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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
17 - 18 February 2025

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/3e08b596-2cc8-4249-8543-0720c29922c8*

SUMMARY REPORT

Section A Information and/or discussion

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 RO has been published

The Commission proposed possible risk management options to address the recent conclusions of EFSA on confirmatory data under Article 12 of Regulation (EC) No 396/2005 for terbuthylazine[1] and triclopyr[2]. For both active substances, the Commission proposed to establish permanent maximum residue levels (MRLs) and delete the concerned footnotes requiring additional information for those commodities for which the data gaps have been satisfactorily addressed.

Member States were invited to submit comments by 14 March 2025

3. Non-approved substances for follow-up

a) Update and information on next mandate

The Commission informed the Committee that the preparation of the second mandate to the European Food Safety Authority (EFSA) on non-approved substances is currently on hold awaiting guidance on the way forward from the new Commission. The list of substances to be included will be updated considering new scientific information and its legislative status. An updated table of non-approved substances was shared with the Committee.

[1] EFSA, Evaluation of confirmatory data following the Article 12 MRL review for terbuthylazine. EFSA Journal 2025, 23(2), e9231, https://doi.org/10.2903/j.efsa.2025.9231

[2] EFSA, Statement on the confirmatory data following the Article 12 MRL review for triclopyr. EFSA 2024, 22 (12), e9176, https://doi.org/10.2903/j.efsa.2024.9176

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

1. General issues

The Commission provided an overview of the main outcome of the meetings of the Standing Committee on Plants, Animals, Food and Feed (PAFF), section Phytopharmaceuticals – Legislation held on 04-05 December 2024. It gave an overview of active substances approved, of active substances for which the approval had been renewed, for which grace periods had expired or will expire soon, and for which follow-up action is therefore needed.

The Commission informed the Committee about the endorsement of the amended renewal report on copper and about the already launched stakeholder consultation on the draft Guidance on negligible exposure.

A.03 Specific substances:

1. Glufosinate

The Commission informed the Committee that, as part of the mandate to EFSA to conduct a toxicological review and an updated risk assessment of the MRLs for glufosinate with a deadline of 15 June 2026, EFSA had launched the data call to invite stakeholders to submit relevant data with a deadline of 10 April 2025[3].

2. Matrine

The Commission provided an update on the first mandate to EFSA regarding matrine with terms of reference related to toxicity and exposure assessment, taking also into account the work done by the German Federal Institute for Risk Assessment (BfR)[4]. A second mandate specifically to assess possible MRLs is planned at a later stage.

3. Folpet

The Commission gave an update on the discussions on the residue definition for enforcement for folpet. One Member State inquired about the EFSA conclusion[5] proposing to change the residue definition for enforcement for products of plant origin from "folpet (sum of folpet and phthalimide, expressed as folpet)" to "folpet". The EU Reference laboratories recommended to keep the current residue definition given that the metabolite (phthalimide) is more frequently found than the parent compound (folpet), especially in commodities with high pH and in processed food, and considering the poor stability of folpet. Issues flagged by the Tea & Herbal Infusions Europe related to phthalimide production resulting from heating processes were considered during the discussion. Most of the Member States who intervened in the discussion advocated for keeping the current residue definition acknowledging that some false positive results may occur. Member States were invited to submit comments by 14 March 2025.

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[3] https://www.efsa.europa.eu/en/call/call-data-submit-data-covering-residue-and-toxicological-data-gaps-glufosinate

[4] https://www.bfr.bund.de/cm/349/plant-alkaloids-in-liquorice-roots-genetic-damage-by-matrine-and-oxymatrine-unlikely.pdf

[5] EFSA, Peer review of the pesticide risk assessment of the active substance folpet. EFSA Journal 2023, 21 (8), e08139. https://doi.org/10.2903/j.efsa.2023.8139

4. Fluoride

The Commission updated the Committee on the ongoing EFSA draft Opinion for fluoride which is expected to be finalised in spring this year. Since data on occurrence of fluoride are needed to review all the existing MRLs Member States were invited to make them available to EFSA.

5. Thiacloprid

The Commission informed the Committee about a draft mandate to EFSA as referred to in Commission Regulation (EU) 2024/2711[6], in order to conclude the assessment of the potential endocrine disrupting properties of thiacloprid, the revision of its toxicological reference values and the consumer risk assessment. In addition, the draft mandate includes an update of the EFSA risk assessment for bees. For both assessments a call for additional data is included if it is considered necessary after the evaluation of the available information.

6. 10 Straight Chain Lepidopteran Pheromones (SCLPs), (Z)-3-Methyl-6-isopropenyl-3,4-decadien-1-yl acetate, and (Z)-3-Methyl-6-isopropenyl-9-decen-1-yl acetate

The Commission informed the Committee that the draft Regulation PLAN/2024/1772 will not be presented for voting following the comments received from Member States and considering the discussion at the last meeting of this Committee on 25-26 November 2024 . Given that the level of naturally occurring compounds is higher than the levels resulting from the use of the plant protection products (PPP) and in view of absence of analytical methods, both the approved and non-approved SCLP substances can remain in Annex IV to Regulation (EC) No 396/2005. One Member State reiterated its preference for splitting Annex IV into two parts, one part including those substances which can be considered to meet the criteria of the guidance document (SANCO/11188/2013 Rev. 2, 14 September 2015)[7], and a second part with substances that cannot be considered to meet those criteria , but for which currently enforcement is impossible due to limitations with regard to their analysis.

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

1. Progress under Article 6-10 of Regulation (EC) No 396/2005

EFSA reported that outputs addressing three processes had been adopted since the last meeting of this Committee on 25-26 November 2024. Currently, outputs addressing 37 processes are at different stages of the procedure. Out of these, 11 are under scientific assessment (eight under Regulation (EC) No 396/2005 and three under Regulation (EC) No 1107/2009) and 26 under clock-stop, as additional data had been requested (22 under Regulation (EC) No 396/2005 and four under Regulation (EC) No 1107/2009).

In 2024, EFSA performed a lean exercise on the Article 10 process with the aim of improving the quality of dossiers and reducing the impact of clock stops on the risk assessment. Some improvement actions have been already taken.

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

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[6] Commission Regulation (EU) 2024/2711 of 22 October 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 thiacloprid in or on certain products. OJ L, 23.10.2024; ELI: http://data.europa.eu/eli/reg/2024/2711/oj

[7] SANCO/11188/2013 Rev. 2, 14 September 2015. Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005

There have been no changes since the last meeting of this Committee on 25-26 November 2024.

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

There is one EFSA assessment ongoing under Article 29 of Regulation (EC) No 178/2002, three EFSA assessments under Article 31 of Regulation (EC) No 178/2002 and five assessments under Article 43 of Regulation (EC) No 396/2005. Five mandates concern cumulative risk assessment.

4. Other issues

a) Implementation plan for the IUCLID MRL Report Generator

A virtual tour between EFSA and specific Members States to discuss issues concerning the evaluation of post-transparency applications on their request is ongoing and has been well received by nine Member States. Next virtual tours are to be planned, and the countries interested in such bilateral meeting are invited to contact EFSA at pesticide.mrl@efsa.europa.eu.

EFSA reminded Member States that a consolidated and updated version of the IUCLID dossier must be available for publication together with the final output.

Discussion took place on the compulsory use of the IUCLUD report generator with some diverging views among Member States. EFSA highlighted the importance of having high quality dossiers to ensure a high-quality report. The Committee agreed to extend the test period for the IUCLID MRL Report Generator tool and continue the discussion in the Pesticide Steering Network.

b) Statement on copper

Discussed under the Agenda item A 12.04

c) Mandates in relation to the work in CCPR

EFSA shared information on the allocation of the active substances to Member States in preparation of the EFSA scientific report for the Codex Committee on Pesticide Residues (CCPR) 2025.

d) 2023 Annual report on pesticide residues

Consultation is open for Member States to provide comments to the draft report from 17 to 28 February 2025. The report is expected to be approved by the end of March 2025.

A.05 Alignment of certain MRLs for multiple-use substances:

Regarding bromide, the Commission informed the Committee that EFSA had published its Scientific Opinion on the risks to human and animal health from the presence of bromide in food and feed[8]. In its Scientific Opinion, EFSA derived Toxicological Reference Values (TRVs) for bromide ion, which will be submitted for endorsement by the section Phytopharmaceuticals-Legislation of this Committee on 11-12 March 2025. Based on the conclusions of the EFSA opinion, the Commission will prepare a

[8] EFSA, Risk to human and animal health from the presence of bromide in food and feed. EFSA Journal 2025;23:e9121. https://doi.org/10.2903/j.efsa.2025.9121

follow up mandate to launch a call for data in order to assess the dietary exposure to bromide, including all relevant sources of exposure.

Regarding cypermethrins, the Commission informed the Committee that EFSA and the European Medicines Agency (EMA) are coordinating on the MRL in milk from mammalian animals. Alpha-cypermethrin and cypermethrin are used as veterinary medicinal products.

A.06 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2024-2025:

1. General overview

The Commission provided an update on the outcome of the analysis of the monitoring data on chlormequat and on 1,4-dimethylnapthalene. Data have been collected by EFSA and by relevant stakeholders. The Commission presented its proposed temporary MRLs (tMRL) values for chlormequat in and on cultivated fungi (with a specific value for oyster mushrooms) and the proposed timeline for review. It also presented its proposed tMRL for 1,4 – dimethylnaphtalene for plant commodities other than potatoes and for animal products and the proposed timeline for review.

Member States were invited to send their comments by 14 March 2025.

A.07 International Matters:

1. OECD Guidance document on the residue definition for risk assessment

EFSA provided an update on the work of the OECD Working Group (WG) on the OECD Guidance document on the residue definition for risk assessment, for which a consultation period has closed. The WG Chairs are looking for volunteers to support the revision of the document, in particular for Chapter 11. The finalisation of the Guidance document could be expected over the summer.

2. OECD Honey Guidelines

A Member State that had attended the OECD WG gave the latest update. The draft Guidance is expected to enter the commenting phase before the summer.

3. OECD Guidance on Stability of Pesticide Residues in Stored Commodities

A Member State that had attended the OECD WG gave the latest update. The revision of the draft Guidance was completed, and the final document was sent to OECD on 16 December 2024, together with a large commenting table, where the group provided answers to all comments received from the OECD Residue Chemistry Expert Group (RCEG). The final document was made available to OECD Working Party on Pesticides (WPP) and to OECD WG of the National Coordinators of the Test Guidelines Programme (WNT) in January 2025. The WG is now waiting for their feedback.

4. OECD Guidance Document on Pesticide Residue Analytical Methods

A Member State that had attended the OECD WG gave the latest update. A revised draft version was circulated for comments from 6 January until 17 February 2025. The timeline for finalisation of the revision will depend on the nature and number of comments received.

5. Codex Alimentarius/JMPR issues

a) Forthcoming meeting of the Codex Committee on Pesticide Residues (CCPR)

The Commission informed the Committee on the upcoming meeting of the CCPR from 19 to 24 May 2025. The Council Working Parties in preparation of the meeting are scheduled on 10 and 30 April 2025. The full summary report of the 2024 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is expected to be published late, only around end February or beginning of March 2025, making the preparation of EU positions on Codex MRLs (CXLs) challenging. The electronic working group (eWG) on *Unsupported compounds* has circulated a table of national registration for input by 31 January 2025, for which Member States were invited to submit data. The eWG on *JMPR-CCPR work enhancement* issued a call for any targeted projects that may enhance the current CCPR's and JMPR's evaluation process. Comments from the EU Reference Laboratory for Residues of Pesticides (EURL) were submitted to the eWG on *Guidelines for monitoring the stability and purity of reference materials and related stock solutions of pesticides*, and a Circular Letter (CL) is expected later. A CL on *Priority list* has been circulated for comments by 26 March 2025, for which the Commission will prepare a draft EU position.

Member States were invited to send their comments on the CL on *Priority list* by 28 February 2025.

A.08 Cumulative Risk Assessment (CRA):

1. Parameters for the prospective Cumulative Risk Assessment for setting MRLs for pesticide residues - for endorsement by Member States:

The Committee endorsed the document as tabled with one single modification to question 5 to clarify that the highest reliable percentile (P97.5 of consumption) refers to the whole population.

The Commission informed the Committee about the planned next steps for this year which include: (i) two (or three) training sessions on the prospective CRA methodology which are jointly organized by EFSA/ RIVM and ANSES and which will take place in April and May 2025; (ii) the organization of a WG meeting before summer to discuss the implementation aspects of the methodology; (iii) the presentation of the updated Commission Working document (SANTE 2015/10216) capturing the endorsed methodology at the June SCoPAFF meeting; and (iv) a stakeholder consultation planned for the second half of 2025.

A.09 Other approaches for risk assessment (IESTI, PRIMO):

EFSA provided an update on the state of play of the assessment of the potential consequences for regulatory decisions of moving from PRIMo 3.1 to PRIMo 4. EFSA presented some preliminary results and listed the main challenges encountered which resulted in some delays. The original deadline (January 2025) has therefore been extended until 31 May 2025. The Committee was informed that the Commission intends to present the document for possible endorsement at the next meeting of this Committee on 23-24 June 2025.

The Commission shared the feedback received form two Member States regarding the EFSA ongoing revision of the International Estimate Short-Term Intake (IESTI) methodology. Among the alternative options for exposure calculation included in the

EFSA report9 both Member States indicated their preference for ESTI 1 which uses the MRL as input value. To accomplish the last task listed in the terms of reference, i.e. assessing the ability of the existing and the alternative IESTI methodology to predict exposure events above the ARfD, further discussions with risk managers are still needed.

To get a better feedback on this important question, the Commission invited more Member States to provided their preferences for the options presented in the EFSA report on IESTI by 7 March 2025.

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

The Member State notifying the use of folpet in pome fruits[10] reported on control actions taken. The Commission acknowledged the information provided.

A.11 Designation of Member States for MRL applications:

No issues were raised under this agenda item.

A.12 Forthcoming draft Regulations (indicative only):

1. Cypermethrins:

The Commission informed the Committee that the output from EFSA proposing MRLs for alpha-cypermethrin and for cypermethrins (sum of isomers) is expected by the end March 2025. A draft Regulation will be presented for discussion at the next meeting of this Committee on 23-24 June 2025.

The EU reference laboratories provided an update on the progress of the work on analytical methods able to discriminate for alpha-cypermethrin, including on issues of isomerization. Work is ongoing in a working group with Member States' experts and a further update will be given at the next meeting of this Committee on 23-24 June 2025.

2. Dithiocarbamates, isopyrazam, myclobutanil and phenthoate:

The Commission informed the Committee that some draft Regulations were temporarily put on hold (PLAN/2023/2019, PLAN/2023/2927 and PLAN/2024/1449) awaiting guidance on the way forward from the new Commission. The EU reference laboratories provided an updated on the progress of the work on analytical methods able to discriminate different groups of dithiocarbamates.

3. Phosphane and phosphide salts

The Commission informed the Committee on the recent EFSA Conclusions on the peer review of phosphine[11] under Regulation (EC) No 1107/2009, in which a genotoxic (clastogenic) potential of phosphine had been identified. Consequently, no toxicological reference values were set and no dietary consumer risk assessment was conducted. As the renewal process is still ongoing, the draft Regulation PLAN/2024/1449 has been put on hold.

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[9] EFSA Scientific Report. Review of the methodology used for the assessment of the short-term (acute) dietary exposure to pesticide residues in food (IESTI methodology). EFSA Journal. 2025;23:e9233. DOI: 10.2903/j.efsa.2025.9233

[10] Please see the Summary report of the meeting of the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues, 23 - 24 September 2025, agenda item A.10

[11] EFSA, Peer review of the pesticide risk assessment of the active substance phosphine, EFSA Journal 2025, 23(1); e9177. https://doi.org/10.2903/j.efsa.2025.9177

4. Copper

The Commission informed the Committee that EFSA finalised the review of MRLs for copper[12]. A draft Regulation will be tabled for discussion at the next meeting of this Committee on 23-24 June 2025.

EFSA presented to the Committee a proposed methodology for the consumer safety risk assessment to be used in the ongoing renewal of approval procedure, in authorising PPPs and in MRL applications.

Member States were invited to send their comments by 14 March 2025.

A.13 MRLs for milk and for infant formula and follow-on formula:

A proposed way forward (stepwise procedure) was presented on MRLs for regular milk and for infant formula and follow-on formula at the latest meeting of this Committee on 25-26 November 2024[13]. No comments were submitted from the Member States. A threshold value of 0,0026 mg/kg body weight had been proposed in the EFSA Scientific opinion on pesticides in foods for infants and young children of 2018[14]. Considering this threshold value, the default MRL of 0.01 mg/kg may not be sufficiently safe for infants and young children below 16 weeks of age for some substances and is higher than the MRL for regular milk in some cases. In a first step, the Commission proposed revised MRLs for infant formula and follow-on formula based on the above referred threshold value for 13 active substances: oxamyl, carbofuran, endrin, chlordane, enamectin, haloxyfop, spirodiclofen, phosmet, flumeturon, fenamiphos, topramezone, difenoconazole and epoxiconazole. The calculated MRL values are proposed to amend Delegated Regulation (EU) 2016/127[15] on infant formula and follow-on formula, and Delegated Regulation (EU) 2016/128[16] on food for special medical purposes.

Member States were invited to submit comments by 28 February 2025.

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

As a follow up of the discussion initiated at the last meeting of this Committee on 25-26 November 2024 about the classification of the product Brassica carinata in Annex I, the Commission shared with the Committee the feedback received from two Member States and the applicant clarifying that Brassica carinata is a by-product of the biofuel production that can be used exclusively as feed. One Member State highlighted that due to its high content in erucic acid[17] this product is not suitable for human consumption. Based on this information, the Committee concluded that Brassica carinata should be considered under the Code 1200000, “Products or part of products exclusively used for animal feed production” for which currently no MRLs apply.

One Member State provided an updated on the next steps for the working group on the footnote 1 of Annex 1 to Regulation (EC) No 396/2005. The Commission shared

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[12] EFSA, Statement on the update of maximum residue levels (MRLs) for copper compounds in light of the EFSA scientific opinion on the re-evaluation of the health-based guidance values (HBGVs) and exposure assessment from all sources. EFSA Journal 2025;23: e9271. https://doi.org/10.2903/j.efsa.2025.9271

[13] Summary report of the meeting of the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues, 25 - 26 November 2024, agenda item A.13.

[14] EFSA Journal 2018;16(6):5286, 75 pp. https://doi.org/10.2903/j.efsa.2018.5286

[15] ELI: http://data.europa.eu/eli/reg_del/2016/127/oj

[16] ELI: http://data.europa.eu/eli/reg_del/2016/128/oj

[17] EFSA Scientific opinion Erucic acid in feed and food. EFSA Journal 2016;14(11):4593 https://doi.org/10.2903/j.efsa.2016.4593

a request for clarification from a Member State on the differences between the commodities cucumbers (Code 0232010) and gherkins (Code 0232020).

Member States were invited to submit their comments by 14 March 2025.

A.15 New proposals for Table 3 of the extrapolation guidelines (SANTE/2019/12752 Rev01):

The Commission shared with the Committee the feedback received after the last meeting of this Committee on 25-26 November 2024 and informed about the next steps in the revision of Table 3 of the extrapolation Guidelines.

A.16 EFSA Guidance on pesticide residues in rotational crops: Action plan:

Based on the comments received from Member States and having consulted EFSA, the Action Plan to the EFSA Guidance on pesticide residues in rotational crops has been updated. The Action Plan includes further clarifications to most recommendations.

The Commission invited Member States to provide their views whether recommendation 1 (on revoking the EU Guidance document (1997)) and recommendation 10 (on circumstances under which rotational crop studies need to be provided for import tolerance applications) should be closed as action taken. They were also invited to consider the new information added to the Action Plan and submit their opinion on the next steps for recommendations 3,7,12 and 13.

Member States were invited to submit comments by 14 March 2025.

A.17 Revised Working document SANCO/12745/2013 - for endorsement by Member States:

The Commission presented the working document on pesticides to be considered for inclusion in the national control programmes and the coordinated multiannual control programme of the Union to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin (SANCO/12745/2013, Rev.16) for endorsement by the Member States. The document, in its revision 16(8), was endorsed by the Member States.

A.18 Other Information points:

1. Copper in processed cereal-based foods for infants and young children – question from a Member State

At the last meetings of this Committee on 23-24 September 2024 and on 25-26 November 2024, the Committee noted that monitoring results of copper compounds in processed cereal-based foods for infants and young children may be higher than the general limit of 0.01 mg/kg for pesticide residues set in Directive 2006/125/EC. At the same time, Directive 2006/125/EC sets maximum limits for vitamins, minerals and trace elements, if added. For copper, this Directive sets a limit of 0.04 mg per 100 kcal, which may lead to residues in the range of 1.5 mg/kg in processed cereal-based foods and 0.3 mg/kg in other foods like purees. In addition, Commission Delegated Regulation (EU) 2016/127 sets minimum and maximum limits of copper in infant formula and follow on formula at 0.06 and 0.1 mg per 100 kcal respectively. Commission Delegated Regulation (EU) 2016/128 sets minimum and maximum limits of copper in vitamins and minerals in food for special medical purposes for infants at 0.06 and 0.12 mg per 100 kcal respectively.

The Commission informed the Committee that a letter had been received from a stakeholder highlighting that there is no health issue with the content of copper in foods for infants and young children, in which copper is added intentionally as an essential nutrient.

The Commission acknowledged the need to amend the provisions of the legislation regarding copper levels. However, a revision of the Regulations on foods for infants and young children regarding copper is not foreseen at the moment. Considering that EFSA concluded in its recent Scientific Opinion[18] that there is no concern with the level of intake of copper, Member States' enforcement measures should be proportional to the level of health risk.

2. Copper analysis and enforcement – question from a Member State

A Member State asked for clarification about the measurement uncertainty to be used in the case of copper analysis. The EURL explained at the meeting that copper is typically analysed by multi-metal methods and currently the measurement uncertainty (MU) is determined experimentally in a way that is typical for metal contaminants. The expanded MU is typically much lower than 50%. In the case of proficiency tests (PTs), a standard deviation smaller than 25% is appropriate to use for calculating the z-scores, and to work towards establishing a fixed fit-for-purpose MU value based on PT data, as for the other pesticides. Based on PT data collected by the EURLs, a fixed fit-for-purpose relative standard deviation of 10% would be suitable for evaluating PT-results on copper. Using a coverage factor of two, this translates into an expanded fit-for-purpose MU of 20% for copper. The new harmonised MU value for copper will be proposed to be introduced in the next version of the SANTE Analytical Quality Control (AQC) Guidelines[19].

3. MRLs applicable to variants and metabolites

Further to discussion held at the last meeting of this Committee on 25-26 November 2025, the Commission informed the Committee that only a few Member States had provided comments on the MRLs applicable to residues of variants or metabolites of active substances that are not included in the residue definition for enforcement of the active substances, whether no MRL is applicable or whether the default MRL of 0.01 mg/kg applies.

Member States were invited to submit their comments by 14 March 2025.

4. Issues related to National Reference Laboratories

The Commission informed that Committee about the performance of the National Reference Laboratories (NRLs) for pesticide residues.

EURLs monitor performance of NRLs through proficiency tests and on-site visits. All four EU reference laboratories identified recurring shortcomings and lack of designation of certain NRLs, which is not in line with Article 100 of Regulation (EU) 2017/625[20]. The Commission will contact the Member States concerned issuing an official letter requesting correcting measures as the performance of NRLs is essential to enforce MRLs and ensure consumer safety.

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[18] EFSA; Scientific Opinion on the Re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources. EFSA Journal 2023;21(1):7728.

[19] ANALYTICAL QUALITY CONTROL

[20] ELI: http://data.europa.eu/eli/reg/2017/625/oj

5. Issues related to processing factors

The Commission informed the Committee that the Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed[21] has been updated. The update concerns a few weblinks, some values and the literature.

The Commission shared requests for clarifications from two Member States regarding the processing factors applicable to imported parboiled rice and cumin powder.

Member States were invited to submit their comments by 14 March 2025.

6. MRLs for biphenyl – question from a Member State

A Member Stated reported new cases of MRL exceedances for biphenyl and asked the Commission to investigate the possible origin of contaminations, which may be linked to smoking processes of food and /or to impurities in plant protection products.

The Commission is currently gathering information on this and informed the Committee that EFSA had been mandated to look into the safety of the compounds formed during conventional smoking processes. If biphenyl is confirmed as a resulting product from the smoking process, it will be included in the Commission recommendation for monitoring as well as in the EFSA safety assessment. Member states welcomed the Commission's initiative. Member States were invited to send their comments by 14 March 2025.

7. Feedback from the AGRIFISH Council meeting

The Commission shared with the Committee the Report from the AGRI-FISH Council of 27 January where under AOB the issue of import tolerances was discussed. In view of the request supported by several Member States, the Commission is currently reflecting on how to ensure a more level playing field for EU farmers regarding pesticide residues for non-approved substances. Conclusions will be reflected in the Vision for Agriculture which is likely to be published very soon.

8. Launching of the public consultation in the framework of the EFSA Evaluation via the European Commission

The Commission informed the Committee about the ongoing evaluation of EFSA activities and that some Committee members may be contacted to take part in this evaluation. The evaluation includes a case study[22] which falls within the scope of the Committee.

[Post meeting note: The public consultation which runs from 7 January 2025 to 1 April 2025, has been already launched via the European Commission "Have your Say" portal. It is available in all EU official languages.]

9. Follow up on the rules of Procedure of the PAFF Committee: - based on the Standard Rules of Procedure, and the basic Comitology Regulation (EU) No 182/2011

The Commission updated the Committee on the process for setting the rules of procedure of the PAFF Committees which is still under consultation in other sections.

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[21] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_proc_imp_sante-2021-10704.pdf

[22] EFSA, Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. The EFSA Journal 2019, 17(3): e05634. https://doi.org/10.2903/j.efsa.2019.5634

Once the consultation is finished, comments received will be addressed and the agreed final version will be communicated to the Permanent Representations of the Member States with further instructions for their approval.

10. Order of the General Court to the case of MRLs for clothianidin and thiamethoxam

The Commission informed the Committee on the conclusion of the court case T-247/23. The applicant, Maud Tea & Seed Co. Ltd, an India-based tea producer, has sought annulment of Commission Regulation (EU) 2023/334[23], which lowers the MRLs for clothianidin and thiamethoxam based on environmental reasons of global concern (pollinator decline). The General Court dismissed the action as inadmissible, considering that the applicant was not directly concerned by the contested regulation. The Court found that Maud Tea failed to provide sufficient evidence to prove that its tea production was exported to the European Union.

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, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amidosulfuron, azoxystrobin, hexythiazox, isoxaben, picloram, propamocarb, sodium silver thiosulfate and tefluthrin in or on certain products

(PLAN/ 2024/2904)

The Commission presented revision 4 of the draft Regulation and gave an overview of the comments received from the Member States ahead of the meeting. One Member State expressed reservations on the proposed MRLs for azoxystrobin and hexythiazox (based on applications for import tolerances) due to concerns on competitive disadvantages for European farmers. The Commission clarified that since these two active substances are approved in the EU, EU authorisations for plant protection products containing them could be granted in the EU at any moment, should an applicant request an authorisation to a Member State. Thus, there would be potential direct benefit also for EU farmers. It was also reminded that imported products must meet the same safety standards as the domestic produced food products.
One Member State was not in favour of the inclusion of sodium silver thiosulfate into Annex IV to Regulation (EC) No 396/2005 and suggested splitting Annex IV into two parts, one part including those substances which can be considered to meet the criteria of the guidance document (SANCO/11188/2013 rev. 2)[24], and a second part with substances that cannot be considered to meet those criteria, but for which currently enforcement is impossible due to limitations with regard to their analysis.

The Commission considered it appropriate to include sodium silver thiosulfate into Annex IV to Regulation (EC) No 396/2005 due to the fact no concerns related to the properties of the substance has been identified and considering that residues resulting

[23] 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 47, 15.2.2023, p. 29–45, ELI: http://data.europa.eu/eli/reg/2023/334/oj

[24] Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013 rev. 2, 14 September 2015)

from the use of sodium silver thiosulfate cannot be distinguished from residues resulting from the presence of silver in the environment, which occurs at higher levels and since thiosulfate degrades rapidly in the environment to substances that are also naturally occurring.

Vote taken: Favourable opinion.

B.02 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 chlorpropham, fuberidazole, ipconazole, methoxyfenozide, S-metolachlor and triflusulfuron

(PLAN/2024/1823)

The Commission presented revision 3 of the draft Regulation and gave an overview of the modifications made ahead of the meeting. The Committee discussed the comments received from one third country following the consultation of trading partners under the World Trade Organization Sanitary and Phytosanitary measures (WTO-SPS) agreement[25].

The residue definition for animal commodities for chlorpropham was discussed as well as the inclusion of the footnote "F". Given that the main objective of the draft Regulation is to reduce the MRL of chlorpropham in potatoes and considering that there is no health risk identified for chlorpropham from animal commodities and since a lower LOQ on animal commodities cannot be achieved at present time there is not available analytical capacity, it was decided to keep the current extended residue definition as well as the current LOQ for the animal commodities. The draft proposal was revised accordingly to this decision, and a new revision (4) was prepared and presented for vote. The annual report on the monitoring of chlorpropham submitted by a food business operator which includes the monitoring plan for the next session was shared with the Committee. Member States were invited to send their comments on this report by 14 March 2025.

Vote taken: Favourable 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 maximum residue levels for cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole, mepiquat and oxathiapiprolin in or on certain products

(PLAN/2024/2410)

The Commission provided an overview of the revised version 2 of the draft Regulation, where the Codex maximum residue limit (CXL) for cyantraniliprole in avocadoes was corrected to 0.4 mg/kg. Additionally, the CXLs for mefentriflucoanzole in lettuce and oats were included in the draft Regulation. No comments were received from Member States.

Vote taken: Favourable opinion.

[25] G/SPS/N/EU/802

B.04 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 acetamiprid in or on certain products

(PLAN/2024/2431)

The Commission presented the draft Regulation proposing to implement those MRLs that were confirmed as safe by EFSA in its 2024 Statement[26], considering the lower Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) and the new residue definition for risk assessment for fruits and leafy crops, namely: plums, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, and honey. In addition, the draft Regulation implements the Codex maximum residue limit (CXL) for soyabean adopted by the Codex Alimentarius Committee in 2024 and supported by the EU. No comments were received from Member States. It is foreseen that this draft Regulation would apply around the same time as Commission Regulation (EU) 2025/128[27] lowering some MRLs for acetamiprid.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a coordinated multiannual control programme of the Union for 2026, 2027 and 2028 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 and repealing Implementing Regulation (EU) 2024/989

(PLAN/ 2024/1771)

The Commission presented revision 6 of the draft Regulation and gave an overview of the comments received from the Member States before the meeting. Addressing comments from Member States, the Commission further amended the draft Regulation. The changes concerned in particular some substances subject to analysis by single residue methods and some products specified under 'Remarks' in Annex I the draft Regulation. The draft Regulation proposal was revised accordingly and a revision 7 was prepared and presented for vote.

Vote taken: Favourable opinion.

[26] EFSA; Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites; EFSA Journal. 2024;22:e8759.

[27] Commission Regulation (EU) 2025/158 of 29 January 2025 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in or on certain products. C/2025/493. OJ L, 2025/158, 30.1.2025, ELI: http://data.europa.eu/eli/reg/2025/158/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 carbendazim and thiophanate-methyl in or on certain products

(PLAN/2024/2763)

The Commission recalled that a draft Commission Regulation 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) obtained a favourable opinion in the meeting of this Committee on 22-23 April 2024. However, in September 2024, the European Parliament objected to the draft Regulation and called on the Commission to present a new draft Regulation that would lower all MRLs to the limit of quantification (LOQ).

The Commission presented the draft Regulation lowering nine MRLs, namely the MRLs for carbendazim in oranges, grapefruits, mangoes, and papayas, and for thiophanate-methyl in oranges, grapefruits, mandarins, mangoes, and papayas. EFSA performed a risk assessment based on the toxicological reference values for carbendazim and thiophanate-methyl and identified acute health risks concerning these nine MRLs[28,29,30]. The Commission explained that a subsequent draft Regulation acting on further MRLs that do not pose a risk to consumer health will follow in due course. However, as quick action is needed to address the acute health risks, this draft Regulation will be submitted to this Committee for vote quickly and the deferral of the application date is proposed to be only three months.

Member States were invited to send their comments by 7 March 2025.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation as regards methods of sampling and analysis for the control of pesticide residues in and on products of plant origin and repealing Directive 2002/63/EC

(PLAN/2023/636)

The Commission presented revision 8 of the draft Regulation and provided a summary of the comments made by Member States before the meeting. In order to address the concerns related to the inclusion of feed in the scope of the Regulation, the Commission proposed a change of the text. This is to facilitate sampling in cases where feed is sampled for multiple purposes (e.g. for undesirable substances and pesticides residues). Commission Regulation (EC) No 152/2009[31] may be used in such cases as an alternative sampling method, as it provides for equally adequate requirements to ensure results are representative for the sampled lot. The Commission confirmed that Regulation (EC) No 152/2009 could be amended, if necessary.

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[28] EFSA; Reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal 2021;19(8):6773.

[29] EFSA; Statement on the assessment of quality of data available to EFSA to derive the health-based guidance values for carbendazim. EFSA Journal. 2024;22:e8756.

[30] EFSA; Updated reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal. 2024;22:e8569.

[31] ELI: http://data.europa.eu/eli/reg/2009/152/oj

The new version of the Regulation specifies that the results of the official sampling prevail to the sampling results of food business operators in the case of dispute, and replicate sample can be taken from both aggregate sample and laboratory/analytical sample.

The Commission confirmed that applicable measurement uncertainty should be based on the Analytical Quality Control Guidelines[32] and Guidelines for the Calculation of Consumer Intake and Evaluation of the Risk for Pesticide Residues[33].

Member States were invited to send their comments by 7 March 2025.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for dimoxystrobin, ethephon and propamocarb

(PLAN/2024/1305)

The Commission explained that no changes had been made to the draft Regulation. Regarding propamocarb, based on the feedback received from Member States, the Commission has sent a mandate to EFSA under Article 43 of Regulation (EC) No 396/2005 to assess possible fall-back good agricultural practices (GAPs) in lettuce, with a deadline in May 2025. The draft Regulation will be updated based on the outcome. Trading partners were notified under the WTO/SPS agreement[34] and no comments were received.

Member States were invited to send their comments by 14 March 2025.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for benfluralin, benthiavalicarb and penflufen

(PLAN/2024/1306)

The Commission presented revision 2 of the draft Regulation and explained the changes made since the first version. Member States did not provide any comments at the meeting.

Member States were invited to send their comments by 28 February 2025.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for difenoconazole

(PLAN/2024/2476)

The Commission presented revision 1 of the draft Regulation and provided a summary of the comments Member States made before the meeting on the MRL values proposed at the previous meeting of this Committee[35]. Member States did not provide any comments at the meeting.

Member States were invited to send their comments by 28 February 2025.

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[32] https://food.ec.europa.eu/system/files/2023-11/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf
[33] https://food.ec.europa.eu/system/files/2023-02/acn_working-instructions_2-2_pest-residues.pdf
[34] G/SPS/N/EU/801
[35] Please see point C.10 of Summary report - 25-26 November 2024 - Standing Committee on Plants, Animals, Food and Feed - Section Phytopharmaceuticals – Pesticide Residues