that are not covered in the proposed measure, and recommended including them. The Commission agreed with the proposal, and informed that the next draft for this measure will also address the risk identified by the earlier Article 12 review.

Another Member State suggested that apart from the fact that the approval of both substances had expired, also the properties of those substances should be considered (they meet the cut-off criteria) and asked the Commission for a more general clarification on the policy approach it intends to take in such cases. The Commission clarified that there is ongoing internal discussion on how to handle substances falling under the cut-off criteria, but that this proposed draft Regulation – in line with all other draft Regulations presented to the Committee so far – was based on a risk assessment. Another Member State encouraged speeding up the approach for addressing substances meeting the cut-off criteria and reiterated its position against maintaining or setting MRLs (including import tolerances) for those substances. The Commission informed, that further information on thiophanate-methyl will become available in 2023, in view of the ongoing mandate to EFSA under Article 43 of Regulation (EC) No 396/2005 to assess the endocrine disrupting properties of thiophanate-methyl.

Member States were invited to submit their comments by 7 March 2023.

[18] EFSA Reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal 2021;19(7):6773.
[19] EFSA Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiophanate-methyl and carbendazim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3919.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fosetyl-Al, potassium phosphonates and disodium phosphonates.

(PLAN/2023/138)

The Commission presented an overview of the draft Regulation reviewing MRLs based on several EFSA ROs related to Article 6 applications (which are covered by the EFSA statement of 2022[20]) and to the 2021 EFSA RO on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates[21]. The Commission described the approach followed and presented the proposed MRLs for discussion.

As a general approach, the Commission suggested the MRL proposed in the EFSA 2022 statement whenever available, and the MRL proposed in the joint review in all other cases (including if data gaps were identified by EFSA). If EFSA could not propose a MRL, then it was lowered to the LOQ (e.g. for several spices groups). In some cases, the joint review proposed increasing an MRL, but, in the meanwhile, a higher MRL was established based on an application and a favourable EFSA risk assessment. In those cases, the draft measure proposes maintaining the current higher MRL. For products belonging to the categories of 'others', for which no MRLs are proposed in the joint review, the Commission suggested to set that MRL at the same level of the other products in the same category, if the same MRL was proposed for all, or to the LOQ, if different MRLs were proposed for different crops within that group.

For other ongoing applications, the Commission noted that, if their assessment could be concluded by June 2022, then they could already be addressed by this measure, while those coming later will not be addressed until this measure will become applicable. A Member State noted that the Regulation should also address the change of the residue definition, as recommended by the EFSA joint review. The Commission confirmed that this will also be addressed by this draft Regulation.

Member States were invited to submit their comments by 7 March 2023.

C.08 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for diethofencarb, fenoxycarb, flutriafol, myclobutanil and pencycuron in or on certain products.

(PLAN/2023/194)

The draft Regulation lowers the MRLs for the substances listed in the title following the expiry of their approvals and of the maximum grace periods that may have been granted by Member States. It considers existing CXLs, EFSA's consumer exposure assessment using PRIMo version 3.1 and the input from EURLs on the achievable LOQs.

For diethofencarb, the MRLs for pears, wine grapes, tomatoes and aubergines, based on EU uses that are now revoked, should be lowered to the LOQ, while the MRL for bananas based on a 2016 import tolerance, found safe for consumers by EFSA, should be maintained. For fenoxycarb, CXLs do not exist and MRLs should be lowered to the LOQ, while for pencycuron, MRLs already lowered to the LOQ will now be moved from Annex II to Annex V to Regulation (EC) No 396/2005.

[20] EFSA Statement on the scientific statement on the maximum residue levels for potassium phosphonates. EFSA Journal 2022;20(7):7400.
[21] https://www.efsa.europa.eu/en/efsajournal/pub/6782

For flutriafol, MRLs based on CXLs (table grapes, bananas, peanuts, soya beans, sweet/bell pepper, tomatoes, wheat and coffee beans) should be maintained, as EFSA did not identify any risk for consumers. The MRL for wine grapes, based on EU use, which is now revoked, should be lowered to the CXL, which was found by EFSA to be safe for consumers. The MRLs based on import tolerances for hops, strawberries, cucurbits with edible peel and inedible peel should be maintained as EFSA found they were safe for consumers.

For myclobutanil, approximately 100 MRLs based on CXLs should be maintained, while MRLs based on revoked EU uses should be lowered to the LOQ. The import tolerance for bananas is a tentative MRL for which information on metabolism is still missing and the deadline for submission of the data has expired, thus it should be lowered to the LOQ.

Member States were invited to submit their comments by 7 March 2023.

C.09 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for (Z)-13-Hexadecen-11yn-1-ylacetate and (Z,Z,Z,Z)-7,13,16,19-Docosatetraen-1-ylisoburyrate, acrinathrin, azimsulfuron, famoxadone, methyl-nonylketone, prochloraz, sodium hypochlorite and ~~sodium silver thiosulfate~~ in or on certain products.

(PLAN/2023/145)

The Commission introduced the draft Regulation as regards the MRLs for the substances listed in the title and clarified that sodium silver thiosulfate was removed, but will be added to a forthcoming draft Regulation.

For (Z)-13-hexadecen-11yn-1-yl acetate and (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isoburyrate and sodium hypochlorite, the default MRL of 0.01 mg/kg applies. The proposed MRLs will be set at the product specific LOQs in Annex V of Regulation (EU) No 396/2005. For acrinathrin and prochloraz, MRLs are currently set in Annex II. They will be lowered to product specific LOQs and moved to Annex V. For azimsulfuron, all MRLs are already at the LOQ in Annex II and will be moved to Annex V. For famoxadone, MRLs are currently established in Annex II. The Commission has asked EFSA to assess whether existing CXLs are safe for consumers in light of the lowered TRVs established following the non-renewal of its approval. According to preliminary results, the MRLs based on CXLs can be maintained except for table grapes for which EFSA identified an acute risk for children. Methyl nonyl ketone, temporarily listed in Annex IV, is proposed to be moved to Annex V with MRLs set at the LOQ. For all substances on all products, except for famoxadone in table grapes (for which an acute health risk was identified), a transitional period is proposed for products placed on the market before the application date of the Regulation. A Member State indicated that use of sodium hypochlorite may result in formation of chlorates for which however specific MRLs are already established.

Member States were invited to submit their comments by 7 March 2023.

C.10 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 2,4 DB, methoxyfenozide, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl in or on certain products.

(PLAN/2022/2563)

The Commission presented the text and Annex of the draft Regulation, clarifying that their wording will be adjusted following the expected EFSA statement (expected 21 April 2023) that will clarify whether or not data was submitted by the applicants to support the tentative MRLs for those substances. Based on the current information, MRLs can be maintained for 2,4DB on cereals, but not for products of animal origin. The draft Regulation also proposes lowering MRLs for iodosulfuron-methyl on linseeds and corn, for mesotrione on sugar canes and for pyraflufen-ethyl on hops. It also proposes lowering the MRLs for methoxyfenozide on aubergines/eggplants, however, for products of animal origin, the EFSA statement will provide further clarity. Following the comments from Member States, the draft Regulation will now undergo the internal consultation with other relevant Commission services and will be notified to trading partners via the WTO/SPS procedure thereafter.

Member States were invited to submit comments by 7 March.

C.11 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for tricyclazole in or on certain products.

(PLAN/2023/136)

The Commission gave an overview of the draft Regulation which proposes modifying the MRL for tricyclazole in rice from 0.01* mg/kg to 0.09 mg/kg, based on an MRL application in support of an import tolerance based on a Brazilian GAP that was submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005. Based on the information provided in the framework of this application, EFSA was able to derive Toxicological Reference Values (TRVs) for this active substance and to conduct a consumer risk assessment, confirming that the proposed MRLs are fully supported by data and safe for consumers.

A Member State informed that it will likely not be able to support setting this import tolerance for tricyclazole, as tricyclazole is a non-approved substance in the EU for which health concerns were expressed earlier. However, since in the context of this application new data were submitted, it will examine the measure in more detail. Another Member State noted that, as it had raised concerns on the TRVs when these were endorsed in the meeting of the last Standing Committee on Plants, Animals, Food and Feed, section Phytopharmaceuticals, Legislation, held on 25 – 26 January 2023 and that therefore it may not be able to support the proposed import tolerance either.

Another Member State flagged more generally that, as a matter of principle, it would no longer support import tolerances for substances not approved in the EU. The Commission thanked the Member State for this relevant information and noted that this would be the fourth Member State that had informed the Commission and the other Member States to follow such an approach (others had expressed similar views in earlier meetings of this section of the Committee).

Member States were invited to submit comments by 7 March.