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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
20 - 21 November 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/9f48b71f-d061-4884-a40f-976ed41bccda?p=1*

SUMMARY REPORT

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

1. Confirmatory data Art. 12 follow-up

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

The Commission informed that the RO on the Article 12 confirmatory data assessment for S-metolachlor was recently adopted by EFSA.

S-metolachlor is no longer approved in the EU, and the data gaps identified in the Article 12 review for strawberry and pineapples were not sufficiently addressed. In addition, in the EFSA Conclusions on the peer review of this substance, EFSA confirmed that a lower Limit of Quantification (LOQ) can be achieved for these products. Therefore, in accordance with EFSA recommendations, the Commission proposed to set the relevant Maximum Residue Levels (MRLs) to the LOQ of 0.01* mg/kg.

Member States were invited to submit their comments by 8 December 2023.

b) Missing analytical standards follow up

For fluroxypyr conjugates, a Member State noted that in the absence of an analytical standard it is not possible to validate the analytical method to derive results aligned with the residue definition. According to another Member State, the low-level findings of fluroxypyr in feed suggest that residues in animal tissues are of minor concern. In a more general discussion, another Member State suggested alternative approaches for substances containing conjugates in their residue definition, such as indicating the specific hydrolysis conditions (e.g. alkaline, acidic, enzymatic) or using suitable model conjugate compounds (markers). The Commission will reflect on possible options for reviewing residue definitions containing conjugates, while for the specific case of fluroxypyr, the footnote requiring the analytical standard to be made commercially available will be maintained for the time being.

c) Commission Staff Working Document on the Evaluation of data submitted to confirm MRLs following their review in accordance with Article 12 of Regulation (EC) No 396/2005 and risk management decisions in the absence of

such data (SANTE/10235/2016, Rev. 5.0) **for endorsement by the Member States**

The document, in its revision 5, formalises existing working procedures followed in case of absence of data to confirm MRLs. Member States endorsed the revised Commission Staff Working Document (SANTE/10235/2016, Rev. 5.0)

2. Non-approved substances for follow up

a) Procedural issues

The Commission presented an updated possible process to deal with the targeted MRL reviews in accordance with Article 43 of Regulation (EC) No 396/2005 for substances that were not approved before Regulation (EC) No 396/2005 came into force, considering the comments received from Member States, EFSA and one stakeholder association after the last meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF) – section Phytopharmaceuticals – Pesticides Residues. The objective of such a process is to provide the opportunity to applicants/interested parties to submit supporting information for those active substances for which EFSA concluded that the Toxicological Reference Values (TRVs) cannot be confirmed since the data available were insufficient compared to existing (most recent) data requirements. Member States were invited to submit their comments by 8 December 2023.

b) Next mandate to EFSA

The Commission reminded that the next mandate to EFSA for a targeted review of non-approved substances' MRLs will include, as previously agreed, carbaryl, dicloran, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, saflufenacil, and terbufos. The Commission will submit it to EFSA as soon as the procedural issues are clarified (see discussion under point A.01.02.a).

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 PAFF Committee, section Phytopharmaceuticals – Legislation held in September and October 2023 and gave an update on the table of active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon, and for which follow-up action was therefore needed. As regards the outcome of the vote on glyphosate see agenda item A.03.01.

2. Toxicological reference values for substances meeting the ED criteria

The Commission referred to a request for clarification from one Member State concerning asulam sodium, benthiavalicarb, clofentezine and triflusulfuron-methyl. Those substances have been identified as meeting the criteria for Endocrine Disruptors (ED), but EFSA was able to derive TRVs. That Member State enquired whether those TRVs would cover the risk from ED-properties to human health and asked for an EFSA statement for clarification.

The Commission had consulted EFSA who confirmed that in all four cases it had considered the ED properties of the substances when establishing the TRVs, as it is EFSA's normal practice to consider all hazards when establishing the most suitable endpoints. Therefore, there would be no need for a specific statement on this issue.

The Commission also clarified that in all four cases those TRVs can be used to assess Codex MRLs (CXLs), and if there is no consumer health risk based on them, CXLs can be established/maintained as they are safe for consumers.

On the other hand, there may be other cases where no threshold mechanism applies to EDs, and therefore TRVs cannot be established by EFSA. In such cases all existing MRLs will need to be lowered to the LOQ.

One Member State reiterated its position that it generally does not agree with setting or maintaining MRLs for substances meeting the cut-off criteria, and especially for the ones having ED properties as in its view there is no clear threshold for endocrine disruptors.

Member States were invited to submit their comments by 8 December 2023.

A.03 Specific substances:

1. Glyphosate

As regards the renewal of approval procedure for glyphosate, the Commission confirmed that no qualified majority was reached, supporting or rejecting its proposed draft Regulation, first at the Standing Committee on Plants, Animals, Food and Feed, section Phytopharmaceuticals - Legislation, in a vote held on 13 October 2023, and again at the Appeal Committee held on 16 November 2023. The Commission announced that, since the current approval of glyphosate expires on 15 December 2023 and since the Commission has the legal obligation to take a decision on the renewal in the absence of a qualified majority at the Appeal Committee, it will proceed to renew the approval of glyphosate. This is based on the assessment made by EFSA of the impact of glyphosate on the health of humans, animals and the environment, which did not identify critical areas of concern that would prevent a renewal of approval. The proposed renewal period is for ten years.

2. *Bacillus thuringiensis* (Bt)

The Commission summarised the information provided by Member States after the last meeting of this Committee on relevant ongoing projects relating to generation of data on possible toxigenicity of *Bacillus thuringiensis* and/or *Bacillus cereus sensu lato*.

A Member State informed about a meeting that recently took place with three other Member States and the industry about the confirmatory data required under Regulation (EC) No 1107/2009. The Commission highlighted that Member States should pay attention to the importance of studies that would also be suitable for clarifying the open questions on consumer health raised by this Committee previously, in view of taking a future decision in this Committee on the way forward under Regulation (EC) No 396/2005.

A Member State introduced a project on the development of micro- and molecular-biological analytical methods for the detection and differentiation of *Bacillus thuringiensis* insecticide strains in the environment (water, soil), primary production and final products. Another Member State informed of a research project about the analytical methods on cytotoxicity which includes three approved *Bacillus thuringiensis* strains. The project is independent from regulatory work, and it is not meant to close the data gaps set for *Bacillus thuringiensis* strains under renewal process. A Member State informed of follow up on the studies they started

3 years ago to evaluate the toxicity of the Bt strains that were involved in the food outbreaks.

3. Copper

The Commission informed that a mandate on copper MRLs had been sent to EFSA with a deadline of 15 July 2024 for its completion.

4. Acetamiprid

The Commission provided an update on the ongoing assessment of acetamiprid performed by EFSA. As new studies that were submitted by the applicant and by Pesticide Action Network (PAN) Europe, and as this new data might affect EFSA's conclusion, the Commission requested EFSA to consider them in its ongoing evaluation and postponed the deadline for EFSA's final outcome to 31 March 2024.

The above-mentioned new data may also impact the evaluation of the safety of existing MRLs and, based on a preliminary screening made by EFSA, a list of plant commodities that might lead to intake concerns was identified. Therefore, the Commission mandated EFSA to collect and investigate fall-back Good Agricultural Practices (GAPs) that could lead to safe scenarios.

EFSA reminded that the call for fall-back GAPs and residue trials was launched, and that Member States are invited to provide the requested data by the end of November 2023.

5. Ethephon

The Commission informed the Committee that, as the renewal of approval of ethephon was voted at the PAFF Committee, section Phytopharmaceuticals – Legislation, a mandate to EFSA to review the MRLs had been sent. This mandate requests EFSA to consider the newest TRVs, the residue data available according to the new residue definitions derived in the framework of the renewal of the approval procedure of ethephon and the newest version of the Pesticide Residue Intake Model (PRIMO).

A Member State informed that in the framework of the renewal of the approval of ethephon, data gaps were identified (the aneugenic potential of 2-hydroxyethyl phosphonic acid (HEPA) and the nature of residues in ruminants (goats)), which may have an impact on the renewal of product authorisations and on the targeted MRL review. The applicant stated that studies to address the data gaps, are under development. The Commission clarified that the assessment under the current mandate should be continued and that procedural aspects to evaluate the studies will be discussed with EFSA. EFSA confirmed that the assessment should continue as there was an acute reference dose (ARfD) exceedance for the parent substance ethephon and that the assessment should therefore not be delayed.

6. Bifenazate

The Commission informed of the several meetings that took place with stakeholder associations for hops and the United States Department of Agriculture (USDA). In the meetings stakeholder associations reported difficulties with the fact that no transitional period had been granted for hops complying with the old (higher) MRL and placed on the market before the application date. Batches of hops were already distributed and often in storage facilities or already at beer brewer's premises, therefore relevant stakeholders in the production chain would need extra time to

segregate compliant and non-compliant lots of hops by the time that the new Regulation (PLAN/2022/2307), voted in this Committee on 10-11 May 2023, will become applicable. The Commission underlined that consumer safety is a priority and that Member States had agreed with the approach on not granting transitional measures. The Rapporteur Member State (RMS) stated that work on the assessment of application under Article 7 of Regulation (EC) No 1107/2009 for an amendment of approval conditions is in progress and that it would give a more detailed update in writing.

7. Difenoconazole

EFSA published a reasoned opinion[1] concerning an Art. 6 application for modifying MRLs for difenoconazole in wheat and rye and concluded that the submitted data are sufficient to derive an MRL proposal for the intended EU use. Nevertheless, EFSA also noted that the impact of the intended uses on the residue levels in animal commodities and the consumer exposure could not be properly assessed and a very narrow margin of safety was noted for the overall chronic exposure. The chronic exposure assessment is considered provisional pending the submission of confirmatory data on possible preferential metabolism/degradation of the four stereo isomers of difenoconazole in plants and animals and the impact of isomerisation on the toxicity of difenoconazole. The peer review assessment on confirmatory information on those stereoisomers is still ongoing in EFSA and an expert meeting will still be needed to finalise that assessment. The Commission considered that it would be inappropriate to take a decision about setting those new MRLs before having received the missing information on stereoisomers. Therefore, it proposed to keep the draft EFSA RO on hold and finalise it when the assessment of stereoisomers under Regulation (EC) No 1107/2009 will be finalised.

Member States were invited to submit their comments by 8 December 2023.

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

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

EFSA reported that outputs addressing 8 processes[2] had been adopted since the previous meeting of this Committee.

Currently, outputs addressing 36 such processes are at different stages of the procedure. Out of these, 14 are under scientific assessment (11 under Regulation (EC) No 396/2005 and 3 under Regulation (EC) No 1107/2009) and 22 under clock-stop, as additional data had been requested (16 under Regulation (EC) No 396/2005 and 6 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, data are pending in the case of 4 active substances, review of 20 active substances are on hold and assessment of 9 active substances is ongoing. The progress report table is publicly available for interested stakeholders[3].

[1] EFSA 2023. Modification of the existing maximum residue levels for difenoconazole in wheat and rye. EFSA Journal, 21(8), 1–42. https://doi.org/10.2903/j.efsa.2023.8207
[2] Each process receives a so called "EFSA question number".
[3] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf

- Clopyralid

The Commission informed that based on the feedback from the Member States the main reason for delays for the renewal of authorisation process under Article 43 of Regulation (EC) No 1107/2009 is that clopyralid is included in plant protection products (PPP) with other active substances such us fluroxypyr, picloram and 2-methyl-4-chlorophenoxyacetic acid (MCPA) for which zonal Rapporteur member State (RMS) are waiting for the applicant/notifier to provide further clarification on data gaps in the context of the renewal of authorisations. In many cases the renewal of authorisations is foreseen in summer 2024, therefore for the time being the Article 12 review is postponed to the end of summer 2024 and the beginning of the review process will be confirmed at the forthcoming meeting of this Committee in April 2024.

- Clofentezine

The Commission informed that on 7 November 2023 Commission Implementing Regulation (EU) 2023/2456 concerning the non-renewal of the approval of the active substance clofentezine[4] was published and the grace period will expire on 11 May 2024. The Committee agreed that the start of the Article 12 review under Regulation (EC) No 396/2005 therefore could be considered for the third quarter of 2024.

3. Update on Article 43 of Regulation (EC) No 396/2005

EFSA finalised five assessments under Article 43 of Regulation (EC) No 396/2005. Eight mandates are ongoing relating to active substances and to the International Estimate Short-Term Intake (IESTI) methodology.

4. Other issues

Mandates in relation to the work in the Codex Committee on Pesticides residues (CCPR)

The EFSA report on the fall-back MRLs identified 178 active substances for which Codex maximum residue limits (CXLs) had been revoked in the 2022 Codex Committee on Pesticide Residues (CCPR). Member States will be consulted to provide further information to identify alternative fall-back MRLs (e.g. an alternative CXL, an MRLs derived from a previous EU assessment, import tolerances, etc.).

The mandate for the upcoming CCPR 2024 is under preparation. The summary report of the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) has been published[5]. There are 34 active substances to assess in total. EFSA is looking for volunteering Members States to assess 7 active substances where no Rapporteur Member State has been assigned. One Member States expressed interest for an active substance at the meeting. Other Members States were invited to volunteer for this task by 5 December.

Pesticides Steering Network (PSN)/Transparency/IUCLID

EFSA informed that the next IUCLID PSN will be held on 22 November 2023.

[4] Commission Implementing Regulation (EU) 2023/2456 of 7 November 2023 concerning the non-renewal of the approval of the active substance clofentezine, 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 (OJ L, 2023/2456, 08.11.2023)

[5] https://www.fao.org/3/cc8226en/cc8226en.pdf

An updated list of the Validation Assistant rules for Plant Protection Products dossiers[6] and an updated IUCLID MRL manual[7] have been published. The IUCLID manuals and training material is under development and the IUCLID "mini-manual" on micro-organisms is close to finalisation. A new IUCLID training for applicants will be available shortly in the EU Academy platform.

Virtual bilateral meetings between EFSA and specific Members States to discuss issues concerning the evaluation of post-transparency applications on their request are currently ongoing. Member States received the initiative well and EFSA already met 6 Member States. EFSA invited the other Member States to express their interest at pesticides.mrl@efsa.europa.eu.

EFSA furthermore reported that the inclusion of IUCLID annotation fields in the MRL application report is being developed to build a new Evaluation Report that can be automatically generated from the IUCLID dossier. It will be shared with IUCLID PSN members.

EFSA invited Member States to systematically inform them and the Commission when the latest version of the Evaluation Report is uploaded to the Document Management System (DMS) after the public consultation.

Cumulative Risk Assessment (CRA)

The evaluation for the call for partnership in the area of retrospective CRA has been completed and the Framework Partnership Agreement has been signed. Other related activities including work of cumulative risk assessment groups. A report on prioritisation of CRA is planned to be approved by the end of 2023.

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

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

As regards the ongoing work on substances with maximum levels set in EU legislation both as pesticides and as food additives, the Commission had received comments from one Member State requesting to delete the mention ‘not relevant difference’ in the overview table for several substances (E239, E284, E285, E520, E523, E554 and E559) due to the toxicity of those substances and/or of their metabolites. The Commission explained however that, as maximum permitted levels for those substances used as additives, are not set for products included in Annex I to Regulation (EC) No 396/2005, there is no need for alignment of those levels with MRLs set under Regulation (EC) No 396/2005. Therefore, the Commission is of the opinion that the differences are not relevant in this specific framework.

Member States were invited to submit their comments by 8 December 2023.

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

1. General overview

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

[6] https://zenodo.org/doi/10.5281/zenodo.5141356
[7] https://zenodo.org/records/10027101

For what concerns the revision of the existing temporary MRL for chlorpropham in potatoes, as new monitoring data will be provided by food business operators before the end of the year, the Commission considers it appropriate to analyse the new data before proposing any modification to the MRL.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed that the in the draft guidance document some chapters still need to be finalised (e.g., Chapters on Derivation of the RD, drinking water, stereoisomers and an Appendix on a case study with spiroxamine). A final draft is expected to be ready by late spring and the final document is expected to be published at the end of 2024.

2. OECD Honey Guidelines

A Member State that had attended the OECD working group meetings on setting MRLs in honey gave an overview of the ongoing work. Currently, work is ongoing to finalise the first full version of the draft guidance document. After that, a pre-commenting period is foreseen followed by an official consultation. Finalisation of the guidelines is expected by spring 2024 with the final publication by end of 2024.

A Member State offered as from the next Committee to give an overview of other OECD working parties related to pesticides residues. This suggestion was welcomed by the Commission.

3. Codex Alimentarius/JMPR issues

a) Follow up for CXLs for which reservations were made in earlier years and proposed amendments of the Terms of reference for the next EFSA scientific report.

The Commission provided an update on the ongoing assessment by EFSA of CXLs for active substances that were never assessed in the EU (for the moment, pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole that were discussed at CCPR53). EFSA had informed the Commission that the presentation of information in the JMPR Monograph is at times not adequate to allow EFSA to perform its evaluation and draw conclusions. EFSA and the Commission had discussed possible ways forward and agreed that the best solution would be for EFSA to finalise its assessment with the information currently available in the Monograph and, as a second step, to consult the JMPR Secretariat to investigate the possibility to contact the rapporteurs for the substances concerned and run a sort of expert consultation. Such an approach, if agreed and considered feasible by both JMPR and EFSA, would provide clarity and based on the outcome, some reservations could possibly be lifted. The first output by EFSA is expected for February 2024, the consultation with the JMPR Secretariat should therefore start soon after.

For what concerns the follow-up of EU reservations made in CCPR in the past based on the rationale that evaluations were ongoing in the EU at the time of making the reservations, a two-step approach will be followed. First, the Commission will mandate EFSA to identify all CXLs for which this was the rationale for reservations and present the outcome in a technical report. Then, the Commission will mandate EFSA to define a work programme for addressing the identified CXLs.

Member States were invited to submit their comments by 8 December 2023.

b) Preparations for the Codex Alimentarius Commission (CAC)

The Commission informed that the lifting of the previous reservations for quinclorac and mefentrifluconazole, as discussed in the latest meetings of this Committee, were included in the EU position presented at the 46th Codex Alimentarius Committee (CAC).[8] Additionally, a reservation for the proposed CXLs for spiromesifen in animal products was included. This information was not available in the Summary report of the 2023 Joint FAO/WHO JMPR and was therefore not considered by EFSA in the preparation of the Scientific support Report[9]. The Commission and the Member State chairing the working group on National Registrations shared information about the Circular Letter recently distributed and reminded the Committee the deadlines for comments.

A.08 Cumulative Risk Assessment (CRA):

The Commission informed about the next steps that will include the evaluation of the results of the mock (acute and chronic) assessments for prospective CRA, that are currently performed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), but also trainings that will enable national authorities to perform such evaluations in the future. To this end, the Commission announced trainings on prospective CRA in May/June 2024.

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

Information on the first meeting of the working group on the planned revision of the sampling regulation was presented at the meeting of this Committee in May 2023. The second working group meeting was scheduled for 7 December 2023 and Member States nominated 24 experts to participate. The Commission informed that it would have to postpone this meeting until the first quarter of 2024 and will communicate the exact date in January 2024. If the nominated experts change due to the change of date, Member States should inform the Commission.

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

No issues were raised under this agenda item.

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

No issues were raised under this agenda item.

A.12 Monitoring of pesticide residues:

1. Feedback from Working Group

The Commission provided an overview of the meeting held on 13 October 2023 which included an update of the EU MRL Database to include Application Programme Interfaces (APIs) enhancing the inter-connection between EFSA, laboratories and other interested stakeholders. This new way of exchanging data will phase out the existing .xml files and will be available following a testing phase with support from EFSA.

[8] The EU comments on pesticide residues are summarised in the CRD23 available in the weblink.

[9] EFSA Scientific support for preparing an EU position in the 54th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2023;21(8):8111

2. Guidance document on Analytical Quality Control and Method Validation Procedures for pesticide residues analysis in food and feed (SANTE/11312/2021, Rev.2) **for endorsement by the Member States**

The EU Reference Laboratory for pesticide residues in Fruits and Vegetables provided an overview of the changes. A Member State supported maintaining in paragraph E12, the sentence "*For further risk management evaluations, in specific and justified cases, laboratories may report to regulatory authorities their own estimated lower expanded MU value if supported by sufficient intra- and inter-laboratory evidence*". The Committee agreed to keep the wording and place it in footnote 8.

3. Document SANTE/11312/2021v2 was endorsed by the Member States.

Working Document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticide residues in and on food of plant and animal origin (SANCO/12745/2013, Rev.15) **for endorsement by the Member States**

The document, in its revision 15(3) was endorsed by the Member States.

A.13 Feedback from EU RLs workshop:

In the Joint EURL Workshop that was held on 17-19 October 2023, there was discussion on the appropriateness of still using as Measurement Uncertainty (MU) the value of 50% of the analytical result. While a 2001 article[10] that was based on data from labs from only 3 (at the time) Member States and on the Horwitz function, indicated that for k=2 and U=25%, indeed 50% is the most appropriate value for the expanded MU, the Commission expressed concerns that after more than 20 years there has been no change, considering that MU reflects technological advancement in equipment and material. Moreover, for the purpose of imports to the EU, the Commission raised concerns as regards the appropriateness of this MU (50%) being used by non-EU laboratories not participating in EU Proficiency Test schemes.

A.14 Forthcoming draft Regulations (indicative only):

1. Penconazole and fenbuconazole

Following the publication of two recent EFSA ROs on the confirmatory data for penconazole and fenbuconazole, the Commission started to work on new measures to review the tentative MRLs that were set during the MRL review under Article 12 of EFSA in 2017 (penconazole)[11] and 2018 (fenbuconazole)[12].

A.15 Issues related to Annex IV to Regulation (EC) No 396/2005:

The Commission proposed to add two low risk substances (fat distillation residues and *Lavandulyl senecioate)* into Annex IV to Regulation (EC) No 396/2005.

In addition, the Commission had made an overview of some basic substances which were not approved and for which for the moment default MRL of 0.01 mg/kg according to Article 18(1)(b) Regulation (EC) No 396 / 2005 applies with the question whether

[10] Alder et al., "Estimation of Measurement Uncertainty in Pesticide Residue Analysis'. Journal of AOAC International, Vol. 84, No.5, 2001
[11] EFSA Journal 2017;15(6):4853
[12] EFSA Journal 2018;16(8):5399

Annex IV inclusion could be considered. A similar exercise was carried out in summer 2018. Recently, the EU Reference Laboratories were also consulted to check whether enforcement methods were available. In the light of the lack of analytical methods for most of the substances and other data gaps, only potassium sorbate was identified as possible candidate for Annex IV inclusion. On potassium sorbate, the scientific opinion carried out by the EFSA FAF Panel in 2019[13] changed the temporary group ADI of 3 mg sorbic acid/kg body weight (bw) per day for sorbic acid (E 200) and its potassium salt (E 202) to a new higher group ADI of 11 mg sorbic acid/kg bw per day. This may alleviate some concerns raised with that substance in earlier EFSA scientific opinions[14,15] where an exceedance of the Acceptable Daily intake (ADI) was found.

With regard to other substances listed by the Commission, the Member States were asked to send comments whether these substances should be placed into Annex IV, Annex V or whether they should remain covered by the currently applicable default MRL of 0.01 mg/kg according to Art 18(1)(b) Regulation (EC) No 396 / 2005.

Member States were invited to send comments by 15 December 2023.

Interpretation of Article 5(1) of Regulation (EC) No 396/2005[16]

As a follow up to a question on interpretation of Article 5(1) of Regulation (EC) No 396/2005 from a Member State, raised at the meeting of this Committee on 18/19 September 2023, the Commission provided its service level interpretation, that inclusion into Annex IV can not only take place after approval of a substance. According to Article 5(1) the pre-condition for Annex IV inclusion is not the approval of a substance as such, but the fact than an evaluation must have taken place. After such an evaluation, in principle, also a non-approved substance, if meeting the requirements of the "Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005[17]", could be included in Annex IV. An example is lactic acid. While Article 5(1) refers to an evaluation under Directive 91/414 (now Regulation (EC) No 1107/2009), the Commission services have so far interpreted this more widely to also include other evaluations, such as for instance MRL evaluations under Articles 6-10 of Regulation (EC) No 396/2005, or even evaluations under other food legislation, e.g. food additives, food flavourings, food supplements legislation. The Guidance Document supports such an interpretation as its flow charts also include other food legislation.

[13] EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2019. Scientific Opinion on the follow-up of the re-evaluation of sorbic acid (E200) and potassium sorbate (E202) as food additives. EFSA Journal 2019;17(3):5625

[14] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal 2015;13(6):4144.

[15] EFSA 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for potassium sorbate for use in plant protection as fungicide on citrus, stone and pome fruits. EFSA supporting publication 2017: 14(6): EN-1232.

[16] This service level interpretation does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

[17] https://food.ec.europa.eu/system/files/2016-10/pesticides_mrl_guidelines_sanco-2013-11188.pdf

A.16 Issues related to Annex I to Regulation (EC) No 396/2005:

The Coordinator of the Minor Uses Coordination Facility (MUCF) was invited to present new monitoring residue data in leaves of small radishes. MUCF provided arguments highlighting the problems of the current classification of radish leaves, linked in part B of Annex I of Regulation (EC) No 396/2005 to kales, and proposed a reclassification linking this commodity to the crop group "lettuces and salad plants" linked to the product Roman rocket/Rucola/Wild rocket (0251060). MUCF experts requested a postponement of the deadline of 1 January 2025 set by Regulation (EU) 2021/1771 by which the MRLs for kale will become applicable to radish leaves, to have more time to compile and review existing data sets and perform a meta-study. The Commission urged to find a solution for the classification of this crop and indicated its strong disagreement with extending one more time the deadline, which in the past has only delayed the process but not led to a solution. Several MS and EFSA welcomed the new proposal for classification and agreed with the Commission not to extend the deadline.

The Commission also summarised the comments received from Member States, EFSA and one stakeholder association after the last meeting of this Committee regarding the 2 options for footnote (1) of Annex I. Several Member States volunteered to actively contribute to the preparation of a guidance document to assist users in the interpretation of footnote 1. The project will be led by one Member State who volunteered for this task, with the support of the other Member States and the Commission.

Member States were invited to submit comments by 8 December 2023.

A.17 Wording of transitional measures in our Regulations:

The Commission informed that, after several rounds of discussion in this Committee, the wording of the Article and the recital relating to the granting of transitional periods for products placed on the market before the application date of the Regulation lowering MRLs, had been changed. The term "produced or imported into the Union" is replaced by "placed on the market in the Union" in all draft regulations, including those for vote in this Committee. The Commission clarified that in practice nothing had changed, as it had already previously interpreted the term "produced" as "placed on the market". However, the Commission considers that the new wording is clearer and less ambiguous than the previous one which had led to frequent questions for clarification. The term "or imported into the Union" had been deleted as it was unnecessary since the term "placing on the market in the Union" clearly includes imports. With the new wording there is no risk for misinterpretation towards unequal treatment of domestic or imported products, which had previously been subject of discussions with third countries. One Member State commented that it would have preferred to keep the notion of "imported into the Union" in view of practical cases it had found during its border controls.

The Commission provided some further clarifications on specific exemplary cases relating to the interpretation of "placing on the market" in the light of the definition in Article 3 of Regulation (EC) No 178/2002 (General Food Law) and the Implementation Guidance[18] thereof. Additional cases were raised by Member States for further discussion.

[18] GPSD and GFL (europa.eu)

A.18 Other Information points.

1. Update on PRAC measures/objections and update on tricyclazole

The Commission provided an update on the ongoing work on the draft measure PLAN/2023/136, intending to set a higher MRL for tricyclazole in rice based on an import tolerance application, for which no qualified majority was reached at the vote during the meeting of this Committee on 10-11 May 2023.

Pursuant to Article 5a of Council Decision 1999/468/EC setting out the regulatory procedure with scrutiny and according to Article 45(4) of Regulation (EC) No 396/2005, the Commission submitted the draft Regulation to the Council and to the European Parliament (EP) for their opinion. The Commission informed that the Council had not delivered an opinion and that there was currently no further news on the procedure at the Parliament. The Commission will provide an update at the next meeting.

For what concerns the draft measure PLAN/2023/961, intending to lower all existing MRLs based on obsolete EU uses and to maintain certain import tolerances and CXLs, found safe by EFSA, for thiacloprid, for which no qualified majority was reached at the vote during the last meeting of this Committee on 18-19 September 2023, the same procedure described above will be followed. The submission of the draft Regulation to the Council and to the Parliament for their opinion is planned before the end of November.

The Commission informed the Committee that it had received information that the Parliament is planning an objection on the draft measure PLAN/2023/962, intending to set a higher MRL for fipronil in some products based on an import tolerance application, for which a qualified majority was reached at the vote during the last meeting of this Committee on 18/19 September 2023. The draft measure is curretnly under scrutiny by the Council and the Parliament.

2. Furathiocarb

Following up on the question from a Member State at the meeting of this Committee in September 2023, another Member State recalled the discussion of this Committee held back in September 2014[19], in which the Commission confirmed that the default MRL of 0.01 mg/kg will continue to apply to the individual components carbosulfan, benfuracarb and furathiocarb even though they are not part of the residue definition (carbofuran) any more, as the breakdown to carbofuran is not fully complete. However, the Member State, while agreeing to the approach in this specific case, raised doubts whether this was in the original spirit of the legislation and suggested to further follow up on this as a general issue. It suggested that in such cases a footnote could be introduced into the legislation that, if one of the parent compounds were found, re-analysis with a method ensuring complete breakdown into the common metabolite (here carbofuran) should be considered. It mentioned fosetyl/phosphonates as a similar future case like that.

3. Future organisation of meetings of the Standing Committee, section Phytopharmaceuticals – Pesticides Residues

The Commission informed about the tentative dates of the meetings in 2024:

- 1-2 February 2024 (virtual or hybrid)

[19] https://food.ec.europa.eu/system/files/2020-11/sc_phyto_20140922_ppr_sum.pdf

- 22-23 April 2024 (virtual or hybrid)
- 27-28 June 2024 (virtual and only if needed)
- 23-24 September 2024 (fully physical)
- 25-26 November 2024 (virtual or hybrid)

4. French national interim emergency measure to ban the placing on the market of cherries from cherry trees treated with phosmet (Article 54 of Regulation (EC) No 178/2002)

The Commission informed that France on 31 October 2023 had withdrawn the national interim emergency measure banning the placing on the French market of cherries imported from countries authorising the use of plant production products containing phosmet on cherry trees[20].

5. Phosmet in olive oil

The Commission gave feedback[21] on the replies received from Member States on specific processing factors (PFs) to be used for phosmet in native olive oil and on the approach to be taken with regard to decisions on granting transitional measures for such oils containing residues of phosmet. With regard to PFs, the Member States practices are different, e.g., some apply the PF only when there is an exceedance of the MRL in the raw commodity, others always apply a PF. For the specific case of phosmet in olive oil, it was agreed that the median PF of 4.8 from the EFSA database could be sued as a basis, therefore, in view of harmonised enforcement action across Member States the Commission encouraged Member States to use a PF of 5 when taking enforcement action for phosmet in native olive oils.

Regarding granting transitional measures Member States indicated that their agreement with the Commission's view expressed at the last meeting and indicate that they do not support granting transitional measures in case of health reasons.

6. Processing factor of refined oil on crude oil

The Commission informed the Committee on the replies[22] received and summarised that if there is a specific PF available for crude oils or for refined oils then the respective PFs should be used. Therefore, in this case, the Member States' authorities should have used the PF for crude oils in crude oil and not the PF for refined oils.

The Commission invited the Member States that, when having doubts on the use of PFs, to contact the Commission and the other Member States to get feedback in order to help them to decide on the PFs.

7. Publication on the SANTE webpage of the Guidelines for harmonised risk management approaches and enforcement action in cases of incidents involving food products containing genotoxic carcinogens

The Guidelines are published on the DG SANTE webpage under this link:

https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/enforcement_en

8. Straight Chain Lepidopteran Pheromones

[20] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000048297166
[21] Agenda item A 19.9 discussed at Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 18 - 19 September 2023
[22] Agenda item 19.10 discussed at Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 18 - 19 September 2023

Straight Chain Lepidopteran Pheromones (SCLPs) are divided into 3 groups, aldehydes, alcohols and acetates.

The Commission informed that, while Commission Regulation (EU) 2023/1719 included all SCLPs to Annex IV, this was done under the wrong assumption that the low-risk status would apply to all SCLPs, while only acetates are approved as low-risk substances.

Therefore, the Commission is of the opinion that Commission Regulation (EU) 2023/1719 should be corrected in order to make clear that only SCLPs, acetates, are to be included to Annex IV, while the default MRLs would continue to apply to SCLPs aldehydes and alcohols.

Member States were invited to submit their comments by 8 December 2023.

9. Processing factors for sweet pepper and chili pepper

A Member State sought clarification regarding processing factors (PFs) for peppers as it had received a request for clarification from a national spice and seasonings association. The Member State provides information on the use of PF for peppers in accordance with a Codex Alimentarius document published in April 2009[23]. The Codex document sets different processing factors for sweet pepper (10) and chilli peppers (7) due to variations in their moisture content. The national spice and seasonings association suggested a processing factor of 10 for all peppers without making difference between the varieties on basis of a recommendation from the European Spices Association (ESA). EFSA clarified that as in the EU, the MRL for sweet peppers/bell peppers (code: 0231020) which includes chilli peppers is based only on the trials for sweet peppers, it would be appropriate to use the PF of 10 for all varieties covered under the commodity of sweet peppers/bell peppers.

Member States were invited to send comments by 15 December 2023.

10. Dimoxystrobin

The approval of the active substance dimoxystrobin was not renewed by Commission Implementing Regulation (EU) 2023/1436, as critical areas of concern had been identified concerning environmental fate and behaviour and ecotoxicology. Based on those main concerns, EFSA has published a Statement that was used as a basis for proposing the non-renewal of the substance and did not finalise the peer review. To facilitate future work related to dimoxystrobin in the context of Regulation (EC) No 396/2005, in July 2023 the Commission mandated EFSA to finalise the Conclusions on the peer review, including the assessment of an application for MRL for different oil seeds, and for the MRL application addressing the confirmatory data identified during the MRL review under Art. 12 of Regulation (EC) No 396/2005 that were submitted with the renewal dossier.

The EFSA Conclusions on the peer review was published in October 2023 and, based on that, the Renewal Report for dimoxystrobin was updated, in particular to add the newly derived toxicological reference values and residues definitions. The adoption of the revised Renewal Report is planned to take place at the meeting of the Standing Committee on Plants, Animals, Food and Feed, section Phytopharmaceuticals – Legislation on 11-12 December 2023.

[23] Further consideration of processing as related to the establishment of MRLs for processed foods: Recommendations and principles and practices (CX/PR 09/41/11)

Member States were invited to submit their comments by 8 December 2023.

11. Evaluation of data on Imazalil post-harvest metabolite R014821

One Member State requested to have an update on the ongoing evaluation of Article 12 confirmatory data for imazalil, and more specifically on metabolite R014821, that is formed during post-harvest use of imazalil (relevant for citrus fruits and melons).

The evaluating Member State (EMS) explained that the assessment took longer than expected due to the necessity of the applicant to generate new data involving animal studies and to some delays due to COVID-19. The evaluation of the data started in 2022 and is still ongoing. For the moment, genotoxicity could be excluded for plant metabolites and for one of the metabolites in animals, while no clear conclusion was yet derived for the remaining metabolite in animals. Therefore, the EMS requested the applicant in August 2023 to repeat one of the studies in order to be able to finalise the risk assessment.

For what concerns the way forward, the EMS noted that it could either submit the evaluation to EFSA already, or wait for the finalisation of the assessment, pointing out that the data should be generated as soon as possible but the timeline is not clear.

The Commission expressed its view that, as no risk for consumers had been identified for the existing MRL of the relevant commodities, the evaluation should not be sent to EFSA yet, but the EMS should report back at the next meeting of this Committee, in February 2024, and provide clearer information about the assessment timeline.

One Member State informed that it has been contacted by food business operators which expressed interest in maintaining the existing MRL for post-harvest uses for citrus fruits and welcomed the Commission proposal to take more time to finalise the assessment.

Another Member State invited the EMS to conduct the assessment as soon as possible.

Member States were invited to submit their comments by 8 December 2023.

12. Current state of play of matrine

A Member State provided an overview of the situation for matrine in confectionary products (liquorice) indicating that withdrawals and recalls have taken place in application of the 0.01mg/kg value and in the absence of any TRVs that would enable a consumer risk assessment.

Another Member State informed that its national risk assessment body was expected to publish a statement on matrine/oxymatrine soon. This could help further discussions in this Committee.

A third country had also reacted on matrine/oxymatrine in the context of the WTO/SPS Committee as it considers the EU MRL of 0.01 mg/kg (default value) inappropriate. The Commission informed that in such case an import tolerance request under Article 6 of Regulation (EC) No 396/2005, supported by a complete data package, should be submitted.

13. Wording Transitional measures.

The item was discussed under agenda item A.17.00.

14. Article 19 of Regulation (EC) 395/2005 - translations

A Member State asked for clarification on the translation of Article 19 of Regulation (EC) No 396/2005 as in different languages the understanding of the Article might be different. The Commission will get back to this question at the next meeting.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, pyrimethanil, quartz sand, and sodium silver thiosulphate in or on certain products.

(PLAN/2023/2303)

The Commission outlined the draft Regulation (revision 3) and its contents. An MRL application on EU uses of azoxystrobin on hops had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. For flonicamid such an application was submitted for Chinese cabbages/pe-tsai, kales and kohlrabies. For isofetamid such an application was submitted for lettuces and salad plants (except lettuces). For mefentrifluconazole such an application was submitted for various commodities of plant and animal origin. For metazachlor such an application was submitted for leeks and honey. For pyrimethanil such an application was submitted for table grapes, garlic, and honey. For pyrimethanil information that was previously unavailable during the Article 12 MRL reviews was assessed by EFSA concluding that the data gap was filled and the relevant footnote could be deleted. The drafts Regulation proposes listing *Metarhizium brunneum strain Ma 43* and Straight Chain Lepidopteran Pheromones (SCLP) in Annex IV to Regulation (EC) No 396/2005, as both substances have been renewed as low-risk active substances.

The Commission noted that some modifications were made as compared to the previous versions. Acibenzolar-S-methyl was removed from the draft measure as it was considered not appropriate to set new MRLs based on EU uses for this substance due to the fact a draft regulation for the withdrawal of its approval is expected to be voted soon. For pyrimethanil the footnote requesting confirmatory data for analytical methods in honey was deleted, as a new method was submitted along with the Article 6 application addressed by this measure and was considered adequate by EFSA.

The Commission noted that it received comments from some Member States against the proposed inclusion of sodium silver thiosulfate in Annex IV and asked Member State to provide their views before the vote.

One Member State commented that, as sodium silver thiosulfate is restricted to non-edible crops, this should be clarified in a footnote. Another Member State proposed to specify that the inclusion in Annex IV would only be valid for non-edible corps, and as an alternative it proposed setting the MRLs for sodium silver thiosulfate in Annex V. Another Member State proposed to include sodium silver thiosulfate in Annex IV, adding a footnote requesting that a new evaluation should be conducted if uses on edible crops were to be authorised.

Considering the fact that there was not a common view on a way forward, the Commission proposed to take out sodium silver thiosulfate from the draft measure, pending the continuation of the discussion on its inclusion in Annex IV to Regulation

(EC) No 396/2005. Member States were invited to submit their comments on the possible inclusion of sodium silver thiosulfate in Annex IV by 8 December 2023.

A new version (revision 4), without sodium silver thiosulfate, was presented for vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl in or on certain products.

(PLAN/2022/2563)

The Commission outlined the draft Regulation (revision 7) with minor changes in the wording of recital (10) and Article 2 of the draft Regulation as regards transition measures. For 2,4-DB, a Member State expressed its support for MRLs at the LOQ for products of animal origin, in the absence of a feeding study, especially regarding the possible conjugates of dichlorohydroxyphenoxyacetic acid (HPAA)- and dichlorohydroxyphenoxybutyric acid (HPBA)- related compounds and the lack of their corresponding toxicological data.

In addition, it provided the following statement:

"In principle, the lowering of MRLs for 2,4-DB to the LOQ in products of animal origin due to the lack of a feeding study is supported. However, as EFSA has confirmed, only in case Member States take action on the pesticide use on grass, clover and alfalfa, the residues of 2,4-DB in livestock are expected to remain below the LOQ. This information should be mentioned in the EFSA assessment of these commodities. A respective amendment of this statement would therefore be appreciated.

We take the view that such a restriction in the national authorisation process, e.g. a feed ban or withdrawal of the authorisations for grass, clover and alfalfa, is not feasible in practice and exceedances of the LOQ for products of animal origin could not be excluded.

This situation is unsatisfactory. In our opinion, the key problem is that until now no MRLs are set in category 12 of Annex I to Regulation (EC) No 396/2005. This example shows again the urgent need to set MRLs for crops exclusively used for animal feed production for the sake of consumer health. As only in this case we will get a complete picture as well as the necessary data."

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 V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bispyribac, metosulam, oryzalin, oxasulfuron and triazoxide in or on certain products.

(PLAN/2023/948)

The Commission introduced the draft Regulation (revision 4) containing non-approved substances for which the MRLs are already set at the LOQ in Annex II to Regulation (EC) No 396/2005 and proposed to include then in Annex V to that Regulation. The

Commission informed that active substance lemon essential oil had been taken out from the draft Regulation waiting for the decision on the renewal of approval of orange oil to have further information on the main component of the essential oil, D-limonene. The draft Regulation was not notified to trading partners via the WTO/SPS notification procedure as there was no change of MRLs and the changes are purely of administrative nature (moving already existing MRLs from Annex II to Annex V of Regulation (EC) No 396/2005).

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion.

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

(PLAN/2023/1772)

This point was not discussed pending the outcome of the procedural questions discussed under Agenda item 01.02a.

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

(PLAN/2023/1863)

The Commission presented amendments of this draft Regulation where transitional measures for products placed on the market before the application date and complying with existing MRLs had been updated, taking into consideration an additional screening exposure assessment. The Commission explained that further revisions will be made in the light of some fall-back Good Agricultural Practices (GAPs) that were provided by EFSA before the meeting and that had not yet been taken into account in this draft. The Commission also presented the comments received from Member States and Tea Herbal Infusions Europe (THIE) and referred to a letter the applicant had shared with the Commission and with several Member States. All the comments received were discussed in detail.

Member States found the approach proposed by the Commission generally appropriate and some of them indicated that they would submit further comments.

Member States were invited to send comments by 15 December 2023 on the revised version to be circulated by the Commission. [Post -meeting Note: as the sending of the revised version was delayed, a new deadline for Member States to comment has been set to 21 December 2023).

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for dithianon in or on certain products (Art. 12).

(PLAN/2023/1782)

The Commission confirmed that there were no changes to the previous version of this draft Regulation presented at the meeting of this Committee in September. The consultation of the trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organisation (WTO) were launched as lowering of some EU MRLs is proposed.

Member States were invited to send comments by 15 December 2023.

C.04 Exchange of views of the Committee on a draft Commission Regulation ~~as~~ as regards maximum residue levels for carbendazim and thiophanate-methyl in or on certain products.

(PLAN/2022/2853)

The Commission presented revision 7 of the draft Regulation, with minor modifications compared to the previous one. The clarification that EFSA concluded that there is evidence that both carbendazim and thiophanate-methyl are not clastogenic but aneugenic and that it was possible to establish Toxicological Reference Values (TRVs) for both substances was added in the recitals.

The Commission recalled that EFSA is currently working on the assessment of endocrine disrupting (ED) properties for carbendazim and thiophanate-methyl and noted that, based on some preliminary results shared by EFSA, for thiophanate-methyl ED properties seem to be confirmed. Nevertheless, the previously established TRVs are protective as a threshold mechanism applies. For carbendazim, the ED properties seem not to be confirmed. Based on those preliminary results, the Commission considered that no modification to the proposed draft Regulation would be needed based on the ED assessment.

EFSA recalled that, as the existing MRLs for citrus fruits were established based on GAPs that were authorised in South Africa, in order to consider maintaining some of those MRLs, a confirmation should be received whether GAPs for those substances on citrus fruits are still authorised in South Africa. The Commission informed EFSA that it had contacted authorities in South Africa and that, in case a reply would not be received in due time, the relevant MRLs would be lowered to the LOQ in the draft Regulation.

One Member State reiterated its position against the support of draft measures containing substances meeting the cut-off criteria and noted that in the recently published 2023 JMPR Summary Report[24], JMPR recommends the revocation of all MRLs for carbendazim due to insufficient toxicological information being provided to allow a re-evaluation of this substance to confirm or amend the TRVs.

Member States were invited to submit their comments by 23 November 2023.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fosetyl-Al, potassium phosphonates and disodium phosphonates in or on certain products.

(PLAN/2023/138)

The Commission presented revision 2 of the draft Regulation with minor modifications compared to the previous one.

One Member State had received a request from food business operators to consider increasing the new proposed MRL values for phosphonic acid in legume vegetables and pulses, as in their view the new MRL would be frequently exceeded. Based on recent monitoring data (2019-2022) provided by EFSA for these pesticide/crop combinations, and shared with Member Sates before the Committee meeting, the

[24] https://www.fao.org/3/cc8226en/cc8226en.pdf

Commission concluded that the values proposed in the draft Regulation were appropriate and would not need to be modified as requested by food business operators.

Member States were invited to submit their comments by 23 November 2023.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for deltamethrin, metalaxyl-M, thiabendazole and trifloxystrobin.

(PLAN/ 2023/326)

The Commission presented revision 3 of the draft Regulation with minor modifications compared to the previous one. For deltamethrin, based on the feedback from several Member States, the Commission proposed to set the MRL for apples at 0.2 mg/kg based on the existing CXL as fall-back Good Agricultural Practice (GAP) and using the conversion factor of 1. For lettuces, one Member Stated indicated that some fall back GAPs could be considered in order to set an MRL at 0,4 mg/kg. For metalaxyl, the Commission reported on the information received from a Member State indicating that the extrapolation to "herbs and edible flowers" from lettuces was possible, because the field trials were performed on open leaf varieties. For thiabendazole, the Commission shared information from EFSA indicating that the application of the peeling factor from mangoes to papayas was not appropriated and therefore the MRL for papayas is proposed to be set at the LOQ due to the exceedance of the acute reference dose (ARfD) identified. The consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organisation (WTO) were launched as lowering of some EU MRLs is proposed.

Member States were invited to send comments by 23 November 2023.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenthrin.

(PLAN/ 2023/951)

This point was not discussed pending the outcome of the procedural questions discussed under Agenda item 01.02a.

C.08 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for cyproconazole, isopyrazam and spirodiclofen in or on certain products.

The Commission introduced revision 1 of the draft Regulation containing active substances cyproconazole, isopyrazam and spirodiclofen and provided an overview, following the comments received after the previous meeting. The Commission informed that the amended EFSA reasoned opinion has been published[25] which now includes the review of CXLs of isopyrazam in or on azaroles/Mediterranean medlars and kaki/Japanese persimmons.

The Commission had received comments from Member States who indicated not to be able to support the setting of MRLs for active substances that are not approved in the EU due to them meeting the cut-off criteria. The Commission clarified that all substances in the draft Regulation meet the cut-off criteria according to the Regulation

[25] European Food Safety Authority; "Reasoned Opinion on the review of the existing maximum residue levels for isopyrazam according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2021;19(7):6684.

on Classification, Labelling and Packaging (CLP Regulation – Regulation (EC) No 1271/2008[26]), but that, nevertheless, since the MRL Regulation (EC) No 396/2005 follows a risk based approach and not a hazard based one, the proposed MRLs can be set as they had been found to be safe by EFSA in a risk assessment.

A Member State clarified that it could support the proposed MRLs for cyproconazole and spirodiclofen as for those two substances the approval expired and hence no implementing Regulation under Regulation (EC) No 1107/2009 had formally established that they would meet the cut-off criteria. It would however not support the MRLs for isopyrazam since in this case a non-renewal decision had been taken. Two Member States indicated that, if isopyrazam remained in the draft Regulation, they intend to vote against the draft Regulation.

Member States were invited to send comments by 15 December 2023.

C.09 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 1,4-dimethylnaphthalene, difluoroacetic acid (DFA), fluopyram and flupyradifurone in or on certain products.

(PLAN/ 2023/2305)

The Commission outlined revision 1 of the draft Regulation and its contents. As regards 1,4-dimethylnaphthalene, an MRL application on EU uses on potatoes had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. In addition, information that was previously unavailable during the Article 12 MRL review was assessed by EFSA, concluding that some data gaps were filled, and the relevant footnotes could be deleted. As regards fluopyram an application based on EU uses was submitted for various commodities of plant origin and an application for import tolerances based on United States GAPs for "pome fruits" and peanuts/groundnuts was submitted pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005. In addition, one Member State request a fast-track application for fluopyram in pumpkin seeds. As regards difluoroacetic acid (DFA) and flupyradifurone, two applications based on EU uses, as well as import tolerances based on Australian, Brazilian and United States' GAPs for several commodities of plant origin and honey, were submitted.

For fluopyram, the Commission highlighted that the draft Regulation proposes to lower the existing MRL for pome fruits from 0.8 to 0.6 mg/kg based on a less critical use authorised in the United States.

For DFA and flupyradifurone, the Commission clarified the draft Regulation implements the risk management decisions that were discussed and agreed at the last meeting of this Committee in September 2023, which included the setting of MRLs for DFA taking into account the soil uptake in rotational crops, and the lowering of the MRL for flupyradifurone in kales from 5 to 4 mg/kg.

One Member State expressed its general agreement with the proposal for DFA/flupyradifurone and suggested to keep a consistent approach for the future, i.e. setting MRLs for rotational crops to consider soil uptake by default without the need of case by case discussions with Member States each time. It also noted that the lowering of the MRL for flupyradifurone in kales may cause delays in the adoption of the draft Regulation, as for this reason a WTO/SPS consultation would be necessary.

[26] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

Another Member State recalled earlier discussions at a previous meeting of this Committee in September 2021 concerning the proposal to lower the existing MRL for fluopyram in pome fruits (and other crops) in order to allow increasing other MRLs and noted that the existing MRL was also based on uses in Canada, for which no information was available whether that use was still applicable. In addition, it noted that the existing MRL for pome fruits in both US and Canada is still set at 0.8 mg/kg. Lastly, that Member State recalled that some reservations to CXLs were introduced in 2019 due to the exposure being close to 100% ADI, and wondered whether it would be appropriate to increase MRLs at all.

Another Member State supported the decision taken to set MRLs for DFA on rotational crops and highlighted the urgency of finalising the work on the new International Estimated Short Term Intake (IESTI) equations, as residues may occur at the level of the MRL.

In the light of these discussions, the Commission proposed modifying the draft proposal, keeping only the proposed increase of the MRL for pumpkin seeds according to the fast-track procedure as its contribution to the ADI is minimal. It also noted that, as several MRLs are proposed to be lowered in the framework of this draft Regulation, the WTO/SPS consultation would be necessary anyhow.

Two Member States supported this approach, and one of them enquired if it would be possible to set different application dates for the MRLs included in this measure (i.e., not to set a deferred application date of 6 months for those that are proposed to be increased).

The Commission noted that it would not be technically possible to set different application dates for different pesticide/product combinations included in the same draft Regulation, due to technical issues related to the EU Pesticide Database. It recalled attempts in the past to do this which resulted in several major issues with the database.

Member States were invited to submit their comments by 23 November 2023.

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

(PLAN/ 2023/2307)

The Commission outlined revision 1 of the draft Regulation and its contents. Applications requesting a modification of the existing MRLs for prothioconazole in garlic, onions, shallots, celeriacs/turnip rooted celeries, rapeseeds/canola seeds, sugar beet roots and chicory roots were submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005. In addition, information that was previously unavailable during the Article 12 MRL reviews (confirmatory data) was assessed by EFSA. EFSA concluded that some gaps were filled, and the relevant footnotes could be deleted, while this was not the case for other data gaps which were proposed to be set at the LOQ.

One Member State informed that, data possibly addressing some of the pending data gaps, were provided in the framework of another Article 6 application for prothioconazole, that is now being evaluated by that Member State.

The Commission therefore proposed to modify the draft Regulation in order to only cover the Article 6 application for sugar beet roots and chicory roots, while putting on hold for the time being the decision on the Article 12 confirmatory data and on the Article 6 application for onions, shallots, garlic, celeriacs/turnip rooted celeries and

rapeseeds/canola seeds (which are related to the Article 12 confirmatory data). Those can be addressed together with the decision on the new Article 6 application currently under assessment.

One Member State supported this proposal and noted that this would also avoid further emergency authorisations granted by Member States for prothioconazole on sugar beet roots and chicory roots.

Member States were invited to submit their comments by 8 December 2023.

C.11 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels napropamide, pyridaben and tebufenpyrad for in or on certain products.

(PLAN/ 2023/2190)

The Commission presented for the first time a draft Regulation to review the tentative MRLs that were set during the MRL review under Article 12 of Regulation (EC) No 396/2005 as data gaps were identified at that time for napropamide, pyridaben and tebufenpyrad. Based on EFSA reasoned opinions on the confirmatory data[27,28,29], for some food groups the data has been evaluated to be sufficient to support the current MRLs, whether at LOQ or at a higher level. For certain food groups the applicant did not submit data and explained that the uses were not supported anymore in the EU. Therefore, these MRLs will be lowered to, or maintained at, the LOQ. On request of a Member State the Commission also clarified that an exceedance in the acute reference dose (ARfD) of the MRL of tebufenpyrad for table grapes in children will be addressed in the current draft Regulation.

Member States were invited to send comments by 15 December 2023.

C.12 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for dithiocarbamates in or on certain products.

(PLAN/ 2023/2019)

The draft Regulation, in its revision 0, reviews the MRLs for maneb, mancozeb, metiram, propineb, thiram and ziram. It proposes maintaining the current residue definition, i.e. *"dithiocarbamates expressed as carbon disulfide (CS2)"*, omitting the term "determined" proposed by EFSA, to allow for further development of the analytical methods enabling determination of the actual compound. The recitals are grouping products for which similar conditions apply, e.g., MRLs based on CXLs that are safe for consumers, MRLs based on CXLs for which EFSA could not exclude a health risk but for which other lower MRL options or background levels are available. The Commission proposed lowering MRLs without transitional measures that for those MRLs based on CXLs for which EFSA identified a consumer health risk.

A Member State proposed that, if for all products in a group the same background (BG) level applies, then that level should also apply to the "others" product category of that group. Another Member State supported the proposed residue definition. Another

[27] European Food Safety Authority; "Evaluation of confirmatory data following the Article 12 MRL review for napropamide", EFSA Journal, 2023;21(7):8125

[28] European Food Safety Authority; "Evaluation of confirmatory data following Article 12 MRL review and modification of the existing MRLs in pome fruits for pyridaben", EFSA Journal, 2023;21(4):7970

[29] European Food Safety Authority; "Evaluation of confirmatory data for tebufenpyrad to address data gaps identified in the MRL review" EFSA Journal 2023;21(2):7774.

Member State questioned on substances belonging to the dithiocarbamates group, which are not included in the draft Regulation, and for which the default MRL value (0.01 mg/kg) applies, regardless of the background levels (e.g., ferbam). The Commission clarified that the default level would continue to apply for those substances. That Member State also suggested that EFSA should perform an additional worst-case consumer risk assessment for all uses based on the highest Supervised Trials Median Residue (STMR) values and/or the Highest Residue (HR) values of CS2 and the lowest toxicological reference values of the most toxic compound, however EFSA already provided such an evaluation using the existing MRL values, which are higher than the STMR/HR values and using the TRVs for metiram (0.026 mg/kg bw). The same Member State considers that natural background levels should only be considered if more than 10% of organic samples provide quantified results. However, EFSA used the upper bound scenario, i.e., used the LOQ value for left-censored data.

The same Member State provided comments from a third country, requiring that the MRL for vine leaves should be set at 0.2mg/kg (based on its monitoring data of 29 samples), instead of 0.1 mg/kg proposed by EFSA. The research center for grapes and a grapes growers' association from another third country provided comments on the significance of mancozeb for their crops and supporting the MRL of 2 mg/kg for table grapes and 5 mg.kg for wine grapes to maintain trade.

Member States were invited to submit their comments by 8 December 2023.

C.13 Exchange of views of the Committee on a draft Commission Implementing Regulation as regards a coordinated multiannual control programme of the Union for 2025, 2026 and 2027 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

(PLAN/ 2023/2295)

The Commission provided an overview of the draft Regulation, in its revision 0. The substance cyflumetofen was added in Part C of Annex I for products of plant origin.

Member States were invited to submit their comments by 8 December 2023.