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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
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SUMMARY REPORT

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

1. Priority list

The Commission presented an updated table.

2. Confirmatory data Art. 12 follow-up

a) Cases where EFSA Reasoned Opinions (ROs) has been published

The Commission informed that the ROs on the Article 12 confirmatory data assessment for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop and for aluminium phosphide and magnesium phosphide were recently adopted by the European Food Safety Authority (EFSA).

For what concerns quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop, EFSA assessed one Article 6 application for several products along with the Article 12 confirmatory data. The Commission proposed lowering to or maintaining at the limit of quantification (LOQ) all the maximum residue levels (MRLs) for plant commodities for which data gaps were not filled, except for lettuces and other salad plants, sunflower seeds, soyabeans and caraway for which it proposed setting the MRLs at the levels derived by EFSA based on the residue trials provided in the framework of Article 6 applications. For spinaches, the Commission proposed setting the MRL identified by EFSA based on residue trials for a fall-back Good Agricultural Practice (GAP) for lettuces. For products of animal origin, the Commission proposed maintaining at the current levels the MRLs for muscle (all species), poultry liver and eggs, and lowering or maintaining at the LOQ all the MRLs for fats and milks. For animal kidney and edible offals and mammal liver, the Commission considered the confirmatory data provided for poultry liver sufficient to address the data gap, and therefore proposed confirming the existing MRLs.

For aluminium and magnesium phosphides, EFSA assessed Article 6 applications for several products along with the Article 12 confirmatory data. EFSA concluded that all data gaps were addressed except for the one on analytical methods for high-oil content commodities, as the applicant provided data on high fat commodities of

animal origin to address it. The Commission consulted the EU Reference Laboratories (EURLs), which noted that while an extrapolation from high-fat commodities of animal origin to high-oil content commodities of plant origin is not foreseen, in the case of phosphane, due to the methodologies used for the analysis, this can be justifiable. Therefore, the Commission proposed considering all data gaps as addressed and setting the new MRLs derived by EFSA based on the Article 6 applications and maintaining (or setting at the levels identified based on the new residue trials) all other MRLs.

One Member State expressed its support to the Commission proposal concerning the data gap for analytical methods for aluminium- and magnesium phosphides, noting that risk assessors from that Member State share the same view as the EURLs.

Member States were invited to submit comments by 1 March 2024.

3. Non-approved substances for follow up

a) Updated mandate

The Commission informed about the content of a planned mandate to EFSA to carry out a stakeholder consultation for the ROs already finalised according to Article 43 of Regulation (EC) No 396/2005 for ten non-approved active substances[1]. EFSA concluded that the Toxicological Reference Values (TRVs) cannot be confirmed since the data available were insufficient compared to existing (most recent) data requirements. EFSA will be requested to launch, by one month after the acceptance of the mandate, a stakeholder consultation divided into two steps:

- A call for expressing interest to provide existing data, covering toxicological data gaps identified by EFSA in the targeted reviews.
- A data call targeting those parties that expressed their interest in the first step to submit the relevant data.

It was emphasised in previous discussions by Member States that those deadlines should remain short, since the purpose of the exercise was not to generate new data, but to provide already existing ones.

EFSA will then evaluate the outcome of the consultation and, if necessary, a follow up mandate will be prepared for the data assessment.

b) Next mandate to EFSA

The Commission reminded that the next mandate to EFSA for a targeted review of the MRLs for non-approved substances will include, as previously agreed, carbaryl, dicloran, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, saflufenacil, and terbufos. The Commission will submit it to EFSA as soon as the assessment of the substances covered by the first mandate will be finalised according to the new procedure (Agenda item A.01.03.a).

[1] Azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin, and profenofos.

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

1. General issues

The Commission provided an overview of the main outcome of the meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation held in December 2023.

2. Endorsed toxicological reference values (TRVs) for spinosad and copper compounds

The Commission informed that the new Acceptable Daily Intake (ADI) for copper compounds that was recently derived in the framework of an EFSA assessment[2] was endorsed by the SCoPAFF, section Phytopharmaceuticals – Legislation held in January 2024.

For spinosad, one Member State had noticed that the new TRVs derived by EFSA in its Conclusion of the peer review[3], had not yet been endorsed by the SCoPAFF, section Phytopharmaceuticals – Legislation, as the renewal process was still ongoing, but that they were already used by EFSA in a recent opinion[4] setting MRLs for that substance. Therefore, that Member State asked the Commission to proceed with the endorsement of the new TRVs as soon as possible, without waiting for the finalisation of the renewal process.

The Commission presented this topic for discussion at the meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation held in January 2024, proposing the use of this new TRV by EFSA on a provisional basis, until the renewal of approval process would be finalised. As no Member State objected to this approach, this will be noted in the Minutes of the meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation. The TRVs will be updated in the Pesticides Database only once the renewal of approval process will be concluded.

A.03 Specific substances:

1. Difenoconazole

EFSA had published a RO concerning an Article 6 application for modifying MRLs for difenoconazole in wheat and rye[5] and concluded that the submitted data were sufficient to derive an MRL proposal for the intended EU use. Nevertheless, the chronic exposure assessment was only considered provisional, pending the assessment of confirmatory data on metabolism/degradation of the four stereo isomers of difenoconazole and the impact of isomerisation on the toxicity of difenoconazole. As the assessment of those data is still ongoing in the framework of the peer review, the Commission had considered it inappropriate to take a decision about setting those new MRLs before the finalisation of that assessment.

Following the discussion on this topic at the last meeting of this Committee in November 2023, the Commission mandated EFSA to organise a residues experts'

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2 EFSA, 2023. Re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources. EFSA Journal 2023;21(1):7728. https://doi.org/10.2903/j.efsa.2023.7728.

3 EFSA, 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad. EFSA Journal 2018;16(5):5252, 33 pp. https://doi.org/10.2903/j.efsa.2018.5252.

4 EFSA, 2021. Reasoned Opinion on the focussed assessment of certain existing MRLs of concern for Spinosad. EFSA Journal 2021;19(2):6404, 27 pp. https://doi.org/10.2903/j.efsa.2021.6404.

5 EFSA, 2023. Modification of the existing maximum residue levels for difenoconazole in wheat and rye. EFSA Journal,21(8), 1–42. https://doi.org/10.2903/j.efsa.2023.8207.

meeting on confirmatory data to allow the finalisation of the consumer risk assessment for difenoconazole. EFSA informed the Commission that it had planned the experts' meeting in March 2024 and expects to reach a conclusion on confirmatory data by May 2024. It also confirmed that it will follow up promptly with the finalisation of the prioritised MRL review right after the experts' meeting.

One Member State commented that the proposed modification of MRLs for wheat and rye do not significantly change the outcome of the provisional risk assessment and that the ADI remains below 100% as cereals are not the main drivers for chronic exposure. In that Member State's view, those MRLs could be set at the new level proposed by EFSA already now.

The Commission proposed to address that MRL application with a routine measure to be presented for vote at the meeting of this Committee in April 2024.

Another Member State recalled that another EFSA RO for the setting of MRLs for difenoconazole in leafy brassica[6] was put on hold due to potential chronic intake concerns and additional uncertainties in relation to metabolites. Nevertheless, in that case, EFSA used a more conservative approach and did not apply some refinement options in its risk assessment that were applied in the most recent RO for wheat and rye. In that Member State's opinion, if those refinements were to be applied, the MRLs for leafy brassica would also be safe, and therefore invited the Commission to follow a coherent approach.

The Commission agreed that a consistent approach should be followed. It invited EFSA to assess if, in case new MRLs were to be set for both leafy brassica, wheat, and rye as derived following the above-mentioned applications, there would be a risk for consumers.

EFSA indicated that they will investigate the topic and report back at the next meeting of this Committee, in April 2024, noting that by then information on the outcome of the experts' meeting should also be available.

Member States were invited to submit comments by 1 March 2024.

2. Sodium silver thiosulfate

Sodium silver thiosulfate was initially included in the draft measure PLAN/2023/2303 (presented for vote at the meeting of this Committee in November 2023), which proposed to include the substance in Annex IV to Regulation (EC) No 396/2005. Nevertheless, as several Member States were not in favour of the proposed inclusion, the Commission removed that substance from the draft measure and invited Member States to comment on possible ways forward.

Several Member States replied in writing proposing the inclusion of sodium silver thiosulfate in Annex V to Regulation (EC) No 396/2005, whereby all MRLs would be set at the default LOQ. Nevertheless, one Member State also noted that EFSA, in its Statement on the active substances that do not require a review of the existing MRLs under Article 12[7], stated that an incomplete toxicological data package was available

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6 EFSA, 2021. Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407, 39 pp. https://doi.org/10.2903/j.efsa.2021.6407.

7 EFSA, 2019. Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(2):5591, 13 pp. https://doi.org/10.2903/j.efsa.2019.5591.

for sodium silver thiosulfate, but that it did not conclude on the compliance with the criteria set out in the Guidance for inclusion into Annex IV[8]. Therefore, that Member State would still favour the inclusion in Annex V, but would not oppose to the inclusion in Annex IV if this was justified in the recitals of the proposal based on EFSA's complete reasoning.

In order to take a prudent approach and based on the comments received, the Commission proposed to add the substance into Annex V, and to set all MRLs at the default LOQ.

Member States were invited to submit comments by 1 March 2024.

3. Straight Chain Lepidopteran Pheromones

Straight Chain Lepidopteran Pheromones (SCLPs) are divided into 3 groups, aldehydes, alcohols, and acetates. The Commission informed that, while Commission Regulation (EU) 2023/1719[9] included all SCLPs into Annex IV of Regulation (EC) No 396/2005, this was done under the wrong assumption that the low-risk status would apply to all SCLPs, while only acetates are approved as low risk substances.

At the meeting of this Committee in November 2023, the Commission proposed to correct Regulation (EU) 2023/1719 to make clear that only SCLPs, belonging to the group of acetates, were to be included into Annex IV, while the LOQ would apply to SCLPs belonging to the groups of aldehydes and alcohols.

Several Member States agreed with the Commission proposal, while several other believed all SCLP should be kept in Annex IV.

One Member State commented that inclusion of all SCLPs into Annex IV would be justified based on the low consumer exposure, even if the criteria of the Guidance for inclusion into Annex IV were considered only partially met by EFSA for some types of SCLPs. In fact, it noted that due to their high volatility and rapid dissipation in air, residues of SCLPs are expected to be negligible following application by spraying or via dispensers. While EFSA noted in its Conclusion[10] on the peer review that a general suggestion for inclusion of SCLPs into Annex IV could not be given as for the use of (E,E)-8,10-dodecadien-1-ol in combination with spray application, residues in apples cannot be excluded, the particular study that led to that result was not in line with the GAP (Good Agricultural Practice) as the spray application was done in late autumn and the low temperatures might have led to the solidification of the substance, possibly leading to findings of residues. Therefore, in that Member State's view all SCLP could be maintained into Annex IV.

Another Member State commented that spray applications are often used in third countries. As, in its view, it cannot be excluded that residues could be found for uses according to GAPs approved there, it would not be appropriate to include all SCLPs

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8 Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005. SANCO/11188/2013 Rev. 2, September 2015

9 Commission Regulation (EU) 2023/1719 of 8 September 2023 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 (OJ L 223, 11.9.2023, p. 9), ELI: http://data.europa.eu/eli/reg/2023/1719/oj.

10 EFSA, 2021. Conclusion on the peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs). EFSA Journal 2021;19(6):6656, 30 pp. https://doi.org/10.2903/j.efsa.2021.6656.

into Annex IV. It also added that, while the Guidance document on Semiochemicals[11] provides solutions for data requirement for semiochemicals (including pheromones), these are not suited for spray applications even if those are the most relevant applications for these substances. Therefore, that Member State suggested the guidance document be updated accordingly.

The Commission took note of the received comments including on the guidance document.

Member States were invited to submit comments by 1 March 2024.

4. Imazalil

One Member State had requested an update on the ongoing evaluation of Article 12 confirmatory data for imazalil, and more specifically on metabolite R014821. This topic was already discussed at the meeting of this Committee in November 2023, where the evaluating Member State (EMS) explained reasons for the delays in the evaluation of the application, which included the need to request additional studies on the toxicity of one of the metabolites in animals (FK772).

The applicant had shared information with the EMS and with the Commission indicating that the new study on FK772 had started in January 2024, and that a draft report should be available in March 2024.

The EMS clarified that for toxicity concerns for metabolite R014821 were already excluded, and that the ongoing evaluation only concerns one of the metabolites in animals (FK772).

One Member State highlighted that the approval of imazalil will expire soon, and that in the framework of the ongoing renewal of approval procedure, an assessment of the potential carcinogenicity and endocrine disrupting properties of this substance will be carried out. Based on the outcome of that process, conclusions on MRLs may need to be revised.

The Commission invited the EMS to provide, if possible, some preliminary views on the evaluation of the draft report on the new study that will be provided by the applicant at the next meeting of this Committee, in April 2024.

5. *Bacillus thuringiensis* (Bt)

The Commission updated the Committee on the latest developments, in particular on the letter of the Bt task force of applicants raising concern on the outcome t of the first meeting with Rapporteur Member State (RMS) and co-RMS to agree on how to generate the confirmatory data required by the specific Regulations on the renewal of approval of the 8 Bt strains, published in May 2023 in the PAFF Commitee, section Legislation. The task force had expressed its concerns that the requests of data by RMS and co-RMS may go beyond the requirements set by the regulations approving these Bt (i.e., spore density decline studies on one representative crop). The Commission called for an approach consistent with the Regulations. A question was raised on the type of a representative crop used in a spore density studies, and it was clarified that one of the representative crops was cherry tomatoes but the rest of the details of the studies still needs to be decided.

Member States were invited to submit comments by 1 March 2024.

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[11] Guidance document on semiochemical active substances and plant protection products. SANTE/12815/2014 rev. 5.2, May 2016.

6. Bifenazate

The Commission informed that several letters had been received from a stakeholder association for hops and the United States Department of Agriculture (USDA), and that a meeting had taken place with USDA. Hops producers highlighted difficulties with the compliance of stored hops, as a transitional period had not been granted for hops, placed on the market after the application date and complying with the old (higher) MRL.

In addition, brewers' association and USDA sought clarification whether the beer that is already on the market must also comply with a new MRL.

The Commission informed of ongoing internal discussions on this matter. Furthermore, it had analysed monitoring data available in the EU (sample results are from 2018-2022, data were available from 4 Member States) which showed that in only 2 out of 431 samples tested, residues were detected in beer. It considers those results re-assuring. Member States were asked to consider the low levels in beer and to apply a proportionate approach for enforcement.

A Member State indicated that an average 100 g hops were needed to produce 100 l of beer, and that therefore the levels of bifenazate in beer are expected to be very low. Another Member State indicated that the results of samples taken on the market would need to be interpreted with some caution, as in some cases, retailers already reject non-compliant products before they get placed on the market.

7. Glufosinate

The Commission informed that it was preparing a mandate to EFSA for updating the risk assessment for glufosinate in line with the current data requirements and considering the most recent consumption data, as agreed at the meeting of this Committee in September 2023. The Commission explained that the mandate will foresee a stakeholder consultation calling for already existing data to support the review of the established toxicological reference values (TRVs), similar to other non-approved substances. The Commission also informed that it had received several letters from stakeholders expressing their interest in the glufosinate MRL review. Particularly, one stakeholder expressed its concerns on the soyabean production in third countries which is highly dependent on the use of glufosinate. One Member State indicated that the MRL review of this active substance should consider herbicide-resistant crops.

Member States were invited to submit comments by 8 February 2024.

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 14 processes[12] had been adopted since the previous meeting of this Committee.

Currently, outputs addressing 27 such processes are at different stages of the procedure. Out of these, 4 are under scientific assessment (1 under Regulation (EC) No 396/2005 and 3 under Regulation (EC) No 1107/2009) and 23 under clock-stop, as additional data had been requested (17 under Regulation (EC) No 396/2005 and 6 under Regulation (EC) No 1107/2009).

[12] Each process receives a so called “EFSA question number”.

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

Since the previous meeting of this Committee, EFSA finalised reviewing 2 active substances, data are pending in the case of 5 active substances, the review of 19 active substances is on hold and the assessment of 7 active substances is ongoing. The progress report table is publicly available for interested stakeholders[13].

3. Update on other mandates (Articles 29 and 31 of Regulation (EC) No 178/2002, and 43 of Regulation (EC) No 396/2005

EFSA finalised 1 assessment under Article 43 of Regulation (EC) No 396/2005. In total, 11 scientific assessments are ongoing relating to active substances, Codex Committee on Pesticide Residues (CCPR) mandates 2023 and 2024 and to the International Estimate Short-Term Intake (IESTI) methodology.

4. Other issues

Mandates in relation to the work in CCPR

EFSA started preparatory work for the 37 active substances assessed by the Joint FAO/WHO Meeting on pesticide Residues (JMPR) in September 2023. Once the JMPR report 2023 is published, comments will be finalised. The overall deadline is August 2024.

The development of a new mapping tool is ongoing to compare the Codex classification of food and feed with Annex I of Regulation (EC) No 396/2005. Difficulties to match some categories were noted.

Pesticides Steering Network (PSN)/Transparency/IUCLID

EFSA informed that, in 2024, the IUCLID PSN meetings will be held on 29 February (online), in June (date to be confirmed, hybrid) and in November (date to be confirmed, online).

An IUCLID training for Evaluators is available on EU Academy[14]. Member States can request training, if necessary. Registration for training needs is to be approved by EFSA to ensure that course participants work for a Member State or for EFSA, as training material includes dedicated and sensitive contents.

A virtual tour of Member States is ongoing and has been well received by a number of Member States.

The testing phase of the IUCLID generated "MRL application report + Annotations" is ongoing. Volunteers from Member States are invited to send feedback by the end of February 2024.

Cumulative Risk Assessment (CRA)

Regarding retrospective CRA, the prioritisation report is under publication and the framework partnership agreements have been signed. The public consultation on the liver effects relevant for CRA is under preparation.

Regarding prospective CRA, a report is under finalisation for the acute mock assessment (tefluthrin/carrots) and the uncertainty analysis is ongoing for chronic mock assessment (fenamidone/lettuce).

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

14 https://academy.europa.eu/courses/iuclid-for-evaluators.

2022 annual Report on pesticide residues

Consultation for comments will be open from mid-February 2024.

Large portion consumption data used in PRIMo

One Member State raised concerns on the consumption data currently used in PRIMo 3/3.1 for acute risk assessment for melon, watermelon, escaroles, and table grapes. EFSA noted that PRIMo 3/3.1 has been used for years and no such requests were received. The problem might be that the large portion data reported included inedible part (peel) and not only the edible portion. EFSA recalled that PRIMo 4 is under development. Indicative calculations to compare results with PRIMo 3.1 showed that for melons, watermelons, and escaroles, the results will be lower in PRIMo 4, but for table grapes higher results will be obtained.

EFSA Guidance on the assessment of pesticide residues in rotational crops[15]

EFSA presented a guidance document on the assessment of studies on the nature and magnitude of pesticide residues in rotational crop studies they prepared. This guidance document supports the practical implementation of the relevant OECD Test Guidelines and OECD Guidance Documents in a harmonised way, respecting the EU regulatory framework for the pesticide assessments.

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

The Commission presented an overview table containing an update of the ongoing work on the alignment of MRLs for multiple use substances.

In particular, the Commission highlighted that two active substances having MRLs set both as pesticides and VMP are included in the ongoing work on non-approved substances (Agenda item A 01.03): diazinon (included in the first batch of substances) and phoxim (included in the second one).

For diazinon, EFSA already published its assessment in a RO[16], but some modification to that output may be made based on the stakeholder consultation to be launched soon (Agenda item A 01.03.a). In that RO, EFSA recommended considering if the MRLs for products of animal origin should be lowered to the LOQ or if the MRL in place for the VMP use should be kept, noting that, lacking robust TRVs for diazinon, the risk assessment is only indicative. Furthermore, EFSA highlighted that in view of the very low EU TRVs, the default LOQ for bovine muscle and milk will not be sufficiently protective for consumer. A consultation between EFSA and the European Medicines Agency (EMA) may be needed to consider how to address the identified issues.

For phoxim, MRLs are different for several matrices/tissues between the pesticide and VMP regulations. The possibility of requesting a joint assessment by EFSA and EMA may be considered for this substance.

For what concerns substances that are used both as pesticides and as biocides, some concrete issues were discussed under Agenda item A 15.08.

Member States were invited to submit comments by 1 March 2024.

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15 EFSA 2023. Guidance on the assessment of pesticide residues in rotational crops. EFSA Journal, 21(11), 1–86. https://doi.org/10.2903/j.efsa.2023.8225.

16 EFSA, 2023. Targeted review of maximum residue levels (MRLs) for diazinon. EFSA Journal, 21(11), e8426. https://doi.org/10.2903/j.efsa.2023.8426.

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 substances listed in the overview table.

The Commission informed that new monitoring data on 1,4-dimethylnaphthalene in several products of plant origin were provided by some stakeholders. The Commission intends providing a first analysis of those data at the next meeting of this Committee, in April 2024, but as new monitoring data for revising the existing temporary MRLs (tMRLs) for 1,4-dimethylnaphthalene can still be provided until August 2024 according to Regulation (EU) 2022/1346[17], no revision of the tMRLs will be proposed before that date.

2. Chlorpropham in potatoes

The Commission informed that new monitoring data on chlorpropham in potatoes were provided by food business operators for the years 2022-2023. The data indicate that the levels, while decreasing, are still frequently above the LOQ. Therefore, the Commission proposed modifying the tMRL based on the provided data. The current tMRLs was set based on monitoring data covering the 97.5th percentile (p97.5) of the data population at the 95 % confidence interval (CI). In line with this approach, the Commission proposed to set the tMRL at 0.2 mg/kg. Alternative values for revising the tMRL were also proposed for risk manager's consideration.

In addition, the Commission proposed to reduce the frequency of monitoring data submission by food business operators from once a year to once every two years.

One Member State supported the proposal to lower the tMRL to either 0.2 mg/kg or 0.25 mg/kg.

One observer welcomed the proposal to keep a consistent approach, noting that the proposed tMRL was proportionate and supported the continuation of the work for decreasing the contamination of potatoes.

Member States were invited to submit comments by 1 March 2024.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed that some chapters of the draft guidance document still need to be finalised (e.g., Chapters on derivation of the residue definition and an Appendix on a case study with spiroxamine, glossary) and terminology needs to be aligned throughout the document. A final draft is expected to be ready by late spring 2024 and the final document is expected to be published at the end of 2024.

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[17] Commission Regulation (EU) 2022/1346 of 1 August 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate in or on certain products (OJ L 202, 2.8.2022, p. 31), ELI: http://data.europa.eu/eli/reg/2022/1346/oj.

2. OECD Honey Guidelines

A Member State that had attended the OECD working group meetings on setting MRLs in honey gave an overview of the ongoing work. The OECD working group had received around 600 comments during the pre-commenting period and aims to finalise the comments by summer 2024. The Member State explained that the goal of the OECD guideline is to further explain and clarify some of the uncertainties from the EU technical guidelines on setting MRLs in honey[18] (e.g., the decision tree is much simpler compared to the EU one). Explanations were given as to the main changes compared to the existing EU Guidelines on honey, e.g., the fact that according to the new OECD guidelines setting MRLs for honey based on monitoring data would no longer be possible. On-target plants are now considered while they were not yet in depth covered in the EU guidelines. The Member State clarified that the OECD guideline will replace the EU guidelines in future.

The date of implementation of the OECD guidelines will be discussed in this Committee after adoption of the OECD guidelines.

In addition, an update was given on two OECD working groups by a Member State that had attended the working groups:

- OECD working group on OECD TG 506 Stability of Pesticide Residues in Stored Commodities. The guideline is from 2007 and certain parts need to be revised (e.g., alignment of terminology, crop commodities to be analysed are narrowed down from 5 to 4 and some commodities like bee derived products are added, update on fish). After revising the guideline, a pre-commenting period is foreseen followed by an official consultation. Finalisation of the guideline is aimed at the end of 2024.
- OECD working group meetings on GD 39 Guidance Document on Pesticide Residue Analytical Methods. The guideline is from 2009 and needs to be revised. Overall, the aim is to align it with the EU guideline and improve harmonisation across OECD Member States. After revising the guideline, a pre-commenting period is foreseen at the end of 2024.

3. Codex Alimentarius/JMPR issues

a) Update on EFSA mandates

The Commission is preparing a mandate to address the follow-up of EU reservations made at CCPR in the past based on the rationale that evaluations were ongoing in the EU and plans to submit it to EFSA shortly.

The preparation of a second mandate, requesting EFSA to assess whether action is needed on CXLs that were revoked by the Codex Alimentarius Commission (CAC) in the past, is also foreseen, but will be kept on hold for the moment.

Member States were invited to submit comments by 1 March 2024.

b) Feedback from the Codex Alimentarius Commission (CAC)

The Commission summarised the points related to CCPR discussed during the CAC meeting. Concerning the preparation of the upcoming CCPR, the Member State chairing the Working group on the National Registration Database indicated that the reception of information is mainly coming from EU Member

[18] Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016, rev. 9, 14 September 2018).

States and highlighted the importance of this information for the electronic working group dealing with the management of unsupported compounds without public health concern scheduled for periodic review.

A.08 Cumulative Risk Assessment (CRA):

The Commission informed that there were no news, but that it would resume the work of a Working group with Member States once the results of the mock-assessments would become available.

A.09 Sampling Regulation – Feedback from WG and next steps:

The next Sampling Regulation Working Group meeting (virtual) is planned for 19 March 2024. Comments submitted after the first meeting in April 2023 will be considered and the draft Regulation revision 3 will be updated. At the meeting, a revised draft text will be discussed.

Member States were invited to review their nominations to participate in the Sampling Regulation Working Group and submit any updates by 8 February 2024.

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

A Member State made a notification of a use for fluopyram in pumpkin seeds for which it had set a national tMRL of 0.4 mg/kg. That tMRL will be kept in place until the MRL of 0.4 mg/kg for that product/crop combination will be established in accordance with the fast-track application addressed by the draft measure PLAN/2023/2305 (presented under Agenda item C 09.00). The tMRL was established based on a risk assessment concluding that it will not pose risks to consumers. The Member State clarified that this notification does not relate to an emergency authorisation, and that the trade of treated pumpkin seeds outside its national territory was prohibited. It also confirmed that appropriate controls were in place.

Member States were invited to submit their comments by 1 March 2024.

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

No issues were raised under this agenda item.

A.12 Forthcoming draft Regulations (indicative only):

1. Upcoming CXL measure

The Commission started to work on a new measure to implement into EU legislation the CXLs for azoxystrobin, famoxadone, flutriafol, and mefentrifluconazole for which the EU did not introduce a reservation at the last CCPR meeting in 2023. As, following discussions at this Committee (Agenda item C 02.00), mandipropamid was taken out of the draft measure PLAN/2023/2897, the Commission will consider addressing this substance in that same measure.

The Commission plans presenting the draft regulation at the next meeting of this Committee, in April 2024.

2. Zoxamide

The Commission informed that work on a draft measure on zoxamide had started based on the EFSA Reasoned Opinion published on 18 December 2023[19].

3. Isopyrazam

The Commission informed the Committee that isopyrazam had been taken out of the draft measure PLAN/2023/1960 and will be dealt with in a separate measure (Agenda item C. 02.00).

A.13 Issues related to Annex IV to Regulation (EC) No 396/2005:

The Commission informed that based on the feedback received and considering that fat distillation residues and *Lavandulyl senecioate* are low risk substances, those will be proposed for inclusion into Annex IV to Regulation (EC) No 396/2005 in one of the forthcoming draft Regulations. A list of basic substances which were not approved and for which for the moment default MRL of 0.01 mg/kg according to Article 18(1)(b) Regulation (EC) No 396 / 2005 applies, was reviewed. Except for potassium sorbate, all substances will remain at the default MRL of 0.01 mg/kg because of the lack of analytical methods or data gaps. For potassium sorbate, the Commission will further explore the possibility to add it into Annex IV, taking into accounts its use as food additives. In addition, the Commission informed on the review of a list of non-approved substances which are considered food, referred to comments received by EFSA and shared some reflections with the Committee.

A.14 Issues related to Annex I to Regulation (EC) No 396/2005:

The Commission announced that it plans to review Table 3 of Appendix D of the Extrapolation Guidelines[20] and requested Member States to provide their proposals for further extrapolations.

The Member State leading the working group on the preparation of Technical Guidelines on the interpretation of footnote 1[21] to Annex 1 to Regulation (EC) No 396/2005 provided a summary of the first meeting and called all Member States to submit information of their national approach on the implementation of footnote 1.

Member States were invited to submit comments by 1 March 2024.

A.15 Other Information points:

1) Update on measures under the regulatory procedure with scrutiny (PRAC), tricyclazole and thiacloprid

The Commission informed that the European Parliament (EP) adopted a resolution objecting the adoption of the draft measure PLAN/2023/136, intending to set a higher MRL for tricyclazole in rice based on an import tolerance application, for which no

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19 EFSA, 2023. Review of the existing maximum residue levels for zoxamide according to Article 12 of Regulation (EC) No 396/2005 and setting of an import tolerance for onions, garlic and shallots. EFSA Journal, 21(12), e8427. https://doi.org/10.2903/j.efsa.2023.8427.

20 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, revision 1, 10 May 2023).

21 MRLs do not apply to products or part of products that by their characteristics and nature are used exclusively as ingredients of animal feed, until separate MRLs are set in the specific category 1200000.

qualified majority was reached at the vote during the meeting of this Committee in May 2023. The EP's objection prevents the Commission from proceeding with its adoption.

The Commission also informed that the EP had tabled an objection to the adoption of the draft measure PLAN/2023/962, intending to set higher MRLs for fipronil in several products based on an import tolerance application, but that the EP had not reached a majority for the adoption of that objection. Therefore, the Commission proceeded with the adoption of the measure[22].

The Commission provided an updated on the draft measure PLAN/2023/961, intending to lower the MRLs for thiacloprid for which EFSA identified a risk for consumers and the MRLs related to obsolete EU uses. The EP adopted a resolution objecting the adoption of this draft measure and requested the Commission to prepare a new draft Regulation lowering all the MRLs for thiacloprid to the LOQ. The Commission discussed with Member States different options to draft an amended Regulation, considering the urgency to lower those MRLs for which EFSA identified a risk for consumers.

Member States were invited to submit their comments by 8 February 2024.

2) Current state of play of matrine

The Federal Institute for Risk Assessment (BfR) published a new assessment for matrine and oxymatrine in liquorice roots and extracts[23] in December 2023 and presented it to the Member States. Based on the toxicological assessment by BfR, a genotoxic potential of matrine and oxymatrine is considered unlikely. It should be noted that this conclusion does not change the fact that the default MRL of 0.01* mg/kg is applicable for enforcement according to Article 18(1)(b) of Regulation (EC) No 396/2005. Therefore, liquorice roots where matrine and oxymatrine are identified above the default value are to be considered as non-compliant and to be rejected at import. Nevertheless, import tolerance applications can be submitted under Article 6(4) of Regulation (EC) No 396/2005.

3) Article 19 of Regulation (EC) No 396/2005 translations

At the last meeting of this Committee in November 2023 (Agenda item A 18.14), a Member State asked for clarification on the translation of the wording of Article 19 of Regulation (EC) No 396/2005, as in different language versions (e.g., English, German, French, Dutch) the understanding of the Article might be different. The Commission informed that it has asked the Council Translation Services to verify the French and Dutch language versions of Article 19 of Regulation (EC) No 396/2005 as those seem not in line with the English version and will follow-up once it will receive a reply.

4) Risk assessment in relation to pesticide residues for import control measures on food and feed of non-animal origin

The Commission provided information concerning the risk assessment of certain commodities from certain third countries, which are proposed by the Member States to

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22 Commission Regulation (EU) 2024/347 of 22 January 2024 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 fipronil in or on certain products (OJ L, 2024/347, 23.01.2024), ELI: http://data.europa.eu/eli/reg/2024/347/oj.

23 Plant alkaloids in liquorice roots: genetic damage by matrine and oxymatrine unlikelyhttps://www.bfr.bund.de/cm/349/plant-alkaloids-in-liquorice-roots-genetic-damage-by-matrine-and-oxymatrine-unlikely.pdf

be listed, or that are already listed, in the Annexes to Commission Implementing Regulation (EU) 2019/1793[24] due to possible contamination by pesticide residues. The Commission explained the process, timeline, and adoption of the regular reviews of the commodities listed in the amended Regulation as required by Article 12 of Regulation (EU) 2019/1793. The Commission asked the Member States to provide their suggestions with the aim to improve the risk assessment, including through a detailed discussion with experts on pesticide residues from Member States, which will fit in the timeline provided for the regular reviews of the Annexes of Regulation (EU) 2019/1793. Member States did not propose any change to the current procedures. The Commission invited Member States to enhance cooperation between authorities responsible for import controls and those responsible for pesticides residues policies.

5) New database of Guidelines and supporting documents on Active Substances and Plant Protection Product**s**

The Commission informed about an ongoing project to develop a database of Guidelines and supporting documents on Active Substances and Plant Protection Products for which Member States comments were requested before this meeting of the Committee.

6) Translation issues with Regulation (EC) No 2023/1783 as regards transition periods for etoxazole

The Commission informed that stakeholder had notified that in the Spanish, Czech, German, Estonian and Italian language versions of Commission Regulation (EU) 2023/1783[25], etoxazole was erroneously included among the substances for which a transitional period would apply, either in a recital or the respective Article (or both). Corrigenda/correcting acts are now being prepared for those language versions. The Commission asked the Member States to remind stakeholders that Regulation (EU) 2023/1783 will apply from the 8 April 2024 and that a transitional period was not granted in case of etoxazole as consumer safety concerns could not be excluded. The same stakeholder also raised concerns about the fact that beer on the market containing etoxazole complying with the old MRL may exceed the new MRL.

7) Presence of chlormequat in sunflower seeds from a Member State

The Commission informed that a letter from a Member State indicated that processing mills and factories from another Member State had been refusing to collect sunflower seeds from that Member State due to due residues of chlormequat. Some Member States provided feedback stating that they had no findings through their official controls and reference was given to a single Rapid Alert System for Food and Feed (RASFF) notification where chlormequat in sunflowers had been reported only once for the Member State concerned.

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[24] Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89), ELI: http://data.europa.eu/eli/reg_impl/2019/1793/oj.

[25] Commission Regulation (EU) 2023/1783 of 15 September 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 denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron in or on certain products (OJ L 229, 18.9.2023, p. 63), ELI: http://data.europa.eu/eli/reg/2023/1783/oj.

8) Feedback from Standing Committee on Biocidal Products on chlorocresol and lambda-cyhalothrin

The Commission reported on a discussion on several draft acts that took place at the last Standing Committee for Biocidal Products (SCBP) in December 2023.

They concern cases of disagreements between Member States in the procedure of mutual recognition of national authorisations for chlorocresol and lambda-cyhalothrin which have been referred to the Commission in order to resolve the disagreement. In both cases there are no consumer health concerns, but the existing MRLs of Regulation (EC) No 396/2005 are expected to be exceeded if the products are authorised.

The Commission also referred to another case – in the context of a Union authorisation for chlorocresol.

The Commission is aware of the implications of the proposed approach, especially with regard to the exceedance of MRLs set by Regulation (EC) No 396/2005, and therefore decided not to present the current versions for vote to the SCBP but to continue internal discussions with the Commission services concerned to see if and how these concerns can be addressed within the applicable legal framework.

One Member State welcomed the decision to re-assess the drafts before presenting them to the SCBP for a vote and emphasised the importance of a thorough assessment of the legal situation.

The Commission underlined that good cooperation also needs to continue between the respective competent authorities at Member State level.

9) Processing factors (PFs) for sweet pepper and chili pepper

At the last meeting of this Committee in November 2023 (Agenda item A 18.09), Member State sought clarification regarding processing factors (PFs) for peppers following a request for clarification from a national Spice and Seasonings Association. The Codex document[26] sets different PFs for sweet pepper (10) and chilli peppers (7) due to variations in their moisture content. The national Spice and Seasonings Association suggested a processing factor of 10 for all peppers without making a difference between the varieties based on a recommendation from the European Spices Association. At the last meeting, EFSA clarified that, as in the EU, the MRL for sweet peppers/bell peppers (code: 0231020, which includes chilli peppers) is based only on trials for sweet peppers, it would be appropriate to use the PF of 10 for all varieties covered under the commodity of sweet peppers/bell peppers. A Member State clarified that, if possible, the use of generic PFs should be avoided and substance specific PF should be used instead. The Committee agreed that PF of 10 could be considered in the absence of the more specific PF.

[26] Further consideration of processing as related to the establishment of MRLs for processed foods: Recommendations and principles and practices (CX/PR 09/41/1).

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 Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels prothioconazole in or on certain products

(PLAN/2023/2307)

The Commission presented revision 3 of the draft Regulation, intending to set new maximum residue levels (MRLs) for prothioconazole. According to the decisions taken at the meeting of this Committee in November 2023, this revision only addresses the Article 6 application for sugar beet roots and chicory roots.

Vote taken: Favourable opinion.

B.02 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 maximum residue levels for fenazaquin, mandipropamid, mepiquat and propamocarb or on certain products

(PLAN/2023/2897)

The Commission presented revision 2 of the draft Regulation and outlined its content.

An MRL application in support of an import tolerance for fenazaquin in hops based on a United States Good Agricultural Practice (GAP) was submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005. MRL applications based on EU uses for mandipropamid in radish leaves and for propamocarb in honey were submitted in accordance with Article 6 of Regulation (EC) No 396/2005. An application requesting a modification of the existing tMRLs for mepiquat in cultivated fungi and oyster mushrooms was also submitted in accordance with Article 6 of Regulation (EC) No 396/2005. Lastly, new Codex maximum residue limits (CXLs) for mandipropamid in several products, for which the EU did not introduce a reservation at the Codex Committee on Pesticides Residues (CCPR), were adopted by the Codex Alimentarius Commission (CAC) in 2023. For the modification to the tMRL for mepiquat in cultivated fungi, EFSA concluded that the existing MRL was sufficient and that no modifications were needed. EFSA confirmed that all the other MRLs proposed are fully supported by data and safe for consumers. Therefore, this draft measure intends raising those MRLs accordingly.

One Member State noted that the values set for mandipropamid in potatoes and courgettes by Commission Regulation (EU) 2024/344[27] are incorrect and differ from those voted by this Committee at its meeting in September 2023 and from those that are shown on the EU Pesticide Database (which are correct) and recommended correcting Regulation (EU) 2024/344 accordingly.

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[27] Commission Regulation (EU) 2024/344 of 22 January 2024 amending and correcting Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for mandipropamid in or on certain products (OJ L, 2024/344, 23.01.2024), ELI: http://data.europa.eu/eli/reg/2024/344/oj.

In addition, that Member State identified an error in the EFSA Opinion regarding the modification of the MRL for propamocarb in honey[28], where the comment/justification for the proposed MRL mentions that submitted data are sufficient to derive an MRL proposal for indoor uses, while this should not only refer to indoor use. That Member State invited EFSA to consider amending its Opinion.

The Commission acknowledged the errors in Regulation (EU) 2024/344, and informed that it will contact its Office of Publication to request a corrigendum. In the meanwhile, it proposed taking out mandipropamid from the draft measure pending the resolution of the identified issue, and to address the MRL modifications for this substance in one upcoming measure.

The Commission revised the draft Regulation, considering the above conclusions, and presented it for vote in its revision 3.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… 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 benzovindiflupyr, chlorantraniliprole, emamectin, quinclorac, spiromesifen, and triflumuron in or on certain products

(PLAN/2024/47)

The Commission outlined the draft Regulation in its revision 1, which proposes transposing into EU legislation the CXLs adopted in 2023 for benzovindiflupyr, chlorantraniliprole, emamectin, quinclorac, spiromesifen, and triflumuron, that were considered safe by EFSA and for which the EU did not introduce a reservation at CCPR.

A Member State requested a clarification concerning the rounding for some MRLs for emamectin in products of animal origin. EFSA explained that, as slightly different residue definitions are used by EFSA and by JMPR for emamectin, a small conversion is necessary for some products, and that it rounded values to the next class according to the OECD MRL calculator[29].One Member State declared that it does not support the setting of MRLs for active substances that are non-approved in the EU (quinclorac, spiromesifen and triflumuron) and therefore would not support the Commission's draft Regulation.

Another Member State noted that an EFSA assessment of the Toxicological Reference Values (TRVs) for quinclorac was currently still ongoing and declared that it would therefore not support the draft measure in the revision as presented. In addition, it noted that a request for additional information on triflumuron was made to the joint FAO/WHO Meeting on Pesticides Residues (JMPR), but that the requested data had not yet been provided.

Vote taken: Favourable opinion.

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[28] EFSA 2023. Modification of the existing maximum residue level for propamocarb in honey. EFSA Journal, 21(11), e8422. https://doi.org/10.2903/j.efsa.2023.8422.

[29] https://one.oecd.org/document/env/jm/mono(2011)3/en/pdf.

B.04 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 maximum residue levels for fosetyl-Al, potassium phosphonates and disodium phosphonates in or on certain products

(PLAN/2023/138)

The Commission presented revision 5 of the draft Regulation. The new revision includes changes in Annex II for the proposed MRLs for durians and parsley to correct clerical mistakes that were made in the previous version of the draft Regulation. For durians the LOQ of 1,5* mg/kg should apply instead of 2* mg/kg. For parsnips an MRL of 6 mg/kg should apply in accordance with the MRL review[30] instead of the LOQ.

The Commission also informed that comments were received during the consultation of the trading partners under the World Trade Organisation (WTO) - Sanitary and Phytosanitary (SPS) agreement from two third countries. Those countries requested to increase some MRLs and to align them for some products with MRLs in place in other countries or, in the case of coffee, with the existing CXL. The Commission replied that increasing those MRL was not supported by the EFSA ROs which served as a basis for this draft Regulation and recalled that the EU had expressed a reservation to the advancement of the CXL for fosetyl in coffee due to insufficient number of residue trials supporting it. Therefore, no changes were made to the draft Regulation based on the received comments.

One Member State expressed its general support to the draft Regulation but informed that it would propose to re-include fosetyl into the residue definition, or, alternatively, to add a footnote in the text explaining that residues of fosetyl should be disregarded. It had been informed by representatives of official laboratories and stakeholders that in some crops there were significant findings of the parent substance "fosetyl" which, with the proposed residue definition relating to "phosphonic acid" only, would no longer be captured. This could lead to enforcement problems as, in such cases, the default MRL of 0.01 mg/kg would apply to "fosetyl".

The Commission highlighted that EFSA had previously concluded that, for enforcement purposes, phosphonic acid was a sufficient marker for all authorised uses and that therefore the Commission and Member States had explicitly agreed on that residue definition before EFSA started its review.

A Member State proposed as an alternative to add a footnote requiring the complete hydrolysis of fosetyl into phosphonic acid before analysis. It also noted that it would be important to ensure that "fosetyl" could still be searched on the MRL side of the EU Pesticides Database to enable laboratories to apply the correct MRL. Another Member State supported the proposal to add a footnote and proposed consulting the EURLs to ensure the feasibility of a complete hydrolysis step.

EFSA suggested adding a separate residue definition for "fosetyl", specifying that for all products the MRLs for phosphonic acid would apply. Another Member State supported EFSAs proposal.

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[30] EFSA, 2021. Reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC)No 396/2005. EFSA Journal 2021;19(8):6782, 203 pp. https://doi.org/10.2903/j.efsa.2021.6782.

The Commission consulted the EURLs, who confirmed that fully hydrolysing fosetyl into phosphonic acid was possible, but there was not much experience with its use. In order to first investigate all possible options, the Commission decided not to proceed with the vote at this meeting and to continue the discussion in the next meeting of this Committee in April 2024. While the draft measure may be voted in April, it is uncertain whether the measure would move in the regulatory procedure with scrutiny due to the recess period of the European Parliament.

Member States were invited to submit comments by 23 February 2024.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… 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 benomyl, carbendazim and thiophanate-methyl in or on certain products

(PLAN/2022/2853)

The Commission presented revision 8 of the draft Regulation, with minor modifications compared to the previous one.

One Member State noted that JMPR re-evaluated carbendazim in 2023 and concluded that the submitted toxicological information were insufficient to confirm or amend the previously established TRVs, and therefore withdrew the TRVs and proposed the revocation of all CXLs above the LOQ. This is planned for discussion at the meeting of CCPR, in 2024. Therefore, that Member State requested to confirm the suitability of the data that were available to EFSA for the confirmation of the TRV for carbendazim in its RO of 2021[31].

Another Member State agreed with the concerns expressed and declared that it will abstain from the vote on the measure as it proposes maintaining some MRLs for a substance meeting the cut-off criteria.

EFSA replied that the full JMPR report was not yet available, and that therefore it could not comment yet on the JMPR conclusions. While EFSA had considered the most complete data package on genotoxicity available, some of the studies were considered to have deficiencies, mostly in relation to the fact that some data were generated before the OECD published its test guidelines for chemicals. Nevertheless, EFSA concluded that the identified deficiencies were only minor and that it had decided to apply uncertainty factors to ensure a conservative approach. By doing so it had confirmed the existing TRVs for carbendazim and derived new ones for thiophanate-methyl. EFSA added that the European Chemical Agency (ECHA) had also assessed carbendazim in 2019, reaching very similar conclusions as EFSA.

Two Member States expressed concerns about the reliability of studies being more than 25 years old, as it is the case for some of those used by EFSA. Another Member State mentioned that, based on the new information shared by EFSA, they may reconsider their support to the adoption of the draft measure.

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[31] EFSA, 2021. 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, 66 pp. https://doi.org/10.2903/j.efsa.2021.6773.

The Commission proposed not to present the draft measure for vote at this Committee, but to mandate EFSA to carry out a follow-up qualitative assessment of the data gaps that were identified for those studies in the framework of the assessment of the TRVs for carbendazim, as to confirm the reliability of the derived TRVs, as well as to explain the way they addressed uncertainties. Once the new output by EFSA will be available, the draft measures will be presented for vote.

One Member State welcomed the proposal and declared that it will revise its position based on the EFSA assessment.

Vote postponed.

B.06 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 deltamethrin, metalaxyl, thiabendazole and trifloxystrobin in or on certain products

(PLAN/ 2023/326)

The Commission presented revision 4 of the draft Regulation and gave an overview of its contents and the modifications made since the last meeting of this Committee. The Committee discussed the comments received from two Member States regarding the MRLs proposed for deltamethrin in apples and lettuces. The Commission informed that the values for lettuces are based on a fall-back GAP that will be included in a re-publication of the EFSA RO. The Committee also discussed the comments received from one third country following the consultation of trading partners under the WTO-SPS agreement. One Member State reiterated its concerns regarding the MRL proposed for apples and emphasised the need for a speedy completion of the revision on the Internationally Estimated Short Term Intake (ESTI) equations. The Commission indicated that EFSA is currently working on this issue. Another Member State welcomed the values proposed for lettuces and highlighted the importance of setting MRLs based on fall-back GAPs when possible.

Vote taken: Favourable opinion.

B.07 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 dithianon in or on certain products (Art. 12)

(PLAN/2023/1782)

The Commission confirmed that there were no changes to the previous version of the draft Regulation presented at the meeting of this Committee in November 2023 (revision 3). No comments were received during the consultation of the trading partners under the WTO-SPS agreement. One Member State informed it would abstain due to concerns regarding the metabolite 1,4- naphtoquinone.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards a coordinated multiannual control programme of the Union for 2025, 2026 and 2027 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/ 2023/2295)

The Commission presented revision 1 of the draft Regulation and informed the Committee that internal consultation procedure with the other relevant Commission Services was still ongoing and therefore this draft Regulation would be voted by written procedure. If needed, an amended version will be shared with Member States.

Outcome of the vote via written consultation: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending and correcting Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, difluoroacetic acid (DFA), fluopyram and flupyradifurone in or on certain products

(PLAN/2023/2305)

The Commission presented revision 4 of the draft Regulation, which was modified according to the decisions taken at the meeting of this Committee in November 2023 as to cover, for fluopyram, only the fast-track application for pumpkin seeds. In addition, one Member State had noticed that no MRL was set for DFA in 'herbal infusions from (d) any other parts of the plant' (0639000). This derives from a clerical mistake made in Commission Regulation (EU) 2021/1842[32], where the previously set MRL of 0.1* mg/kg for this product was deleted, leaving a blank case. Therefore, the current revision corrects Annex II re-instating the previously set MRL for this product. The title of the draft Regulation was modified to clarify that it now also intends to correct Annex II and a recital was added to explain the rationale of the changes implemented.

The Commission informed that the consultation of trading partners under the WTO-SPS agreement was still ongoing and, while no comments were yet received, this draft Regulation would be voted after the end of the consultation, by written procedure.

Outcome of the vote via written consultation: Favourable opinion.

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32 Commission Regulation (EU) 2021/1842 of 20 October 2021 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 flupyradifurone and difluoroacetic acid in or on certain products (OJ L 373, 21.10.2021, p. 76), ELI: http://data.europa.eu/eli/reg/2021/1842/oj.

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 cypermethrins in or on certain products (Art. 12)

(PLAN/2023/1863)

The Commission introduced the revision 3 of the draft Regulation. Changes were made to recital 14 providing better explanation on setting MRLs for cypermethrins being based on the most toxic isomer alpha-cypermethrin. Comments received from Member States and stakeholders were presented and discussed. It is now proposed to maintain the existing value of 0.1* mg/kg for herbal infusions from flowers, leaves and herbs and of 0.05* mg/kg for teas (instead of 0.01*mg/kg, as previously proposed), and to add footnotes indicating that monitoring data are necessary. The footnote cross-referencing confirmatory information required under Regulation (EC) No 1107/2009 was deleted to avoid duplication of requirements under two pieces of legislation. The MRL for oranges and melons at 0.01* mg/kg, derived using peeling factors, is proposed as it is considered safe for consumers.

The Commission received one comment during the consultation of the trading partners under the WTO-SPS agreement, that was shared with Member States. Brazil requested to set the MRL for oranges at 0.3 mg/kg which is the CXL. The request cannot be accommodated as EFSA identified a possible risk to consumers for oranges in its RO on the review under Article 12 of Regulation (EC) No 396/2005 regarding cypermethrins[33]. EFSA provided additional comments based on which footnotes in the draft Annex will be revised.

Member States were invited to send comments by 1 March 2024.

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

(PLAN/2023/1960)

The Commission introduced revision 2 of the draft Regulation containing the active substances cyproconazole and spirodiclofen. The Commission informed the Committee that isopyrazam had been taken out of the measure and will be dealt in a separate draft Regulation, as some Member States had indicated that they intended to vote against the draft Regulation if isopyrazam remained in it. In addition, some Member States indicated that they have different approaches on substances meeting the cut-off criteria, depending on whether there had been an active non-renewal decision taken under Regulation (EC) No 1107/2009, or whether the approval expired without such non-renewal decision.

Member States were invited to send comments by 23 February 2024.

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[33] EFSA, 2023. Reasoned opinion on the review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2023;21(3):7800, 210 pp. https://doi.org/10.2903/j.efsa.2023.7800.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for napropamide, pyridaben and tebufenpyrad in or on certain products

(PLAN/ 2023/2190)

The Commission introduced the revision 1 of a draft Regulation addressing the confirmatory data submitted in response to the data gaps identified during the Article 12 MRL review for napropamide, pyridaben, and tebufenpyrad. The revised version was based on the comments received from the Member States and EFSA. The Commission informed that, due to an exceedance of the ARfD for children, the MRL for tebufenpyrad in table grapes was proposed to be lowered to the LOQ, but a Member State proposed to lower the MRL to 0.4 mg/kg instead, based on a less critical and safe fall-back GAP which was evaluated in the framework of the Article 12 MRL review[34]. A Member State had run the PRIMo 3.1 with the proposed new MRLs for tebufenpyrad and had found ARfD exceedance in several food groups. The Commission clarified that the Member State had performed the additional calculation for the acute risk assessment using the MRLs rather than highest residues (HRs) while the agreed international methodology for acute risk assessment (IESTI) is based on HRs. Furthermore, the Commission proposed to set the MRL for herbs and edible flowers at 0.02* mg/kg, following the agreed internal working procedures for Article 12 measures.

Member States were invited to send comments by 23 February 2024.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for dithiocarbamates in or on certain products

(PLAN/2023/2019)

The Commission presented revision 1 of the draft Regulation and gave an overview of its contents and the modifications made since the last meeting of this Committee addressing the comments received from Member States and EFSA. The Commission clarified that for those active substances belonging to the group of dithiocarbamates that are already included in Annex V, such us thiram and propineb, the draft Regulation does not intent to modify the existing MRLs set at the LOQ by previous regulations[35,36]. The Commission explained the different opinions received as regards the residue definition for enforcement and called for comments on this specific issue. The Commission informed about several letters received from non-EU countries regarding the proposed MRLs for mancozeb in grapes and citrus fruits and the intention of a Citrus Growers Association to submit an import tolerance application on mancozeb in citrus fruits.

Member States were invited to send comments by 23 February 2024.

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34 EFSA, 2016. Reasoned opinion on the review of the existing maximum residue levels for tebufenpyrad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(4):4469. https://doi.org/10.2903/j.efsa.2016.4469.

35 Commission Regulation (EU) 2022/1406 of 3 August 2022 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 methoxyfenozide, propoxur, spinosad and thiram in or on certain products (OJ L 215, 18.8.2022, p. 1), ELI: http://data.europa.eu/eli/reg/2022/1406/oj.

36 Commission Regulation (EU) 2021/1864 of 22 October 2021 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 amisulbrom, flubendiamide, meptyldinocap, metaflumizone and propineb in or on certain products (OJ L 377, 25.10.2021, p. 3), ELI: http://data.europa.eu/eli/reg/2021/1864/oj.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards radish leaves classification in Annex I to Regulation (EC) No 396/2005

(PLAN/2023/2900)

The Commission presented the contents of a new draft Regulation aiming to modify the classification of the commodity "radish leaves" in Annex I to Regulation (EC) No 396/2005. In Regulation (EU) 2018/62, the commodity "radish leaves" was introduced in Part B of Annex I linked to the commodity "kales" in Part A of the same Annex[37]. At the time of application of the Regulation, residue trial data were not available to confirm whether this classification would be appropriate, and therefore a transitional period was established[38] (and then extended until 1 January 2025) to enable Member States to generate such data. The minor uses coordination facility summarised the generated data in a report that was shared with Member States. Based on the new data, the draft Regulation proposes to link the commodity small radish leaves (*Raphanus sativus var. radicula*) to the commodity "Roman rocket/rucola" in Part A of Annex I to Regulation (EC) No 396/2005 as it is more appropriate and can be applied immediately. For this solution, no further transitional period is necessary and footnote (3) in Part B of Annex I to Regulation (EC) No 396/2005 establishing a transitional period for "radish leaves" is proposed to be deleted. At the same time the draft Regulation is proposing to specify that the entry "radish leaves" that is linked in Part A of that Annex to "kale" with the code 0243020-008 is related to "large radish leaves" (*Raphanus sativus var. longipinnatus* and *Raphanus sativus var. niger*).

The Commission informed that this Regulation would follow the feedback mechanism under the Better Regulation guidelines and toolbox and invited Member States to send comments by 23 February 2024.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fenbuconazole and penconazole in or on certain products

(PLAN/2024/23)

The Commission presented the proposed MRL values for a draft Regulation addressing the confirmatory data submitted in response to the data gaps identified during the Article 12 MRL review for fenbuconazole and penconazole. The values reflect the risk management decisions agreed with Member States at the meeting of this Committee in May 2023 for penconazole and in September 2023 for fenbuconazole.

Member States were invited to send comments by 1 March 2024.

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37 Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 18, 23.1.2018, p. 1), ELI: http://data.europa.eu/eli/reg/2018/62/oj.

38 Commission Regulation (EU) 2018/1049 of 25 July 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 189, 26.7.2018, p. 9), ELI: http://data.europa.eu/eli/reg/2018/1049/oj.