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Section *Phytopharmaceuticals – Pesticide Residues*
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CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/78eb369a-150b-46bc-ab1f-2b7eb013a882?p=1*

SUMMARY REPORT

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

1. Priority list

The Commission presented an updated table.

2. Confirmatory data Art. 12 follow-up

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

The EFSA RO on the Article 12 confirmatory data assessment for metalaxyl-M was discussed in the past, and a risk management decision was pending for herbs and edible flowers. As no Good Agricultural Practice (GAP) is authorised in any Member State for these products, it was agreed to lower their Maximum Residue Level (MRL) to the Limit of Quantification (LOQ).

The Commission informed that the ROs on the Article 12 confirmatory data assessment for napropamide and fenbuconazole were recently adopted by EFSA.

For napropamide, a substance approved in the EU, the data gaps identified in the Article 12 review were not addressed, and several uses are no longer supported in the EU. Therefore, in accordance with EFSA recommendations, the Commission proposed to set the relevant MRLs to the LOQ.

For fenbuconazole, which is no longer approved in the EU, EFSA had highlighted certain issues that were for further consideration by risk managers. For grapefruits, oranges, limes, lemons, pome fruits, cherries (sweet), peaches and blueberries a data gap concerning residues of Triazole Derivative Metabolites (TDMs) was addressed. While for peaches and cherries (sweet), residue decline trials were lacking, this was considered to be a minor deficiency by EFSA. Therefore for all of the above products the Commission proposed to either keep the MRLs at the existing values (corresponding to existing CXLs) or lower them to the level of the relevant CXLs where the existing MRLs were based on now obsolete EU uses. For a number of other products data gaps were not addressed, therefore the Commission proposed to set the relevant MRLs to the LOQ.

Member States were invited to submit their comments by 16 October 2023.

b) Missing analytical standards follow-up

In its communication to the Commission, the manufacturer of fluroxypyr claimed that an analytical standard for fluroxypyr conjugates was not needed because the analytical method they had provided included a hydrolysis step breaking the conjugates down to the acid form which was then analysed. However, having assessed that analytical method, the EU Reference Laboratories (EURLs) for pesticide residues, still considered there was a need for such an analytical standard. In addition, the manufacturer considered that the Commission's request for a commercially available analytical standard for fluroxypyr conjugates contradicted recital 10 of Regulation (EU) 2022/1363[1], which had concluded that the data gap for the analytical method for fluroxypyr on several products had been addressed. The Commission will investigate this matter with support of the Member States.

Member States were invited to submit their comments by 10 October 2023.

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)

The document was updated with a more detailed procedure as regards cases where confirmatory data had not been submitted by the applicant by the deadline indicated in the respective footnote requiring confirmatory data. It also includes some additional procedural information mainly as regards the International Uniform ChemicaL Information Database (IUCLID). It will be tabled for endorsement by the Member States at the next meeting of this Committee on 20/21 November 2023.

Member States were invited to submit their comments by 10 October 2023.

3. Non-approved substances for follow up

a) Next mandate to EFSA

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 certain procedural issues are clarified (see discussion under point A.03 b). EFSA noted that the time needed to finalise such a second mandate would depend on the procedure that will be followed, and therefore concrete discussions on a time frame would need to start at a later stage.

Member States were invited to submit their comments by 3 October 2023.

b) Procedural issues

The Commission presented a first draft for a possible process to deal with the targeted MRL reviews under Article 43 of Regulation (EC) No 396/2005 of non-approved substances covered by the first mandate and the planned second mandate to EFSA (see point A. 03 a). In developing this process, it had taken into account the proposals from a Member State and from EFSA. The draft procedure includes involvement of applicants/interested parties and should give the opportunity to submit existing additional data. It was acknowledged that the process for the first and the second batch of substances could be different, given that EFSA outputs of the first batch are already either finalised or at an advanced stage, while for the

[1] OJ L 205, 5.8.2022, p. 207–225

second batch the Commission has not yet sent the mandate to EFSA (see point A. 03 a). It was also acknowledged that the decision-making process for the substance bifenthrin was also already in an advanced stage and that for this substance an ad hoc approach might be necessary. Furthermore, since some substances had never been evaluated in the EU, Rapporteur Member States (RMS) would need to be appointed.

Two Member States and EFSA indicated some concerns on the overall delay that such a new process could cause and the potential impact on resources.

The Commission indicated that the presented suggestions were a starting point for further discussions and that contributions for its improvement were welcomed.

Member States were invited to submit their comments by 3 October 2023.

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

1. General issues

The Commission provided an overview of the main outcome of the meetings of the SCoPAFF, section Phytopharmaceuticals – Legislation held in May and July 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. It also informed that no new active substances (NAS) had been put on the agenda of that section of the Committee since the last meeting of this section of the Committee on 10-11 May 2023.

A.03 Specific substances:

1. Glyphosate

The Commission informed about the status of the ongoing procedure for the renewal of approval. A specific meeting of the SCoPAFF – section Phytopharmaceuticals – Legislation will take place on 22 September and will be dedicated to glyphosate only. The vote is planned for the forthcoming meeting of that section of the Committee on 12-13 October 2023.

2. Bacillus thuringiensis (Bt)

The Commission recalled that on 23 March 2023, at the SCoPAFF – section Phytopharmaceuticals – Legislation[2], the approvals of the eight active substances of *Bacillus thuringiensis* (Bt)[3] were renewed, with certain conditions. In particular as a precaution, a minimum time period was set to elapse between the application of a plant protection product (PPP) containing those active substance and the harvesting of edible crops for consumption; this applies if residues' data reported by the EFSA conclusion showed a Bt density above the level of 10^5 CFU/g. In addition, the respective Regulations[4] call for the generation of more data regarding the decline of Bt concentration after application, and for storage stability data. Currently, the

[2] https://food.ec.europa.eu/system/files/2023-07/sc_phyto_20230322_ppl_sum.pdf

[3] Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, EG 2348, PB 54, SA 11, SA 12 and subsp. Aizawai strains ABTS-1857, GC-91, and subsp. Israeliensis (serotype H-14) strain AM65-52)

[4] As an example for the 8 Regulations on the different strains: Commission Implementing Regulation (EU) 2023/998 of 23 May 2023 renewing the approval of the active substance Bacillus thuringiensis subsp. kurstaki ABTS-351 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.

Commission is collecting information on projects relating to generation of data on possible toxigenicity of Bt and/or *Bacillus cereus (Bc) sensu lato*. The Commission invited Member States to provide information in case they were aware of any such relevant ongoing projects.

3. Copper

The Commission is finalising a follow-up mandate to EFSA under Article 43 of Regulation (EC) No 396/2005 to update EFSA's Article 12 review of MRLs[5], which had not been implemented by the Commission pending the conclusions of the Scientific Committee's re-evaluation of the existing health-based guidance values for copper and the exposure assessment from all sources, now published[6]. The mandate will include updating the background levels of copper compounds on all commodities using the latest monitoring data, considering all pending applications for which EFSA's ROs under Article 10 of Regulation (EC) No 396/2005 are already published but not yet implemented in EU legislation, namely for fresh herbs and edible flowers[7] and other small fruits and berries[8], but not collecting new GAPs from Member States. EFSA will provide a list of possible MRLs, distinguishing between levels resulting from Plant Protection Products (PPP) uses and background levels, for further consideration by risk managers. The EFSA output could be finalised between March and June 2024, and a draft Regulation may then be discussed at the SCoPAFF meeting of September 2024.

The Commission noted that, following the last meeting, several Member States reported difficulties in enforcing the current MRL of 10 mg/kg for chia seeds, with reported levels as high as 22 mg/kg. Other difficulties in enforcing MRLs for copper had previously been reported also for honey and bovine liver. These difficulties will be addressed by the upcoming Regulation which will propose to update the MRLs for these commodities. In the meantime Member States – in view of those upcoming changes – should already apply proportionate enforcement measures as regards those commodities.

4. Folpet

At a previous meeting of this Committee, a Member State highlighted that an acute risk was identified by EFSA for folpet in table grapes (exceedance of the ARfD for children, 104%) and invited the Commission to take action. Following this communication, the Commission had consulted with EFSA.

EFSA informed the Commission that in its recent Conclusion on the peer review for folpet[9], the ARfD folpet is proposed to be raised from 0.2 to 0.6 mg/kg bw, with which no exceedances are identified for the existing MRLs using the Pesticide Residues Intake Model (PRIMo) version 3.1 (the highest acute exposure of 104% calculated for table grapes/current ARfD will decrease to 35% of the new ARfD). Therefore, the existing MRL for folpet in grapes is safe, and no action is needed.

[5] Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3):5212.
[6] Re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources. EFSA Journal 2023;21(1):7728.
[7] Modification of the existing maximum residue levels for copper compounds in fresh herbs and edible flowers. EFSA Journal 2020;18(7):6180.
[8] Modification of the existing maximum residue levels for copper compounds in other small fruits and berries. EFSA Journal 2022;20(8):7528.
[9] Peer review of the pesticide risk assessment of the active substance folpet. EFSA Journal 2023;21(8):8139

5. Acetamiprid

The Commission provided an update on the ongoing assessment of acetamiprid performed by EFSA. The original mandate required EFSA to provide advice if new evidence, made available since the assessment conducted prior the renewal in 2018, warranted re-evaluation of: i) toxicological parameters used for the risk assessment during the renewal process, including toxicological endpoints, ii) the residue definition in products of plant origin, and iii) the safety of existing MRLs, and the EFSA output was expected by the end of July 2023.

Meanwhile, one applicant submitted new toxicology studies to EFSA and claimed them to be relevant for the response to the mandate, in particular regarding the toxicological profile of the metabolite N-desmethyl-acetamiprid (IM-2-1), while Pesticide Action Network (PAN) Europe recommended considering recent scientific literature, which might be relevant. As this new data might affect EFSA's conclusion, the Commission requested EFSA to consider them in its ongoing evaluation.

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 GAPs that could lead to safe scenarios.

Considering that the additional analysis will require additional efforts, i.e. a new call for fall-back GAPs, residue trials and a consultation with experts from Member States in a peer-review meeting to confirm the reference values of the metabolite, the deadline for EFSA's final outcome was postponed to 31 March 2024.

6. Captan

At the last meeting of this Committee, a Member State had informed that residues of captan were detected in samples of honey during its 2020 – 2022 monitoring programme, in some cases exceeding the EU MRL of 0.05 mg/kg. Risk mitigation measures for crops cultivated in open air, including a restriction to exclude use during flowering, were introduced, but this posed issues to the sector, as the use of captan during flowering is critical for pome fruits, while for strawberries and berries there is a long period of flowering, and it often overlaps with the period of harvest. Therefore, that Member State was looking into options to set a higher MRLs, including the possibility of setting a temporary MRL (tMRL) based on monitoring data first and a subsequent permanent MRL based on residue trials.

Meanwhile, an applicant informed that Member State that it had initiated honey residue trials and that it plans to apply for a permanent EU MRL by end of 2023. Therefore, consideration of monitoring data for an application for tMRLs is no longer needed. The Commission and EFSA nevertheless reminded Member States to submit their monitoring data to EFSA within the standard data collection timeframe and format.

One Member State inquired if, as captan is only approved for uses in greenhouses in the EU, the application for honey will be an import tolerance request. The Member State in contact with the applicant did not have this information yet.

7. Ethephon

The Commission informed that a mandate to EFSA has been prepared as a recent preliminary risk assessment indicated that the existing MRLs might pose acute risks to consumers according to calculations performed with PRIMO rev. 3.1. In addition, in

the framework of its renewal of approval under Regulation (EC) No 1107/2009, EFSA published a conclusion lowering ethephon's current ADI from 0.03mg/kg to 0.02mg/kg. EFSA proposed a new residue definition for enforcement for cereals, which is the same as the definition for cereals and straw used in Codex Alimentarius. In 2016, the Codex maximum residue limits (CXLs) for cereals (wheat, barley and rye) were not implemented in EU legislation[10] due to the incompatibility of the residue definitions. Since then, some of the CXLs on which certain EU MRLs were based, have been withdrawn or have become obsolete. EFSA will take all this into consideration when reviewing the MRLs. The mandate will be finalised once the renewal of approval of the substance has been voted at the SCoPAFF Section Phytopharmaceuticals – Legislation.

8. Bifenazate

The Commission informed of several letters received from stakeholder associations for hops concerning the lack of transitional measures in the draft Regulation (PLAN/2022/2307) voted in this Committee on 10/11 May 2023. The Commission explained that Article 49(2) of Regulation (EC) No 396/2005 allows for transitional measures only if the obligation of maintaining a high level of consumer protection is fulfilled. Since EFSA had not confirmed that food containing residues of bifenazate at previously valid MRLs is safe for consumers, that obligation is not fulfilled, and transitional measures could not be granted. However, a standard deferred application date of six months as part of the usual procedure has been granted.

In addition, the Commission informed that it asked the Rapporteur Member State (RMS) for this substance to give high priority to the assessment of the application under Article 7 of Regulation (EC) No 1107/2009 which had been submitted by the applicant in order to change the current conditions of approval to lift the restriction to non-edible crops only. The Commission will meet the stakeholder association for hops to better understand the situation and asked Member States to share monitoring data for bifenazate in hops or hop pellets. The MRL for hops is applicable to "dried cones, also in the form of pellets and unconcentrated powder", therefore processing factors cannot be applied. The RMS confirmed having received and currently processing the application with high priority but informed that it had already asked the applicant to revise the dossier since relevant data were missing.

9. Flupyradifurone/DFA

The Commission informed that EFSA recently adopted a RO on the modification of the existing MRLs and setting of import tolerances for flupyradifurone and DFA in various products, based on an Article 10 application, where it highlighted the need for certain risk management considerations. Flupyradifurone exhibits high soil persistence, forming DFA as a soil metabolite, resulting in its uptake in rotational crops. In particular, for leafy brassica, sunflower seed, maize, oat and rye grain, the expected soil uptake of DFA was identified to be significant and thus, it may affect MRL values. Therefore, EFSA recommended risk managers to consider two options for setting MRLs for DFA for those products:

[10] Commission Regulation (EU) 2017/626 of 31 March 2017 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 acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products (OJ L 96, 7.4.2017, p. 1).

- Option 1: an MRL proposal accounting for residues expected only from primary crop treatment; or
- Option 2: combined MRL proposal, which reflects residues in a crop from the primary crop treatment and from the soil uptake in rotational crops.

As no acute nor chronic risk for consumers was identified for the two options, the Commission proposed to set MRLs for those crops in accordance with option 2, i.e., to support the setting of MRLs for DFA considering the residue soil uptake.

While no acute consumer intake concerns were identified, EFSA noted that for the uses on oranges and kales, if residues of flupyradifurone occur in kales at the derived MRL value and in oranges at the existing EU MRL, the dietary exposure of certain consumers may exceed the ARfD under certain extreme and non-standard conditions. As the safety margin of the exposure assessment is sufficient according to the agreed international methodology, the Commission proposed to maintain those MRLs.

For kales, based on the new submitted residue trials, a lower MRL of 4 mg/kg was derived by EFSA, and the applicant proposed the lowering of the existing MRL accordingly. Therefore, the Commission proposed lowering the MRL for flupyradifurone in kales from 5 to 4 mg/kg.

Member States were invited to submit their comments by 3 October 2023.

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 21 processes[11] had been adopted since the previous meeting.

Currently, outputs addressing 42 such processes are at different steps of the procedure. Out of these, 21 are under scientific assessment (16 under Regulation (EC) No 396/2005 and 5 under Regulation (EC) No 1107/2009) and 21 under clock-stop as additional data had been requested (15 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

EFSA presented the state of play of the ongoing Article 12 reviews. Since the previous meeting, 1 MRL review was finalised, 20 are on hold, 8 are currently being assessed at different stages of the procedure, while for 6 substances data is pending. The progress report table is publicly available for interested stakeholders [12].

- Zoxamide

  The Commission informed that the draft reasoned opinion reviewing the MRLs under Article 12 of Regulation (EC) No 396/2005 also addresses the application under Article 6 of that Regulation for setting an import tolerance for bulb vegetables.

- Clopyralid

  The Commission informed that the approval for clopyralid was renewed on 1 October 2021 and under Article 43 of Regulation (EC) No 1107/2009 12 months

[11] Each process receives a so called "EFSA question number".
[12] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf

are foreseen for the Member States to decide on the renewal of the authorisation of PPPs. The Article 12 review process under Regulation (EC) No 396/2005 was supposed to start in August but the RMS Finland informed the Commission that according to the applicant the renewal of authorisation process under Article 43 of Regulation (EC) No 1107/2009 has not yet been finished in several Member States. The Commission recalled that it was agreed in the past[13] that in standard cases the Article 12 procedure should start 2 years after the renewal of the approval, but that in some cases some flexibility and longer delays were needed to allow for the authorisation process to be finished. As the information received so far indicated that in the current case Member States needed more time, they were asked to comment on the situation in their country and give an estimate for the completion of the authorisation procedures.

Member States were invited to submit their comments by 16 October 2023.

3. Update on other mandates

Adoptions since the last meeting

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

- Targeted reviews of MRLs for azocyclotin, cyhexatin, fenpropathrin, endosulfan and fenarimol under Article 43 of Regulation (EC) No 396/2005;
- Targeted risk assessment for prochloraz under Article 43 of Regulation (EC) No 396/2005;
- Guidance document on the assessment of studies concerning residues in rotational crops under Article 31 of Regulation (EC) No 178/2002.

Ongoing mandates

10 mandates are ongoing relating to substances or horizontal issues. Details can be seen on the dedicated page of the EFSA website[14].

EFSA's report regarding Scientific support for preparing an EU position in the 54th Session of the Codex Committee on Pesticide Residues (CCPR) was published on 30/08/2023. The report concerns active substances the Joint Meeting on Pesticide Residues (JMPR) evaluated in 2022. EFSA is working on a separate report on the fall-back MRLs for 178 active substances for which CXLs were revoked in 2022 CCPR. In addition, EFSA started a toxicological assessment of the 4 active substances assessed by the JMPR in 2021 considering the information provided in the JMPR Monograph 2021.

Pesticide Residues Intake Model (PRIMo) Version 4

The public consultation on the tool was open until 30 June 2023 and assessment of comments is ongoing. The final PRIMo tool and technical report are expected by end of 2023.

[13] Agenda item A..05.02 of the SCoPAFF meeting, section Phytopharmaceuticals, Pesticides Residues of 21-22 November 2017, Agenda item A.07.04 of the SCoPAFF meeting, section Phytopharmaceuticals, Pesticides Residues of 12-13 June 2017

[14] https://open.efsa.europa.eu/questions

4. Other issues

2022 Annual Report on Pesticide Residues (ARPR)

Data submissions for the annual report were accepted until 31 August 2023 and all Members States met this deadline. EFSA reminded Member States to submit all data available in-house through the reporting window to avoid duplication of work and recalled that the country section of the National Summary Report can be amended until 30 September 2023. The Multiannual National Control Plans for 2024 are collected via Microsoft Teams. Comments on the draft Annual Report will be possible until end of January 2024.

Pesticides Steering Network (PSN)/Transparency/IUCLID

EFSA presented some highlights from the IUCLID PSN subgroup meeting held in Parma on 18-19 June 2023, for example:

- The recent, improved version of IUCLID (6.7) has been available since May 2023 and IUCLID Manuals and Training Material is under development. Training for applicants and evaluators is under finalisation.
- Virtual bilateral meetings between EFSA and specific Members States to discuss issues concerning the evaluation of post-transparency applications on their request is currently ongoing. MSs are invited to express their interest at pesticides.mrl@efsa.europa.eu.
- The next IUCLID PSN will be held online in November 2023 (exact date to be confirmed) and the next EFSA PSN meeting is scheduled for 24 October 2023.

A Member State raised the issue of too many long-term clock-stops and suggested to set MRLs on a tentative basis (with footnotes requiring confirmatory data). The Commission clarified that such footnotes would not be possible for application under Article 6 of Regulation (EC) No 396/2005 as complete dossiers are required as per the applicable data requirements. A decision could however be taken on a case-by-case basis that, after a certain delay with no reaction of the applicant, EFSA issues a negative opinion highlighting the lack of data and related uncertainties.

EFSA reminded Member States to always notify, via e-mail, in case of submission or revision of any relevant document for all MRL processes.

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 and noted that, following the comments received after the last meeting for the alignment of MRLs for substances used both as pesticides and as food additives, the table had been amended accordingly.

Concerning substances with MRLs set in EU legislation both as pesticides and as veterinary medical products (VMP), the Commission intends to lower the MRL for cypermethrin in bovine milk based on EFSA's RO on the Article 12 review[15] from 0.05mg/kg to 0.015mg/kg, as the old value is based on obsolete EU uses. In the same EFSA RO, EFSA highlighted that the MRL for cattle milk deriving from the veterinary use of cypermethrin (at 0.02 mg/kg) leads to a potential acute and chronic intake

[15] EFSA Journal 2023;21(3):7800; https://www.efsa.europa.eu/en/efsajournal/pub/7800

concern and recommended risk managers to reconsider the VMP MRL for this animal commodity.

Concerning substances with MRLs set in EU legislation both as pesticides and as food additives, for several substances, MRLs/maximum permitted levels may need alignment. For cases when the maximum permitted level as food additive is set according to the "*quantum satis*" principle while the default MRL applies according to pesticides legislation, the possibility of including the substance into Annex IV of Regulation (EC) No 396/2005 adding a footnote specifying that the MRLs applies without prejudice to other specific food and/or feed legislation and referring to the safety assessments under that other sector specific legislation should be considered.

One Member State commented that boric acid and sodium tetraborate were recently re-evaluated by EFSA, and that based on the most recent toxicological data (and more specifically on reproductive toxicity effects) they may not be re-approved as food additives.

Member States were invited to submit their comments by 16 October 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.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed that the draft guidance document is taking shape but there are still chapters needing modifications. A draft is expected to be ready by the end of this year and the final document published in summer 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, there is work on the first full version of the draft guidance document. In particular, there is work on a protocol to carry out testing of certain active substances (e.g., herbicides). Therefore, the OECD working group decided to collect all the tests available and invited the members of this Committee to submit tests available with herbicides in order to finalise the first full version by autumn 2023. This will be followed by an informal and later a formal consultation according to OECD procedures.

3. Codex Alimentarius/Joint FAO/WHO Meeting on Pesticides Residues (JMPR)

a) Guidelines for general principles for EU coordinated positions for the Codex Committee on Pesticides Residues (CCPR) **for endorsement by Member States**

The Commission presented a new draft considering comments received from Member States and reminded that the document is to be considered as an internal procedural working document that will not be published.

Several editorial comments were addressed and, in accordance with a comment from a Member State, it was clarified that the implementation of a Codex maximum

residue limit (CXL) in the EU legislation is not automatic but takes the form of an amendment to Regulation (EC) No 396/2005, governed by comitology rules.

Replying to a Member State's request proposing that reservations should be introduced for CXLs proposed for substances meeting the so-called cut-off criteria, the Commission reiterated that decisions for MRLs are risk-based rather than hazard-based and that it will therefore continue to propose implementation of CXLs into EU legislation if a risk assessment carried out by EFSA found them to be safe for consumers. It explained that even if a substance meets the cut-off criteria in Regulation (EC) No 1107/2009 in some cases it can have a safe threshold allowing safe MRLs to be established. In cases no safe threshold could be identified by EFSA, the risk assessment would anyhow come to the conclusion that MRLs above the limit of quantification would not be safe for consumers.

The Commission presented the last version (Rev. 9) of the Guidelines for the preparation of the EU positions for CCPR54 for endorsement.

The final Guidelines were endorsed by the Member States, however on the specific issue of substances meeting the cut-off criteria, two Member States asked to take note of their reservations.

One Member State, France, had previously already announced not to be in a position any longer to support implementation into EU legislation of CXLs for substances meeting the cut-off criteria.

Another Member State, Germany, made the following statement to be recorded in the Summary Report: "*Germany does in general not support the setting or inclusion in EU legislation of CXL for active substances that are not approved in the EU due to health concerns. The decisive factor here is that the cut-off criteria have been established within the framework of the (re-) approval procedure of an active substance pursuant to Regulation (EC) No 1107/2009. In the framework of the Council Working Group meetings, Germany will argue in favour of introducing a reservation in such cases*."

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

The Commission provided an update on the ongoing discussion with EFSA on the way to address the follow-up of EU reservations made in CCPR in the past based on the rationale that evaluations are ongoing in the EU. To this end, the Commission is considering requesting an EFSA assessment via a specific mandate to conclude on the acceptability of CXLs after the completion of the EU assessment that was the reason for the reservation. For more detailed planning and agreement on the work plan, an inventory of the cases is under preparation and will be shared with EFSA and Member States. On the basis of that, the discussion will continue to define the terms of reference and timeframe for a dedicated mandate.

c) Feedback from CCPR meeting and preparations for the Codex Alimentarius Commission (CAC)

The Commission summarised the developments in the different working groups, highlighting the finalisation of the revision of classification of food and feed during the 54th Session of CCPR after 19 years since its initiation in 2004. The Commission thanked the Member State co-chairing the electronic Working group

for its intensive work over many years. The Commission informed that in preparation of the CAC, there will be a Council Working Party on 23 October 2023. The Commission presented additional information received from stakeholders and EFSA after the CCPR meeting in June 2023 for quinclorac on cranberries and rapeseeds and for mefentrifluconazole on tree nuts and sugar cane. Since the new information was considered sufficient to address the previous concerns that formed the basis for the reservations the EU made in CCPR, the Commission proposed to lift those reservations and communicate this in the meeting of the CAC in November 2023. However, the Commission proposed to maintain the reservation for mefentrifluconazole on pome fruits (except Japanese persimmon) because the acute consumer risk identified for pears could not be excluded.

Member States were invited to submit their comments by 10 October 2023.

A.08 Cumulative Risk Assessment (CRA):

1. Follow up on CRA EFSA/SANTE Action Plan

EFSA updated the Committee on the state-of-play of its actions listed under the four main pillars in the joint EFSA/SANTE Action Plan[16].

As regards the prioritisation and development of new Cumulative Assessment Groups (CAGs), EFSA will publish end of 2023 a scientific report listing organs/systems and pesticides requiring CAGs and CRAs.

For retrospective CRA, following the reports on the thyroid, the nervous system, chronic acetylcholinesterace inhibition and cranio-facial malformations, EFSA is working on the kidneys and the liver and is expected to deliver its reports by end of 2024 and by mid-2025, respectively. EFSA will then work on the reproductive and developmental effects and on the male reproductive system (effect on fertility excluded). EFSA's overall target is to have all CAGs established between 2026 and 2030, depending on the number of prioritised organs/systems. To this end, EFSA will outsource certain activities and has recently launched a call for cooperation on CRA with interested parties.

For prospective CRA, EFSA is performing mock assessments, working through a tasking grant with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), currently performing an acute prospective assessment (tefluthrin/carrots), expected to be finalised end of 2023, while the chronic assessment (fenamidone/lettuce) is expected to be delivered in April 2024. The assessments are using the approach discussed in document SANTE/10216/2015 Rev.8. EFSA has also a partnership with the Dutch National Institute for public health and the environment (RIVM) for the routine use of the Monte Carlo Risk Assessment (MCRA) Tool, currently in version 10.

To pave the way for future integration of non-dietary exposure, EFSA is elaborating a 6-years work programme starting from 2024, comprising 5 work packages (WPs): WP1 on the adjustment of current dietary CAGs as regards the composition and characterisation of the included substances, WP2 on the definition of the conceptual model to perform cumulative non-dietary exposure estimations, WP3 on translation the conceptual model into a (prototype) calculator, WP4 on a prioritisation methodology

[16] https://food.ec.europa.eu/system/files/2021-03/pesticides_mrl_cum-risk-ass_action-plan.pdf

(pesticides, toxicological effects, population groups of concern) and WP5 on a pilot assessment.

2. Feedback from RIVM training/ WG on risk management issues

On 30 May 2023, the Commission held a meeting of the Working Group for CRA and a training on MCRA provided by RIVM. The discussion involved the open questions for prospective CRA calculations that EFSA had addressed to risk managers during previous WG meetings. Those preliminary conclusions that are subject to change following the results of the mock assessments, along with the discussion on the metric that could represent the "risk cup" and initial views as regards the gradual implementation of prospective CRA into regulatory practice are reflected in SANTE/10216/2015 Rev.8. However, EFSA explained it would prefer waiting for the results of the mock assessments prior to reaching preliminary conclusions relating to the open questions to risk managers and prior to performing any prospective CRA.

However, the Commission clarified that this is a pilot phase and as such the answers to the specific questions on risk management aspects may not be perfect. They can, be finetuned in the future at any moment after having gained more experience.

3. Working document on risk management aspects related to the assessment of cumulative exposure (SANTE/10216/2015, Rev. 8) **for endorsement by Member States**

The document in its Revision 8 was endorsed by the Member States. As this is a working document reflecting continuous discussions and views exchange among Experts, it is subject to changes and, therefore, will not be published at this stage.

4. Training needs of MS and views on implementation

Following the meeting of the WG CRA, some Member States expressed the need for more trainings and better understanding of the prospective CRA scenario. The Commission will work with EFSA to further address this matter.

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

Following the meeting of the Working Group for sampling held on 24 April 2023, the work on a draft Regulation is on-going to take into account the comments received following that meeting. The Commission clarified that it is planned that the draft Regulation would cover both elements relating to the sampling procedure, but also key analytical aspects that are part of a risk management decision and currently covered in the Analytical Quality Control Guidelines updated regularly by the EU RLs. For instance, the Commission considers it relevant to include a clarification on the use of the measurement uncertainty (MU), applicable to all active substances, including those that are classified as per Regulation (EC) No 1272/2008 as meeting the cut-off criteria or that can be considered as genotoxic carcinogens. As further discussion is needed also on many other detailed aspects covered by the current sampling Directive 2002/63/EC, the Commission announced a second meeting of the Working Group for 7 December 2023.

Member States were invited to nominate representatives of their authorities by 16 October 2023.

A.10 State of play on genotoxic carcinogens and Guidelines for harmonised risk management approaches and enforcement action in cases of incidents involving food products containing genotoxic carcinogens (for endorsement by the Member States):

Member States' competent authorities' experts in the field of pesticides residues and contaminants had met on 19 January 2023 and 22 June 2023 to discuss harmonised risk management approaches/enforcement actions in cases of incidents involving food products containing genotoxic and carcinogenic substances, or suspected ones. The aim is to be prepared to react quickly with a common EU approach if such a food safety incident would happen in the future.

The Commission informed that, following the second technical meeting, a large majority of Member States supported the approach in full and agreed to follow it. Even though full harmonisation could not be achieved, the approach will facilitate the future management of incidents and some of its elements could be useful as guidance for the Member States for the day-to-day risk management of local contamination events outside an EU-wide food safety incident. The Commission presented the final version of the Guidelines, with minor editorial changes made for clarity.

All Member States, except Germany, endorsed the final Guidelines. Germany made the following statement: "*Germany fully supports the aim of the guidelines to harmonise risk management in Europe, especially for (potentially) genotoxic and carcinogenic substances. Regrettably, however, the competent authorities continue to have concerns about the implementability of the proposed approach and thus also with regard to the achievement of the stated objective. In particular, the lack of legal certainty in the implementation in enforcement due to the absence of the required risk assessment and proportionality check in individual cases as well as the legally non-binding character of the guidelines is pointed out as problematic. From our Federal State's perspective, an amendment of the relevant EU regulations would be necessary for legally secure enforcement*."

The Committee noted that the Guidelines are a technical document, not adopted by the Commission, and not intending to produce legally binding effects. The Guidelines will now be submitted for endorsement by the section Novel Food and Toxicological Safety of the SCoPAFF at its meeting on 22 September 2023, and will subsequently be published on the Commission website, on the respective pages related to pesticide residues and to contaminants.

A.11 Notifications under Article 18(4) to Regulation (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 2023 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.

Member States were invited to submit their comments by 16 October 2023.

The Commission informed of its monitoring of emergency authorisations granted by Member States and on the increased scrutiny by the Commission by mandating EFSA to check for the justification of repeated emergency authorisations granted by Member States. Emergency authorisations are granted for mostly EU approved active substances (around 85% of the cases) and for the vast majority of them there is no need to set any

national tMRLs as those uses are covered by existing EU MRLs. The Commission highlighted that the number of national tMRLs resulting from such authorisations is extremely low and that consignments that do not respect the EU harmonised MRLs cannot be traded outside the territory of the Member State that established such a national tMRL. The Commission also highlighted that, if there was a need for the regular use of an approved substance, this should always be dealt with by a regular MRL application (only one such case was identified and, in the meantime, a regular MRL had been established).

As some misreporting cases were identified, where erroneously Member States had reported the values of the existing EU MRLs as a national tMRL, the Commission asked Member States to prevent mistakes when reporting emergency authorisations and informed of the work that it had initiated to improve the clarity of the respective form that Member States need to fill in when notifying emergency authorisations to the EU database. Furthermore, the existing guidance document on emergency authorisations is also being updated also to reflect the judgement for case C-162/21. The Commission reminded once again that cases of setting such national tMRLs would always need to be reported also to this Committee (as done for prothioconazole under this agenda item), coupled with explanations as to the controls for such national tMRLs that may not leave the national territory. Notification in the database alone is not sufficient to fulfil the notification requirements of Article 18(4) of Regulation (EC) No 396/2005.

A.12 Designation of Member States for maximum residue levels (MRL) applications:

A Member State received an application for inclusion of Polyoxin D zinc salt in Annex IV of Regulation (EC) No 396/2005. That Member State would be willing to accept this application and requested the Committee whether there would be any objections to it.

One Member State pointed out that there had already been an MRL application for including that active substance in Annex IV in the past, from the same company, and that it had evaluated it. That Member State had initially supported, in its draft evaluation report, the inclusion in Annex IV, but after receiving additional data from EFSA it did not support that view any longer. Based on this evaluation outcome, the applicant withdrew the application in August 2019 and also requested not to forward the updated evaluation report to EFSA. The Member State that had received the new application acknowledged this information shared by the other Member State and confirmed that it would still be willing to accept the application.

One Member State noted that the provision of Article 5 (1) of Regulation (EC) No 396/2005 can be interpreted as requesting that the inclusion of an active substance in Annex IV can only take place after its approval. In that Member State's view this would not be the correct interpretation, and a full evaluation according to Articles 6-10 would also provide the possibility to include a substance in Annex IV. Therefore, that Member State requested an interpretation of Article 5 (1) of Regulation (EC) No 396/2005. The Commission recalled some earlier discussions on this issue and will get back to the Committee with further information in the next SCoPAFF meeting, on 20-21 November 2023.

At the previous meeting of this Committee, one Member State informed about its willingness to accept an application for the setting of an import tolerance for isotianil, an active substance that was never notified and approved in the EU, in citrus and bananas. That application is based on uses of isotianil in Honduras, Panama, Colombia,

Guatemala and Cambodia, and the applicant clarified that no national legislation exists in these countries as they defer to CXLs and also sometimes include deferrals to U.S. and/or EU MRLs. Nevertheless, in the case of isotianil, no national U.S. MRLs and CXL seem to apply. Therefore, that Member State requested the Commission's views on the possibility to set an MRL based on an import tolerance.

The Commission noted that the Commission guidelines for setting MRLs[17] allow for some flexibility, as some Third Countries do not establish MRLs, solely relying on CXLs or MRLs set by other countries. Therefore, in case there is proof of authorised GAPs or registered labels in a Third Country that does not set national MRLs and that request the setting of an import tolerance, the application can be accepted even in the absence of an established MRL.

Two Member States suggested to better clarify this in the Commission guidelines and noted that as several Third Countries declare setting MRLs only for export purposes, having import tolerance established in the EU based on GAP used in those countries may help the setting of national MRLs.

No objections were raised, and Member States were invited to submit their comments by 16 October 2023.

A.13 Monitoring of pesticide residues:

The next meeting of the Working Group for the monitoring of pesticide residues will take place on 13 October 2023. The Commission invited Member States to nominate representatives by 3 October 2023.

The Commission recalled that document SANTE/11312/2021 is intended for laboratories involved in the official control of pesticide residues in food and feed across the European Union, as designated according to Article 37 of Regulation (EU) 2017/625. Therefore, the measurement uncertainty 50% of the analytical value only applies for the analytical results produced by such laboratories.

The enforcement of residue definitions that include conjugates of substances (e.g. fluroxypyr conjugates) is often hindered by the lack of analytical standards for conjugates, the absence of analytical methods to determine or break them down to substances that can be analysed, and the lack of understanding of exactly which conjugates to enforce, which can potentially lead to under-estimation of results. Further discussion will follow at the meeting of the Working Group on 13 October.

A.14 Forthcoming draft Regulations (indicative only):

1. Dithiocarbamates

The work on a draft Regulation reviewing MRLs for dithiocarbamates is ongoing and based on the recent EFSA RO[18]. The Commission recalled that the approvals for thiram, propineb and mancozeb were not renewed due to concerns for their endocrine disrupting properties. For metiram EFSA's peer review[19] concluded that both metriram and its metabolite ETU meet the criteria for endocrine disruptors for human, but the decision making process is still ongoing. For ziram, the renewal of approval is ongoing, but the peer review is suspended to allow for the necessary time to carry-out an

[17] SANTE/2015/10595 Rev. 6.1, 23 September 2021
[18] EFSA Journal 2023;21(5):7987
[19] EFSA Journal 2023;21(4):7937

assessment relating to its possible endocrine disrupting properties. The approval of maneb expired in 2016.

The Commission recalled the discussion under point A.03.01 of the meeting of the SCoPAFF of 10-11 May 2023 as regards setting MRLs for substances meeting the cut-off criteria[20], that the current risk assessment considers Toxicological reference Values (TRVs) that take into account the endocrine disrupting properties of these substances and provided an overview of such possible MRLs using the residue definition proposed by EFSA, "dithiocarbamates determined and expressed as carbon disulfide (CS2)", despite the possible findings of metabolite M222F001 in rotational crops, which according to EFSA should be addressed by Member States by taking risk mitigation measures to avoid residues occurring after metiram uses.

A Member State recalled the analytical research performed to enable the determination of the actual substance used in the field and suggested that the residue definition should exclude the word "determined", thus be broad enough to enable the development and use of such methods. EFSA clarified that the proposed definition considers background levels as these are only determined as CS2. Another Member State informed that a Third Country encounters problems with finding of dithiocarbamates in vine leaves exceeding the current level of 0.05*mg/kg and would prefer the level of 0.2mg/kg.

The Commission also informed of a letter from a banana association supporting the use of mancozeb in many banana producing countries (mainly Latin American and Caribbean countries), its importance against Black Sigatoka and that the current MRL for banana should be maintained.

Member States were invited to submit their comments by 16 October 2023.

2. Fenarimol and fenpropathrin

The Commission will prepare a draft Regulation for non-approved active substances for which EFSA recently completed a targeted MRL review and for which Member States have identified potential consumer risks. EFSA recently published the targeted MRL reviews for fenarimol[21] and fenpropathrin[22], in both cases concluding that the TRVs cannot be confirmed since the data available were insufficient according to the current toxicological standards. The draft Regulation will be prepared in accordance with the conclusion of the procedural issues discussed under the agenda point A01.03b. Other active substances recently evaluated by EFSA may still be included in this draft Regulation.

3. Fluopyram, napropamide, pyridaben and tebufenpyrad

The Commission is preparing 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. EFSA assessed the confirmatory data and for some food groups the data has been evaluated to be sufficient to support the current MRLs whether at LOQ or at 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. Fluopyram concerns an import tolerance request and will be handled in a separate draft Regulation.

[20] https://food.ec.europa.eu/system/files/2023-06/sc_phyto_20230510_ppr_sum.pdf
[21] EFSA Journal 2023;21(7):8113
[22] EFSA Journal 2023;21(6):8057

A.15 Issues related to Annex 1 of Regulation (EC) No 396/2005:

The discussion about the classification of radish leaves in the Annex 1 of Regulation (EC) No 396/2005 was proposed to be postponed for the meeting of the SCoPAFF on 20-21 November 2023.

The Commission informed of a request for information from a Member State about *Tabebuia impetiginosa*, a plant that has been banned in some Member States due to its toxicological potential but that is included in Annex 1 to Regulation (EC) No 396/2005. The Commission indicated that inclusion of products in Annex I to regulation (EC) No 396/2005 does not imply that this product can be considered authorised as food or feed in the European Union.

The Commission also provided the feedback it received from Member States on the proposal to delete footnote 1 in Annex 1 of Regulation (EC) No 396/2005. Until now, 6 Member States have submitted their views showing divergent opinions. Also, the letters from several stakeholder associations were shared with the Member States. The Commission clarified – in response to several comments - that it will not be feasible to fill the empty category for "feed" and establish specific MRLs for feed products anytime soon due to lack of resources both in the Commission and in EFSA given the current priorities. Stakeholders proposed preparation of guidance material that would assist users in the application of footnote 1. The Commission indicated its clear preference to delete the footnote and create legal certainty but asked Member States for their comments on this option and possible volunteers for such a task. Two Member States already reacted indicating their divergent views.

Member States were invited to submit their comments by 16 October 2023.

A.16 Regular review of designations of EU Reference Laboratories:

The discussion on this point was postponed.

A.17 Data extraction from TRACES for the purpose of EFSA's reporting:

The Commission recalled that the official controls on imported products of non-animal origin from third countries performed at border control points also include controls under Regulation (EU) 2019/1793[23] which are reported by Member States in the TRACES platform as required by Regulation (EU) 2019/1715[24]. However, for the purpose of its Annual Report on pesticides Residues, EFSA cannot extract information from that system as the level of detail provided is not equivalent to the Standard Sample Description version 2[25] (SSD2) used by EFSA. Discussions on possible harmonisation is ongoing between EFSA and the Commission, but until then, the Commission requested from Member States to continue submitting the results of those controls both to EFSA and TRACES.

A.18 Wording of transitional measures in our Regulations:

The Commission recalled that the topic had been raised following concerns expressed by some non-EU countries that domestic and imported products would be treated differently in the EU Regulations setting MRLs, since the respective Article of the Regulations is referring to products "*produced in or imported into the Union*". While

[23] https://eur-lex.europa.eu/eli/reg_impl/2019/1793/oj
[24] https://eur-lex.europa.eu/eli/reg_impl/2019/1715/oj
[25] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2015.EN-918

the Commission had clarified previously that there was no different treatment in practice between domestic and imported products, as already today the term "produced" is interpreted as "placed on the market", it had proposed to start a discussion with Member States on a possible clearer wording.

The Commission provided an update on comments received from Member States since the last meeting and the Committee discussed various options. Feedback had been received from 12 Member States, with broad support for a clarification, with some questions raised on interpretation. A Member State raised concerns on changing the wording and stressed that it should provide very clear legal certainty.

As next steps, the Commission will consult internally on the proposed amendments and the questions raised by Member States and will come back to the Committee at a subsequent meeting to continue the discussion.

A.19 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 SCoPAFF meeting 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 on 30 August the draft Regulation to the Council for its opinion. The Council shall act on the proposed measure by a qualified majority within one month of referral to it.

If the Council would oppose the measure, the Commission cannot adopt it. If the Council would envisage adopting the measure as such or in an amended form, the Commission shall without delay submit it to the European Parliament for its opinion.

If the Parliament would not oppose the measure, the latter shall be adopted by the Commission. If the Parliament would oppose the measure, it shall not be adopted by the Commission.

2) Brexit

No issue was raised under this point.

3) Draft revised Communications on data requirements (Commission Regulation (EU) No 283/2013 and 284/2013)

The Commission shared with Member States the endorsed version of the revised Communications on data requirements. (Post meeting Note: on 29 September 2023 the Communications were published in the Official Journal[26]).

4) Update on F2F -measure lowering MRLs for clothianidin and thiamethoxam

The Commission informed Member States about an application against the European Commission requesting the annulment of the Commission Regulation 2023/334 (T-247/23).

[26] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2023:344:TOC

5) Furathiocarb

A Member State informed that it had found levels of carbofuran (0,054 mg/kg) and furathiocarb (0,11 mg/kg) in hops. The residue definition for carbofuran includes also carbofuran generated by carbosulfan, furathiocarb and benfuracarb, but those parent compounds are not included in this definition. The Member State questioned whether the default MRL of 0,01 mg/kg set in Article 18 (1)(b) of Regulation (EC) No 396/2005 MRL applies for those parent compounds.

The Commission recalled that those substances were used in the past in PPPs. Moreover, MRLs for furathiocarb and benfuracarb were listed at the LOQ in Annex V to that Regulation, while MRLs also existed for carbosulfan in Annexes II and IIIB. Regulation (EU) 2015/399[27] established a common residue definition for the three parent compounds as they all rapidly degrade to carbofuran.

Member States were invited to submit their comments by 10 October 2023.

6) Future organisation of PAFF meetings

The Commission informed of the tentative planning of the meetings of this Committee in 2024. Four meetings are currently provisionally planned for early February, end of April, end of September and end of November, the exact dates still need confirmation. With the CCPR meeting scheduled for the first week of June 2024, the two Council Working Parties for its preparation could be scheduled in May 2024. The Commission intends to have at least one meeting of this Committee with fully physical attendance, the other ones could be organised in hybrid or fully virtual mode, depending on the budget and the agenda.

7) MRLs for chili peppers

The Commission informed Member States of a letter from a stakeholder sharing its interpretation on the MRLs that should apply for residues in dried powder of imported chili peppers. In the view of the stakeholder, MRL for peppers should apply to chili peppers, taking into account the pertinent processing factors. The stakeholder informed about some border rejections because the residues for the imported chili powder were compared to the MRL for spices instead the one for peppers. The Commission shared the interpretation of the stakeholder and invited Member States to submit their comments by 16 October 2023.

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

On 16 March 2023, France had taken a 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[28], based on health concerns with the applicable MRL for phosmet on cherries.

France informed that, since Regulation (EU) 2023/1029 lowering all MRLs for phosmet to the LOQ became applicable on 15 September 2023, this measure was in the process of being withdrawn, which should be finalised in a matter of days.

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[27] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32016R0399

[28] Arrêté du 16 mars 2023 portant suspension d'introduction, d'importation et de mise sur le marché à titre gratuit ou onéreux en France de cerises fraîches destinées à l'alimentation produites dans un pays autorisant le traitement des cerisiers avec des produits phytopharmaceutiques contenant la substance active phosmet (AGRG2306968A)

9) Residues of phosmet in olive oil

In August 2023, a Member State had sent a letter to the Commission requesting an amendment to Regulation (EU) 2023/1029 lowering all MRLs for phosmet to the LOQ to grant transitional measures for olive oils, i.e., so that olive oil already produced before the application date of 15 September 2023 and compliant with the old MRL but not the new MRL could remain on the market. The Member State reported that olive oil producers' associations had difficulties with stocks of olive oil produced with olives treated with phosmet before the end of grace periods in the EU on 1 November 2022, in particular in view of uncertainties on the EU olive oil market. According to the analysis conducted, the levels of residues of phosmet in these stocks of olive oil are below 0.01 mg/kg in the majority of samples analysed, and only slightly exceeding 0.01 mg/kg in most of the rest of the samples.

In Regulation (EU) 2023/1029, the MRL for phosmet on olives for oil production is lowered from 3 mg/kg to the LOQ of 0.01* mg/kg. The Regulation does not provide for transitional measures, so that, as of the application date of 15 September 2023, all products placed on the EU market have to comply with the new MRLs. The Commission recalled that the decisions not to renew the approval of phosmet in the EU and consequently to lower the MRLs for phosmet on all products to the LOQ were taken in view of important concerns related to health risks for consumers identified by EFSA, due to the high toxicity of phosmet as well as uncertainties on the toxicity and genotoxicity of its metabolite phosmet-oxon. These concerns were discussed and agreed with Member States in meetings of the SCoPAFF, sections Phytopharmaceuticals – Legislation and Pesticides Residues. In view of the health risks, Member States had agreed that shorter than usual timelines should be set for the length of grace periods for the use of existing stock of plant protection products containing phosmet, and for the date of application of the new lower MRLs.

However, the Commission pointed out that the MRL at the LOQ of 0.01* mg/kg applies to the product in Annex I of Regulation (EC) No 396/2005, i.e., the unprocessed olives for oil production. For the processed product, i.e., olive oil, a processing factor (PF) should be applied to the MRL in line with Article 20 of Regulation (EC) No 396/2005 and the guidance document SANTE-10704-2021. PFs can be retrieved from the EFSA database[29], national databases or from the information directly provided by Food Business Operators (FBOs) and can be used by the Member States' enforcement authorities who are responsible for their application. The MRL for olive oil is then PF * 0.01 mg/kg.

The Commission encouraged the Member State to investigate internally and with the relevant FBOs on which specific PF should be used for their olive oil, with a view to share the information with all Member States and enhance harmonised enforcement action across Member States.

In addition, the Member State requested to start a discussion on the approach to be taken with decisions on granting transitional measures, stressing the issues that can arise for stocks of processed products produced with raw products compliant with old MRLs. The Commission noted that it was open to start a broader discussion on transitional measures and proposed that other Member States share their views.

Member States were invited to send their comments by 3 October 2023.

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[29] European database of processing factors for pesticides in food https://zenodo.org/record/1488653#.YHBgL44zZaQ

10) Use of processing factor of refined oil on crude oil

The Commission informed of a communication from a company looking for guidance on addressing recent RASFF notifications from a Member States' competent authorities regarding sunflower and/or soybean crude oils from Ukraine, linked to MRL exceedances for chlorpyrifos. The Member States' authorities are using PFs[30] for refined oils and not for crude oils in their decision process. As a result, none of the batches are compliant with the derived MRLs and have been rejected.

The Commission has contacted the authorities of this Member State for feedback. It drew the attention of the Committee to the agreed elements in the Information Note[31]. The correct PF should be used also by the competent authorities and justification for the use should be provided to the FBOs. In addition, the specific LOQ should be considered eg., 0.01mg/kg and the measurement uncertainty (MU), i.e., specific MU or default MU of 50%, should be applied when competent authorities take a decision on compliance with MRLs.

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

(PLAN/2023/947)

The Commission presented revision 1 of the draft Regulation lowering the MRLs for oxamyl. The approval of oxamyl in the EU has not been renewed in 2022 and grace periods granted by Member States for use of existing stocks of PPPs containing oxamyl will have expired on 1 November 2023. As previously discussed, with the new lower Acceptable Daily Intake (ADI) and acute Reference Dose (ARfD), EFSA identified acute and chronic risks for many commodities even with LOQs lower than 0.01* mg/kg. Therefore, the draft Regulation sets LOQs at lower achievable levels for several commodities: 0.002* mg/kg for oranges and tomatoes, 0.001* mg/kg for all other commodities of high water and high acidic content, cow milk, herbs, 0.005* mg/kg for avocados, cereals, muscle of mammals and eggs. In addition, in view of the high consumer health risks, the deferred application date is 3 months and therefore deliberately shorter than the usual 6 month period. For the same reason, transitional measures for products placed on the market before the application date have not been granted.

The Committee discussed the comments received from one non-EU country following the consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO), sharing concerns relating to the low LOQs set for many commodities and to the short period given for the deferral of the application date. The Committee noted that the lowering of the MRLs is based on health risks identified by EFSA[32]. EFSA identified extremely high acute and chronic risks: 82 commodities exceed the ARfD for children's diets (e.g. bananas: 970%). The

[30] https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors
[31] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_proc_imp_sante-2021-10704.pdf
[32] European Food Safety Authority; Statement on the risk assessment of maximum residue levels (MRLs) for oxamyl in view of consumer protection. EFSA Journal 2023;21(3):7823.

ADI is exceeded for 34 diets (e.g. for the Dutch toddler: 1200%). Given the risks identified for oxamyl and the conclusions by EFSA that the existing CXLs are unsafe for consumers and that lower LOQs than 0.01* mg/kg are necessary to ensure consumer protection, the Committee agreed that LOQs lower than 0.01* mg/kg should be set, while acknowledging that it could be challenging for some laboratories especially in non-EU countries. When such low levels need to be achieved, the EU Reference Laboratories (EURLs) are supporting other official control laboratories with their advice, which can also be given to non-EU laboratories on their request. In addition, the new MRLs should apply as soon as possible to ensure consumer protection. The Committee noted that the new MRLs would become applicable approximately in March 2024.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for levels for desmedipham, etridiazole, flurtamone, profoxydim, difenacoum, and potassium permanganate in or on certain products.

(PLAN/2023/946)

The Commission presented revision 2 of the draft Regulation updating and lowering MRLs for desmedipham, etridiazole, flurtamone, profoxydim, difenacoum and potassium permanganate. The substances are no longer approved in the EU and grace periods have expired. No CXLs or import tolerances exist, so that all MRLs are proposed to be set at the LOQ in Annex V of Regulation (EC) No 396/2005. The Commission informed that the MRL for etridiazole on sugar plants, which is at the LOQ, had been corrected to 0.01* mg/kg.

A Member State commented that, as highlighted by the EURLs, the MRLs for potassium permanganate are difficult to enforce in practice as potassium permanganate is highly reactive and degrades rapidly to manganese and its dioxide, which are ubiquitous and of no toxicological concern. This raises the question of how to deal with such substances and whether it is relevant to set MRLs for them in Annex V of Regulation (EC) No 396/2005. Another Member State agreed with this and brought up again its previous suggestion to create a second part for Annex IV of Regulation (EC) No 396/2005 with substances that cannot be controlled. The Commission acknowledged the issue and noted that including potassium permanganate in Annex V, as proposed in the draft Regulation, is not a change in practice to the current situation, where in the absence of specific MRLs, the default MRL of 0.01* mg/kg already applies. Further reflection might be needed on a solution for substances that are in a similar situation, as the established levels cannot be controlled.

The Committee noted that no comments had been received from non-EU countries following the consultation of trading partners under the SPS agreement of the WTO.

The Committee noted that the new MRLs would become applicable approximately in June 2024 and that transitional measures for products placed on the market before the application date have been granted for all products.

Vote taken: Favourable opinion.

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

(PLAN/2023/242)

The Commission presented revision 5 of the draft Regulation and gave an overview of its contents and the modifications made since the last meeting of this Committee.

The Commission reminded that EFSA identified a possible risk to consumers due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature. For products that are usually processed at high temperature, the MRLs based on CXLs cannot be confirmed as safe for consumers. For products that are usually not processed at high temperature, and thus for which those metabolites and degradation products would not be expected to be formed, the Committee discussed that the existing MRLs based on CXLs could be maintained. The Committee agreed that this would be the case for cranberries and teas.

Therefore, the MRLs on all products, except cranberries and teas, are lowered to the LOQs. The MRLs for cranberries and teas are maintained at 1 mg/kg and 5 mg/kg respectively.

The Committee discussed the comments received from two non-EU countries following the consultation of trading partners under the SPS agreement of the WTO requesting not to lower the EU MRLs as indoxacarb is used on many crops exported to the EU, in particular cranberries, grapes, peppers, tomatoes, apples, hazelnuts, cucumbers, corn, and eggplant. In addition, they requested longer deferred application periods, of 2 years, as well as transitional measures. A request was also made that the new MRLs would apply from the date of production and not of importation for imported products. The Committee discussed the comments and noted that the lowering of the MRLs is based on health risks identified by EFSA[33], with exceedances of the ARfD. The Committee recalled that a concern form requesting the prioritisation of indoxacarb for re-evaluation by JMPR had been submitted to Codex ahead of the CCPR meeting in June 2023.The Committee also noted that due to the health risks, no transitional measures could be granted for products placed on the market before the application date. The same concept applies to all products placed on the market in the EU, which is not discriminatory between imported and domestic products. A discussion is ongoing to clarify the wording in future EU Regulations setting MRLs to avoid misunderstandings (see item A.18).

The Committee noted that the new MRLs would become applicable approximately in June 2024.

Vote taken: Favourable opinion.

[33] European Food Safety Authority; Targeted review of maximum residues levels (MRLs) for indoxacarb. EFSA Journal 2022;20(8):7527.

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 cyflumetofen, oxathiapiprolin and pyraclostrobin in or on certain products.

(PLAN/2023/1703)

The Commission presented revision 3 of the draft Regulation and outlined its contents. As regards cyflumetofen, a fast-track application requesting a modification of the existing MRL in courgettes and gherkins was submitted. An MRL application on EU uses of oxathiapiprolin on radish leaves had been submitted in accordance with Article 6 of Regulation (EC) No 396/2005. An MRL application in support of an import tolerance for pyraclostrobin in papayas based on a Brazilian GAP was submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005. EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers. Therefore, this draft measure intends raising those MRLs accordingly.

Vote taken: Favourable opinion.

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

(PLAN/2023/750)

The Commission presented revision 4 of the draft Regulation and gave an overview of its contents, following an MRL application in support of an import tolerance for mandipropamid in papayas based on a Brazilian GAP that was submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005. EFSA confirmed in its RO[34] that the proposed MRLs are fully supported by data and safe for consumers. Therefore, this draft measure intends raising that MRL accordingly. In addition, this draft Regulations intends including a footnote requiring information on the toxicity of metabolite SYN 500003 for potatoes, beetroots, and radishes, as in its review of MRLs for mandipropamid conducted in accordance with Article 12 of Regulation (EC) No 396/2005, EFSA identified some information on the toxicity of metabolite SYN 500003 as unavailable as regards root crops, but due to a mistake this was previously only implemented in a Regulation for onions, spring onions/green onions and Welsh onions.

Vote taken: Favourable opinion.

B.06 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 fipronil in or on certain products.

(PLAN/2023/962)

The Commission presented revision 2 of the draft Regulation which proposes modifying the MRLs for fipronil in sugar canes from 0.005* mg/kg to 0.01 mg/kg, based on an MRL application in support of an import tolerance based on a Brazilian GAP that was submitted in accordance with Article 6(2) and (4) of Regulation (EC) No

[34] European Food Safety Authority; Setting import tolerances for mandipropamid in papayas. EFSA Journal 2023;21(1):7741

396/2005. As sugar canes can be fed to animals, the draft Regulation also proposes raising some of the existing MRLs in fat from bovines, sheep, and goats. EFSA confirmed in its RO[35] that the proposed MRLs are fully supported by data and safe for consumers. Therefore, this draft measure intends raising those MRLs accordingly.

Four Member States did not support the draft Regulation presented by the Commission and another one abstained from the vote as they do not support import tolerances for substances no longer approved in the EU. In addition, one Member State noted that the toxicological data used by EFSA to draw its conclusions are very old (1995), and therefore the safety of the proposed MRLs is debatable and reminded that the periodic review of fipronil by JMPR is planned by 2024, and therefore recommended to wait for its outcome before setting new MRLs for this substance. Another Member State added that this active substance poses problems to bees.

Vote taken: Favourable opinion.

B.07 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 diethofencarb, fenoxycarb, flutriafol and pencycuron in or on certain products.

(PLAN/2023/194)

The Commission presented revision 7 of the draft Regulation and provided an overview, following the comments received after the previous meeting. Myclobutanil was removed from the draft, as new information to support an import tolerance for bananas is now available and time is needed for its evaluation. For flutriafol, the recent 54th Session of the Codex Committee on Pesticide Residues[36], proposed new CXLs for barley, liver (swine, bovine, sheep, goat, equine, other farmed terrestrial animals), while for poultry (liver, kidney, edible offals other than liver and kidney) current CXLs were proposed to be maintained. The EU supported those levels in CCPR since EFSA did not identify any concerns. As it is likely that they will be adopted by the Codex Alimentarius Commission in 2023, the draft Regulations maintains the MRLs for the above-mentioned products.

The Commission informed of the comments received from one non-EU country during the consultation of trading partners under the SPS agreement of the WTO which was in support of maintaining the current MRLs for flutriafol in livestock and poultry products.

The Committee noted that transitional periods for products placed on the market before the application date have been granted and that the Regulation will become applicable approximately in June 2024.

One Member State did not support the draft Regulation as the measure establishes import tolerances for flutriafol, an active substance that is not approved in the EU. Another Member State abstained due to the lack of a voting mandate.

Vote taken: Favourable opinion.

[35] European Food Safety authority, Setting of import tolerances for fipronil in potatoes, sugar canes and products of animal origin, EFSA Journal 2023; 21(4):7931

[36] Joint FAO/WHO, Codex Alimentarius Commission, Report of the 54th session of the Codex Committee on Pesticide Residues, 2023

B.08 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 (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, acrinathrin, azimsulfuron, famoxadone, prochloraz and sodium hypochlorite in or on certain products.

(PLAN/2023/145)

The Commission presented revision 5 of the draft Regulation and gave an overview of the changes made since the last meeting of this Committee. Methyl nonyl ketone was removed from the draft Regulation and will be dealt with in a future routine measure. For (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, acrinathrin, azimsulfuron, prochloraz and sodium hypochlorite the MRLs were proposed to be lowered to LOQ and set in Annex V to Regulation (EC) No 396/2005. For famoxadone MRLs based on CXLs were proposed to be maintained in Annex II to the same Regulation.

EFSA[37,38] could not exclude exceedances of the ARfD for prochloraz in or on granate apples/pomegranates and papayas and for famoxadone in or on table grapes. For all substances on all products, except for famoxadone in table grapes and for prochloraz in granate apples/pomegranates and papayas, a transitional period is proposed for products placed on the market before the application date of the Regulation. The draft Regulation was notified to trading partners via the WTO/SPS notification procedure and no comments were received.

The Committee noted that the Regulation will become applicable approximately in June 2024.

A Member State abstained from the vote as the assessment on endocrine disrupting properties under Regulation (EC) No 1107/2009 has not been finalised.

Vote taken: Favourable opinion.

B.09 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 haloxyfop in or on certain products.

(PLAN/2023/897)

The Commission presented revision 4 of the draft Regulation, proposing to lower all existing MRLs based on obsolete EU uses, to maintain the existing MRL for soybeans based on an import tolerance and to set the MRLs for rapeseeds and linseeds based on an import tolerance request that was assessed favourably by EFSA. The Commission shared the comments received from Member States indicating that the MRLs for haloxyfop in onions and sunflower seeds should be maintained because they correspond to CXLs that were considered safe for consumers[39]. The Committee agreed to lower the LOQ for milk to 0.002 mg/kg, because the product specific LOQ for milk of 0,01 mg/kg was the major contributor to chronic exposure according to the EFSA targeted review.

[37] EFSA Statement on targeted risk assessment for prochloraz, EFSA Journal 2023;21(8):8231.
[38] EFSA Statement on targeted risk assessment for famoxadone, EFSA Journal 2023;21(3):7932.

[39] European Food Safety Authority reasoned opinion on the targeted review of maximum residues levels (MRLs) for haloxyfop-P. EFSA Journal 2022;20(11):7658.

The Committee noted that no comments had been received from non-EU countries following the consultation of trading partners under the SPS agreement of the WTO.

One Member States did not support the draft Regulation presented by the Commission while two abstained from the vote as they do not support import tolerances for substances no longer approved in the EU. In addition, one Member State abstained from the vote because of the excessively low MRL at the LOQ for milk which it considers not analytically achievable in routine work of laboratories. The Member State not supporting the measure agreed with the latter point and noted that, in addition to the issue of import tolerances, it considers the overall margin of exposure was too narrow and that the lower LOQ for milk was not a solution to address this issue.

Vote taken: Favourable opinion.

B.10 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 thiacloprid in or on certain products.

(PLAN/ 2023/961)

The Commission presented revision 5 of the draft Regulation. Following the non-renewal of approval for this active substance and the subsequent revocation of existing authorisations for PPPs, it proposes to lower all existing MRLs based on obsolete EU uses and to maintain certain import tolerances and CXLs, in particular those that were recently reviewed and found safe by EFSA[40]. The Committee discussed the comments received from two non-EU countries following the consultation of trading partners under the SPS agreement of the WTO relating to the lowering of MRLs of thiacloprid in fat tissues from mammals to the LOQ. The Commission indicated that MRLs for fat were not initially proposed because no CXL proposal was derived for fat. However, after further evaluation by EFSA, the Commission proposed an MRL of 0,07 mg/kg for fat from mammalian animals and maintain the proposed MRL for muscle at 0.1 mg/kg to take into account that Codex Alimentarius, different from the EU, established MRLs for "meat" which consists of a mixture of "muscle" and "fat" and the distribution of residues of thiacloprid in those two matrices in a ratio 3:2 (established by JMPR). EFSA had confirmed that the levels are safe for consumers.

Eight Member States did not support the draft Regulation. Six of them mentioned first and foremost their concerns with maintaining CXLs and import tolerances for a non-approved substance which meets on of the cut-off criteria under Regulation (EC) No 1107/2009 (toxic for reproduction). In addition, one Member State that did not support the draft Regulation had concerns that EFSA had indicated exceedances of the acute reference dose for some products in certain non-standard circumstances, another one mentioned the discrimination of EU farmers that may no longer use plant protection products containing this active substance, while farmers in third countries could still do so, thus leading to unfair competition.

[40] European Food Safety Authority Statement on the short-term (acute) dietary risk assessment and evaluation of confirmatory data for certain maximum residue levels (MRLs) for thiacloprid. EFSA Journal 2023;21(3):7888.

Germany requested the following declaration to be included in the Summary Report of this meeting, which was noted by the Committee:

"Thiacloprid is a cut-off active substance according to Regulation (EC) No 1107/2009. During the re-approval procedure of the active substance, it was determined that it meets the cut-off criteria as it has a classification as toxic to reproduction 1B. Accordingly, the active substance was not re-approved.

Germany does in general not support the setting of MRLs for active substances that are not approved in the EU due to health concerns. The decisive factor here is that the cut-off criteria have been established within the framework of the (re-)approval procedure of an active substance pursuant to Regulation (EC) No 1107/2009."

Vote taken: No opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Pythium oligandrum strain* M1, *Trichoderma atroviride* strain AGR2 and *Trichoderma atroviride* strain AT10.

(PLAN/ 2023/1697)

The Commission presented an overview of the revision 1 of the draft Regulation.

Two Member States abstained from the vote as they were not in favour of including *Pythium oligandrum strain M1, Trichoderma atroviride strain AGR2 and Trichoderma atroviride strain AT10* into Annex IV of Regulation (EC) No 396/2005 in line with their earlier decisions not so support those three active substances to be re-approved as low risk substances in the section Phytopharmaceuticals – Legislation of this Committee.

Germany requested the following statement to be recorded in the Summary Report of the meeting, which the Committee took note of:

"*Regarding Pythium oligandrum strain M1, Trichoderma atroviride strain AGR2 and Trichoderma atroviride strain AT10, Germany already opposed the approval of the active substances as "low-risk active substances" in the re-approval procedure and accordingly abstained from the vote in the Standing Committee "Legislation". The decisive issues were:*

- *Pythium oligandrum strain M1: the absence of pathogenicity and infectivity could not be established from the literature review which was considered insufficient. Accordingly, the risk assessment for the effects on human health could not be finalised.*
- *Trichoderma atroviride strain AGR2: a data gap was identified on the potential production of trichothecenes and peptaibols. Therefore, amongst others, the dietary consumer risk assessment for metabolites of potential health concern were not finalised.*
- *Trichoderma atroviride strain AT10: a data gap is still pending on the identity of the peptaibols. Consequently, inter alia, the dietary consumer risk assessment for metabolites of potential health concern could not be finalised.*

In summary, from our point of view, these three active substances are not "low-risk active substances" and we cannot agree with their inclusion into Annex IV to Regulation (EG) 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)

The Commission presented this draft Regulation for the first time and recalled that internal discussions on how to deal with MRLs for substances meeting the cut-off criteria had recently been concluded and that a decision had been taken to continue to base regulatory decisions on a risk assessment carried out by an Evaluating Member State and EFSA.

The Commission explained that for glufosinate, those MRLs that were based on now obsolete EU uses should be lowered, while existing CXLs could be maintained if safe for consumers and sufficiently supported by data. The Commission noted that in the current draft Regulation circulated before the meeting, the CXL for soyabean at 2 mg/kg was missing and should be considered in the next draft.

The Committee discussed whether the EFSA RO on the Article 12 review of MRLs for glufosinate, which was published in 2015, would be a sufficient basis for the current Regulation. In this assessment, EFSA had used the Toxicological Reference Values (TRVs) set in the EU in 2007 in the framework of Directive 91/414/EEC, and version 2 of PRIMo. JMPR had set lower TRVs in 2012. Two Member States commented that EFSA should review the TRVs for glufosinate and perform a new consumer exposure assessment using the potentially new TRVs and the latest version 3.1 of PRIMo.

Member States were invited to send comments by 10 October 2023.

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.

(PLAN/2023/1863)

The Commission presented an overview of this draft Regulation for the first time. It is based on the EFSA RO[41] on the Article 12 review. The group of cypermethrins consists of 4 isomers with the same residue definition: cypermethrin (approved in the EU as a candidate for substitution), alpha-cypermethrin, beta-cypermethrin, and zeta-cypermethrin (the latter three not approved in the EU), with alpha-cypermethrin being the most toxic isomer (lowest TRVs). MRLs can be set based on updated uses authorised in the EU for cypermehtin, as well as CXLs and import tolerances in place, if confirmed safe by EFSA. The MRLs based on outdated uses or uses not supported by data, and the MRLs identified as unsafe and for which there is no safe fall-back GAP, will be lowered to LOQ. EFSA screened the LOQ of 0.01* mg/kg to verify whether this value would be sufficiently protective to consumers and concluded that for potatoes, melons, pears and oranges, a lower LOQ of 0.005* mg/kg would be needed to provide sufficient protection. Transitional measures can be granted in case there are no health risk with the previous MRLs.

Furthermore, the Commission highlighted that EFSA had identified some areas of uncertainties and left risk managers to take a decision on all MRLs.

[41] EFSA Reasoned Opinion on Review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2023;21(3):7800

Firstly, the approval of cypermethrin has been renewed in the EU with the condition of submitting confirmatory data related to endocrine disrupting properties by end 2023. It was considered during the renewal process in 2021 that cypermethrin is unlikely to be an endocrine disruptor. Nevertheless, in order to increase the confidence in its decision, the Commission had set in the Commission Regulation on the renewal of its approval a requirement for confirmatory data to be delivered within two years, in line with the current criteria to identify endocrine disrupting properties and using the related guidance document. For consistency with this decision, the Commission proposed not to lower all MRLs to LOQs for this reason at this moment. A footnote referring to the requested confirmatory data in the framework of Regulation (EC) No 1007/2009 can be set, and submission of the data will trigger a review of the data gap and of the MRLs.

Secondly, potential acute health risks were identified by EFSA for the MRLs for 34 commodities in case the quantified residue consists only of alpha-cypermethrin, which is the most toxic of the 4 compounds. The 34 commodities for which there would be an exceedance of the ARfD are: oranges, quinces, table grapes, wine grapes, carambolas, potatoes, beetroots, carrots, celeriacs/turnip rooted celeries, parsnips, radishes, salsifies, swedes/rutabagas, turnips, onions, tomatoes, melons, broccoli, head cabbages, lamb's lettuces/corn salads, roman rocket/rucola, red mustards, watercresses, chervil, chives, parsley, sage, basil and edible flowers, beans (with pods), lentils, asparagus, celeries, rhubarbs, rice. The Commission proposed to take this into account to protect consumers and lower the MRLs for these 34 commodities to the LOQs.

Additionally, the Commission highlighted that EFSA identified health risks with some of the uses authorised for cypermethrins in the EU and that Member States should consider withdrawing authorisations for these uses.

Member States were invited to send comments by 10 October 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.

(PLAN/2023/1782)

The Commission presented revision 1 and gave an overview of the draft Regulation based on the EFSA RO on the Article 12 MRLs review[42].

The Commission recalled that EFSA identified a data gap on the mutagenicity potential of the metabolite 1,4-naphthoquinone, which is expected to be addressed during the ongoing renewal procedure for dithianon by the submission of a further Ames test. EFSA informed that the Renewal Assessment Report (RAR) is expected to be submitted by the RMS by end 2024, and therefore the renewal procedure may be expected to be finalised around end 2025. A conclusion on the mutagenicity potential of the metabolite 1,4-naphthoquinone is expected to be reached at that time.

In view of the ongoing renewal process, it is proposed to modify only those MRLs for which EFSA identified exceedances of the ARfD, and for which urgent action should be taken. This means lowering the MRLs for apples and pears from 3 mg/kg to 1.5 mg/kg. All MRLs would remain in part A of Annex III, and footnotes would be set on all MRLs not at LOQ, referring to the data gap on the metabolite 1,4-naphthoquinone

[42] EFSA Reasoned Opinion on Review of the existing maximum residue levels for dithianon according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2023;21(1):7731

to be filled under Regulation (EC) No 1107/2009. All MRLs would be reviewed following the completion of the renewal process.

Member States were invited to send comments by 17 October 2023.

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

(PLAN/2022/2853)

The Commission presented revision 6 of the draft Regulation, with minor modifications compared to the previous one. As carbendazim and thiophanate-methyl are no longer approved for use in the EU, it proposes to lower existing MRLs that are based on EU uses, and for which no import tolerances or CXLs are in place, to the LOQ of 0.01* mg/kg (with the exception of complex matrices which might warrant higher LOQs).

For MRLs based on import tolerances[43], in cases where EFSA identified a risk for consumers (i.e., carbendazim in grapefruits, oranges, papayas and mangoes, and thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes), the draft measure proposes lowering the MRL to the LOQ without any transitional arrangements for products placed on the market before the application date. It proposes maintaining or setting those MRLs that EFSA found to be safe for consumers.

The Commission highlighted that for carbendazim in mandarins and lemons and for thiophanate-methyl in lemons, EFSA noted that the worst-case approach they had followed in their RO (assuming co-occurrence of carbendazim and thiophanate-methyl on these three products) leads to an overestimation of the exposure, while in practice such co-occurrence of these residues is not expected. Therefore, EFSA concluded that those MRLs are safe for consumers, provided that residues are not co-occurring. The current draft proposed therefore to set the MRLs not taking into account co-occurrence.

For carbendazim in products of animal origin, the draft measure proposes an MRL of 0.01* mg/kg (as this was considered achievable by the EURLs and in line with the proposed LOQs for thiophanate-methyl and benomyl), while EFSA indicated the possibility of setting the MRL at 0.02* mg/kg.

The draft measure proposes separating the residue definition (RD) for benomyl from the one of carbendazim, and creating a new separate RD for benomyl in Annex V to Regulation (EC) No 396/2005.

The Commission recalled that EFSA is currently working on the assessment of endocrine disrupting properties for carbendazim and thiophanate-methyl and noted that, based on that outcome (foreseen by December 2023) changes to the current draft Regulation may become necessary.

One Member State recommended clarifying in the recitals 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.

One Member State informed that it would not support this draft measure, as it contains substances meeting the cut-off criteria, and noted its disagreement with the proposed

[43] EFSA Reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal 2021;19(7):6773.

approach of considering some MRLs safe based on the assumption that residues would not co-occur. Moreover, it noted that if the residues were to be considered at MRL level, an exceedance of the acceptable daily intake would occur (130% of ADI). The Commission replied that using the internationally agreed methodology for exposure assessment there was no risk for consumers.

Another Member State referred to its earlier position on substances meeting the cut-off criteria (ref. agenda item B.10) and informed that it will implement this new approach in all cases when MRLs are proposed to be maintained or established for active substances that are non-approved in the EU and meet the cut-off criteria as established under Regulation (EC) No 1107/2009. It also noted that a revision of the MRLs for carbendazim and thiophanate-methyl was expected for a long time, and that the industry had sufficient time to adapt accordingly.

Member States were invited to submit their comments by 10 October 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 1 of the draft Regulation based on several EFSA ROs related to Article 6 applications (2022 EFSA statement[44]) and on the 2021 EFSA RO on the Joint Review of MRLs[45]. EFSA's recent assessment of an Article 6 application for potassium phosphonates in spring onions and leeks[46] is also considered in the draft.

All MRL values proposed are based on the new residue definitions for enforcement ("phosphonic acid and its salts expressed as phosphonic acid" for products of plant origin and "phosphonic acid" for products of animal origin). Therefore, the current version proposes recalculating the previously established LOQ of 2* mg/kg for products of plant origin according to the new residue definition, resulting in a level of 1.5* mg/kg (while for complex matrices the LOQ of 20* mg/kg is proposed). Moreover, as some Member States had noted that in the previous version of the draft some MRLs were expressed according to the old residue definition, these were corrected.

For all products belonging to the subgroups "others", no MRLs values are proposed in the Joint Review (JR). The proposal sets those MRLs equal to the lowest value established for a commodity in a group. Following recommendations from two Member States, the MRLs for "0231990 (a) Solanaceae and Malvaceae Others" and for "0251990 (a) lettuces and salad plants Others" were set at 70 mg/kg and 150 mg/kg respectively, due to existing national authorisations. For the group "1017000 (g) other farmed terrestrial animals" no MRL proposals were included in the JR. Nevertheless, as EFSA noted that usually for these animal products the same values as for bovine are proposed, the MRLs were set accordingly. For the products "Edible offals (other than

[44] EFSA Statement on the scientific statement on the maximum residue levels for potassium phosphonates. EFSA Journal 2022;20(7):7400.

[45] EFSA Reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl,disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6782

[46] EFSA Reasoned Opinion on the modification of the existing maximum residue levels in leeks and spring onions/green onions/Welsh onions resulting from the use of potassium phosphonates. EFSA Journal 2023;21(5):8033

liver and kidney)" for all species, the MRL was set to the highest available MRL amongst those of muscle, fat, liver or kidney of the same species following a recommendation from one Member State. Nevertheless, the Commission noted that this decision may be revised and that those MRLs should rather be set to the lowest value established for a commodity in a group, consistently with the internal Commission's working procedure on Article 12 proposals and in line with what was already proposed for products of plant origin.

In cases where EFSA had identified data gaps, the draft Regulation proposes establishing footnotes with requirements to fill existing data gaps by different deadlines, depending on the kind of data gap.

Member States were invited to submit their comments by 10 October 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 2 of the draft Regulation addressing the confirmatory data that were submitted in response to the data gaps identified during the Article 12 MRL review for deltamethrin[47], metalaxyl-M[48], thiabendazole[49] and trifloxystrobin[50]. The Commission shared the comments received from Member States, EFSA and one applicant on the previous revision and proposed some amendments based on this information. Regarding deltamethrin, it proposed to maintain the existing MRLs for rape seeds, radishes and to increase the MRLs for carobs/Saint John's bread to 0.7mg/kg. For apples, one Member State and EFSA expressed the view that the conversion factor of 1:1 could be applied to maintain the CXL at 0.2mg/kg. For thiabendazole, this revision proposed to maintain the existing MRLs for papayas by refining the consumer risk assessment calculations with the peeling factor for similar crops (mangoes), as it was concluded that the proposed value was safe for consumers. However, one Member State indicated that the application of the peeling factor for mangos to papayas was not specifically included in the OECD Extrapolation Guidance document. Therefore, this MRL will be reviewed again for further discussion. The Commission informed that the draft Regulation includes reviewed MRLs for honey based on a recent conclusion from EFSA[51].

Member States were invited to submit their comments by 10 October 2023.

[47] Reasoned opinion on the Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for deltamethrin in tomatoes and okra/lady's fingers. EFSA Journal 2022;20(3):7107.
[48] Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for metalaxyl-M. EFSA Journal 2021;19(12):6996.
[49] Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for thiabendazole. EFSA Journal 2022;20(8):7539.
[50] Reasoned opinion on the modification of existing maximum residue levels in various crops and evaluation of confirmatory data following the Article 12 MRL review for trifloxystrobin . EFSA Journal 2022;20(1):7048
[51] European Food Safety Authority Reasoned Opinion on the modification of the existing maximum residue level for trifloxystrobin in honey EFSA Journal 2023;21(8):8189

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

(PLAN/2023/951)

The Commission presented revision 2 of the draft Regulation reviewing the existing MRLs for bifenthrin and the exchange of information with Member States, EFSA and the applicant. Based on the applicant's commitment to provide confirmatory data necessary to update the existing TRVs according to the current scientific standards, the Commission proposed to lower only those MRLs based on obsolete EU uses while maintaining those MRLs based on non-EU uses for a limited time period, based on the indicative risk assessment performed by EFSA[52]. The procedural options to consult stakeholder during the MRL review of non-approved active substances was discussed under agenda point A.01.03.b.

Member States were invited to submit their comments by 10 October 2023.

C.08 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl in or on certain products.

(PLAN/2022/2563)

The new revision 5 of this draft Regulation does not include methoxyfenozide, as following the previous proposal to lower its MRL for aubergines to the LOQ due to the lack of confirmatory data, a Member State reported that such data was available. While the manufacturer of the substance confirmed it had no interest to support the existing MRL, the Member State confirmed that it intends to submit this data in an application under the procedure described in Article 6 of Regulation (EC) No 396/2005 in support of the sector's association in its territory. Provided that the data are complete and a favourable assessed by EFSA is received, the existing MRL could be maintained permanently.

For 2,4-DB while the draft measure proposes maintaining MRLs for cereals, for products of animal origin MRLs are proposed to be lowered to the LOQ. Two Member State warned of possible MRL exceedances for those products in case MRLs are lowered to the LOQ. The Commission reported that previous monitoring data (2017-2021) indicate that the substance was not quantified in more than 1000 samples of animal products and, therefore, exceedance of MRLs (set at LOQs) is not expected.

Member States were invited to submit their comments by 10 October 2023.

C.09 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.

(PLAN/2023/1960)

The Commission presented for the first time the draft Regulation reviewing the MRLs for the non-approved substances cyproconazole, isopyrazam and spirodiclofen under Article 12 of Regulation (EC) No 396/2005. The approval of isopyrazam was

[52] EFSA (European Food Safety Authority), 2023. Targeted review of maximum residue levels (MRLs) for bifenthrin. EFSA Journal 2023;21(2):7864

withdrawn by Commission Regulation (EU) 2022/782[53]. The approvals of cyproconazole and spirodiclofen have expired and no application for renewal of its approval had been submitted. The three substances meet the criteria to be classified as toxic for reproduction category 1B. All EU authorisations for plant protection products containing those active substances have therefore been revoked. For all three substances the draft Regulation proposes to maintain existing MRLs based on CXLs and to lower MRLs which were based on now obsolete EU uses to existing lower CXLs which EFSA found to be safe for consumers. All other MRLs are proposed to be lowered to the LOQ. For isopyrazam and spirodiclofen, import tolerances exist and are proposed to be maintained as they were found to be safe for consumers. In some food groups the existing MRLs were based on the older EU methodology (R_{ber}/R_{max}) as the OECD MRL calculator was not yet developed. The new MRLs were derived by the OECD calculator leading to higher MRL values in some cases. Regarding CXLs of isopyrazam in or on azaroles/Mediterranean medlars and kaki/Japanese persimmons, the Commission noted that the CXLs were by mistake not reviewed under Article 12 of Regulation (EC) No 396/2005 and therefore, EFSA will proceed with a corrigendum of its RO.

A Member State indicated it would not support the draft Regulation as it proposes maintaining MRLs for substances meeting the cut-off criteria.

Member States were invited to submit their comments by 10 October 2023.

C.10 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bispyribac, lemon essential oil, metosulam, oryzalin, oxasulfuron and triazoxide in or on certain products.

(PLAN/2023/948)

The Commission introduced revision 2 of the draft Regulation containing non-approved substances for which the MRLs are already set at the LOQ in Annex II to Regulation (EC) No 396/2005 except for lemon essential oil for which the default MRL of 0.01 mg/kg applies according to Article 18(1)(b) of Regulation (EC) No 396/2005. Grace periods have expired, and for all substances MRLs are proposed to be set at the LOQ in Annex V to Regulation (EC) No 396/2005.

For lemon essential oil, which was not approved as a basic substance, the Commission informed that following comments received in its internal consultation procedure and from a Member State, it is suggested to include it into Annex IV to Regulation (EC) No 396/2005. As citrus essential oils generally consist of a variety of compounds, "lemon essential oil" is an unspecific residue definition and the proposed MRL is not enforceable. Furthermore, citrus natural oils occur in various raw and processed foods. This natural background is likely to cause several exceedances of the default MRL of 0.01 mg/kg, independent of any pesticide application. On the other hand, in the EFSA technical report[54] a dietary exposure assessment / comparison with background levels had not been provided and the uncertainty linked to the main component of lemon essential oil, which is D-limonene, was not fully addressed. The Member States were

[53] Commission Implementing Regulation (EU) 2022/782 of 18 May 2022 withdrawing the approval of the active substance isopyrazam 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 1037/2012 (OJ L 140, 19.5.2022, p. 3.)

[54] EFSA Technical Report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of lemon essential oil to be used in plant protection as an acaricide, insecticide and fungicide in fruit trees (citrus), EFSA Supporting publication 2021:EN-6873.

invited to indicate whether they support the permanent inclusion into Annex IV or whether they would rather consider the inclusion into Annex V of Regulation (EC) No 396/2005.

The draft Regulation will not be notified to trading partners via the WTO/SPS notification procedure as there will be no change of MRLs and the changes are purely of administrative nature (establishing already existing levels in Annex V).

Member States were invited to submit their comments by 16 October 2023.

C.11 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for nicotine in or on certain products.

(PLAN/2023/1999)

The Commission presented revision 1 of this new draft Regulation reviewing MRLs for nicotine in spices and presented the rationale for the proposed MRL modifications.

Following Regulations (EU) 2023/377[55] and 2023/1536[56], the Commission received new monitoring data from stakeholders indicating that nicotine residues may occur in spices at higher levels than the tMRLs established by those measures. Stakeholder organisations had explained that their previously submitted data were not correct and not complete. Although it is not appropriate to change tMRLs constantly in light of new evidence, the Commission nevertheless considered it appropriate in this particular case in order to avoid major trade disruptions and under the condition that revised MRLs based on such new data would be confirmed to be safe for consumers by EFSA. Therefore, the Commission mandated EFSA to perform a new acute dietary risk assessment for nicotine in spices and a new chronic exposure assessment, of which the final EFSA outcome is expected at the end of September 2023. Meanwhile, this draft Regulation proposes setting the MRLs for nicotine in all spices at 0.3 mg/kg.

If EFSA confirms that the proposed MRLs are safe, the Commission plans to present this draft Regulation for vote at the upcoming SCoPAFF – section Phytopharmaceuticals-Legislation on 12 October 2023.

One Member State expressed satisfaction for the proposed draft measure and thanked the Commission for its reactivity on the topic.

One Member State confirmed that the newly proposed MRL of 0.3 mg/kg for nicotine in spices was safe for consumers. Moreover, it added that stakeholders should be reminded that this kind of information should be brought to the attention of the Commission early in the MRL setting process, and not only once the decision for modifying an MRL had already been taken. Lastly, that Member State noted that a chronic risk for consumers may be identified if residues for all food products occurred at the LOQ and invited the Commission to address this issue.

Member States were invited to submit their comments by 21 September 2023.

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[55] Commission Regulation (EU) 2023/377 of 15 February 2023 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 (OJ L 55, 22.2.2023, p. 1).

[56] Commission Regulation (EU) 2023/1536 of 25 July 2023 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for nicotine in or on certain products (OJ L 187, 26.7.2023, p. 6).