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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*
23 - 24 September 2024

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SUMMARY REPORT

The Committee was organised in fully physical mode and comprised a meeting of the Section Phytopharmaceuticals- Pesticides Residues and Pesticides Legislation. For the latter a separate summary report is available.

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 provided an update on the recently adopted reasoned opinions (ROs) on the Article 12 confirmatory data assessment for amidosulfuron[1] and for cycloxydim[2].

For amidosulfuron, the European Food Safety Authority (EFSA) concluded that the confirmatory data that was required to address the data gap on analytical methods identified during the Article 12 review of Regulation (EC) No 396/2005 had been provided by the applicant and sufficiently addressed. The Commission therefore proposed to delete the footnotes requesting confirmatory data and to maintain the existing MRLs for barley, oat, rye and wheat.

For cycloxydim, FSA concluded that the confirmatory data that was required for residue trials for maize under the Article 12 of Regulation (EC) No 396/2005 review had been sufficiently addressed. EFSA also concluded that the data submitted in accordance with Article 6 of Regulation (EC) No 396/2005 was sufficient to derive MRL proposals for pome fruits, peas with pods and sugar beet roots. The Commission proposed to maintain the existing MRL for maize and to delete the

[1] EFSA, 2024, Peer review of the pesticide risk assessment of the active substance amidosulfuron. EFSA Journal, 22(9), e8984,https://doi.org/10.2903/j.efsa.2024.8984.
[2] EFSA, 2024, Modification of the existing maximum residue levels for cycloxydim in various crops. EFSA Journal, 22(9), e8996, https://doi.org/10.2903/j.efsa.2024.8996.

footnote requesting additional residue trials, as well as to increase the existing MRLs for pome fruits, peas with pods and sugar beet roots as recommended by EFSA.

Member States were invited to submit comments by 11 October 2024.

3. Non-approved substances for follow-up

a) Update and information on next mandate

The Commission provided an overview of the outcome of the EFSA stakeholder consultation (including all relevant interested parties) for 10 non approved active substances[3]. The call was launched for two months and widely advertised to reach relevant stakeholders interested in submitting additional existing toxicological data not considered in the latest targeted MRLs reviews for the 10 non-approved active substances. For the active substances azocyclotin and cyhexatin, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos no interest in submitting additional data was notified from any party. For the active substances chlorfenapyr and diazinon the information submitted was not sufficient to trigger a new assessment based on new data. EFSA will update the published reasoned opinions on the targeted reviews for all those substances reporting the outcome of the stakeholder consultation.

For bifenthrin, some of the studies submitted were considered potentially relevant to address the data gaps identified in the EFSA targeted review of 2023 and to support the evaluation of the toxicological reference values. Therefore, the Commission will prepare a follow-up mandate.

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

1. General issues

The Commission provided an overview of the main outcome of the meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation held in May, June and July 2024. It gave an overview on active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon, and for which follow-up action is therefore needed.

2. Changes made in database on carbendazim

The Commission informed the Member States that the meeting of the SCoPAFF, section Phytopharmaceuticals – Legislation of 22-23 May 2024 endorsed new toxicological reference values as derived in the EFSA reasoned opinion[4], namely for the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD). The EU pesticides database has been updated with the new values including a reference to the EFSA reasoned opinion.

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[3] Outcome of the stakeholder consultation on the reasoned opinions for azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos. EFSA Journal. 2024; doi: 10.2903/sp.efsa.2024.EN-9002

[4] 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, https://doi.org/10.2903/j.efsa.2024.8569

3. TRVs for acetamiprid (see agenda of the section 'Legislation' of this Committee)

The issue was discussed under agenda item A.02 of the agenda of the section Legislation of this Committee.

A.03 Specific substances:

1. Imazalil

The evaluating Member State submitted the evaluation report to EFSA and the Commission mandated EFSA to perform the confirmatory data assessment under Article 12 of Regulation (EC) No 396/2005. This work will focus on imazalil in citrus and the toxicological relevance of one of the metabolites (FK772). The applicant requested to include in the same procedure the assessment of the Codex Alimentarius maximum residue limit (CXL) for bananas for which the EU previously had a reservation. The Commission clarified that the main focus of the assessment should remain on imazalil on citrus. A short reference to bananas could be considered by EFSA, but only in case the evaluation would result in a residue definition aligned with the existing CXL. Another Member State did not support a joint evaluation of citrus and bananas.

2. Bacillus thuringiensis (Bt)

The Commission gave an overview of a letter received by the Bt task force of applicants and informed of the latest scientific article on *Bacillus cereus*. The Commission informed on the internal discussion on the possibility to mandate EFSA to provide a scientific opinion on the possible enterotoxigenic potential of Bt. The discussions are also ongoing at The Organisation for Economic Co-operation and Development (OECD) where at the next meeting of the expert group on biopesticides a dedicated discussion on the taxonomy of Bt and *Bacillus cereus* will be held.

3. Etoxazole

The Commission informed the Committee that the Regulation[5] correcting the Spanish, Czech, German and Italian language versions of Commission Regulation (EU) 2023/1783 had been adopted and entered into force on 26 June 2024.

4. Glufosinate

The Commission informed that a mandate had been sent to EFSA to conduct a full toxicological review of glufosinate and an updated risk assessment of the MRLs for glufosinate. The reasoned opinion is expected by 15 June 2026. Stakeholders will be invited to submit relevant data (toxicological data and residue data to support the current MRLs) to fill the data gaps identified by the Rapporteur Member State for the renewal process. Member States will be consulted on the draft Evaluation Report and on the draft EFSA reasoned opinion.

5. Cypermethrins

The Commission reminded that the proposed approach for the Regulation is now to set two separate MRLs: an MRL for cypermethrin (sum of isomers) and an MRL

[5] Commission Regulation (EU) 2024/1595 of 5 June 2024 correcting certain language versions of Regulation (EU) 2023/1783 as regards the transitional provision on the applicability of Regulation (EC) No 396/2005 of the European Parliament and of the Council to certain active substances OJ L, 2024/1595, 6.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1595/oj

for alpha-cypermethrin. With this approach, there would be no need to lower the MRLs for cypermethrin (sum of isomers) to the LOQ for those 34 commodities previously identified by EFSA as presenting a health risk if all residues consisted of the more toxic alpha-cypermethrin, since a separate safe limit would be set with the MRL for alpha-cypermethrin. It would also allow for staying aligned with CXLs as CXLs are set for cypermethrin (sum of isomers).

Further to concerns raised by some Member States on analytical methods for alpha-cypermethrins, the Commission informed that it had asked the EU Reference Laboratories (EURLs) to support with high priority the goal of having validated and accredited methods in place in all Member States by the end of 2025, well before any new MRLs could be expected to apply. The Commission presented the EURLs action plan to this end, including technical discussions in a working group, training session for laboratories, and proficiency tests.

The Member States supported the Commission's approach and the sending of a mandate to EFSA to provide a statement on MRLs for alpha-cypermethrin. MRLs for alpha-cypermethrin will be derived by EFSA based on the Good Agricultural Practices (GAPs) reported to the joint FAO/WHO Meeting for Pesticides residues (JMPR) to support CXLs, converting the residue trial results to alpha-cypermethrin with appropriate conversion factors.

6. Matrine

Matrine in liquorice was already discussed under point A.03.09 at the meeting of this Committee[6] held on 22-23 April 2024. The Commission had consulted EFSA and the DG SANTE unit dealing with contaminants in food, as matrine residues in food can occur due to unintended co-harvest of a foreign plant material and/or use as pesticide.

EFSA carried out some research regarding consumption data of liquorice and consulted the Compendium of Botanicals[7]. As no monitoring data are currently available at EFSA for matrine and oxymatrine in liquorice and related products, EFSA concluded that, at this stage, no significant relevant information is at their disposal that would be additional to the risk assessment carried out by the German risk assessment body, the BfR[8].

The Commission suggested performing an exposure assessment using the consumption data submitted by four Member States It also clarified that this substance needs to be dealt under Regulation (EC) No 396/2005 when deciding about MRLs even though contamination could be a possible source of residues. The Commission will further reflect on the scope and content of a possible mandate to EFSA.

7. Copper

The Commission informed that during the Member States' consultation on the draft EFSA statement on the update of MRLs for copper compounds in light of the EFSA scientific opinion on the re-evaluation of the Health-Based Guidance Values

[6] https://food.ec.europa.eu/document/download/81bfed61-27b9-41c5-8821-2ad93310d68e_en?filename=sc_phyto_20240422_ppr_sum.pdf
[7] https://www.efsa.europa.eu/en/data-report/compendium-botanicals
[8] https://www.bfr.bund.de/cm/349/plant-alkaloids-in-liquorice-roots-genetic-damage-by-matrine-and-oxymatrine-unlikely.pdf

(HBGV) and exposure assessment from all sources, a Member State highlighted that for some of the commodities for which a lowering of the current MRL is proposed in the draft statement, they have additional GAPs not reported during the MRL review and authorised after 2018 (the year when the MRL review was finalised) that would not be covered by the proposed lower MRL. Therefore, the Commission asked EFSA to perform an additional consultation asking Member States to report these GAPs, and to consider them in the final statement. The deadline of the mandate was extended to 15 November 2024.

Additionally, the Commission reported on letters received from, and a meeting held in August, with the applicant, the EU Copper Task Force. The EU Copper Task Force expressed concerns about possible inconsistencies in risk assessment methodologies between MRL settings, product authorisations, and the renewal of the approval of the active substance process. It also explained that applicants needed guidance on the methodology to use in applications. The Commission clarified that the risk assessment methodology used by EFSA in its recent statement will be used for all future assessments of copper, including MRL setting and the ongoing renewal process. The Commission will discuss with EFSA and the Member States which guidance could be given to applicants.

8. Chlorocresol - Feedback from Standing Committee on Biocidal products

The Commission made a short introductory presentation on biocidal products. It informed that some uses of biocidal products containing chlorocresol may lead to residues in food or feed and that it should be assessed whether relevant MRLs exist and if they would be respected if biocidal products containing chlorocresol would be authorised.

The Commission circulated a note to the members of the Committee explaining that chlorocresol, which was never approved as an active substance for plant protection products in the EU, was considered out of the scope of Regulation (EC) No 396/2005. Consequently, the default level of 0.01 mg/kg according to Article 18(1)(b) does not apply to chlorocresol.

One Member State was of the view that, contrary to the Commission's view, chlorocresol should be considered to be within the scope of Regulation (EC) No 396/2005 and that therefore MRLs should be set for that biocidal use. It cautioned that other substances would be in the same situation. The Commission clarified that it considers this case as a rather an exceptional case, but acknowledged that follow-up is needed on other substances potentially in the same situation.

9. Haloxyfop in infant formula and follow-on formula, and food for special medical purposes

The Commission informed that the haloxyfop MRL in milk recently set in Commission Regulation (EU) 2024/398[9], is lower than the level specified in Commission Delegated Regulation (EU) 2016/127[10] on requirements on infant

[9] Commission Regulation (EU) 2024/398 of 29 January 2024 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for haloxyfop in or on certain products, OJ L, 2024/398, 30.1.2024, ELI: http://data.europa.eu/eli/reg/2024/398/oj

[10] Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25, 2.2.2016, p. 1–29, ELI: http://data.europa.eu/eli/reg_del/2016/127/oj

formula and follow-on formula and in Commission Delegated Regulation (EU) 2016/128[11] on requirements for food for special medical purposes. Therefore, it is appropriate to amend the above two delegated acts to lower the MRLs for haloxyfop from 0.003 mg/kg to 0.002 mg/kg to align with the more protective level which has been established under Regulation (EC) No 396/2005. EFSA commented that MRLs for other substances with low levels set for milk should be checked for their compatibility with the above referred two delegated acts. Therefore, the topic will be further discussed.

Member States were invited to send their comments by 4 October 2024.

10. Metribuzin

The Commission informed that the non-approval of the active substance metribuzin will be discussed at the next SCoPAFF, section Phytopharmaceuticals – Legislation taking place on 2-3 October 2024. The MRLs of the substance should be reviewed under Article 12 of Regulation (EC) No 395/2006. There are no MRLs based on CXLs and in only few food groups the MRLs are above the Limit of Quantification (LOQ). The Commission invited the Member States to report if any of those MRLs are based on import tolerances. Should the existing MRLs be based only on the EU uses, the full Article 12 review might not be necessary and can be dealt by EFSA statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005.

Member States were invited to send their comments by 18 October 2024.

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 eight processes[12] had been adopted since the previous meeting of this Committee. Currently, outputs addressing 31 processes are at different stages of the procedure. Out of these, five are under scientific assessment (two 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 (20 under Regulation (EC) No 396/2005 and 4 under Regulation (EC) No 1107/2009).

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

Since the previous meeting of this Committee, EFSA finalised reviewing one active substance, the data are pending for three active substances, the review of 19 active substances is on hold and the assessment of seven active substances is ongoing.

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

There are two EFSA assessments ongoing under Article 29 of Regulation (EC) No 178/2002, three assessments under Article 31 of Regulation (EC) No 178/2002 and eight assessments under Article 43 of Regulation (EC) No 396/2005.

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[11] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes, OJ L 25, 2.2.2016, p. 30–43, ELI: http://data.europa.eu/eli/reg_del/2016/128/oj

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

4. Other issues

a) Codex

EFSA informed on the publication of the EFSA Report[13] to support the preparation of the EU position in the Codex Committee on Pesticide Residues (CCPR) 2024. It also informed about an ongoing assessment for fall-back MRLs for the 110 CXLs revoked by CCPR 2024. EFSA will launch a call for data inviting Member States to submit information on national good agricultural practices (GAPs), supporting residue trials and other relevant information (e.g. on import tolerances).

b) Transparency Regulation/IUCLID

A virtual tour of Member States is ongoing and has been well received by eight Member States. Next visits are to be planned and the countries interested in such bilateral meeting are invited to contact EFSA at pesticide.mrl@efsa.europa.eu.

EFSA noted that the updated IUCLID manuals had been published for active substances[14] and MRLs[15].

c) IESTI methodology

Work at EFSA is ongoing to review the current methodology, propose alternative calculation algorithms and perform an impact assessment comparing the outcome of the exposure assessment obtained with the current and new calculation methodologies. A second round of public consultation on the full report is planned to be launched in the second week of October 2024.

d) PRIMo rev. 4

In August 2024, PRIMo rev. 4 was released and accompanied by a technical report[16] detailing the changes compared with the current version PRIMo 3.1. The web-based platform is publicly available and its user interface has been improved. To support the transition from PRIMO rev. 3 to 4, EFSA is assessing the consequences of this update. Once informed about these consequences, the Committee will discuss the implementation plan for PRIMo 4.

e) ANSES Cumulative Risk Assessment (CRA) mock assessments

ANSES presented the main conclusions merging from the acute and chronic mock assessment reports where the interim parameters of the tiered approach for prospective scenarios were tested. EFSA presented the list of questions that require risk management consideration for the finalization of the prospective CRA methodology. The risk management aspects will be discussed by the CRA working group in a dedicated meeting scheduled on 10 October 2024 (see agenda point A.08).

[13] Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2024; DOI: https://doi.org/10.2903/sp.efsa.2024.EN-8990
[14] https://zenodo.org/records/12783176
[15] https://zenodo.org/records/12783239
[16] EFSA (9 August 2024) Use and underlying principles of the EFSA Pesticide Residue Intake Model (PRIMo), revision 4

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

The Commission presented the state of play of the ongoing discussion on residues of substances subject to the different EU legislations due to their multiple use, as for example pesticides, biocides and/or veterinary medicinal products.

A detailed presentation was provided from the perspective of biocidal products containing substances for which MRLs may be set or may have to be set in other EU legislations. The so-called updated 'interim approach' on the way to set MRLs for biocidal active substances suggests setting or modifying MRLs under Regulation (EC) No 396/2005 for active substances currently or formerly used as plant protection products, when residues are expected in food from the use of biocidal products.

Regulation (EC) No 396/2005 provides two processes to set MRLs. The usual application requires data from GAPs and allows for MRLs to be derived from residue data. Temporary MRLs can also be set based on monitoring data under certain conditions and in exceptional circumstances. Both legal routes could be investigated to adapt or set MRLs, if needed, and the worst-case scenario corresponding to the multiple use of the substance should be considered to generate the data.

Regarding existing MRLs set in different pieces of the EU legislation for the same substances, the European Chemicals Agency (ECHA) provided a first list of multiple use substances subject to the different EU legislation (biocides, pesticides, veterinary medicinal products).

The Commission explained that it was fully aware of the practical difficulties resulting from divergent levels in different pieces of legislation, hence the aim of the exercise was to align them as much as possible. It explained that currently, when two different MRLs apply for the same substance, in order to comply with EU legislation, food business operators would need to comply with the lowest value to remain compliant with the strictest piece of legislation. One Member States noted that this interpretation was disputed by some operators, who consider that the higher MRL should apply. Another Member State agreed that this could pose problems in practice and that investigation of the source of the residues was needed.

The Commission invited Member States to consider the list provided by ECHA, which will allow for the identification of possible conflicting MRL values and the prioritisation of the substances for which MRLs would need to be adapted.

Member States were invited to send their comments by 18 October 2024.

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 state of play for chlormequat in cultivated fungi, nicotine in coffee beans, chlorpropham in potatoes, and 1,4-dimethylnapthalene in food commodities (except potatoes).

Member States were invited to send their comments by 11 October 2024.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The latest version of the draft guidance document had been shared with the OECD Residue Chemistry Expert Group (RCEG) for their feedback by end of October 2024. There is still some work to do on Chapter 11 which describes the final steps of the decision scheme to derive the residue definition for risk assessment and on a study case on spiroxamine. The finalisation of the Guidance is foreseen by early 2025.

2. OECD Honey Guidelines

The OECD working group continued to review the remaining comments received during the pre-commenting period.

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

A Member State that had attended the OECD working group gave the latest update. Since the kick-off meeting in February 2023, 10 full group meetings and several meetings of the three subgroups have been organised. The working group has liaised with the Analytical Methods Group to harmonise terms, definitions and matrix/commodity groups in both documents. The final draft of the revised version is under preparation. The aim is to distribute it in the fourth quarter of 2024 to OECD Working Party on Pesticides and to the National Coordinators.

4. OECD Guidance Document on Pesticide Residue Analytical Methods

A Member State that had attended the OECD working group gave the latest update. Since the kick-off meeting in February 2023, 10 full group meetings have been organised. The first draft of the revised document will be circulated for internal review in the working group in October 2024 and will be followed by distribution to the RCEG members for commenting by the end of 2024.

5. Codex Alimentarius/JMPR issues

1. Update on EFSA mandates

The Commission informed that two mandates were sent to EFSA and asking for:

- a database of CXLs for which the EU had introduced a reservation pending an ongoing evaluation between 2009 and 2023, and for which such evaluation is now concluded.

  This will allow EFSA to create an inventory of such cases in the form of a technical report, and to estimate the magnitude of the work to be performed, paving the way for decisions whether or not those CXLs could be implemented in EU legislation.

- an inventory of revoked CXLs covering the period 2010- 2022 and a proposal for a work programme for elaborating scientific advice on the appropriate follow-up to the corresponding EU MRLs.

2. Forthcoming meeting of the Codex Alimentarius Commission (CAC)

The Commission presented views on which reservations to CXLs introduced at the CCPR meeting in June 2024 could potentially be lifted at the CAC meeting in November 2024 in view of new information. Unfortunately, the full JMPR

evaluation report is not yet published so some necessary information can still not be checked.

Member States were invited to send their comments by 4 October 2024.

3. Other issues

The Commission highlighted the importance of submitting information on the EU Good Agricultural Practices during the JMPR call for data to facilitate that the MRLs based on the EU uses will be considered into the international standards.

A.08 Cumulative Risk Assessment (CRA):

a. Forthcoming Working Group meeting

The Commission provided an update on the state of play concerning the upcoming Working Group meeting on Cumulative Risk Assessment scheduled for 10 October 2024 via web conference. The Commission encouraged participants to read in detail the two mock assessment reports[17,18] for which a summary was presented under agenda item A.04.04e, and to familiarise themselves with the questions for risk managers to be able to contribute to a fruitful discussion.

A.09 Monitoring Working Group:

The Commission informed that the next monitoring working group meeting on pesticide residues will take place on 14 October 2024 and nominations of participants had been received. The agenda and the associated documents will be sent to the participants in due course.

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

The Commission informed that a Member State made a notification of an emergency use under Article 53 of Regulation (EC) No 1107/2009 for a use of folpet in pome fruits due to a severe scab (*Venturia inaequalis*) infestation in pome fruits on about 1500 ha in total. The current EU MRL of 0.3 mg/kg was not sufficient to cover the higher dosage needed and an temporary MRL of 6 mg/kg was set at national level. The notifying Member State carried out a risk assessment considering the new toxicological reference values for folpet endorsed at the SCoPAFF, section Phytopharmaceuticals- Legislation meeting on 11 July 2024,[19] concluding that the temporary MRL does not show any health concerns. The emergency authorisation is valid for 120 days and the trade of treated fruits outside the national territory is not allowed. The Commission reminded the notifying Member State that compliance with the latter requirement must be controlled.

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

A Member State informed the Commission that they had received an import tolerance application for the approved active substance fenazaquin in citrus, and would like to

[17] Mock Assessment: Acute prospective cumulative risk assessment. EFSA Journal 2024, doi: 10.2903/sp.efsa.2024.EN-9014

[18] Mock assessment: Chronic prospective cumulative risk assessment. EFSA Journal 2024, doi: 10.2903/sp.efsa.2024.EN-9013

[19] https://food.ec.europa.eu/document/download/658b61d5-8fc8-49fb-ae05-1b23b9ff7f4d_en?filename=sc_phyto_20240710_ppl_sum.pdf

proceed with the evaluation. They contacted the Rapporteur Member State who agreed with this. The Committee also did not have any objections to this procedure.

A.12 Forthcoming draft Regulations (indicative only):

1. CXL implementing measure

The Commission informed that a draft Regulation including the CXLs that were supported by the EU at the last Codex Committee meeting in June 2024 would be initiated, taking also account of the evolution of the reservations (cf. Agenda A07.05b) and the formal adoption of the CXLs at the coming Codex Alimentarius Commission meeting.

2. Difenoconazole (Article 12)

The Commission updated the Committee on the forthcoming draft Regulation reviewing the MRLs for difenoconazole based on the EFSA review of the existing maximum residue levels for difenoconazole according to Article 12 of Regulation (EC) No 396/2005 that was published on 30 July 2024[20].

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

The Commission informed that at the SCoPAFF meeting on 22-23 April 2024 the Commission sought advice from the Member States on non-approved substances which are considered food according to Regulation (EC) No 178/2002. For these currently the default MRL of 0.01 mg/kg applies according to Article 18(1)(b) of Regulation (EC) No 396/2005.[21] The Commission received a reply from a Member State, who suggested keeping the substances covered by the default MRL of 0.01 mg/kg until EFSA has done a comprehensive risk assessment. In addition, they suggested dividing Annex IV to Regulation (EC) No 396/2005 into two parts[22]. The Commission agreed to keep the substances covered by the default MRL of 0.01 mg/kg, and to consider sending EFSA a mandate to assess those substances in the future. The Commission will further explore the possibilities of splitting Annex IV.

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

The Commission shared with the Committee the requests from some Member States to discuss the MRLs applicable for crops included in Annex I to Regulation (EC) No 396/2005 with different growth stages (such as baby-leaf spinach vs regular-spinach or onions vs green onions/spring onions). It also shared the feedback received after the previous Committee meeting in April from some Member States and a stakeholder association related to the discussion on MRLs applicable for herbal infusions. For those products not listed under the category 0630000 but exceptionally used as herbal infusions, several Member States were of the view that the MRL for an existing commodity in Annex 1 applies with a processing factor according to Article 20 of Regulation (EC) No 396/2005. However, if the final products marketed as an herbal infusion, for which there is a clearly defined MRL under the category 0630000, then

[20] Review of the existing maximum residue levels for difenoconazole according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal. 2024;22:e8987, https://doi.org/10.2903/j.efsa.2024.8987

[21] More info in the Summary report of Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22 - 23 April 2024, agenda item A 13.

[22] More info in the Summary report of Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22 - 23 April 2024, agenda item A 13.

this MRL should apply. One Member State informed the Committee about the outcome of a meeting with several stakeholder associations on their interpretation of the footnote 1 of Annex 1 to Regulation (EC) No 396/2005.

Member States were invited to send their comments by 11 October 2024.

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

The Commission shared with the Committee a template designed to compile the details of proposals for new extrapolations.

Member States were invited to send their comments by 18 October 2024.

A.16 EFSA Guidance on pesticide residues in rotational crops – *for endorsement by Member States:*

The Commission recalled that at the Committee meeting on 22-23 April, the Commission proposed this Guidance for endorsement which was then postponed. After that meeting, comments from three MSs were received, and some clarifications provided by EFSA. The Guidance was presented to the meeting of SCoPAFF, section Phytopharmaceutical - Legislation on 22-23 May 2024 and no comments were received.

The Commission has started to work on an action plan to handle the 20 recommendations of the EFSA guidance. It will be shared at the next Committee meeting in November. A Member State commented that recommendations, in particular 9, 12 and 13, should be specified in the action plan as their interpretation can lead to non-harmonised implementation. The Commission clarified that the action plan will take into account comments from the Member States and that the Guidance is a living document that can be modified at any moment.

EFSA will provide a training, in a modular form, including videos, starting before the end of 2024.

Member States endorsed the EFSA Guidance on pesticide residues in rotational crops. The application date of the guidance is 1 April 2025.

A.17 Other Information points:

1. Article 19 of Regulation (EC) No 395/2005 translations

The Commission informed the Committee that the Corrigendum to rectify the translation error of the wording of the Dutch and French version of Article 19 of Regulation (EC) No 396/2005 was published in the Official Journal on 13 May 2024[23].

2. Piperonylbutoxide – question from a Member State

Piperonylbutoxide is a biocide and a synergist, therefore no EU MRLs are set under Regulation (EC) No 396/2005. A question was raised by a Member State on whether other Member States have set national MRLs and at which levels. Sharing this information would be useful to facilitate trade in the single market. The Commission informed that several Member States have shared information. A broader question was raised on MRLs for safeners and synergists.

[23] ELI: http://data.europa.eu/eli/reg/2005/396/corrigendum/2024-05-13/oj (FR, NL)

Member States were invited to send their comments by 18 October 2024.

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

A Member State raised a question regarding monitoring results of copper compounds in processed cereal-based baby food. According to Directive 2006/125/EC[24], processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg. However, the MRLs under Regulation (EC) No 396/2005 are higher. Copper compounds may originate from various sources. They may have been added as a nutrient in line with Directive 2006/125/EC, where maximum limits for vitamins, minerals and trace elements, if added, are set (the maximum limit for copper is 40 µg per 100 kcal). They may also come from a use as a fertilizer or a pesticide, or from environmental background. Other Member States shared similar issues. The Commission recalled that similar questions had been raised in the past with other substances.

Member States were invited to send their comments by 18 October 2024.

4. Objections from the European Parliament

The Commission shared with the Committee that on 18 September 2024 the European Parliament adopted resolutions[25,26] opposing the adoption of the two draft Regulations lowering most of the MRLs for benomyl, carbendazim and thiophanate-methyl and for cyproconazole and spirodiclofen. The European Parliament calls on the Commission to submit a new draft to the Committee lowering all MRLs for carbendazim, thiophanate-methyl and cyproconazole and to refuse any requests for import tolerances. As a consequence of the European Parliament objections, the Commission now cannot adopt the draft Regulations which means that the existing MRLs continue to apply.

5. Organisation of future meetings and Working Groups

The Commission informed that the next meeting of this Committee takes place in November in hybrid mode. It also informed about the provisional meeting dates for 2025 which are still subject to confirmation. For working groups under the Standing Committee some changes are foreseen as from next year. Procedures will be aligned with those currently in place for Standing Committee meetings (i.e., invitations via the 'Advanced Gateway to your Meetings' (AGM), contact through Permanent Representations, etc.).

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[24] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version) OJ L 339, 6.12.2006, p. 16–35 (ES, CS, DA, DE, ET, EL, EN, FR, IT, LV, LT, HU, NL, PL, PT, SK, SL, FI, SV), OJ L 338M, 17.12.2008, p. 766–794 (MT). ELI: http://data.europa.eu/eli/dir/2006/125/oj

[25] European Parliament resolution of 18 September 2024 on the draft Commission regulation 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 cyproconazole and spirodiclofen in or on certain products (D091952/05 – 2024/2759(RPS)) https://www.europarl.europa.eu/doceo/document/TA-10-2024-0007_EN.html

[26] European Parliament resolution of 18 September 2024 on the 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 (D089819/05 – 2024/2758(RPS)), https://www.europarl.europa.eu/doceo/document/TA-10-2024-0006_EN.html

6. Residue definition for mercury

EFSA informed the Committee on a recent question from the public related to mercury compounds triggering a question whether elemental mercury was covered by the current residue definition. The Commission proposed to re-word the current residue definition as ‘Mercury compounds and elemental mercury (expressed as mercury)’ in order to solve the issue, as originally the intention was to also cover elemental mercury.

7. Forchlorfenuron

The Commission informed the Committee that, according to the information shared by EFSA and available on CIRCABC, even considering the lower TRVs derived during the peer review, there is a large margin of safety for the existing uses. Therefore, there is no urgency to assess the new metabolism study on cherries. This later study was submitted together with an application for the authorisation of a plant protection product containing forchlorfenuron. EFSA clarified that they have not received the new metabolism study and that as the data gap for the new study was not 'formalised' as a confirmatory data in the Regulation, EFSA does not expected to be involved in the assessment of such study , unless an ad-hoc request is made.

It was also clarified that, in case the new study shows a completely different picture with formation of metabolites significantly more toxic than the parent, it could become relevant to have a new residue definition and new risk assessment performed. EFSA therefore invited MSs that received and assessed the new study to inform the Committee in case they see the need to revise the residue definition and perform a new risk assessment for this active substance because of possible concern.

Member States were invited to send their comments by 11 of October.

8. Methyl - nonyl ketone

Point not discussed - erroneously included in the agenda.

9. Isoxaben (dry beans & dry peas) and pyrimethanil (beans without pods

The Commission informed the Committee about a recent request from a Member State for a fast-track procedure concerning isoxaben in dry beans and dry peas and pyrimethanil in beans without pods.

Member States were invited to send their comments by 11 of October.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluxapyroxad, lambda-cyhalothrin, metalaxyl, and nicotine in or on certain products

(PLAN/2024/1647)

The Commission presented revision 2 of the draft Regulation and gave an overview of its contents. All proposed MRLs have been assessed by an Evaluating Member State and EFSA and are safe for consumers. One Member State enquired about the footnote for nicotine in coffee beans. The Commission clarified that the footnote is not needed since the proposed MRL value is based on analytical considerations and not a temporary MRL based on monitoring data.

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 dithiocarbamates in or on certain products

(PLAN/2023/2019)

The Commission presented revision 6 of the draft Regulation and gave an overview of its contents and the modifications made since the previous meeting of this Committee including comments from Member States and EFSA. The Committee discussed the comments received from several stakeholders and third countries following the consultation of trading partners under the World Trade Organization Sanitary and Phytosanitary measures (WTO-SPS) agreement. The Committee also discussed several aspects related to the EFSA risk assessment and the planning proposed by the EU Reference Laboratories for the development of a method as an alternative to the Kakitani method, able to differentiate between the main three dithiocarbamates groups.

Five Members States indicated their intention not to support the draft Regulation, and one Member State announced that it would abstain. The reasons provided were related to the fact that several substances in the group of dithiocarbonates are not approved at EU level and meet the cut-off criteria under Regulation (EC) No 1107/2009. One Member State raised the issue of the impact that Codex MRLs for feed products, for which the EU normally do not raise reservations, might have on animal products.

Vote postponed.

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

(PLAN/2024/23)

The Commission presented revision 5 of the draft Regulation and gave an overview of the modifications made since the previous meeting of this Committee. A Member State

indicated that it could not support the draft Regulation as fenbuconazole is not an approved substance and that endocrine disrupting properties could not be ruled out.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for isopyrazam in or on certain products

(PLAN/2023/2927)

The Commission presented revision 2 of the draft Regulation and gave an overview of its contents and the modifications made since the previous meeting of this Committee. The Committee discussed the comments received from a third country following the consultation of trading partners under the WTO-SPS agreement. The country requested clarifications on the decrease of MRLs in certain food groups. No changes were made to the draft Regulation based on the received comments.

A Member State indicated it would abstain from the vote as the substance meets the cut-off criteria under Regulation (EC) No 1107/2009. Six Member States indicated they would not support the draft Regulation as they had concerns with maintaining MRLs based on import tolerances for substances not approved in the EU and/or meeting the cut-off criteria (isopyrazam being classified reproduction category 1B).

Vote postponed.

B.05 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 zoxamide in or on certain products

(PLAN/2024/307)

The Commission presented revision 4 of the draft Regulation, gave an overview of the modifications made since the previous meeting of this Committee and informed that no comment was received from third countries following the consultation of trading partners under the WTO-SPS agreement.

Vote taken: Favourable opinion.

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 of the Committee as regards maximum residue levels for acetamiprid in or on certain products

(PLAN/2024/1403)

This agenda item was discussed together with item A.02.01 of the agenda of the meeting of the SCoPAFF, Section Phytopharmaceuticals – Legislation.

The Commission presented the draft Regulation lowering MRLs for acetamiprid in 38 commodities. The draft Regulation is based on the conclusions in the EFSA *Statement on the toxicological properties and maximum residue levels of acetamiprid and its*

metabolites published in May 2024[27]. In this Statement, EFSA conducted an updated risk assessment using Primo 3.1, proposing a new residue definition for risk assessment for fruit and leafy crops that includes the metabolite IM-2-1, and proposing a lower ADI of 0.005 mg/kg bw/day and a lower ARfD of 0.005 mg/kg bw. The lowering of the ADI and ARfD is based on the introduction of an additional uncertainty factor of 5 to account for missing data on developmental neurotoxicity. The Commission presented comments received from non-EU countries following the WTO-SPS notification as well as letters received from stakeholders.

The Commission explained that the Renewal Report for acetamiprid was proposed to be amended accordingly for the residue definition for risk assessment and for the ADI and ARfD. Additionally, the Commission informed that it plans to shortly initiate a review procedure and request additional data from the applicant under Article 21 of Regulation (EC) No 1107/2009 to address the identified uncertainties.

Five Member States expressed concerns on the procedure followed and considered that, even though EFSA had held a peer-review panel with external experts, it should also have held a peer-review meeting with Member States' experts before finalising its conclusions. Two Member States expressed preference that dietary and non-dietary TRVs should all be updated in the same process.

The following protocol declarations were made:

Germany:

From a German perspective, comprehensive, precautionary consumer protection is a top priority.

In case of acetamiprid, however, from a risk assessment point of view, the precautionary lowering of the toxicological reference values (TRVs) while introducing an additional safety factor of 5 is not considered to be scientifically justified on the basis of uncertainty of the relevant developmental neurotoxicity (DNT) study quoted by EFSA, as there are no new findings in this regard. In fact, this study has already been the subject of extensive discussions in the re-approval procedure and at international level. In addition, 17 further in vitro tests (tests according to the OECD-IATA protocol) are now available. In these assays, acetamiprid apparently was proven negative, rather providing evidence supporting the absence of a potential for developmental neurotoxicity.

Furthermore, it is questionable why – if indeed any safety factor was required – this safety factor would not be applied to the AOEL and AAOEL, since the experimental basis for the derivation of ADI, ARfD and A(AOEL) is the same.

Germany instead supports the preparation of a new DNT study to conclusively assess the TRVs in a subsequent evaluation under Article 21 of Regulation (EC) No 1107/2009. We consider it necessary to involve the Member States in the peer review process to base any decision on sound scientific process.

Accordingly, Germany can support neither the new TRVs nor the resulting MRLs for acetamiprid.

We would also like to reiterate our concern regarding the Commission's on the spot approach of linking the vote on the draft regulation to amend / lower MRLs -

[27] Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites, EFSA Journal. 2024;22:e8759, https://doi.org/10.2903/j.efsa.2024.8759

automatically to an acceptance of the TRVs, without the underlying TRVs having been taken note of beforehand, which would be a precondition to amending the MRLs. Thus far, there has been no agreement between the Member States in this regard. We would very much welcome it if the agreed order of procedural steps, i.e. a) note taking of the TRVs b) amending respective MRLs, were to be adhered to again in the future.

Spain:

In the evaluation of the new acetamiprid ADI and ARfD values, a new, unvalidated methodology was used, neither endorsed by the OECD nor by the SCoPAFF Legislation Section, and unrelated to the relevant data requirements of Regulation (EC) No 1107/2009. Although a peer review process without Member State experts was presented as a valid option, we still believe that a proper peer review involving those experts would be necessary. The findings raised unresolved issues that required additional data from the applicant, who should have been given a reasonable timeframe to submit studies and confirm the need to lower the MRLs.

In view of some concerns raised on the time needed to adapt to the new lower MRLs, the Commission proposed to amend the draft Regulation to include a deferral of the application date of 6 months and presented revision 2 for vote.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards 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 informed that it had received a number of comments (such as on the scope (applicability to food and feed), Measurement Uncertainty, sampling by Food Business Operators and of fish) from Member States and some stakeholders to the revision 6. The Commission presented a table with some identified key issues for Member States' views and comments before proceeding with the detailed discussions on the draft Regulation. A question from a Member State regarding a possible contradicting interpretation between the draft sampling Regulation and the feed legislation was also discussed. The Commission clarified that Commission Regulation (EC) No 152/2009[28] on feed sampling specifies requirements to ensure the minimum compliance with the other EU sampling legislation e.g., pesticide residues. The purpose is to allow sampling and analysis for multiple purposes for feed. However, it was stressed that sampling primarily for food purposes Commission Directive 2002/63/EC[29] applies.

Member States were invited to send their comments by 18 October 2024.

[28] Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed, OJ L 54, 26.2.2009, p. 1–130, ELI: http://data.europa.eu/eli/reg/2009/152/oj

[29] Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC, OJ L 187, 16.7.2002, p. 30–43, ELI: http://data.europa.eu/eli/dir/2002/63/oj

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for gamma-cyhalothrin in or on certain products (Article 12)

(PLAN/2024/1180)

The Commission informed that for gamma-cyhalothrin a further discussion is needed before the draft Regulation can be presented at the Committee. The current residue definition for monitoring covers both lambda-and gamma-cyhalothrin and the applicable MRLs cover lambda-and gamma-cyhalothrin. EFSA has reviewed gamma-cyhalothrin under Article 12 of Regulation (EC) No 396/2005[30] and the MRLs for gamma-cyhalothrin are covered by the existing MRLs. However, during the Article 43 focused review for lambda-cyhalothrin and gamma-cyhalothrin in 2017[31] EFSA identified data gaps for MRLs in all food groups. Consequently, Commission Regulation (EU) 2018/960[32] asked confirmatory data to be submitted by 6 July 2020. Some of those data gaps were partly addressed during the Article 12 review. As the renewal of approval of lambda-cyhalothrin is ongoing, the Commission is waiting for information from the rapporteur MS for the renewal of approval report on whether the information submitted by the applicant would address the data gaps. If data gaps are addressed, the existing MRLs can be confirmed and the footnotes asking for confirmatory data can be deleted. If the data gaps are not addressed the MRLs should be lowered to the LOD.

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 presented the first version of a draft Regulation reviewing the MRLs for dimoxystrobin, ethephon and propamocarb.

Dimoxystrobin was non-renewed by Commission Implementing Regulation (EU) 2023/1436[33] and all MRLs are proposed to be lowered to LOQ and moved to Annex V to Regulation (EC) No 396/2005.

In the framework of the renewal of the approval of ethephon under Regulation (EC) No 1107/2009, EFSA on 31 January 2023 published a conclusion proposing lowering the existing acceptable daily intake (ADI) from 0.03 mg/kg to 0.02 mg/kg bodyweight per day. Consequently, EFSA was asked to review MRLs for ethephon based on the

[30] Review of the existing maximum residue levels for gamma-cyhalothrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal, 22(5), e8758. https://doi.org/10.2903/j.efsa.2024.8758

[31] Reasoned opinion on the focussed review of the existing maximum residue levels for lambda-cyhalothrin in light of the unspecific residue definition and the existing good agricultural practices for the substance gamma-cyhalothrin. EFSA Journal, 15(7), 4930.

[32] Commission Regulation (EU) 2018/960 of 5 July 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for lambda-cyhalothrin in or on certain products (OJ L 169, 6.7.2018, p. 2)

[33] Commission Implementing Regulation (EU) 2023/1436 of 10 July 2023 concerning the non-renewal of the approval of the active substance dimoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408

lowered ADI[34]. The draft Regulation proposes reviewed MRLs in several food groups and proposes a new residue definition for enforcement in cereals. EFSA found that it could not be excluded that the acute reference dose of ethephon would be exceeded for apples. It is proposed to set a lower MRL for apples, based on the less critical and safe fall-back GAP. No transitional period is therefore proposed for apples.

EFSA published on 24 November 2023 a reasoned opinion[35] concluding that it could not be excluded that the acute reference dose would be exceeded for propamocarb in lettuces. The draft Regulation proposes a MRL based on the less critical and safe fall-back GAP which is fully supported by data. No transitional period is therefore proposed for lettuces.

Member States were invited to send their comments by 11 October 2024.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for chlorpropham, fuberidazole, ipconazole, methoxyfenozide, s-metolachlor and triflusulfuronmethyl

(PLAN/2024/1823)

The Commission presented the first version of a draft Regulation which intends to move fuberidazole, ipconazole, s-metolachlor and triflusulfuronmethyl to Annex V to Regulation (EC) No 396/2005; to lower the temporary MRL for chlorpropham in potatoes based in monitoring data and to lower the MRL of methoxyfenozide in aubergines/eggplants based on an Article 6 to Regulation (EC) No 396/2005 application.

Member States were invited to send their comments by 11 October 2024.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for benfluralin, benthiavalicarb, penflufen, plant oil/citronella oil and sodium silver thiosulfate

(PLAN/2024/1306)

The Commission informed the Committee that contrary to the agenda that was circulated before the meeting, this agenda item also includes sodium silver thiosulfate among the active substances to be discussed.

The Commission explained the difficulties to set MRLs for two active substances of that draft Regulation:

- Plant oil/citronella contains some marker compounds, but they all are ubiquitous in the environment and not specific enough to make a reliable residue definition.

- Sodium silver thiosulfate residue definition is also challenging because thiosulfate is not stable enough and silver is ubiquitous in the environment.

The Commission invited Member States to consider maintaining these active substances in Annex IV to Regulation (EC) No 396/2005 as active substances for which no MRLs are needed.

Member States were invited to send their comments by 11 October 2024.

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[34] European Food Safety Authority: Statement on targeted review of the maximum residue levels (MRLs) for ethephon (EFSA Journal, 22(4), e8757)

[35] European Food Safety Authority: Reasoned opinion on modification of the existing maximum residue level for propamocarb in honey (EFSA Journal, 21(11), e8422).

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for aluminium phosphide, magnesium phosphide, myclobutanil, phenthoate and dinotefuran

(PLAN/2024/1449)

The Commission explained the initial work done on the draft Regulation regarding aluminium phosphide, magnesium phosphide, myclobutanil and phenthoate. Dinotefuran will be taken out due to an ongoing evaluation of MRL application to set import tolerances for dinotefuran in tomato, pepper, aubergine, okra, Florence fennel, cucurbits with edible peel, lettuce, salad and spinach. For aluminium phosphide, magnesium phosphide and myclobutanil the draft Regulation is based on EFSA assessments of confirmatory data submitted under Article 12 of Regulation (EC) No 396/2005[36]. For Phenthoate, MRLs are set for spices/seeds based on CXLs, while for the remaining commodities the default MRL value of 0,01 mg/kg according to Article 18(1)(b) currently applies. To enhance clarity, product specific LOQs are proposed to be set.

Member States were invited to send their comments by 11 October 2024.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards inclusion of maximum residue levels for 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 into Annex V to Regulation (EC) No 396/2005

(PLAN/2024/1772)

The Commission presented the first version of a draft Regulation reviewing MRLs for the twelve[37] not approved substances under Regulation (EC) No 1107/2009 for which no specific MRL are established and currently the default MRL of 0.01 mg/kg according to Article 18(1)(b) of Regulation (EC) No 396/2005 applies. Advice from the EU Reference Laboratory is awaited on the technical and product specific adaptation of the LOQs.

Member States were invited to send their comments by 11 October 2024.

[36] Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for aluminium phosphide and magnesium phosphide, EFSA Journal. 2024;22:e8446, https://doi.org/10.2903/j.efsa.2024.8446

[37] (7Z-9Z)-7,9-Dodecadien-1-ol; (E)-10-Dodecen-1-yl acetate; (E)-9-Dodecen-1-yl acetate; (E,Z)-4,7-Tridecadien-1-yl acetate; (E,Z)-8-Dodecen-1-yl acetate; (Z)-9-Dodecen-1-yl acetate; (E,Z)-9-Dodecen-1-yl acetate, (E,Z)-9-Dodecen-1-ol, (Z)-11-Tetradecen-1-yl acetate; (Z)-13-Hexadecen-11-yn-1-yl acetate; (Z)-3-Methyl-6-isopropenyl-3,4-decadien-1-yl acetate; (Z)-3-Methyl-6-isopropenyl-9-decen-1-yl acetate; (Z)-5-Dodecen-1-yl acetate and (Z,Z)-Octadien-1-yl acetate.