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

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table. As there are not many substances left in the table and new ones have not been added lately, the Commission proposed to give an update only every other meeting of the Committee.

2. Confirmatory data Art. 12 follow-up

a) Cases where an EFSA Reasoned Opinion (RO) has been published

In its ROs on the assessment of Article 12 confirmatory data for diquat and thiabendazole, the European Food Safety Authority (EFSA) reported the need for some risk management considerations.

For diquat, the existing EU Maximum Residue Level (MRL) for all products of animal origin was based on the livestock dietary burden reflecting EU authorised uses for feed in 2015. A new dietary burden was calculated, showing that livestock is no longer exposed to residues via feed produced in the EU and that a no-residue situation is expected. The data gap concerning a confirmatory method and an independent laboratory validation for enforcement in products of animal origin has been addressed. The enforcement method for the current residue definition is validated at a limit of quantification (LOQ) of 0.005 mg/kg for milk and 0.01 mg/kg for all other products of animal origin. Considering the withdrawal of EU uses in feed, the Commission proposes lowering all the existing MRLs to the LOQ. This will align EU MRLs with Codex MRLs (CXLs) established in 2019 except for milk for which the CXL is 0.001mg/kg.

For thiabendazole, the data gap for avocado was addressed by new trials leading to a MRL lowered from 20 mg/kg to 7 mg/kg. However, the Commission proposes to align the EU MRL with the existing CXL of 15 mg/kg as it is safe for consumers. For animal products, the livestock dietary burden was re-calculated considering EU authorised uses for feed, showing that for all animal products a no-residue situation is expected. However, thiabendazole is authorised for use in veterinary medicinal products (VMP) for bovines and goats, and MRLs are set in

Regulation (EU) No 37/2010. Therefore, the Commission proposed lowering all MRLs for products of animal origin to the LOQ, with the exception of the MRLs for bovines and goats (including their milks) which should be aligned with those set in Regulation (EU) 37/2010. The data gap for information on the residues of the metabolite benzimidazole was not addressed, therefore, the duration of the footnote requesting this information should be extended.

One Member State informed that it had identified an acute risk for both the MRL of 7 mg/kg and the CXL of 15 mg/kg for thiabendazole in avocados using the International Estimate of Short-Term Intake (IESTI). EFSA confirmed that when running the IESTI equation with the values of 7 and 15 mg/kg, an acute risk is identified. However, EFSA explained that while the MRL is set for the whole product, the consumer risk assessment for commodities with inedible peel may be refined taking into account the residue concentration in pulp fraction only. Therefore, EFSA proposed to run the consumer risk assessment after the meeting with the IESTI equation and considering the peeling factor for avocadoes to check whether the derived MRL of 7 mg/kg and the CXL of 15 mg/kg are safe for consumers.

Lastly, the Commission informed that, in its RO on the assessment of Article 12 confirmatory data for deltamethrin, EFSA identified an erroneous calculation of the acute exposure assessment for dried pulses and cereals, due to a bug in the EFSA Pesticide Residue Intake Model (PRIMo) rev.3.1, which has now been corrected in a revised version that was re-published. According to the revised calculations, an exceedance of the acute reference dose (ARfD) was identified for the CXL for dry beans. Consequently, the Commission proposed to lower the MRL for dry beans to the LOQ, differently to what was proposed earlier. The Commission also informed that an applicant had submitted additional data on deltamethrin residues in several crops to EFSA and to the Commission, requesting to still consider them. The Commission clarified that this was no longer possible given the deadlines and the advanced stage of the procedure.

Member States were invited to submit their comments by 21 October 2022.

b) Cases where data have not been submitted

Concerning footnotes of tentative MRLs for which the deadline to submit data has expired, the Commission presented a table containing 6 substances (2,4-DB, diuron, iodosulfuron, mesotrione, methoxyfenozide and pyraflufen-ethyl) for which no information had been submitted by applicants within the legal deadlines.

EFSA and Member States were invited to check this and submit their possible comments by 21 October 2022.

c) Missing analytical standards follow up

The Commission provided an update of missing analytical standards for substances and/or their metabolites, marked with footnote (A) next to the residue definition of each substance concerned, and informed that reminder letters had been sent out to applicants that had not yet provided information on the commercial availability of the following substances within the legal deadlines: cyflufenamid (E-isomer), fluroxypyr conjugates and spiroxamine carboxylic acid metabolite M06. The situation will be further monitored and followed up by the Commission to ensure commercial availability of analytical standards.

3. List of non-approved substances for follow up

In June 2022, the Commission sent the first mandate to EFSA to address a first batch of non-approved substances (azocyclotin, bifenthrin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin, and profenofos) for which potential consumer risks were identified. The outcome of EFSA's assessment is expected by 22 May 2023.

A second mandate to EFSA is planned for a next batch of non-approved substances, and its drafting will start in 2023. The Commission has pre-selected some of the active substances that may be covered by such mandate, as below:

- Diquat: the recent peer review from EFSA highlighted a need of revision of the residue definition and of CXLs for products of animal origin;
- Dicloran: while MRLs were already revised in 2014 following the Article 12 review for this substance, a CXL was kept that has now been revoked by the Codex Alimentarius Commission (CAC);
- Phorates: the current residue definition does not include sulfoxides, which are relevant according to the EU Reference Laboratories, and are included in the Codex residue definition;
- Carbaryl, cyanides, methoprene, quinclorac: a Member State identified them as a priority due to potential risks for consumers;
- Phoxim, pyrasulfotole, saflufenacil: never authorised in the EU.

For terbufos, an acute consumer risk could not be excluded, thus, it was decided to urgently address this substance through a dedicated EFSA mandate according to Article 43 of Regulation (EC) No 396/2005.

Member States were invited to submit their comments by 28 October 2022.

4. Use of footnotes under Article 12 when the MRL is set at LOQ

The Commission presented a revised version of the draft general principles to define a harmonised approach on setting footnotes for MRLs set at the LOQ, following the discussion paper presented at the previous meeting. While this question arose for MRLs set under the Art. 12 review procedure, it could also be applicable to other situations. Once agreed, the approach could be integrated into the Commission Working Document on drafting measures to amend pesticides MRLs following Art. 12 of Regulation (EC) No 396/2005 (SANCO/11485/2012).

Possible scenarios were presented and discussed in the form of a table, considering the various types of data gaps (e.g. analytical methods for enforcement, residue trials, residue definition, metabolism, rotational crop studies) and various bases for setting MRLs (EU GAP, Codex maximum residue limit (CXL), third country GAP (import tolerances), no use).

Member States were invited to share their comments on the revised proposal by 21 October 2022.

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

The Commission provided an overview of the main outcomes of the last meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation held in May and July 2022.

A draft measure restricting the use of penflufen only to treat cereal seeds before or during sowing and seed potato tubers before or during planting, was voted by the Committee and obtained a favourable opinion.

Two draft measures proposing the non-approval as basic substances of calcium propionate and black soap E470 were voted by the Committee and obtained a favourable opinion.

EFSA published its conclusions on New Active Substances for which discussion has started: Limestone powder (calcium carbonate), *Purpureocillium lilacinum* strain PL11, *Trichoderma atroviride* strain AT10, isoflucypram.

Finally, the Commission provided 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.

A.03 Specific substances:

1. Glufosinate ammonium

The Commission informed that there were no news on this substance as internal discussions were still ongoing. A Member State commented that the situation was very unsatisfactory as the last toxicological evaluation from JMPR was from 2012 and the grace period expired in January 2020. The Commission will inform the Member States as soon as there will be new information on the next steps with that substance.

2. Glyphosate

Regarding the Article 12 review of the MRLs for glyphosate and the pending application under Article 6 of Regulation (EC) No 396/2005 on borage seeds, further discussion on the draft Regulations will be kept on hold until the renewal of approval process has been finalised. The Commission also provided information and views that were shared by the European Coffee Federation (ECF) regarding the MRL for green coffee beans. According to ECF, this MRL should remain at the level of 0.1mg/kg, not be lowered to 0.05*mg/kg proposed by EFSA[1], because the studies/trials supporting this lower MRL, performed on the Canary Islands of Spain, hardly represent the situation of glyphosate use across the globe and could lead to trade disruptions. The Commission recalled the possibility to apply for an import tolerance as an available option.

3. Ethylene oxide

The Commission made reference to the communication received from some Member States and a statement from Starch Europe on the RASFF notifications[2] concerning the findings of 2-chloro ethanol (2CE) in gluten wheat. The information received concerning the use of monochloramine (MCA) as a processing aid, authorised at national level, indicated that the presence of 2CE is unintentional and the consequence of the authorised use of MCA for the disinfection of process water, thus not relating to any use of the non-approved pesticide ethylene oxide (ETO). To clarify this, the Commission services changed the heading of the respective RASFF notifications to remove the link to ETO in those cases, but, nevertheless, reflect the findings of 2CE which were non-compliant with the corresponding MRL. The

[1] https://www.efsa.europa.eu/en/efsajournal/pub/5862
[2] 2022.1006, 2022.2206, 2022.2318, 2022.2433 and 2022.3015

enforcement authorities of some Member States, informed that they would recall wheat gluten or products containing wheat gluten in the case of 2CE findings not complying with the MRL for ETO (sum of ETO and 2CE, expressed as ETO), but not if there were no quantified findings of 2CE in such products.

4. Bacillus thuringiensis

The Commission informed that in the last meeting of the Standing Committee on Plants, Animals, Food and Feed, section Phytopharmaceuticals – Legislation, Member States were informed that after bilateral discussions on a potential mandate with EFSA and the European Centre for Disease Prevention and Control (ECDC), a proposal for a renewal of approval setting risk management conditions seems the most appropriate way to proceed. The Commission suggested to address the uncertainties on dietary exposure based on the information available for each strain, and proposed to set pre-harvest intervals and a request for monitoring data on residues. The discussions are still ongoing, but if the outcome would be that the pre-harvest intervals were to be set, then setting the MRLs should be discussed in this Committee.

5. Haloxyfop-P

The Commission informed that it sent a mandate in accordance with Article 43 of Regulation (EC) No 396/2005 to EFSA in May 2022 and that the deadline for the Reasoned Opinion is 25 February 2023. EFSA has already shared a draft version with Member States and requested comments by 5 October 2022.

6. Acetamiprid

The Commission recalled that during the previous meeting, a Member State presented evidence that high levels of the acetamiprid metabolite N-desmethyl-acetamiprid (IM-2-1) were found in some food products, especially in spinach, despite the fact that this compound is not included in the current residue definition for acetamiprid. Following that meeting, some other Member States also reported similar findings. Moreover, a Member State informed that a potential acute consumer risk for pears and lettuces was identified when using the most recent version of PRIMo (rev. 3.1). In addition, a recent study[3] on methods for detection of pesticide residues in the cerebrospinal fluid of children detected IM-2-1 in most of the analysed samples.

Therefore, in order to investigate the aspects above, the Commission sent a mandate in accordance with Article 31 of Regulation (EC) No 178/2002 to EFSA in July 2022; the deadline for the Reasoned Opinion is 31 July 2023. The mandate requires EFSA to provide advice if new evidence, made available since the assessment conducted prior the renewal in 2018, warrants re-evaluation of i) toxicological parameters used for the risk assessment of acetamiprid during the renewal process, including toxicological endpoints, ii) the residue definition for acetamiprid in products of plant origin, and iii) the safety of existing MRLs.

One Member State was approached by an applicant asking whether the mandate to EFSA was publicly available. EFSA clarified that once it is formally accepted it will be published on the Open EFSA portal[4].

[3] Laubscher, B., Diezi, M., Renella, R. et al. Multiple neonicotinoids in children's cerebro-spinal fluid, plasma, and urine. Environ Health 21, 10 (2022). https://doi.org/10.1186/s12940-021-00821-z

[4] https://open.efsa.europa.eu/

7. Bromide

As announced at the last meeting of this Committee, a mandate on bromide was sent to EFSA in April 2022 with a deadline of 31 December 2023. Based on the outcome, the Commission may request EFSA to carry out a follow-up assessment on dietary exposure and associated MRLs.

One Member State informed of high level findings of bromide in animal commodities and in honey which exceed current MRLs.

8. Bifenazate

Regulation (EU) 2022/698[5] renewed the approval for bifenazate with a use restriction to non-edible crops in permanent greenhouses, because the risk assessment for edible crops could not be finalised. This was due to data gaps that could have an impact on the assessment of residue levels in the different crops and due to missing toxicological reference values (TRVs) for metabolite D3598 (bifenazate-diazene) included in the residue definition. Therefore the Commission proposed to draft a Regulation where all MRLs, including the ones which are based on CXLs, are lowered to the LOQ.

9. Thiophanate-methyl/carbendazim

The Commission informed that an Article 43 mandate, requesting EFSA to assess possible endocrine disrupting (ED) properties will soon be sent to EFSA. In parallel, the Commission is considering taking action on the acute health concerns that were identified by EFSA in 2021[6], without waiting for the finalisation of the ED assessment. In addition, the Commission will table the new toxicological reference values (TRVs) for thiophanate-methyl for endorsement by the SCoPAFF – Legislation.

10. Thiacloprid

Following the non-renewal of thiacloprid in 2020[7], the Commission informed that it is preparing a mandate to EFSA according to Article 43 of Regulation (EC) 396/2005 to perform a risk assessment considering the updated TRVs[8], the latest version of PRIMo and any confirmatory data. Subsequently, and based on the EFSA recommendation, the Commission will prepare a draft Regulation lowering certain MRLs to the LOQ.

11. Imidacloprid

Following the expiry of the grace period in June 2022, the Commission plans to prepare a draft Regulation lowering existing MRLs to the LOQ, similar to the Regulation lowering MRLs for clothianidin and thiametoxam to prevent the global decline of pollinators and implementing the European Green Deal and Farm to Fork Strategy.

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

[6] https://www.efsa.europa.eu/en/efsajournal/pub/6773

[7] https://eur-lex.europa.eu/eli/reg_impl/2020/23/oj

[8] https://www.efsa.europa.eu/en/efsajournal/pub/5595

12. Trimesium cation

The Commission provided information from Tea and Herbal Infusions Europe (THIE) regarding the presence of trimethyl-sulfonium cation (trimesium) in tea, herbal and fruit infusions. MRLs of trimesium are applicable based on the residue definition *"trimethyl-sulfonium cation, resulting from the use of glyphosate"*. According to THIE, and based on industry investigation and studies, findings of trimesium are unavoidable in dried plant products, but they occur as a processing contaminant and not due to the use of glyphosate. In this sense, it should not be considered as a "residue" in the context of Regulation (EC) 396/2005 and should be decoupled from glyphosate. The Commission recalled the current situation for glyphosate (see point A.03.02). Considering the low average annual MRL exceedance rate[9] and as the discussion on trimesium would benefit from the outcome of the renewal process for glyphosate, it is appropriate to align the timelines for this discussion with that on glyphosate to better identify possible options. In the meantime Member States should collect monitoring data. Stakeholders will be also invited to provide further monitoring data to be able to get a better overview on the presence of trimesium in different foodstuffs first.

13. Oxamyl

In the recent EFSA conclusions on the peer review for oxamyl (in the context of the renewalof approval of that substance) the Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) were both lowered by a factor of 10, to 0.0001 mg/kg. With these new extremely low TRVs, EFSA identified exceedances of the ARfD in several products. In view of the risk to consumers, the Commission intends to mandate EFSA under Article 43, without waiting for the outcome of the renewal process, to perform the consumer exposure assessment with the new TRVs and to investigate the need and feasibility of LOQs lower than 0.01* mg/kg. The SCoPAFF – Legislation will be invited to take note of this mandate and endorse the new TRVs at its upcoming meeting on 13 October 2022.

14. Meptyldinocap

The Commission informed of the outcome of a discussion it had with two Member States on the responsibilities for taking the role as Evaluating Member State (EMS) for assessing the confirmatory data under Article 12. The applicant withdrew the application for the renewal of approval procedure, therefore the assigned Rapporteur Member State for that process could not acquire expertise on the substance. As the EMS who previously dealt with the Article 12 MRL review has this expertise, it was decided that this EMS should carry out the confirmatory data assessment. The two concerned Member States had agreed to this and no objections were received from any other Member State.

15. Matrine

The Commission informed of a communication from a Member State regarding the feasibility of using processing factors (PFs) for the extract from liquorice roots, as matrine does not occur in those roots, rather on the roots of the Sophora plant that are co-collected with liquorice roots as extraneous plant material. While there are industry guidelines for the tolerance of extraneous plant material[10], these tolerances

[9] 0.2%, based on EFSA monitoring data for 2018-2019-2020

[10] https://www.teeverband.de/files/bilder/Publikationen/Recht/2018-07-17_Compendium_of_Guidelines_for_Herbal_Infusions_-_ISSUE_6.pdf

can only be applied if there is no consumer health risk. Therefore, in the case of matrine in liquorice extract, PFs cannot be used, rather the submission of data to perform a risk assessment should be prioritised and forwarded to EFSA. Towards this direction, a Member State informed that it is aware that the confectionery industry is performing studies assessing possible genotoxiclity of matrine and that they will be submitted to its national agency for risk assessment.

16. Sodium hydrogen carbonate

Currently two separate entries exist in the EU MRL database; one as "Sodium hydrogen carbonate (basic substance)" and another one as "Sodium hydrogen carbonate (low risk active substance)". This is because the same active substance was approved by different Regulations at different times and following different processes. As a result, the first entry appears in Annex IV of Regulation (EC) 396/2005 (no MRL necessary), while for the second one the default MRL of 0.01mg/kg according to Article 18(1)(b) applies. As both entries refer to the same active substance, this discrepancy may create confusion with Member States' competent authorities responsible for enforcement. The Commission proposed to align the two entries and to include "Sodium hydrogen carbonate (low risk active substance)" in Annex IV as well as the substance, as confirmed by EFSA[11], fulfils the Annex IV inclusion criteria[12].

Member States were invited to submit their comments by 21 October 2022.

17. Terbufos

The Commission will draft a mandate in accordance with Article 43 of Regulation (EC) No 396/2005, requesting EFSA to provide a targeted risk assessment for the existing MRLs, as a potential acute risk for bananas was identified in the past. The mandate may also request EFSA to assess the suitability of the existing residue definitions and to consider aligning them with the existing Codex ones. The mandate will be sent to EFSA between the end of 2022 and the beginning of 2023. Lastly, the Commission recalled that at the meeting of the Codex Committee on Pesticide Residues (CCPR) in July 2022, a concern form was sent by the EU.

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

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

EFSA reported that outputs addressing 12 processes[13] had been adopted since the last meeting of this Committee.

Currently, outputs addressing 46 such processes are at different steps of the procedure. Out of these, 7 are under scientific assessment and 39 under clock-stop as additional data had been requested (30 under Regulation (EC) No 396/2005 and 9 under Regulation (EC) No 1107/2009). 2 new mandates have been received in September 2022 with submissions via IUCLID.

An exercise to ask for Member States' feedback on long lasting clock-stops was launched with a deadline by 23 September 2022, as there are 14 clock-stops with a duration over 6 months. So far, no updated Evaluation Report (ER) was received,

[11] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5407
[12] SANCO/11188/2013, Rev.2 Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) 396/2005
[13] Each process receives a so called "EFSA question number".

but 4 ERs are expected by the end of 2022. Member States were kindly requested to provide feedback if not done yet, and to consult the applicants on the status of these applications if needed.

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

EFSA presented the state of play of the ongoing Article 12 reviews. Since the last meeting of this Committee, 3 MRL reviews were finalised, 21 are on hold, 15 are currently being assessed at different stages of the procedure, while for 16 substances data is pending. The progress report table is available for interested stakeholders [14].

3. Update on other mandates

Adoptions since the last meeting

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

- a statement under Article 31 of Regulation (EC) No 178/2002 summarising the different MRL proposals for potassium phosphonates made by EFSA in the joint review under Articles 12 and 43 of Regulation (EC) No 396/2005 and the latest Article 10 Reasoned Opinion for which risk management decisions are still pending and which was adopted in May 2022 (cf. agenda item A.16.03).
- a technical report under Article 31 of Regulation (EC) No 178/2002 to support discussions of the Commission with Member States about measures to address possible shortages of food and feed supply due to the Russian invasion of Ukraine, which was adopted in June 2022 (cf. agenda item A.11).
- a targeted review of MRLs under Article 43 for indoxacarb, for which the Reasoned Opinion was adopted in July 2022.
- a statement under Article 43 of Regulation (EC) No 396/2005 on the short-term (acute) dietary risk assessment for the temporary MRLs for nicotine in rose hips, teas and capers, which was adopted in September 2022 (cf. agenda item B.09).

Ongoing mandates

The following new mandates were received by EFSA from the Commission:

- mandate for a Guidance document on the assessment of studies concerning pesticide residues in rotational crops, which is planned to be submitted to the Member States and public consultation prior to its finalization, expected by end of January 2023.
- mandate for an updated consumer exposure assessment under Article 43 of regulation (EC) No 396/2005 for haloxyfop-P (cf. agenda item A. 03.05), which is expected to be finalised end February 2023.
- mandate for a targeted review of MRLs under Article 43 of Regulation (EC) No 396/2005 for 10 non-approved substances (azocyclotin, bifenthrin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos), which is expected to be finalised in 2022.

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

- mandate for scientific and technical assistance on toxicological properties and MRLs of acetamiprid and its metabolites under Article 43 of Regulation (EC) No 396/2005, which is expected to be finalized end July 2023. EFSA launched a survey to collect information on the available monitoring data on acetamiprid metabolites by end September 2022.
- mandate for a scientific opinion under Article 29(1) of Regulation (EC) 178/2002 on the risks for human health related to the presence of bromide ion in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed, which is expected to be finalised by end March 2024.
- mandate for a scientific opinion under Article 29(1) of Regulation (EC) 178/2002 on the re-evaluation of the existing health-based guidance values for copper, expected by end of December 2022. The public consultation on the draft opinion prepared by EFSA's Scientific Committee closed in August 2022 and the respective EFSA working group is currently addressing the comments received.

Forthcoming mandates currently under discussion

The following mandates are currently being prepared:

- a mandate under Article 31 of Regulation (EC) 178/2002 for an exposure assessment concerning the risks for public health related to the presence of benzalkonium chloride (BAC), didecyldimethyl ammonium chloride (DDAC) and chlorates in/on fish and fish-products.
- a mandate for a scientific argumentation to support the modification of the acute risk assessment methodology (IESTI).
- a mandate for the assessment of ED properties in line with Commission Regulation (EU) 2018/605 and for a targeted review of MRLs for carbendazim and thiophanate-methyl.

4. Other issues

International – EFSA Report on scientific support for preparing the EU position for the 53rd and 54th Sessions of CCPR

The Commission had mandated EFSA under Article 43 of Regulation (EC) No 396/2005 for a report on scientific support for preparing the EU position for the 53rd Session of CCPR. The report was adopted in July 2022 and published on 19 September 2022[15].

A mandate under Article 43 is under discussion for the yearly report on scientific support for preparing the EU position for the 54th Session of CCPR. The exact scope is currently still being discussed between EFSA and the Commission.

EFSA 2021 Annual Report on Pesticide Residues

EFSA informed that the consultation of Member States on the draft 2021 monitoring report will be launched in January 2023. Member States should provide their data by end September 2022 for the 2021 National Summary Report and the 2023 Multiannual National Control Programmes.

[15] https://www.efsa.europa.eu/en/efsajournal/pub/7521

Cumulative Risk Assessment

The EFSA Scientific report on Retrospective cumulative dietary risk assessment of craniofacial alterations by residues of pesticides has been adopted and will be published shortly.

EU database of processing factors for pesticide residues

EFSA has started the second update of the EU database of processing factors for pesticide residues (FPA GP/EFSA/AMU/2020/02) in collaboration with the German Federal Institute for Risk Assessment (BfR). New processing studies will be collected from Member States by end August 2023.

Pesticides Steering Network/Transparency/IUCLID

EFSA informed that following the first IUCLID post-transparency MRL dossiers received, one Reasoned Opinion has already been adopted (copper-hydroxide) and 2 are ongoing.

In terms of noted benefits, the "dossier header", the Good Agricultural Practices (GAP) tables and the summary on MRL request allow to retrieve the essential information of an MRL application. The IUCLID format allows detailed description of the GAPs, but EFSA will further improve it.

Main issues encountered are i) a mismatch between the GAP and the requested MRLs (pre-existing issue), ii) a difference between the GAP(s) submitted by the applicant in IUCLID and the GAP(s) assessed by the Evaluating Member State (EMS) in the ER, and iii) studies submitted by the applicant in IUCLID not mentioned/assessed by the EMS in the ER.

EFSA reminded that the GAP defined in IUCLID is the reference for the assessment and that section 6.7.2 (Summary on the requested MRLs) is where the applicant shall specify the MRL proposal (if a commodity is omitted in this document, no MRL can be proposed in the EFSA opinion for this commodity).

From the first 48 IUCLID post transparency MRL dossiers received, 27 are pending finalisation of the admissibility checks, 21 were declared admissible by EMSs. From the 21 admissible dossiers, 13 are still pending finalisation of the confidentiality assessment (EFSA/applicant), 8 passed the confidentiality assessment.

EFSA is currently investigating further actions that can improve and increase the speed of the admissibility check and confidentiality assessment, for example by organizing ad hoc teleconferences between EFSA and the EMS to anticipate any issues encountered.

The 4th meeting of the Pesticide Steering Network (PSN)-IUCLID subgroup was held on 22 September 2022, for which minutes will be published online shortly[16].

Article 12 work programme

The Commission presented the work programme for 2023 as agreed with EFSA. The launch of the MRL review for gamma-cyhalothrin will start in January 2023 and for clopyralid will start in June 2023. The Committee agreed with the work programme as presented.

[16] https://www.efsa.europa.eu/en/events/4th-meeting-pesticide-steering-network-iuclid-sub-group

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

The Commission presented an update of the ongoing work on the harmonisation of MRLs for pesticides and VMPs. The working table was revised to include information on whether the active substances are also approved as biocides. Moreover, it was proposed to prioritise the substances based on the urgency for action according to clear criteria that were presented to the Member States.

One Member State supported the proposed prioritisation. EFSA suggested adding imazalil (known as enilconazole under the VMP Regulation) to the list of substances.

For cyfluthrin, the draft Regulation SANTE/11128/2021, proposes the alignment of MRLs for cattle and goat muscle between Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005. Cyromazine is included in the draft Regulation SANTE/10088/2022, which proposes lowering several MRLs but maintains the current alignment of MRLs in sheep products. For thiabendazole, the draft Regulation SANTE/10090/2022 proposes alignment of all MRLs. The draft Regulations were presented for vote during this meeting under agenda points B 03.00, B 06.00, and B 09.00, respectively.

Member States were invited to submit their comments by 28 October 2022.

A.06 Discussion on the inclusion of certain microorganisms into Annex IV:

The Commission gave an overview of the microorganisms for which the decision on inclusion or non-inclusion into Annex IV of Regulation (EC) 396/2005 was left to risk managers, as EFSA did not recommend including those substances into Annex IV due to data gaps. The Commission, based on the respective Review Reports for approval/renewal, proposed to add *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45, *Beauveria bassiana* strain IMI389521, *Beauveria bassiana* strain NPP111B005, *Purpureocillium lilacinum* strain PL 11 and *Streptomyces lydicus* strain WYEC 108 into Annex IV.

Member States were invited to submit their comments by 21 October 2022.

A.07 Monitoring of pesticides residues:

The Commission announced that the Working Group for the monitoring of pesticide residues will take place, only virtually, on 17 October 2022.

Member States were invited to nominate Experts by 10 October 2022.

A.08 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2022-2023:

The Commission provided an update on the state of play for the remaining substances listed in the overview table. The table was updated to include information about the extension of validity of, and changes to, the existing temporary MRLs that were established by Regulation (EU) 2022/1290 and that are proposed by the draft Regulation SANTE/10090/2022.

In addition, the Commission informed that the European Group of Mushroom Growers has shared the outcome of their studies investigating residues of mepiquat and chlormequat in cultivated mushrooms. The Commission will consider these studies and

share them with Member States before the next meeting of this Committee in November 2022.

A.09 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission thanked the Member States for their comments on the draft OECD Guidance document on the definition for risk assessment and informed of the progress made in the OECD expert group. One Member State indicated that in the toxicological part of the draft document there is a requirement to address mutagenicity for all trace metabolites and this will cause extra work and will impact the capacities of the evaluating bodies. The current planning is to have the guidance document in a final state during the third quarter of 2023 and ready for implementation during the fourth quarter of 2023.

Member States were invited to submit their final comments by 10 October 2022.

2. OECD Honey Guidelines

A Member State that attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. The first draft is ready but there are still topics to discuss, mainly the following: residue definition, decision tree for MRL setting, the non-target plants and rotational crops. On the study design which is well advanced there is a need for further discussion on the case of herbicides, including a protocol for herbicides and whether syrup trials should be maintained. The draft document is expected to be ready for commenting at the beginning of next year.

3. OECD Report on exposure models

The Commission drew the attention of the Committee to a survey launched by OECD on exposure models used in the regulatory context. This survey updates an earlier one that was conducted in 2012[17]. Member States were invited to make comments directly to the contact indicated by OECD by 15 October 2022. EFSA, the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA) have already been consulted by the Commission who will forward their comments.

4. Codex Alimentarius/JMPR issues

a) Guidelines for general principles for EU coordinated positions for CCPR

The Commission presented a first draft of a Technical Guideline for the development of EU coordinated positions for CCPR. The guideline was developed as a follow up from discussions held during the preparation for CCPR53, regarding the need to ensure the consistency and harmonisation of decision-making for the preparation of the EU's positions, as well as to improve the transparency of the whole procedure.

The document describes the principles that the Commission and Member States follow for defining agreed EU positions on the proposed CXLs prior to the annual CCPR meetings, and provides guidance for their presentation during those meetings. While this document strives to cover as many cases as possible, it is nevertheless noted that specific cases might arise which would require a case-by-case discussion to agree on an EU position.

[17] (ENV/JM/MONO(2012)37)

While the terms of reference of CCPR are not limited to the establishment of CXLs in food and feed products, but also consider other more horizontal matters in relation to the safety of food and feed containing pesticide residues, the scope of the current guidance will initially only cover matters related to the proposed CXLs. Expanding it to other matters may be considered in a second step.

The document will also include general introduction on the Codex Alimentarius and on procedural aspects of the development of the EU positions, but these preliminary chapters were not shared with Member States yet as they are currently still being discussed internally in the Commission.

Member States were invited to submit their comments by 28 October 2022.

b) Discussion paper on the Joint eWG CCPR/CCRVDF

The Commission presented an update of the work done by the joint Electronic Working Group (eWG) between CCPR and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). The eWG drafted a Discussion Paper and some questions that were shared with its members in order to better orientate its future work.

In its proposed reply to the Discussion Paper, the Commission highlights the fundamental role of data sharing as a cornerstone for better collaboration, and encourages the increased coordination both at risk assessment and at risk management level, through the establishment a joint JMPR/ Joint FAO/WHO Expert Committee on Food Additives (JECFA) for performing the assessment of dual use substances, operating alongside with a CCPR/CCRVDF eWG for risk management considerations, such as the establishment of CXLs. The Commission also invites the eWG to consider the work already carried out by other bodies (e.g. Draft OECD Guidance Document on Definition of Residue) to avoid duplication of work.

Member States were invited to submit their comments on the draft reply to the eWG by 4 October 2022.

c) Other matters

The Commission informed of the status of the reservations to the advancement of CXLs introduced by the EU CCPR53. Most of the reservations related to ongoing evaluations, for which the status has not changed. One reservation, regarding the CXL for pendimethalin on leeks, might be lifted at a later stage, but currently the assessment of an application under Article 6 of Regulation (EC) No 396/2005 is still ongoing (report from the Rapporteur Member State expected soon). The Commission will follow up with Member States to confirm whether the reservation for this CXL could be lifted, ahead of the annual meeting of the Codex Alimentarius Commission (CAC) on 21 November 2022.

In addition, the Commission shared considerations on how to better communicate to CCPR about any reservations lifted by the EU and CXLs implemented since previous meetings. The Commission will seek discussion with the CCPR Secretariat on this point.

A Member State raised the question of substances not evaluated at EU level. The Commission clarified that EFSA cannot perform the toxicological assessment ahead of the CCPR because the monographs are published by the JMPR too late in the year. In these cases, the EU will have to introduce a reservation, which could

potentially be lifted in the following year once the monographs are published and assessed.

Further to a proposal by a Member State, the Commission confirmed that it considers providing a statement at the annual meeting of the CAC on 21 November 2022 on its position with regards to clothianidin, thiamethoxam and quinoxyfen.

A.10 State of play on Cumulative Risk Assessment (CRA):

Following EFSA's call of interest, the French national food safety agency (ANSES) will perform the acute risk assessment for prospective (MRL-setting) CRA, within a partnership agreement with EFSA, starting in October 2022 with a 12-month deadline. According to EFSA, the chronic risk assessment will start after the finalisation of the acute assessment and will be included in a separate partnership agreement with ANSES with a deadline of another 12 months. Therefore, a follow-up on the prospective CRA methodology is expected after October 2024.

A Member State questioned whether it is possible to speed up this planning and to develop more Cumulative Assessment Groups (CAGs), thus allowing for a realistically systematic application of the new methodology in MRL assessments. While reiterating its commitment to advance with the CRA methodology, the Commission acknowledged the delays, but informed it will follow-up with EFSA to possibly curtail them. Moreover, it recalled the EFSA/SANTE Action Plan[18], explaining that prospective CRA will be gradually implemented in risk management practice for existing CAGs first and will later be extended to additional ones.

A.11 Update on Member States' measures setting temporary MRLs under Article 18(4) of Reg. (EC) No 396/2005 in view of shortage of feed due to Russian invasion of Ukraine:

At the meeting of this Committee on 11 March 2022[19] and 11-12 April 2022[20], the Commission and Member States discussed measures with regard to expected shortages of feed supply in some Member States due to Russia's invasion of Ukraine. Article 18(4) of Regulation (EC) No 396/2005 enables Member States to set national temporary MRLs (tMRLs) in exceptional circumstances to authorise the placing on the market and/or the feeding to animals within its territory of non-compliant food or feed, provided that such food or feed does not constitute an unacceptable risk.

The Commission invited the two Member States which had enacted such national temporary measures to give an update on the situation in their countries and on the status of their measures, which had been implemented in mid-March 2022 for 6 months. Both Member States provided a detailed report on their imports of maize and controls put in place. Imports of feed are systematically controlled at the border and traceability is ensured through the Trade Control and Expert System (TRACES). Controls revealed that the measure had required application only once in one Member State, where one shipment of maize had presented residues above the EU MRL and below the national tMRL.

Since the situation with regard to maize imports and stocks has improved since the enaction of the measures in March 2022, both Member States have decided not to

[18] pesticides_mrl_cum-risk-ass_action-plan.pdf (europa.eu)
[19] https://food.ec.europa.eu/system/files/2022-03/sc_phyto_20220311_ppr_sum.pdf
[20] https://food.ec.europa.eu/system/files/2022-05/sc_phyto_20220411_ppl_sum.pdf

extend the measures beyond their term of mid-September 2022. They will keep monitoring closely the situation and the maize markets and keep the option to re-enact the measures in case the situation would deteriorate.

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

A Member State made a notification of an emergency use for prothioconazole in sugar beet roots, for which it had set a tMRL of 0.03 mg/kg applicable for the 2022 harvest. It clarified that the export of treated sugar beet roots outside its national territory is prohibited. The tMRL was established for 120 days based on a risk assessment concluding that it will not pose risks to consumers.

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

A Member State received an application for setting MRLs for acetamiprid in peaches and escaroles, which is linked to the evaluations carried out in another Member State in the context of authorisations. Although, in general, applications for setting MRLs should be submitted to the Member State granting the authorisations, the latter one was not in a position to accept it. Therefore, the Committee agreed that the Member State that received the application would act as an EMS in this case. Both the EMS and the applicant are aware that any decision concerning the setting of new MRLs for acetamiprid will depend on the outcome of the ongoing assessment by EFSA (cf. agenda item A.03.06).

A.14 Feedback from working group on RASFF procedures as regards pesticides residues:

The Commission recalled that this working group was convened following a request from Member States for a harmonised approach in evaluating and notifying risk and in determining compliance with MRLs. In particular, such a uniform approach described in the Work Instruction (WI) 2.2[21] should account for the use of Measurement Uncertainty (MU) and for performing consumer exposure assessments in case of substances with no TRVs, e.g. genotoxic carcinogens.

The working group held a technical meeting on 28 March 2022, the outcome of which was presented at the meeting of this Committee on 11-12 April 2022. Member States had been invited to send their further comments in writing, which revealed still diverging views with regard to the use of MU, in particular in cases of substances with no TRVs and no threshold.

The Commission noted that a wider discussion on the approach for genotoxic carcinogens was needed before focusing on RASFF procedures. Pending further internal discussion, the Commission will convene a meeting of the working group including also experts from the additives and contaminants sectors. This Committee will subsequently be invited to review and endorse the final approach.

A.15 Classification issues related to Annex I of Regulation (EC) No 396/2005:

The Commission informed that the discussion on the establishment of separate MRLs for Cadmium[22] on tiger nuts was initiated in the working group on industrial and environmental contaminants under the Standing Committee for Plants, Animals, Food

[21] https://ec.europa.eu/food/system/files/2022-03/rasff_reg-guid_sops_wi-2-2_en.pdf
[22] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1881

and Feed, section Novel Food and Toxicological Safety that was held on 28 June 2022. The discussion will continue in the autumn meeting of that working group (date to be defined) and Member States will be informed of the developments during the next meeting of the above Standing Committee on 19 October 2022.

A.16 Forthcoming draft Regulations (indicative only):

1. Phosmet, pyriproxyfen

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for phosmet and pyriproxyfen under Article 12 of Regulation (EC) No 396/2005. The Commission highlighted the situation of phosmet, for which the approval was not renewed and for which the peer review revealed data gaps with regard to the toxicity and genotoxicity of its metabolites.

The Commission also shared letters from an applicant and a stakeholder organisation, highlighting that food containing residues of phosmet may remain on the market until at least July 2023. The Commission had already replied that in view of the procedural steps required to adopt a Regulation, it is most likely that the application date of any new MRLs from this Regulation would not be before summer 2023.

Member States were invited to submit their comments by 4 October 2022.

2. Teflubenzuron, etoxazole, methomyl, diuron, denathonium benzoate

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for the non-renewed substances teflubenzuron, methomyl, diuron, denathonium benzoate and etoxazole. The Commission highlighted the situation of etoxazole, renewed on 1 February 2021 with a restriction to ornamental plants in greenhouses, for which the peer review revealed data gaps with regard to the toxicity of metabolites.

The Commission also shared a letter regarding etoxazole from industry indicating that they intend to submit new data under Art. 7 of Regulation (EC) No 1107/2009 to support uses for edible crops. The Commission shared its views that this process will take some time and that the progress of the forthcoming Regulation lowering MRLs should not be delayed. A new MRL application could be made by the applicant at any moment. The Commission also clarified that any grace periods set by Member States should have expired by 1 August 2022.

The Commission will present a proposal at the next meeting of this Committee.

3. Potassium phosphonates

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for this group of substances based on EFSA's Scientific statement, published in July 2022, which contains a summary of the MRLs proposed in several EFSA outputs and includes a justification for the selected values when different ones were proposed by the different outputs. This draft Regulation will also take into account the 2021 EFSA Reasoned Opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates[23].

[23] https://www.efsa.europa.eu/en/efsajournal/pub/6782

4. Carbendazim, thiophanate-methyl

The Commission informed of a forthcoming draft that intends lowering the existing MRLs for carbendazim in grapefruits, oranges, papayas and mangoes and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes to the LOQ, as EFSA identified acute risk for consumers with the current MRL for these products. The measure will take into consideration the most recent TRV derived by EFSA in its reasoned opinion of 2021[24].

One Member State commented that, as the current residue definition for carbendazim also includes benomyl, this active substance should also be considered. EFSA noted that the MRL review for carbendazim[25] proposes modifying the residue definition to exclude benomyl, with additional information for a risk management decision, but this is not yet implemented in the EU legislation. The Commission will liaise with EFSA about this aspect.

5. Carbetamide, carboxin, famoxadone, fenbuconazole, triflumuron

The Commission informed that for these active substances the approval under Regulation (EC) No 1107/2009 expired in 2021 therefore, for triflumuron all MRLs will be lowered to LOQ. As regards carbetamide and carboxin, as all existing MRLs are already established at the default level of 0.01 mg/kg they will be moved to Annex V of Regulation (EC) 396/2005. For fenbuconazole, the MRLs based on EU uses will be lowered to the LOQ. MRLs which are based on CXLs will be maintained after a case-by-case examination. For famoxadone, the MRLs based on EU uses will be lowered to the LOQ. The MRLs based on the CXLs will be modified based on EFSA's targeted review of those CXLs.

6. Bifenazate

See agenda item A 03.08.

7. Deltamethrin, metalaxyl-M, trifloxystrobin

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for those substances based on the EFSA evaluation of confirmatory data following the Article 12 MRL review. This draft measure will take into account risk management decisions taken by this Committee in its previous meetings.

8. Quinoxyfen, lufenuron

The Commission informed that it intends to prepare a new draft Regulation implementing the approach announced by the Commission in the European Green Deal and the Farm to Fork Strategy to lower the existing MRLs for quinoxyfen and lufenuron. The Commission explained that the use of both active substances is no longer authorised in plant protection products in the EU as they have Persistent, Bioaccumulative and Toxic (PBT) properties and that the contamination of the environment with PBTs is a matter of global concern.

9. Fenoxycarb, diethofencarb, pencycuron, flutriafol, myclobutanil

The Commission will include those substances in a new draft Regulation, which, following the expiry dates of their approvals and of their grace periods, will lower

[24] https://www.efsa.europa.eu/en/efsajournal/pub/6773
[25] https://www.efsa.europa.eu/en/efsajournal/pub/3919

MRLs to LOQs in consideration of certain CXLs and/or import tolerances, where appropriate.

10. Measure addressing confirmatory data under Article 12, substances to be defined

The Commission announced that a new draft Regulation will address the substances identified under point A.01.02b.

A.17 Draft revised Communications on data requirements (Commission Regulation (EU) No 283/2013 and 284/2013):

The Commission informed of a coordinated consultation between the two sections of the Committee Phytopharmaceuticals - Legislation and Pesticides Residues) on the revised Communications. Member States were invited to provide their comments by 27 September 2022. The Commission informed that a consultation of stakeholders had been launched in parallel.

A.18 Other Information points:

1. Update on PRAC measures/objections

The Commission informed it decided not to submit the draft measure SANTE/11278/2021 (setting MRLs for acetamiprid) for scrutiny by the European Parliament and the Council despite its favourable vote by the SCoPAFF in February 2022. This exceptional decision was taken as the Commission received, after the vote of the draft Regulation, new evidence related to unexpected levels of one acetamiprid metabolite found in some food products. The Commission considered the new elements as sufficiently serious to mandate EFSA to examine the new information. Following the outcome of EFSA's assessment, the Commission will propose the next steps.

This information was also shared with the European Council and with the Parliament.

2. Information exchange with the United Kingdom under the Protocol on Ireland and Northern Ireland

No issues were discussed under this point.

3. Update on the legal status of the sampling Directive 2002/63/EC

Following the request from a Member State regarding the legal status of Directive 2002/63/EC[26] sampling , the Commission explained that while its Article 1 makes reference to Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC which were repealed by Article 48 of Regulation (EC) 396/2005, this repeal has no impact on the validity of Directive 2002/63/EC. The Commission confirmed that this Directive still applies. The Commission also informed that it envisages to update it and transform it into a Regulation that would include more elements to further support sampling, analytical methods and enforcement. Some Member States supported this update and also called for training on sampling and sampling methods.

Member States were invited to submit their comments by 28 October 2022.

[26] 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

4. Update of Extraction Efficiency guidelines

Following the latest update of the guidelines SANTE/2017/10632[27] in February 2022, a Member State identified further needs for a more substantial revision of the document. The Member State announced that it would voluntarily take the lead for this revision. The Commission welcomed this initiative.

5. Future organisation of PAFF meetings

The Commission informed that the November 2022 meeting will again be held in hybrid mode. For 2023, the Commission proposed to have meetings alternating between physical (with option hybrid) and fully virtual. It asked the Member States for feedback on their foreseen attendance in physical meetings. A Member State commented that it clearly would prefer physical meetings over virtual ones. Another one favoured hybrid meetings as it allows remote participants to join in for certain points, in addition to those physically present. Several Member States would need to check with their national administrations and will get back to the Commission with a reply. The Commission also informed the Member States of the provisional dates for the meetings of this Committee planned for 2023 (February, May, September and November), which are however still subject to confirmation. It informed that the dates would tie in with the planning for the 2023 CCPR meeting that will be held from 26-30 June 2023.

6. MRL application form and IUCLID applications

At the meeting of this Committee in April 2022, a discussion was held on whether an applicant still needs to submit an application form for a new MRL according to Article 6 of Regulation (EC) No 396/2005 or when applying for Article 12 confirmatory data. At the end of that discussion, the Commission proposed that, in this transition phase, application forms would still be needed for some specific cases. Several Member States supported the proposed approach.

EFSA took note of the decision and clarified that only the information provided through IUCLID will be the reference point for EFSA and for the public (not the information included in the application form) and called for accurate IUCLID information.

Lastly, the Commission informed that internal discussions and with EFSA concluded that no IUCLID application would be needed for setting temporary MRLs under Article 18(4) of Regulation (EC) No 396/2005 (e.g. in case of emergency uses), due to the urgency of the procedure, and for setting MRLs according to the "fast-track procedure" when a previous EFSA output is already available from which extrapolation is possible (cf. chapter 3.6 of the MRL setting Guidelines (SANTE/2015/10595 Rev. 6.1)). In the latter case there would be no applicant and no need for submission of a dossier.

7. Time plan for copper

The point was added to the agenda on request of a Member State.

The Commission informed that the EFSA Scientific Committee is currently finalising its opinion for copper from all sources (see agenda item A.04.03). The public consultation for this opinion was closed. On the basis of the outcome, further risk management action might become necessary. This might include action on

[27] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf

MRLs, based on a potential review of all existing MRLs by EFSA. As the timing of possible next steps depends on the outcome, more concrete details could not be given at this stage.

8. Presentation of certain quaternary ammonium compounds in the database

The item was added to the agenda on the request of Member States and was raised under agenda item B.09.

One Member State noted that for quaternary ammonium compounds, the EU MRL database includes 10 different active substances, of which 2 have MRLs based on monitoring data (BAC and DDAC), and 8 have default MRLs. However, most of these 8 compounds are included in the 2 residue definitions for BAC and DDAC. The Member State invited the Commission to consider if further action was needed. The Commission informed the Member State that a similar concern had been also noted by another Member State and was confirmed by the EURL. The Commission will investigate potential solutions to this situation.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl in or on certain products (Art. 10).

(SANTE/10180/2022)

The Commission outlined the draft Regulation and its contents. An MRL application for acequinocyl in sweet peppers/bell peppers had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005 concerning EU uses. EFSA confirmed that the proposed MRL is fully supported by data and safe for consumers.

In addition, an application was submitted for modifying the MRL for kaki/Japanese persimmons using the fast-track procedure to set a MRL based on residue trials on apples.

One Member State noted that another Regulation covering acequinocyl (Regulation (EU) 2022/1343) has been adopted but will be applicable only from the 22 February 2023. It suggested setting the application date for the new MRLs set by this draft Regulation to a date after the application date of Regulation (EU) 2022/1343 in order to avoid conflicts of diverging values set by the different Regulations. It was decided that the draft Regulation should apply as from 23 February 2023 as regards all proposed MRLs.

Revision 3 of the draft Regulation, which takes into account all the decisions listed above, 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 azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products (Art. 10).

(PLAN/2022/1665)

The Commission outlined the draft Regulation and its contents.

The draft Regulation proposes implementing into EU legislation the CXLs for azoxystrobin in guavas and for valifenalate in onions, shallots, tomatoes, and eggplants, since EFSA concluded they are safe for consumers and the EU had not expressed any reservation at the CCPR. For valifenalate in tomatoes, a footnote highlighting the need for additional data was added by Regulation (EU) 2022/1346. One Member State noted that as for the proposed CXL a sufficient number of residue trials was submitted and EFSA concluded that these data were sufficient for the uses under consideration and to support a new higher MRL, the footnote could be deleted. Therefore, the footnote for valifenalate in tomatoes was deleted.

In addition, this draft Regulation proposes modifying some MRLs for azoxystrobin, sedaxane and prosulfocarb based on applications submitted in accordance with Article 6 of Regulation (EC) No 396/2005 concerning EU uses. EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers. As sufficient data were provided through the application for setting the new higher MRL for prosulfocarb in herbs and edible flowers, the respective footnote that was previously established was deleted and the issue explained in a recital.

One Member State noted that, as other Regulations covering some of the substances included in this draft Regulation have been adopted but are not yet applicable, it would be appropriate to set the application date for the new MRLs set by this draft Regulation to a date after the application date of those other Regulations in order to avoid conflicts of diverging values set by the different Regulations. It was decided that the draft Regulation should apply as from 26 February 2023 as regards all proposed MRLs.

Revision 3 of the draft Regulation, which takes into account all the decisions listed above, was presented for vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products (Art. 12).

(SANTE/11128/2021)

The Commission provided clarifications on Revision 5 of the draft Regulation and its Annexes, which contain amendments following the comments received by Member States, stakeholders and third countries. The Committee agreed with the proposed MRLs of cyflumetofen in other farmed terrestrial animals for liver, kidney and edible offals as they are safe for consumers.

The Commission informed the Committee of the comments received from third countries and industry following the consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the WTO.

One Member State indicated that beta-cyfluthrin is another example where there is a need to change the IESTI equations as for pears, sweet peppers/bell peppers, tomatoes and apples the derived MRL in certain conditions may lead to an exceedance of ARfD.

Three Member States informed the Commission that they will no longer support draft Regulations which raise MRLs (e.g. through import tolerances) for substances not approved in the EU.

One Member State indicated that it will vote against the draft Regulation as it did not support raising some of the MRLs for the non-approved substance cyfluthrin. Another Member State indicated to vote against the draft Regulation for the same reason and highlighted in addition the narrow margin of safety for some of the proposed MRLs, and the fact that cyfluthrin belongs to the group of pyrethroids and is not approved since 2014. A Member State indicated that it was against the raising of MRLs based on import tolerances for substances that are not approved in the EU, but that, in order not to delay the process on the other substances, it would vote in favour this time.

One of the three Member States proposed that import tolerances for non-approved substances should always be presented in separate draft Regulations concerning only the individual substances. It further stated that it intends to vote against any forthcoming draft Regulation proposing either keeping or raising CXLs or import tolerances for non-approved active substances. The Commission indicated that it will consider the comments made by the Member States when preparing draft Regulations for such substances in the future.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin in or on certain products (Art. 43).

(SANTE/11316/2021)

The Commission outlined the draft Regulation and its contents and informed the Committee of the comments received from third countries following the consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the WTO. The Commission explained that the MRL of apples was lowered to 0.006 mg/kg to align it with that of peasr. The residue trials for abamectin were carried out for pome fruit, and the LOQ of 0.006* mg/kg (*sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a*) was achieved for both, apples and pears, with most trials being on apples. A Member State indicated that it was against the setting of LOQ below the default MRL 0.01mg/kg as this would affect the capacity of the laboratories with not much added value.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products.

(SANTE/11226/2021)

The Commission presented the draft Regulation lowering MRLs for clothianidin and thiamethoxam to the LOQ based on environmental issues of global concern, specifically the worldwide decline of pollinators. This measure is implementing for the first time the principles announced in the European Green Deal[28] and the Farm to Fork Strategy[29]. The draft Regulation intends to lower the MRLs derived from uses in the EU and from CXLs based on the EFSA[30] conclusion that the exposure from outdoor use of clothianidin and thiamethoxam leads to unacceptable risks for bees. The draft Regulation was submitted for consultation of trading partners under the Technical Barriers to Trade (TBT) agreement[31] and in addition for information to the Sanitary and Phytosanitary (SPS) agreement[32] of the WTO. The Commission had shared the comments received from Member States, WTO members[33] and stakeholder associations[34] with the Member States well in advance of the meeting in order to allow for a thorough discussion. The Commission particularly drew the attention of the Member States to the deferred application date of 36 months (instead of the standard period of 6 months) in order to provide third countries sufficient time (at least two growing seasons) to adapt to the new provisions.

Member States welcomed the draft Regulation acknowledging that it is in line with the announcements made in the Farm to Fork Strategy and thanked the Commission for providing additional explanations on the legal basis, the compliance with WTO obligations and other related issues such as emergency authorisations, as well as possible forthcoming measures for other active substances for which global environmental concerns should be considered.

The comments received were discussed grouped by subject, addressing similar concerns of third countries and stakeholders in batches. The concerns of third countries will be responded to in detailed replies from the EU to the third countries (based on the rationales discussed with the Member States) and the Committee agreed that in the light of the comments received there are no grounds to change the content of the draft Regulation, since there is currently no alternative that would be less trade restrictive but equally sufficient to address the objectives of the draft Regulation.

Vote taken: Favourable opinion.

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[28] Communication on the European Green Deal, COM(2019) 640 final, p. 12, stating that "imported food that does not comply with relevant EU environmental standards, is not allowed on EU markets"

[29] Communication on a Farm to Fork Strategy, COM(2020) 381 final, p. 18, announcing that the Commission will "take into account environmental aspects when assessing requests for import tolerances for pesticide substances no longer approved in the EU, while respecting WTO standards and obligations"

[30] European Food Safety Authority; Peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5177.

[31] G/TBT/N/EU/908

[32] G/SPS/GEN/2054

[33] Argentina, Australia, Brazil, Canada, China, Colombia, Ecuador, El Salvador, Guatemala, India, Indonesia, Israel, Japan, Paraguay, Peru, Senegal, South Africa, United States of America and Uruguay

[34] Cereals Canada, China Chamber of Commerce for imp&Exp of foodstuffs, native produce & animal by-products, China Chamber of International Commerce, CIBE-CEFS, CropLifeColombia, CropLifeEurope, Industria de protección de cultivos de México, European Coffee Federation, Junta de Usuarios de Riegos Presurizados (Perú), National Cotton Council of America, Procultivos ANDI (Colombia), Tea and Herbal Infusions Europe, The Cranberry Institute, US Hop Industry Plant Protection Committee and Wine Institute

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

(SANTE/10088/2022)

The Commission provided a general overview of the draft Regulation, which proposes to lower to the LOQ all the MRLs for the active substances, with the exception of the MRLs of cyromazine in ovine products (except milk) as this is due the uses as a pharmacological active substance in veterinary medicine. The Commission shared the feedback received from the EU Reference Laboratories and the comments from a Member State about calcium phosphide. Since calcium phosphide shares a common metabolite with other approved active substances[35], the Commission proposed to review its MRLs in a separate draft Regulation, once the renewal process of the those substances would be concluded. The Commission presented a revised draft Regulation without the active substance calcium phosphide.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, bromoxynil, chlorsulfuron, fenamiphos and epoxiconazole in or on certain products.

(SANTE/10176/2022)

For the substances included in this draft Regulation, the approval for use in PPPs has expired and has not been renewed. Revision 3 addresses comments received by Member States. For fenamiphos, following consultation with the EURLs, the LOQs were lowered to address concerns regarding its very low toxicological reference values.

The draft Regulation was notified to trading partners via the WTO/SPS notification procedure. Comments were submitted by two third countries. In addition, comments from industry had been received on the need for transitional periods.

The Commission confirmed that transitional periods for products placed on the market before the application date were not proposed, since for benalaxyl, bromoxynil and epoxiconazole endocrine disrupting properties cannot be excluded, for fenamiphos the available data package is not sufficient to exclude possible genotoxicity of its metabolites M01 and M02, while for chlorsulfuron, MRLs have not been reviewed since Regulation (EC) 149/2008[36]. However, the deferred application of 6 months from the entry into force for operators to adapt themselves to the new standards is still included.

Vote taken: Favourable opinion.

[35] Phosphane, aluminium phosphide, magnesium phosphide and zinc phosphide

[36] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto, OJ L 58, 1.3.2008, p.1-398

B.08 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 DDT and oxathiapiprolin in or on certain products (Art. 10).

(PLAN/2022/1667)

The Commission outlined the draft Regulation and its contents. An MRL application in support of import tolerances for oxathiapiprolin used in the United States on blueberries, had been submitted in accordance with Article 6(2) and 6(4) of Regulation (EC) 396/2005. EFSA had confirmed that the proposed MRL is supported by data and safe for consumers.

In addition, the draft Regulation aligns the existing MRL for DDT in wild boars with the existing MRL in swine (which includes farmed wild boars), using a footnote. In fact, the Working group on residues of veterinary medicinal products in food of animal origin under the Standing Committee on Plants, Animals, Food and Feed, section Novel Food and Toxicological Safety of the Food Chain brought to the attention to the Commission that, while DDT has been banned since 1983 in the EU, due to its persistence in the environment, residues of this substance in wild boar products still occur at levels higher than the current MRL for wild terrestrial animals, but in the same order of magnitude as the current MRL for swine. As EFSA's monitoring data ranging from 2016 to 2020 confirm this finding, the Commission proposed aligning these MRLs.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products.

(SANTE/10090/2022)

The Commission provided clarifications on the draft Regulation and its Annexes in consideration of comments provided by the Member States, third countries and stakeholders. There were no changes for BAC, chlorpropham, DDAC, flutriafol, metazachlor, quizalofop-P, sodium aluminium silicate, and thiabendazole. Editorial changes were made for other active substances.

The approval for flutriafol expired in 2021, but grace periods are still ongoing. Therefore, the draft Regulation does not intend to lower MRLs based on EU uses to LOQ. This will be addressed by another measure following the expiry of the grace periods that may be granted by Member States.

For sodium aluminium silicate, despite the concerns raised previously by a Member State regarding its natural occurrence and the lack of enforcement methods, the Commission reiterated its proposal of including sodium aluminium silicate in Annex V (all MRLs to be set at the default MRL of 0.01 mg/kg), in line with recent decisions of the Commission for this active substance in other areas (e.g. restriction of uses as food

additive[37]) and given the toxicity of aluminium. A Member State reiterated its concerns about the lack of methods to monitor the substance and noted that exposure to aluminium may occur from several sources, including natural exposure and exposure through food contact material or food additives. The Member State enquired the possibility to split Annex IV into two sections: one containing substances for which no MRL is needed, and another for substances that may pose toxicological concerns but for which the exposure does not primarily derive from the use of the substance as PPP. The Commission noted that Regulation (EC) 396/2005 does not foresee the splitting of Annex IV, therefore such action could not be proposed by the Commission.

For nicotine, the draft Regulation was revised to take into account new information. Based on the comments received, it was decided to consider separately the two groups of "seed spices" and "fruit spices". The MRL for both sub groups is now proposed at 0.02mg/kg instead of 0.01mg/kg. For the current MRL in teas and rose hips, EFSA identified a risk for consumers. Therefore, the draft measure lowers this MRL to protect consumers. Although an MRL of 0.5 mg/kg in teas would be safe for consumers, the draft measure proposes lowering it to 0.4 mg/kg, as it corresponds to the 95th percentile of the data at 95% confidence level, in accordance with provisions set by Commission Regulation (EU) No 283/2013 and in line with the ALARA (as low as reasonably achievable) principle.

Several MSs and stakeholders commented on the lowering of MRLs for teas. In particular, the industry noted that a MRL at 0.4 mg/kg may be disruptive for trade for two of the main tea production areas in India (Assam and Darjeeling), where nicotine residues are higher, though not used as a PPP. Therefore, the industry invited the Commission to consider separately the data from these two regions and derive new MRLs accordingly. The industry criticised the validity of EFSA's PRIMo seemingly including excessive tea consumption data for Irish children leading to an acute risk. The Commission clarified that it would not be appropriate to perform the analysis of monitoring data according to specific regions, but that the data set should be considered as a whole. Nevertheless, the Commission presented a compromise solution and proposed to amend the draft Regulation, setting the MRL in teas at 0.5 mg/kg with a provision for automatic decline to 0.4 mg/kg three years after the publication of the Regulation, unless data supporting the need to maintain the higher level of 0.5 mg/kg would be submitted by 30 June 2025. One Member State supported the Commission's proposal. Another Member State agreed with the MRL of 0.5 mg/kg but instead of automatically lowering it, it proposed to re-assess it based on monitoring data within 3 years. Nevertheless, that Member State agreed to support the proposal.

For triadimenol, the previous version of the draft Regulation intended lowering all MRLs based on EU uses, as well as the CXLs for cucurbits with inedible peel and globe artichokes (which were not fully supported by data), to the LOQ. For the CXL in grapes, in its Article 12 review, EFSA noted that it was not fully supported by data and that it was not compatible with EU residue definitions. Therefore, the draft Regulation proposes lowering the MRL for grapes to the LOQ.

The Commission clarified that, after publication of the draft Regulation, a 6-month delay for its application is foreseen to give food business operators the possibility to adapt to the new MRLs. Once these 6 months will have elapsed, teas and rose hips placed on the market before the application date will have to comply with the MRL

[37] European Food Safety Authority, 'Re-evaluation of sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) as food additives', EFSA Journal 2020;18(6):6152

proposed by the Regulation on the date of application with no further transition periods given that EFSA identified a health risk with the current MRL.

Revision 7 of the draft Regulation, which takes into account all the decision listed above, was presented for vote.

Two Member States declared that they would vote in favour but that in the future they would vote against any measure proposing import tolerances for non-approved substances, such as flutriafol.

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 isoxaben, novaluron and tetraconazole in or on certain products (Art. 12).

(SANTE/10108/2022)

The Commission presented an overview of the draft Regulation. For isoxaben, the Member States agreed to set the LOQ for herbal infusions and hops at 0.05*mg/kg in view of the data gaps on analytical methods, and at 0.01*mg/kg for herbs and edible flowers. For tetraconazole, for the subcategory "others" under pome fruits, cereals, and the various products of animal origin, the Member States confirmed they had no specific authorizations so that the MRL could be set at the LOQ of 0.01*mg/kg.

The Commission also shared a letter from industry regarding novaluron, asking to postpone the draft Regulation and maintain MRLs as they commissioned missing studies which they would like to submit in the future. The Commission clarified that once new data is available, applicants can submit it under Article 6 of Regulation (EC) No 396/2005.

Member States were invited to submit their further comments by 21 October 2022.

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

(PLAN/2022/1666)

The Commission outlined the draft Regulation and its contents. An MRL application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting modification of the existing MRLs was submitted for folpet in lettuces. EFSA confirmed that the proposed MRL is supported by data and safe for consumers. In addition, import tolerance requests for cyantraniliprole used in Canada and the United States of America on several crops and a MRL application for cyantraniliprole in apricots were submitted.

EFSA concluded that some information on the magnitude of residues and on the formation of cyantraniliprole degradation products in processed products (due to cooking/boiling) were not available. The draft Regulation does not modify the MRLs for products for which EFSA identified the data gap, but proposes changes of the MRLs for products not concerned by this data gap as recommended by EFSA. For lettuces, EFSA was able to derive an MRL of 15 mg/kg from a data set of residue trials on open leaf lettuces only, and an MRL of 10 mg/kg, derived according to the EU rules from a

combined data set of closed and open leaf lettuces. No risk for consumers were identified with any of the two MRLs. In the presented draft Regulation the Commission proposed to set the MRL for lettuces at 10 mg/kg, following the ALARA principle.

EFSA noted that the Commission proposal raises the MRL for the product category "other lettuces and salad plants" (code 0251990) to 15 mg/kg, as it is done for all other products of the group "lettuces and salad plants" except for escaroles (due to the above mentioned data gap) and lettuces. It pointed out that, as this category may include products that undergo boiling or cooking, a similar approach as the one followed for escaroles may be followed. The Commission agreed with EFSA's position, and proposed to modify the current draft, maintaining the existing MRL for the product category "other lettuces and salad plants" (code 0251990), which is set at the LOQ.

One Member State noted that, as EFSA identified a wide margin of safety for the MRL of 15 mg/kg for lettuces, the MRL should be set at this level. Another Member State commented that the data set of closed and open leaf lettuces present broad differences and should not be merged, and that only the open leaf lettuce data should be considered, setting the MRL at 15 mg/kg.

Member States were invited to submit their comments by 21 October 2022.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards for bromopropylate, chloridazone, fenpropimorph, imazaquin and tralkoxydim in or on certain products.

(SANTE/10644/2021)

The Commission explained that the draft Regulation has not been modified since the previous meeting and it will be submitted for vote at the next one, after the completion of pending administrative procedures.