EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2023)6015465

Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Residues*

10 - 11 May 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/b889e265-ea8b-4682-850d-0d85bf374c35?p=1*

SUMMARY REPORT

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

1. Confirmatory data Art. 12 follow-up

a) Cases where a Reasoned Opinion (RO) has been published by 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 Practice (GAP) had been authorised in any of the Member States. One Member State had confirmed having authorised an indoor GAP (identical to the critical GAP for lettuces, but with lower application rate), for which the scaled data leads to the same Maximum Residue Level (MRL) as the current one. Another Member State had noted that the GAP for herbs and edible flowers was inappropriate because of the lettuce variety concerned. Therefore, the Commission proposed lowering the MRL for herbs and edible flowers to the Limit of Quantification (LOQ). For the MRLs for apples and pears, the Commission recalled that while no fall- back GAPs were available at the time of the EFSA assessment of confirmatory data, new Codex MRLs (CXLs) were proposed by the Codex Committee on Pesticide Residues (CCPR). However, as the Commission had introduced reservations for those CXLs, these should not be considered and the MRLs should be lowered to the LOQ.

The Commission informed of the ROs for penconazole and pyridaben, for which certain risk management considerations are necessary.

For penconazole, it proposed to increase the MRLs for blackberries and raspberries based on new data and to confirm the existing MRLs for pumpkins and watermelons. For all other crops, data addressing the previously established data gap for residue trials based on the residue definition for risk assessment were not provided. Since MRLs could be derived by EFSA based on a conversion factor, the Commission suggested to follow the EFSA proposal.

For pyridaben, the Commission proposed to lower the MRLs for pome fruits based on the provided alternative GAPs. For apricots, peaches and beans (with pods), the

previously established data gap was not addressed and the Commission proposed to lower the MRLs to the LOQ. For all products of animal origin (including those for which no footnote was added after the Art 12 review), except honey, the Commission proposed to lower the MRLs to the new LOQ of 0.01* mg/kg which was confirmed to be achievable with a new analytical method proposed for products of animal origin.

Member States were invited to submit their comments by 2 June 2023.

b) Missing analytical standards follow up

The analytical standard for spiroxamine carboxylic acid metabolite M06 has been made commercially available by its manufacturer. For fluroxypyr conjugates, despite two reminders from the Commission, the standard has not been made available by its manufacturer, therefore the Commission will consider lowering the existing MRLs to the LOQ in a forthcoming draft Regulation.

2. List of non-approved substances for follow up

The Commission presented the table containing the list of non-approved substances for follow up, and informed Member States that the finalisation of the EFSA targeted MRL review of the first batch of non-approved substances was delayed, and is now expected by the end of October 2023.

Concerning the list of substances to be covered by the planned second mandate to EFSA, the Commission proposed to remove diquat and to add terbufos. For diquat, the applicant informed that new studies are being performed in the framework of an import tolerance application that will be available in early 2024. If the new studies are not available by 2024, diquat should be addressed by the following (i.e., third) mandate from the Commission to EFSA. For terbufos, the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) reassessed the acute neurotoxicity study used to derive the Acute Reference Dose (ARfD) and concluded that there is no reason to review its Toxicological Reference Values (TRVs). EFSA noted that further clarifications are needed for the difference of the Acceptable Daily Intake (ADI) value between a Canadian and the JMPR assessment and that a toxicological assessment of terbufos and its metabolites expected in food is not available.

Therefore, the second mandate to EFSA will cover carbaryl, dicloran, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, saflufenacil, and terbufos.

Member States were invited to submit their comments by 9 June 2023.

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

The Commission presented an updated table on follow-up actions on the EFSA recommendations in the latest EFSA statement[1].

The permanent inclusion of fish oil and sheep fat into Annex IV was already voted at the last meeting of this Committee. For Metarhizium brunneum strain Ma 43 and straight chain Lepidopteran pheromones, the inclusion into Annex IV was included in a routine MRL proposal (agenda item B.01). For plant oils/citronella oil, for which at the last SCoPAFF it was proposed to withdraw the substance from Annex IV and move it to Annex V. The active substance will be moved to Annex V once the grace period expires, thus after 1 March 2024.

[1] Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2023; 21(2):7723. https://doi.org/10.2903/j.efsa.2023.7723

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 meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation held in March 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. Procedural document on setting TRVs derived via an MRL application or MRL review process (outside an assessment for approval or renewal of approval of an active substance)

The new procedure was endorsed by the SCoPAFF, Section Phytopharmaceuticals – Legislation in March 2023.

One Member State had communicated to the Commission that for two active substances for which MRLs were recently reviewed (abamectin and spinosad), new TRVs had been proposed but were not yet updated on the EU pesticides database. The Commission agreed to update the TRVs for abamectin, but noted that for spinosad the renewal process was still ongoing, and therefore the new TRVs were not yet formally endorsed.

3. Specific cases

a) Bifenthrin

Based on EFSA's conclusion[2], the ARfD and ADI set in 2009 could not be confirmed since the available data do not provide sufficient evidence to exclude genotoxicity. EFSA recommended to withdraw those TRVs. Discussions on the revision of bifenthrin MRLs[3] are still ongoing in this Committee (see Agenda Pt. C 08).

b) Fosetyl-Al, disodium phosphonates and potassium phosphonates

A document proposing the endorsement of new TRVs established by EFSA in the framework of the peer review of fosetyl will be presented at the meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation in May 2023.

A.03 Specific substances:

1. Glufosinate ammonium

The Commission informed that internal discussions on how to deal with MRL setting for substances falling under the cut-off criteria had recently been concluded and that a decision had been taken to deal with them in the same way as other non-approved substances, i.e. to continue to base regulatory decisions on a risk assessment carried out by an Evaluating Member State and EFSA. Specifically for glufosinate, this means that a draft Regulation will be prepared lowering those MRLs that were based on now obsolete EU uses, while considering to maintain existing CXLs and import tolerances if safe for consumers and sufficiently supported by data. Decisions will be taken case by case as done for other non-approved substances.

---

[2] EFSA (European Food Safety Authority), 2023. Targeted review of maximum residue levels (MRLs) for bifenthrin. EFSA Journal 2023;21(2):7864

[3] PLAN/2023/951, under Agenda Item C.08

2. Glyphosate

The renewal of the approval of the substance is ongoing. EFSA is expected to publish its Conclusion mid-2023. Further developments as regards MRLs will take into account the considerations of that Conclusion.

3. Bacillus thuringiensis

a) Tour de table on risk management options

On 23 March 2023, at the SCoPAFF, Section Phytopharmaceuticals – Legislation, the renewal of approval of the 8 active substances of Bacillus thuringiensis subsp. were voted. To follow-up on the renewal of approval decisions of 8 active substances of *Bacillus thuringiensis subsp.* under Regulation (EC) No 396/2005 the Commission asked the Member States' preference for several possible risk management options which could be envisaged as such or in combination. A majority of Member States expressed a preference for an option which would aim at still taking into account the additional data to be provided by the applicant by 14 December 2025, confirming the minimum time period between the application of plant protection products and the harvest of edible crops, as set out in the use conditions of the renewal Regulation. Ad interim it could be envisaged to maintain the current status quo in this case. The Commission took note of the outcome and will reflect on the next steps. A Member State asked whether it is possible to convert 0.01 mg/kg into CFU/g. The Commission clarified that this is not possible.

4. Trimethyl-sulfonium (Trimesium) cation

Further to its analysis of residue data of years 2019 and 2021 in tea, EFSA could not conclude whether the presence of the trimethyl-sulfonium cation (TMS) can be linked to the use of glyphosate or not. However, the available data were not sufficient to provide concrete results, therefore the Commission invited Member States to include TMS in their National Control Programmes (NCPs), not only for tea but also for other products, as the current residue definition for TMS is linked with glyphosate for all products. EFSA recalled that this was due to the fact that TMS is not an active substance on its own, rather a counter-ion, so it had to be associated with an active substance such as glyphosate in Regulation (EC) No 396/2005.

5. Copper

EFSA presented an overview of the main conclusions from its recent scientific opinion on the re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources[4]. EFSA's Scientific Committee established that there are no health risks below the copper retention threshold of an intake 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 for children. It also concluded that plant protection products were not a major contributor to exposure.

The Commission is discussing with EFSA a follow-up mandate to update the Article 12 review carried out by EFSA in 2018[5] which had not yet been implemented by the Commission pending the outcome of the conclusions of the Scientific Committee. This mandate will include the currently pending applications for MRLs for copper under Article 6 of Regulation (EC) No 396/2005.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/7728
[5] https://www.efsa.europa.eu/en/efsajournal/pub/5212

The Commission suggested that the Working Document on national monitoring plans[6] should include more commodities for analysis of copper and will follow up on this.

Three Member States reported difficulties in enforcing the current levels in Regulation (EC) No 396/2005 due to the importance of background levels of copper on various products, including honey, various products of animal origin, and chia seeds.

Member States are invited to send by 9 June 2023 any preliminary comments on copper, and any data in particular on chia seeds.

6. Folpet

A Member State highlighted that an acute risk was identified by EFSA for folpet in table grapes (exceedance of the ARfD for children, 104%) and invited the Commission to take action. Following this communication, the Commission had consulted with EFSA and agreed that this risk should be addressed by a dedicated draft measure, with the intention to lower the MRL for table grapes to the LOQ.

Member States were invited to submit their comments by 9 June 2023.

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

1. Progress under Articles 6 and 10 of Regulation (EC) No 396/2005

EFSA reported that outputs addressing 8 processes[7] had been adopted since the last meeting of this Committee.

Currently, outputs addressing 57 such processes are at different steps of the procedure. Out of these, 4 are under approval, 18 are under scientific assessment (22 under Regulation (EC) No 396/2005 and 4 under Regulation (EC) No 1107/2009) and 27 under clock-stop as additional data had been requested (20 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 of this Committee, 4 MRL reviews were finalised, 20 are on hold, 6 are currently being assessed at different stages of the procedure, while for 9 substances data is pending. The progress report table is made publicly available for interested stakeholders [8].

On the current Article 12 work programme the Evaluating Member State for the substance clopyralid informed that the Article 12 review is delayed and will only start in August 2023.

3. Update on other mandates

Adoptions since the last meeting

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

- Targeted risk assessment for famoxadone under Article 43 of Regulation (EC) No 396/2005;

[6] https://food.ec.europa.eu/system/files/2022-11/pesticides_mrl_guidelines_wrkdoc_12745.pdf
[7] Each process receives a so called "EFSA question number".
[8] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf

- Lack of confirmatory data following Art.12 MRL reviews under Article 31 of Regulation (EC) No 1107/2009;
- Risk assessment related to the presence of benzalkonium chloride (BAC), didecyldimethyl ammonium chloride (DDAC) and chlorates in/on fish and fish-products under Article 31 of Regulation (EC) No 1107/2009;
- Review of the residue definitions for risk assessment of pyrethroids forming common metabolites under Article 31 of Regulation (EC) No 1107/2009.

Ongoing mandates

16 further mandates are currently ongoing relating to several substances or horizontal issues. Details can be seen on the dedicated page of the EFSA website[9].

4. Other issues

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)

EFSA provided a summary of the outcome of its assessment for the residues of benzalkonium chloride (BAC), didecyldimethylammonium chloride (DDAC) and chlorate on fish. Based on the monitoring data collected for the years 2012-2021, EFSA did not identify any consumer intake concern for any of those substances found on fish. However, for chlorate, EFSA identified a narrow margin of safety for the acute exposure as it reached 82% of its ARfD. In addition, EFSA highlighted the uncertainties of this assessment, mainly associated with data limitations not allowing, for example, for sufficient geographical representation or for differentiation among fish species. Based on this outcome, the Commission concluded that further action as regards the residues of those substances on fish is not needed. However, a Member State questioned whether the assessment took into account all samples it had submitted, and which had indicated acute exposure risks for its population. EFSA clarified that samples for which it was not clear that they were taken under an objective sampling scheme were not considered in the assessment, and that this was the case for many of the samples submitted by that Member State.

International – EFSA Report on scientific support for preparing the EU position for the 54th Sessions of CCPR

A mandate under Article 43 of Regulation (EC) No 396/2005 has been sent to EFSA for the yearly report on scientific support for preparing the EU position for the 54th Session of CCPR. The mandate includes an additional request for EFSA to evaluate the availability of analytical enforcement methods. The report of the JMPR annual meeting held on 12-23 September 2022 was published on 15 March 2023 and includes 35 substances. EFSA prepared a first draft report on these 35 active substances and general considerations on 21 April 2023, which is for consultation with Member States by 12 May 2023. Following these comments, a second draft report will be prepared for 19 May 2023.

EFSA is also requested to produce a second report where it will identify fall-back MRLs for withdrawn CXLs that were previously implemented in the EU, and perform a detailed assessment of toxicological properties of new substances that have not been previously assessed in the EU (assessed by JMPR in 2021: pyrasulfotole, pyraziflumid,

[9] https://open.efsa.europa.eu/questions

spiropidion, tetraniliprole), based on information that will be presented in the JMPR monograph on toxicology (not yet published). This report will be prepared for February 2024.

Pesticide Residues Intake Model (PRIMo) Version 4

The beta version of PRIMo 4 is now accessible as a web-based tool through self-registration on the EFSA R4EU platform[10]. EFSA held a webinar on 22 March 2023[11] and a public consultation on the tool is open until 30 June 2023. The final PRIMo tool and technical report are expected by end of October 2023. Implementation of the new tool will be further discussed by this Committee, including assessments of potential impacts and transitional measures. The Commission highlighted that in particular the optional calculation of chronic risks using higher percentiles of exposure would need further discussion.

2022 Annual Report on Pesticide Residues (ARPR)

EFSA recalled that Member States are encouraged to submit monitoring data of the year 2022 until end of June 2023, but that submissions will still be accepted until 31 August 2023. As Member States are also obliged to submit data in the framework of the Report for the Official Controls Regulation (EU) 2017/625, EFSA encouraged them to provide the data as early as possible to avoid duplicating work. Comments on the draft Annual Report will be possible until end of January 2024. For the National Summary reports, EFSA recalled that the deadline is 30 September 2023 and that collection of those reports will be done via Microsoft Teams.

Cumulative Risk Assessment

For retrospective Cumulative Risk Assessment (CRA), EFSA launched in March 2023 a new call for cooperation which comprises two lots: one concerning establishing Cumulative Assessment Groups (CAGs) and one concerning cumulative exposure assessments. The deadline for the submission of proposals is 30 June 2023. Meanwhile, EFSA is working on elaborating CAGs for kidneys and the liver, while the collection of relevant toxicological endpoints for kidney has already been outsourced via a tasking grant.

Pesticides Steering Network (PSN)/Transparency/IUCLID

EFSA presented highlights from the IUCLID PSN subgroup meeting held on 28 March 2023. A new, improved version of IUCLID (6.7) will soon be released by the European Chemicals Agency (ECHA). EFSA presented the exceptional measures taken to enable a more efficient progression of Risk Assessment for MRL applications, as discussed in previous meetings. EFSA is having a round of bilateral meetings with Member States to discuss relevant issues and challenges encountered during the evaluation of post-transparency applications. PSN members are invited to express their interest in participating those meetings at pesticides.mrl@efsa.europa.eu.

EFSA also reminded Member States that it is essential to check that the information in the Evaluation Report is consistent with the information in the IUCLID dossier. Prior to the declaration of admissibility, a teleconference between the Rapporteur/Evaluating Member State and EFSA is strongly recommended. The Rapporteur/Evaluating

[10] https://r4eu.efsa.europa.eu/
[11] https://www.youtube.com/watch?v=ZenOlnQbc3U

Member State should contact EFSA (FDP@efsa.europa.eu) to set up this teleconference prior to the declaration of admissibility.

The next IUCLID PSN will be held in Parma on 19-20 June 2023.

Interactive pesticide residues exchange platform

EFSA presented its new trial project for the establishment of an interactive pesticide residues exchange platform (IPREP) as a network on scientific issues to enhance the collaboration between Member States and EFSA, aiming to increase the efficiency of risk assessment processes. Member States had been invited to answer to a survey on the usefulness of this new tool, and the detailed survey outcome will be discussed at the next PSN meeting.

EFSA re-organisation

EFSA informed of its internal re-organisation as of 1 April 2023, with the MRL Article 12, Article 10 and peer review residue teams being now within the PREV unit. The functional mailboxes for MRLs (pesticides.mrl@efsa.europa.eu) and peer review (pesticides.peerreview@efsa.europa.eu) continue to be used for issues/questions regarding MRL and approval/renewal process, respectively.

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

The Commission presented the table containing the ongoing work on the alignment of MRLs for multiple use substances and noted that, while it received comments after the last meeting for the alignment of MRLs for substances used both as pesticides and as food additives, that information was not yet scrutinised. The Commission will present an update on this aspect during the meeting of this Committee in September.

The Commission referred to the scientific article *"Multiple source substances - Regulation (EC) No 396/2005 and its limitations"*, shared by FoodDrinkEurope, and noted that while the paper incorrectly interprets the provisions of Regulation (EC) 396/2005, it provides a list of active substances for which some better alignment of MRLs may be needed. The Commission invited Member States to provide their views on the need for addressing some of the substances mentioned in that article.

Member States were invited to submit their comments by 9 June 2023.

A.06 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2023-2024:

1. General overview

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

2. Chlormequat and mepiquat in cultivated fungi

An application for setting new MRLs for mepiquat in fungi was recently received by a Member State, who provided a preliminary update of its assessment.

The applicant proposes setting a permanent MRL of 0.1 mg/kg for mepiquat (sum of mepiquat and its salts, expressed as mepiquat) in cultivated fungi and of 3 mg/kg in oyster mushrooms on the basis of commercial monitoring data (2013-2022 for cultivated fungi, 2015-2022 for oyster mushrooms) and applying the FAO approach, using the 99th and 95th percentile, respectively. The applicant also pointed out that residue levels in straw vary from season to season, and there is a greater potential for

sporadic residues in mushrooms when the use of mepiquat chloride is greater (for example, in a wet spring) and/or when straw yields are lower. Therefore, due to dry summers of recent years, the use for growth regulators may have been lower than in normal conditions and therefore their content in straw in recent years may not present a reliable worst-case scenario.

The Commission recalled that permanent MRLs cannot be set based on monitoring data, but only temporary MRLs (tMRLs) with a maximum duration of 10 years. The idea of setting tMRL is to review them periodically, and thus having MRLs based on old data is not appropriate. The dataset for oyster mushrooms is limited, and further clarification is needed whether the submitted data are in accordance with the existing EU residue definition (sum of mepiquat and its salts, expressed as mepiquat chloride) or not.

Member States were invited to submit their comments by 9 June 2023.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The working group is still working on different chapters before these can be compiled into a new version of the Guidance Document (GD). 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 working group is still working on the chapter on non-target plants and on a decision scheme which is not in the EU guideline. A model that calculates the pesticides that can be accumulated in honey will be added as an Appendix. In addition, other parts are being finalised. The most challenging is defining the critical GAP for honey as different pesticides on different crops need to be combined.

The first draft of the guidelines is expected to be ready by summer 2023.

2. 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 reiterated 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.

The Commission informed that one Member State suggested to modify the table showing the workflow for the Codex Alimentarius Commission's procedure for the elaboration of standards in order to mention step 5/8 too, and invited the Member State that had prepared the table to modify it accordingly.

Replying to a Member State request, the Commission reiterated its position that in case new CXLs are proposed for animal products due to higher CXLs for feed products, and EFSA identifies a health risk from the CXL for animal products, a reservation for those should be introduced. However, no reservation is needed on the feed products that lead to that exceedance in case those are not included in Annex I to Regulation (EC) No 396/2005. Those feed products may be mentioned in the reservation on the animal product. The Member State accepted this approach.

Concerning the lack of analytical methods for advancing a CXL, the wording was amended according to the recommendations provided by the Member States.

The Commission informed that it intends testing the Guidelines for the preparation of the EU positions for CCPR54 and, if the document proves to be adequate, to table it for endorsement in the SCoPAFF meeting of September.

Member States were invited to submit their comments by 9 June 2023.

b) Issues arising from eWGs

The Commission confirmed with Member States that they had no comments on the concern form for phosmet prepared by the Rapporteur Member State. The concern form will be submitted to CCPR ahead of the meeting in June 2023.

The Commission provided an overview of the ongoing developments of the electronic Working Groups and the corresponding deadlines to reply to Codex Circular Letters (CLs). The discussions on the EU positions for each specific Agenda item of the CCPR will take place during the Council Working Parties (CWP) planned for 24 May and 9 June 2023. Prior to those meetings, the draft EU replies to CLs will be distributed via the Council Participants Portal.

3. WTO – Plurilateral Meeting of 17 March 2023

a) Wording of transitional measures in our Regulations

The Commission informed of a plurilateral meeting held in the margin of the WTO/SPS Committee meeting in Geneva in March 2023 organised on request of 8 Latin American countries, plus the US and Canada. Main topics related to procedural aspects of MRL setting, i.e. implementation of CXLs, transition periods and transparency, as well as participation and preparedness of third countries with regard to EU regulatory processes in advance of the official notification of a measure through the WTO/SPS or TBT systems. In addition, the EU system of emergency authorisations and the recent court ruling of the European Court of Justice on neonicotinoids were discussed.

Two points came out from the meeting that deserve further discussion with Member States, namely on: (a) the possibility of setting national temporary MRLs under Article 18(4) of Regulation (EC) No 396/2005 and (b) transitional measures.

As regards point (a), Article 18(4) of Regulation (EC) No 396/2005 enables Member States to grant national temporary MRLs as a consequence of granting an emergency authorisation under Article 53 of Regulation (EC) No 1107/2009, if needed. The Commission recalled that cases where such tMRLs had been established in the past were extremely rare and exceptional, since most of the time EU MRLs were already existing or established. It reminded Member States to always actively signal such national tMRLs to this Committee under the existing standing agenda item established for this purpose in order to ensure full transparency.

Point (b) concerned the date of enforcement of new MRLs for domestic versus imported products. Non-EU countries that were present at the meeting considered that domestic and imported products were treated differently in the EU Regulations setting MRLs, since the respective Article of the Regulations is referring to products "produced in or imported into the Union". The Commission noted that there was no different treatment in practice but that the wording could possibly be clarified. It

therefore proposed to take up again the discussions in this Committee. The Commission will prepare a proposal for clearer wording for discussion and asked for some initial reflections.

Member States were invited to send their comments by 9 June.

A.08 Update of the Commission Working Document on drafting measures to amend pesticide MRLs following Article 12 of Regulation (EC) No 396/2005 (SANTE 11485/2012) for endorsement by Member States:

The Commission presented a fifth version of the draft general principles on setting footnotes for MRLs set at the LOQ, with minor edits following the version presented at the previous meeting. 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 have more consistency and harmonisation across measures, although special cases may arise.

Member States endorsed the revised Commission Working Document on drafting measures to amend pesticides MRLs following Article 12 of Regulation (EC) No 396/2005 (SANCO/11485/2012).

A.09 Forthcoming WG on Cumulative Risk Assessment (CRA):

The Commission announced a training on the Open Monte Carlo Risk Assessment (Open MCRA) Tool that will be provided by EFSA and the Dutch National Institute for Public Health and the Environment (RIVM) on 30 May 2023. The training will be followed by a discussion on risk management options for the implementation of prospective risk assessment in regulatory practice. On 2 May, the Commission circulated a communication to Member States inviting them to appoint participants by 20 May 2023.

A.10 Feedback from the WG on Sampling Regulation:

On 24 April 2023, the Commission organised a meeting with experts from the Member States to discuss the update of Directive 2002/63/EC[12] by means of an Implementing Regulation under Article 34(6) of Regulation (EU) 2017/625.

The main points of discussion concerned: the consideration of more products for sampling, such as honey, fish, terrestrial invertebrate animals, amphibians and reptiles (in alignment with Annex I to Regulation (EC) No 396/2005), the clarification of the sampling requirements for certain products (such as for very large-sized or high-value products), formalisation in a legal text of certain enforcement elements that are now included in the Guidance Document SANTE/11312/2021[13] (such as the use of measurement uncertainty in interpreting analytical testing results), the option to provide food business operators with the possibility to apply the same sampling rules as competent authorities, and updating the quantities of laboratory samples (where appropriate and possible), whilst maintaining alignment with Codex standards to the maximum extent possible. The Commission is now preparing a draft Implementing Regulation for comments from the experts of Member States. Based on these comments, the Commission may organise a second WG meeting, prior to presenting a draft Implement Regulation to the Committee.

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0063
[13] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf

A.11 State of play on genotoxic carcinogens:

Member States' competent authorities' experts in the field of pesticides residues and contaminants met on 19 January 2023 to discuss 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 informed that further comments had been received after that meeting, providing broad support for the principle of a harmonized approach. The Commission is revising the details of the approach further to take into account Member States' comments and will share a revised position shortly. A second meeting with Member States' experts will be held before the summer to agree on a final approach, which will then be put forward for endorsement by this section of the Committee in September 2023, and by the section on Novel food and Toxicological Safety.

A.12 Notifications under Article 18(4) to Regulation (EC) No 396/2005:

No issues were raised under this agenda item.

A.13 Designation of Member States for maximum residue levels (MRL) applications:

A Member State received an application for setting MRLs for acetamiprid in soybean, barley and rye, but reported not to be able to perform the evaluation. As another Member State is already evaluating another Article 6 application for the same substance, the Commission proposed to that Member State to act as an Evaluating Member State in this case, in view of its expertise on this active substance. That Member State accepted.

Another Member State was approached by an applicant willing to submit import tolerance applications for setting MRLs for two active substances that were never notified and authorised in the EU, isotianil and spidoxamat. The respective Member State would be willing to accept those applications and requested the Committee whether there would be any objections to it.

No objections were raised and Member States were invited to submit their comments by 9 June 2023.

A.14 Update of the Technical Guideline on the Evaluation of Extraction Efficiency (SANTE/2017/10632 Rev. 4) for endorsement by Member States:

Following up on the update discussed during the previous meeting, the Committee endorsed revision 5 of the document.

A.15 Forthcoming draft Regulations (indicative only):

1. Dithiocarbamates

EFSA has drafted a Reasoned Opinion and its publication is expected in summer 2023. The Commission's work on the review of the MRLs will start in autumn 2023.

2. Cypermethrins

The EFSA Reasoned Opinion on the Article 12 MRLs review, published on 16 March 2023, identified some areas of uncertainties. Furthermore, EFSA's Statement on the review of the residue definitions for risk assessment of pyrethroids forming common

metabolites has been adopted and will be published shortly. A draft Regulation on MRLs for cypermethrins will now be prepared.

Member States were invited to send any preliminary comments by 9 June 2023.

3. Dithianon

In its RO on the Article 12 MRLs review, EFSA considered additional information 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. The Commission presented options for reviewing the MRLs considering the ARfD exceedances identified by EFSA for some commodities, the data gap on the mutagenicity potential of the metabolite 1,4-naphthoquinone, and the upcoming renewal procedure for dithianon.

Member States were invited to send comments by 9 June 2023.

4. Cyproconazole and spirodiclofen

The Commission informed of a new draft Regulation reviewing the MRLs for the non-approved active substances cyproconazole, isopyrazam and spirodiclofen, while also considering the EFSA ROs on the review of the existing MRLs for those substances according to Article 12 of Regulation (EC) No 396/2005. The intention is to maintain the MRLs based on CXLs and import tolerances if those are safe for consumers.

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

The Commission informed about the procedural status of the draft revised Communications on data requirements and the potential date of adoption by the SCoPAFF, section Phytopharmaceuticals – Legislation.

A.17 Issues related to Annex 1 of Regulation (EC) No 396/2005:

The Commission presented two draft tables summarising previous discussions on the classification of food and feed in Annex I to Regulation (EC)No 396/2005. The first draft table summarises the proposed classifications of novel foods and other minor products in the category "Others" from the group/subgroup considered most representative for the product. The second table summarises the decisions made on different reclassification requests.

The Coordinator of the Minor Uses Coordination Facility (MUCF) was invited to present their position paper to the Committee advocating the reclassification of radish leaves. The expert provided arguments highlighting the problems of the current classification of radish leaves, linked in part B of Annex I of 396/2005 to kales, and proposing a reclassification linking this commodity to the crop group "baby leaf crops". The position was supported by scientific studies and field trials, which were presented by one expert from the Member State in which the study was conducted. Member States acknowledged the study and requested additional information such as the comparability of the good agricultural practices applied during the field trials, the applicability to the leaves from different varieties of radishes and the number of trials performed. Member States were invited to evaluate the information provided and submit additional questions, as well as field trials on radish leaves to continue the discussion. The Commission also informed about the comments received from some Member States on the proposal of deleting footnote (1) of Annex I relating to some

exemptions for animal feed as well as the comments received from some stakeholders in feed production. Since some Member States requested more time for evaluation, the discussion of this point was postponed.

Member States were invited to submit their comments by 9 June 2023.

A.18 Revision of the technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials, and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752) for endorsement by Member States.

The Commission presented the revision 01 of SANTE/2019/12752, the technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials, and extrapolation of residue data on products from plant and animal origin. The revision included a modification of the Annex II addressing the request from a Member State on its division in geographical zones.

A.19 Other Information points:

1. Update on PRAC measures/objections

No issues were raised under this agenda item.

2. Brexit

No issue was raised under this point.

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

The Commission informed about the publication of a Corrigendum[14] to the Commission Regulation (EU) 2023/334 amending the footnote 19 of Recital 8.

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

Following the discussion at the last meeting, no issues have been reported by Member States as regards responding to comments from third countries sent to Rapporteur Member States. The Commission concluded that no further follow-up is needed. Member States are strongly encouraged to respond to all letters received, or to re-direct the enquiry to the appropriate interlocutor.

5. Cyflumetofen - fast track procedure for courgettes and gherkins

A Member State requested to use the fast-track procedure, foreseen by the Technical Guidelines on the MRL setting procedure (chapter 3.6 of document SANTE/2015/10595 Rev. 6.1), to set a MRL for cyflumetofen in courgettes and gherkins based on residue trials for cucumbers, which were assessed by EFSA in the framework of the MRL review of the substance[15].

Member States were invited to submit comments by 9 June 2023

6. Captan - consideration for a temporary MRL for honey

A Member State informed that residues of captan were detected in samples of honey during their 2020 – 2022 monitoring programme, in some cases exceeding the EU MRL

[14] Corrigendum to Commission Regulation (EU) 2023/334 of 2 February 2023 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. OJ L 96, 5.4.2023, p. 89–89

[15] EFSA. Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6812.

of 0.05* mg/kg. Therefore, risk mitigation measures for crops cultivated in open air, including a restriction to exclude use during flowering, were introduced. However, this decision is problematic for the sector as the use of captan during flowering in pome fruit is critical, while in strawberry and berries there is a long period of flowering, and it overlaps often with the period of harvest. Therefore, that Member State is looking into different options to set a higher MRL for captan in honey, including the possibility of setting a tMRL based on monitoring data, a permanent MRL based on residue trials, or a national MRL.

As data on residues in honey were not required at the time of the approval of captan (which will expire on 31 July 2023), one applicant would be willing to initiate honey residues trials as soon as possible and make an application for a permanent EU MRL. Data will only be available at the end of 2023.

In the view of the Member State, the possibility of setting a tMRL would be preferable as it would be more rapid, but it acknowledged also the ongoing discussions on restriction of captan to uses under greenhouse at the SCoPAFF Section Phytopharmaceuticals – Legislation.

The Commission clarified that setting a national MRL is not an option. It noted that setting a permanent MRL based on field trials would be the most appropriate solution, but acknowledged that, in view of the time constraints, a tMRL based on monitoring data could also be envisaged. The timing for this would depend on when that Member State would be able to receive monitoring data from EFSA (if available) and draft the Evaluation Report accordingly, and on the time that will be needed by EFSA to assess it. The Commission will check with EFSA if monitoring data for captan in honey are available, and inform Member States accordingly.

Member States were invited to submit comments by 9 June 2023

7. Discussion on the inclusion of certain microorganisms into Annex IV

The Commission gave an overview of the microorganisms for which a decision on inclusion or non-inclusion into Annex IV of Regulation (EC) 396/2005 would need to be taken by risk managers, as EFSA did not recommend including those substances into Annex IV due to data gaps. Based on the respective Review Reports for approval/renewal, it proposed to add *Trichoderma atroviride* AGR2, *Trichoderma atroviride* AT10 and *Pythium oligandrum* strain M1 for inclusion into Annex IV.

Member States were invited to submit their comments by 9 June 2023

8. Fast track procedure acetamiprid/kaki

A Member State requested to use the fast-track procedure, foreseen by the Technical Guidelines on the MRL setting procedure (chapter 3.6 of document SANTE/2015/10595 Rev. 6.1), to set a MRL for acetamiprid in kaki/Japanese persimmons based on residue trials for apples/pears, which were assessed by EFSA in the framework of the focused MRL assessment[16]. The Commission noted that, even if the fast track procedure is accepted, the proposed changes to the MRL for kaki/Japanese persimmons will be kept on hold pending the finalisation of the work on the EFSA mandate for scientific and technical assistance on toxicological properties and MRLs of acetamiprid and its metabolites.

[16] EFSA. Reasoned Opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):526

Member States were invited to submit comments by 9 June 2023.

9. Future organisation of PAFF meetings

The Commission informed that the next meeting of this Committee, to be held on 18-19 September 2023 will be a fully physical meeting, while the format for the meeting planned for 20-21 November 2023 was not yet decided and will depend on the available meeting budget.

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 isoxaben, metaldehyde, Metarhizium brunneum strain Ma 43, paclobutrazol and Straight Chain Lepidopteran Pheromones (SCLP) in or on certain products.

(PLAN/2023/950)

The Commission outlined the draft Regulation and its contents. An MRL application on EU uses of metaldehyde on flowering brassica and leafy brassica had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. As regards isoxaben, a fast-track application requesting a modification of the existing MRL in gherkins was submitted. EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers. In addition, as regards metaldehyde and paclobutrazol, information that were previously unavailable during the Article 12 MRL reviews were assessed by EFSA, concluding that the data gaps were fulfilled, and the footnotes could be deleted. Lastly, the draft Regulation proposes listing *Metarhizium brunneum strain Ma 43* and Straight Chain Lepidopteran Pheromones (SCLP) in Annex IV to Regulation (EC) No 396/2005, as both substances have been renewed as low-risk active substances.

Germany requested the following statement to be recorded in the minutes of the meeting:

"*With regard to Metarhizium brunneum strain Ma 43, Germany already opposed the approval of the active substance as a "low-risk active substance" in the re-approval procedure and accordingly abstained from the vote in the Standing Committee "Legislation". The decisive issue was that the risk assessment of the relevant metabolite swainsonine could not be finalised. In addition, the existing data gaps concerning potentially toxicologically relevant metabolites as well as the open points for antimycotic resistances and bees argue against an approval as "low-risk active substance". In our opinion, Metarhizium brunneum strain Ma 43 is not a "low-risk active substance", so we cannot agree to its inclusion into Annex IV to Regulation (EG) No 396/2005.*"

Vote taken: Favourable opinion.

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

(PLAN/2023/136)

The Commission presented Revision 4 of the draft Regulation, which clarifies that the MRLs for tricyclazole should be set in Annex II to Regulation (EC) No 396/2005. It proposes modifying the MRL for tricyclazole in rice from 0.01* mg/kg to 0.09 mg/kg, based on an import tolerance request based on a Brazilian GAP, for which EFSA confirmed that the proposed MRL is fully supported by data and safe for consumers.

Several Member States did not support the draft Regulation presented by the Commission and therefore no qualified majority was reached. The following reasons were given by those Member States voting against the measure:

Non-acceptability of import tolerances for substances no longer approved in the EU (three Member States); one Member State added the earlier consumer health concern with this substance, but acknowledged that EFSA did not find any concerns in its recent assessment;

Negative impact on the competitiveness of European rice farmers that are deprived of using the same tools as third countries for an effective control of *pyricularia*, one of the most important rice diseases for which a limited number of active substances are available. However the proposed MRLs were considered safe for consumers;

Concerns on the Toxicological Reference Values, already raised by one Member State when these were endorsed in the January 2023 meeting of the SCoPAFF - section Phytopharmaceuticals, Legislation,

One Member State voted in favour of this draft Regulation, despite concerns from growers and consumers on the approach for import tolerances, but noted that this may no longer be possible in the future.

Vote taken: No opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards 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 of this Committee.

The Committee discussed the comments received from two non-EU countries following the consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the WTO, mainly relating to the basis for setting Limits of quantification (LOQs) on different products, the lowering of MRLs for crops such as blueberries, poultry and eggs and as regards transition periods.

It was clarified that as per the usual EU process, the EURLs for residues of pesticides were consulted on the achievable LOQs for pyriproxyfen on the various products and the proposed LOQs were found to be achievable. For blueberries, poultry and eggs,

lowering of MRLs was due to the fact that no relevant EU authorisations or import tolerances had been reported to EFSA and no CXL was established. Moreover, MRLs were already set at the LOQ since 2008. A deferred application date was granted for this measure which will become applicable in spring 2024. Additionally, because there are no health risks with the current MRLs, transitional measures are granted for all products placed on the market before the application date.

The Commission shared a letter from an industry requesting to maintain the MRL on grapes pending the submission of an import tolerance, foreseen for 2024. Member States noted that the MRL for grapes had already been set at the LOQ in 2008 and was now updated to reflect technological progress (lowered from 0.05* mg/kg to 0.01* mg/kg). The Committee agreed that there are no special circumstances that would warrant maintaining the MRL. An application for the setting of an important tolerance may be submitted at any time under the conditions set out in Article 6(4) of Regulation (EC) No 396/2005.

A Member State made a general comment that, in case an existing MRL appears not to be supported any more by an authorised GAP during an Article 12 review, it is possible that a new GAP has been authorized in a Member State after the GAP collection stage of the Article 12 procedure. In this case, instead of lowering the MRL to LOQ, the Member State proposed that the possibility of maintaining the existing MRL as tMRL could be discussed on a case-by-case basis. EFSA noted that if new GAPs are authorized after the GAP collection stage, they should be communicated to EFSA as soon as possible. The Commission clarified that, while special cases can arise and be discussed, the general principle is that an applications under Article 6 of Regulation (EC) No 396/2005 should be made.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards 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 lowering the MRLs for denatonium benzoate, diuron, methomyl and teflubenzuron, and for etoxazole, and the modifications made since the last meeting of this Committee.

The Committee discussed the comments received from three non-EU countries following the consultation of trading partners under the SPS agreement of the WTO mainly relating to the lowering of MRLs for etoxazole on various commodities and as regards transition periods. Additional comments were received from an industry association.

Concerning the reason for lowering the MRLs of etoxazole, in particular on tea, citrus fruits, pome fruits, grapes, cherries and hops, the Commission recalled that, in the peer review process of the renewal application, EFSA identified that risks for human health from consumption of edible crops treated with etoxazole could not be excluded because of the missing data on toxicology of dietary metabolites R-4 and R-7. These concerns are cross-cutting and apply to all commodities. As regards transition periods, a deferred application date was granted for this measure which will become applicable in spring

2024. Additionally, because there are no health risks with the current MRLs for denatonium benzoate, diuron, methomyl and teflubenzuron, transitional measures are granted for all products placed on the market before the application date. For etoxazole, because of the health risks noted above, such transitional measure is not proposed.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 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 MRLs will be lowered to LOQ and set in Annex V to Regulation (EC) No 396/2005.

The Committee discussed the comments received from three non-EU countries following the consultation of trading partners under the SPS agreement of the WTO relating to the lowering of MRLs of triflumuron and carboxin in certain products to the LOQ. The Commission clarified that for those MRLs there was no change as these had already been established at LOQ by Commission Regulation (EU) 2018/151617 and Commission Regulation (EU) 2019/90[18].

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate in or on certain products.

(PLAN/2022/2307)

The Commission presented 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 established by Commission Implementing Regulation (EU) 2022/69819 following the renewal of approval procedure.

The Committee discussed the comments received from two non-EU countries following the consultation of trading partners under the SPS agreement of the WTO relating to the lowering of MRLs of bifenazate in certain commodities to the LOQ, as well as the

[17] Commission Regulation (EU) 2018/1516 of 10 October 2018 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 penoxsulam, triflumizole and triflumuron in or on certain products. (OJ L 256, 12.10.2018, p. 45) ELI: http://data.europa.eu/eli/reg/2018/1516/oj

[18] Commission Regulation (EU) 2019/90 of 18 January 2019 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 bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products. (OJ L 22, 24.1.2019, p. 52). ELI: http://data.europa.eu/eli/reg/2019/90/oj

[19] Commission Implementing Regulation (EU) 2022/698 of 3 May 2022 renewing the approval of the active substance bifenazate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (OJ L 130, 4.5.2022, p. 3) ELI: http://data.europa.eu/eli/reg_impl/2022/698/oj

additional comments that were received from the applicant requesting a delay of the application date.

The Committee agreed that, in view of the fact that the consumer risk assessment had not been finalised and that sufficient evidence that the existing MRLs can be considered to be safe for consumers had not been provided, the MRLs should be set at the LOQ without transitional period for products placed on the market before the application date. Nevertheless, as is usual procedure, a deferred application date of 6 months was granted.

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 indoxacarb in or on certain products.

(PLAN/2023/242)

The Commission presented an overview of the draft Regulation.

The approval of the substance was not renewed, and grace periods granted by Member States expired on 19 September 2022. In the EFSA Conclusions on the peer review the ADI and ARfD were significantly lowered. In the recent Reasoned Opinion on the review of MRLs20, following up on the Conclusions on the peer review21, EFSA identified exceedances of the ADI and ARfD for consumers for a wide range of products (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. Member States agreed that, in view of the narrow safety margin and uncertainties on the metabolites formed during processing, the MRLs for basil, eggs and poultry tissues should be set at the LOQ. For milks, while some Member States supported lowering MRLs to LOQ, it was noted that it should be checked whether uses on feed may lead to exceedances of the LOQ. A Member State commented that uncertainties on the metabolites formed during processing apply to almost all products.

Member States also agreed that the MRLs for mammalian muscle should set at 0.04 mg/kg, following a re-assessment by EFSA of the data evaluated by JMPR in 2009 in view of the current classification in the Union, which no longer establishes MRLs for meat, but establishes separate MRLs for muscle and fat.

Member States were invited to submit their comments by 2 June 2023.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for carbendazim and thiophanate-methyl in or on certain products.

(PLAN/2022/2853)

The Commission presented Revision 4 of the draft Regulation addressing carbendazim, thiophanate-methyl and benomyl. As carbendazim and thiophanate-methyl are no

[20] https://www.efsa.europa.eu/en/efsajournal/pub/7527
[21] https://www.efsa.europa.eu/es/efsajournal/pub/5140

longer approved for use in EU, it intends to lower all existing MRLs that are based on EU uses, and for which no import tolerances or CXL are in place, to the LOQ of 0.01* mg/kg (with the exception of complex matrices which might warrant higher LOQs).

As regards the MRLs for which import tolerance were reported in the Article 12 review and assessed by EFSA[22], in cases where EFSA had identified a risk for consumers, the draft measure proposes lowering the MRL to the LOQ without any transitional arrangements for products placed on the market before the application date. It proposes maintaining or setting those MRLs that EFSA found to be safe for consumers.

For MRLs of carbendazim in products of animal origin, the draft measure proposes an MRL of 0.01* mg/kg (as this was considered achievable by the EURLs and more in line with the proposed LOQs for thiophanate-methyl and benomyl), while EFSA indicated that possibility of setting the MRL at 0.02* mg/kg. The Commission invited Member State to comment on the proposed LOQ for animal products.

Lastly, this draft measure intends separating the residue definition (RD) for benomyl from the one of carbendazim, and creating a new separate RD for benomyl, which is proposed to be added to Annex V.

One Member State informed that it will vote against this draft measure, as it contains substances meeting the cut-off criteria. Another Member State asked for clarification as regards the general approach to be followed for setting MRLs for this type of substances and indicated that it had not yet decided whether it could support the measure. A third one had communicated in writing in advance of the meeting that it will likely not support the measure which contains import tolerances for non-approved substances. The Commission provided an overview of the outcome of the internal discussion as regards substances meeting the cut-off criteria (see Agenda Pt. A 03.01).

Member States were invited to submit their comments by 9 June 2023.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fosetyl-Al, potassium phosphonates and disodium phosphonates in or on certain products.

(PLAN/2023/138)

The Commission presented the draft Regulation reviewing MRLs based on several EFSA ROs related to Article 6 applications (2022 EFSA statement[23]) and on the 2021 EFSA RO on the Joint Review (JR) of MRLs for fosetyl, disodium phosphonate and potassium phosphonates[24].

The MRL values proposed are based on the new residue definitions for enforcement ("phosphonic acid and its salts expressed as phosphonic acid" for products of plant origin and "phosphonic acid" for products of animal origin). The Joint Review states that, according to the EURLs, LOQs of 0.1* mg/kg and 0.2* mg/kg (depending on the matrices) are achievable, but in view of the persistence of those substances in the environment (also leading to findings in organic crops), and in line with comments received from a Member State, the current version proposes to maintain the previously established LOQ of 2* mg/kg for products of plant origin (20* mg/kg for complex

[22] 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.
[23] EFSA Statement on the scientific statement on the maximum residue levels for potassium phosphonates. EFSA Journal 2022;20(7):7400.
[24] https://www.efsa.europa.eu/en/efsajournal/pub/6782

matrices). A Member State noted that this LOQ may need to be recalculated according to the new residue definition and would then result in a level of 1.5* mg/kg. The Commission proposed this LOQ for all products for which EFSA had proposed the LOQ of 0.1* mg/kg.

For all products belonging to the subgroups “others”, no MRLs values are proposed in the Joint Review. If all MRLs of a group are at the same value, the draft Regulation proposes setting the MRL for “others” at that value, while if where there are different MRLs in a group, the MRL for the subgroup “others” is proposed to be set at the relevant LOQ. The Commission will consider the comment of a Member State to use the lowest value established for a commodity in a group, instead of the LOQ, to cover the subgroup "others" in such cases.

In cases where EFSA had identified data gaps, the draft Regulation proposes establishing footnotes with different deadlines, depending on the kind of data gap.

One Member State agreed that setting the LOQ at 0.1 mg/kg would not be appropriate, due to background levels, especially in permanent corps and noted that in the future different LOQs may be needed for arable crops with frequent rotation and permanent ones. It also was in favour of using the lowest value in a group to cover the MRL for the "others" subgroup. Another Member State highlighted that, according to its data, lowering the LOQ may pose issues also with non-permanent crops, and therefore concurs with a recalculated LOQ of 1.5* mg/kg. It confirmed that this would pose no risk for consumers.

The Commission recalled that EFSA is currently assessing another Article 6 application for potassium phosphonates in spring onions and leeks and that it the EFSA output will be available by June 2023, that output could still be addressed by this measure.

Member States were invited to submit their comments by 26 May 2023.

C.04 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)

Revision 1 of the draft Regulation takes into consideration the comments provided by Member States. For myclobutanil, the MRL for bananas is based on an import tolerance which is not supported by data and therefore the draft Regulation proposes lowering it to the LOQ. However, EFSA informed that confirmatory data in support of that MRL had been submitted to a Member State. The Commission proposed removing the substance from this draft Regulation and including it in a following one, thus allowing sufficient time for the assessment of this confirmatory data in the meanwhile.

A Member State announced that it will not support the draft measure which contains MRLs based on import tolerances for the non-approved substances diethofencarb, flutriafol and myclobutanil.

Member States were invited to submit their comments by 2 June 2023.

C.05 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 in or on certain products.

(PLAN/2023/145)

The Commission presented an overview of the draft Regulation.

For famoxadone, the Commission had sent a mandate to EFSA requesting to assess whether existing CXLs were safe for consumers in light of the lowered TRVs established in the EFSA Conclusions on the peer review in the context of the non-renewal of its approval. EFSA[25] concluded that, the MRLs based on CXLs can be maintained except for table grapes for which it identified an acute risk for children.

For methyl-nonylketone, listed in Annex IV and proposed to be moved to Annex V with MRLs set at the LOQ, the Commission informed that following comments received in its internal consultation procedure it proposes to keep the substance in Annex IV. The active substance was not approved because of the non-submission of confirmatory data that are not related to residues or dietary exposure. Furthermore, when the substance was approved, it did not have any MRLs set, indicating that dietary exposure to the substance does not constitute any risk and that there is no need to monitor residues in food.

For prochloraz, there is an indication that there are exceedances of TRVs with some of the existing MRLs. Therefore, EFSA will perform a consumer exposure calculation using PRIMo rev 3.1. in order to support a decision on whether or not transitional measures for products placed on the market before the application date are appropriate. Depending on the outcome, the draft Regulation will be modified accordingly. In parallel to the work ongoing at EFSA, as a next step the draft will already be notified to the trading partners via the WTO/SPS notification procedure to allow them sufficient time to comment.

Member States were invited to submit their comments by 2 June 2023.

C.06 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)

Revision 1 of the draft Regulation takes into consideration EFSA's statement[26] on the lack of confirmatory data for these substances and the comments provided by Member States. For 2,4-DB while the draft measure proposes maintaining MRLs for cereals, for products of animal origin MRLs are proposed to be lowered to the LOQ. While a Member State warned of possible MRL exceedances for those products in case those are lowered to the LOQ, the Commission reported that previous monitoring data indicate that the substance was not quantified in animal products and, therefore, exceedance of MRLs (set at LOQs) is not expected. For iodosulfuron-methyl on linseeds and maize, for mesotrione on sugar canes and for pyraflufen-ethyl on hops, the

[25] European Food Safety Authority's Statement on the targeted risk assessment for famoxadone. EFSA Journal 2023; 21(3):7932. https://doi.org/10.2903/j.efsa.2023.7932

[26] https://www.efsa.europa.eu/en/efsajournal/pub/8013

previously established data gaps have not been addressed, thus the draft Regulation proposes lowering those MRLs to the LOQ.

For methoxyfenozide, in accordance with the EFSA Statement, no information was submitted to address the data gap on residue trials for aubergines. A Member State suggested that such data was submitted during the renewal of the approval of the substance, which according to EFSA's Peer review[27], leads to a MRL of 0.2m/kg. The Commission clarified that those residue trials concerned a different GAP compared to the GAP reported during the Article 12 review of the substance. While the former referred to one application on tomatoes, then extrapolated to aubergines, the latter concerned two applications on aubergines. Therefore, those trials cannot address the data gap.

However, another Member State proposed lowering the MRL for aubergines to 0.3mg/kg, based on new residue trials with three applications on tomatoes with extrapolation to aubergines. The Commission clarified that this is new information that should follow the procedure described in Article 6 of Regulation (EC) No 396/2005 and proposed removing methoxyfenozide from the draft Regulation until further evaluation of the information under that procedure.

Member States were invited to submit their comments by 2 June 2023.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for deltamethrin, metalaxyl-M, thiabendazole and trifloxystrobin.

(PLAN/2023/326)

The Commission shared a new draft Regulation reviewing the MRLs for deltamethrin, metalaxyl-M, thiabendazole and trifloxystrobin, based on the latest EFSA RO on the assessment of confirmatory data, as well as the assessment of new MRL applications according to Article 6 of Regulation (EC) No 396/2005. The draft Regulation takes into account the feedback provided by the EURLs on residue definitions and LOQs in different food matrices. Based on these inputs, the draft Regulation proposes to change the residue definition for animal commodities for both metalaxyl and trifloxystrobin in line with the ones used by Codex Alimentarius. One Member State indicated that the data that were submitted in order to address the data gap for metalaxyl in herbs and edible flowers were not in line with the extrapolation guidelines. It therefore considers that the data gap was not addressed and that, consequently, those MRLs should be lowered to the LOQ. Another Member State requested additional information on the MRL values derived from the new uses of deltamethrin in carobs. This issues was solved after the Committee, with the confirmation from EFSA that such value could be considered safe for consumers.

Member States were invited to submit their comments by 2 June 2023.

C.08 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenthrin.

(PLAN/2023/951)

The Commission presented an overview of the draft Regulation as regards the review of the MRLs for bifenthrin, following the expiry of all possible grace periods that

[27] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4978

Member States might have granted. In order to clarify whether the existing MRLs based on CXLs or import tolerances (non-EU uses) were sufficiently supported by data and safe for the European consumers, the Commission mandated EFSA, in accordance with Article 43 of Regulation (EC) 396/2005, to review the existing MRLs for bifenthrin, the quality of the toxicological reference values (TRVs) and to perform a risk assessment. EFSA concluded[28] that the TRVs derived in 2009 could not be confirmed since the available data do not provide sufficient evidence to exclude genotoxicity, the data available were insufficient compared to current standards, and uncertainty factors could not be established. Based on these deficiencies, EFSA recommended to withdraw the TRVs for bifenthrin. Despite those deficiencies, EFSA performed an indicative risk assessment using the existing TRVs, taking into account those existing MRLs based on non-EU uses and using PRIMo revision 3.1. No exceedances were observed, and the highest chronic exposure represented 40% of the ADI.

The Commission presented a draft Regulation lowering all existing MRLs for bifenthrin to the limit of quantification (LOQ) and moving all MRLs to Annex V to Regulation (EC) No 396/2005. It however also outlined the option of an alternative approach for consideration of Member States, i.e. lowering only those MRLs based on obsolete EU uses while maintain those MRLs based on non-EU uses for a limited time period, requiring the confirmatory data necessary to update the existing TRVs according to the current scientific standards. The Commission explained that this option would give a last opportunity to producers to come forward with the additional data, but a strict time limit would be needed in that case. Two Member States indicated their disagreement on setting footnotes to MRLs based on CXLs, emphasised the health concerns with regard to the substance and highlighted the fact that the support of an applicant to provide such data had been lacking previously (otherwise a renewal dossier would have been submitted). They therefore indicated their preference to lower all the existing MRLs to the LOQ.

Member States were invited to submit their comments by 2 June 2023.

C.09 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for haloxyfop.

(PLAN/2023/897)

The Commission presented an overview of the draft Regulation reviewing the MRLs for haloxyfop. The draft Regulation proposes to lower all existing MRLs based on obsolete EU uses, to maintain the existing MRL for soybeans based on an import tolerance and to set the MRLs for rapeseeds and linseeds based on an import tolerance request[29] that was assessed favourably by EFSA. EFSA confirmed that the proposed product specific LOQs were safe for consumers, with no need of using excessively low LOQs, as indicated in its targeted MRL review[30]. The Commission shared the conclusions of its communication with the applicant, who informed about the availability of additional data covering the missing information identified during the targeted MRL review. The Commission proposed to set the MRLs for soybeans,

[28] EFSA (European Food Safety Authority), 2023. Targeted review of maximum residue levels (MRLs) for bifenthrin. EFSA Journal 2023;21(2):7864

[29] European Food Safety Authority reasoned opinion on the setting of import tolerances for haloxyfop-P in linseed and rapeseed. EFSA Journal 2018;16(11):5470

[30] European Food Safety Authority reasoned opinion on the targeted review of maximum residues levels (MRLs) for haloxyfop-P. EFSA Journal 2022;20(11):7658

rapeseeds and linseeds on a temporary basis with footnotes requiring confirmatory data, thus providing time for their submission and assessment.

A Member State informed that it will likely not be able to support this draft Regulation as certain MRLs are based on import tolerances for this substance which is not approved in the EU.

Member States were invited to submit their comments by 2 June 2023.

C.10 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for oxamyl in or on certain products.

(PLAN/2023/947)

The Commission presented an overview of the draft Regulation lowering the MRLs for oxamyl. With the new significantly lower ADI and ARfD, EFSA identified acute and chronic risks for many commodities even with LOQs lower than 0.01* mg/kg. Therefore, the draft Regulation proposes to set LOQs at lower achievable levels for several commodities: 0.002* mg/kg for oranges and tomatoes, 0.001* mg/kg for all other commodities of high water and high acidic content, cow milk, herbs, 0.005* mg/kg for avocadoes, cereals, muscle of mammals and eggs.

Member States were invited to submit their comments by 26 May 2023.

C.11 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for desmedipham, etridiazole, flurtamone, profoxydim, difenacoum, and potassium permanganate in or on certain products.

(PLAN/2023/946)

The Commission presented an overview of the draft Regulation. The substances are no longer approved in the EU and any grace periods that Member States might have granted have expired. No CXLs or import tolerances exist, so that all MRLs are proposed to be set at the LOQ and proposed to be moved to Annex V of Regulation (EC) No 396/2005. For difenacoum and potassium permanganate, it was noted that specific MRLs were previously not set for these substances, so that the default value of 0.01 mg/kg according to Article 18(1)(b) of Regulation (EC) No 396/2005 applies. A question was raised on the residue definition to be set for potassium permanganate, in view of its rapid degradation.

Member States were invited to submit their comments by 9 June 2023.

C.12 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for thiacloprid.

(PLAN/ 2023/961)

The Commission presented an overview of the draft Regulation updating the MRLs for thiacloprid based on a recent EFSA risk assessment[31] which concluded that some MRLs based on Codex MRLs and import tolerances are safe for consumers. The draft Regulation proposes to lower some existing MRLs based on obsolete EU uses following the non-renewal of approval of thiacloprid. Moreover, since an exceedance of the ARfD cannot be excluded for peaches and sweet peppers, those MRLs were

[31] EFSA Journal 2023;21(3):7888: Statement on the short-term (acute) dietary risk assessment and evaluation of confirmatory data for certain maximum residue levels (MRLs) for thiacloprid

proposed to be lowered to the LOQ, without any transition measure. All other existing MRLs based on CXLs and import tolerances are proposed to be maintained as they are safe for consumers. The Commission recalled that thiacloprid belongs to the group of neonicotinoids actives substances. However, since it has different properties than clothianidin and thiamethoxam, it is currently not envisaged to follow the same approach as for clothianidin and thiamethoxam implementing the Farm to Fork Strategy by lowering all MRLs to the LOQ.

Member States were invited to submit their comments by 2 June 2023.

C.13 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for mandipropamid in or on certain products.

(PLAN/2023/750)

The Commission gave an overview of the draft Regulation which proposes modifying the MRL for mandipropamid in papayas from 0.01* mg/kg to 0.8 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) 396/2005. EFSA confirmed that the proposed MRL is 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 mandipropamid, as in general it is against the setting of import tolerances.

The Commission highlighted that mandipropamid is an approved substance in the EU, and that it concerns exotic fruits that are mostly produced outside the EU. It also recalled that the setting of import tolerances is an integral part of the EU legislation, which recognises that different agricultural practices may be legally applied in third countries, sometimes resulting in pesticide residues differing from those resulting from uses in the EU, and that it is therefore appropriate that MRLs are set for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce.

That Member State later informed the Committee that after further checking its position internally it will be able to support the proposed draft Regulation.

Member States were invited to submit their comments by 9 June 2023.

C.14 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fipronil in or on certain products.

(PLAN/2023/962)

The Commission presented the draft Regulation which proposes modifying the MRLs for fipronil in sugar canes from 0.005* mg/kg to 0.01 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) 396/2005. As sugar canes can be fed to animals, the draft Regulation also proposes raising some of the existing MRLs in fat from bovines, sheep and goats. EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers.

Two Member States informed that they will likely not be able to support setting this import tolerance for fipronil, as it is a non-approved substance in the EU for which health concerns were expressed earlier.

Member States were invited to submit their comments by 9 June 2023.

C.15 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bispyribac, lemon essential oil, metosulam, oryzalin, oxasulfuron and triazoxide in or on certain products.

(PLAN/2023/948)

The Commission introduced the draft Regulation of non-approved substances for which the MRLs are already set at the LOQ in Annex II except for lemon essential oil for which the default MRL of 0.01 mg/kg according to Article 18(1)(b) of Regulation (EC) No 396/2005 currently applies. Grace periods that Member States might have granted have expired, and all MRLs are proposed to be moved to Annex V of Regulation (EC) No 396/2005.

For bispyribac, the EURLs proposed different options for its residue definition as the available analytical method could cover a larger scope than that of the residue definition proposed by EFSA, which does not comprise conjugates. A Member State asked clarification why the approval status in the database on lemon essential oil is still indicated as "pending". The Commission will clarify[32] but indicated that the Regulation[33] concerning the non-approval of lemon essential oil (Citrus limon essential oil) as a basic substance has already been published and is in force.

Member States were invited to submit their comments by 9 June 2023.

[32] Post meeting Note: the status of lemon essential oil has been updated in the database from "pending" to "not approved".

[33] Commission Implementing Regulation (EU) 2023/200 of 30 January 2023 concerning the non-approval of lemon essential oil (Citrus limon essential oil) as a basic substance 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