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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
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CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/1f0b4026-83ab-48ce-8ae8-a2f5e580e131?p=1&n=10&sort=modified_DESC*

SUMMARY REPORT

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

1. Confirmatory data Art. 12 follow-up

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

The EFSA RO on the Article 12 confirmatory data for thiabendazole provided two options for risk managers as regards the Maximum Residue Level (MRL) for avocados: a MRL of 7 mg/kg based on an adjusted Good Agricultural Practice (GAP) or the existing Codex MRL (CXL) of 15 mg/kg based on data from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Using the Pesticide Residues Intake Model (PRIMo) version 3.1, EFSA concluded that the CXL did not present risks for consumers.

In its evaluation, EFSA considered the risk assessment values available from JMPR since 2000 in which a peeling factor of 0.13 was derived and calculated the acute exposure for the highest residue in the edible portion (pulp) of avocados at 91% of the Acute Reference Dose (ARfD).

During the meeting of this Committee in September, a Member State indicated acute exposure concerns for the CXL for avocados when considering the new International Estimate for Short Term Intake (IESTI) equation. According to EFSA, this is possible only if the CXL is used directly, without considering the peeling factor. However, when the CXL is corrected with that factor, the acute exposure for avocados is 42% of the ARfD.

Therefore, the Commission reiterated its initial proposal for considering a modification of the current MRL for thiabendazole in avocados as to equal the CXL of 15 mg/kg.

b) Missing analytical standards follow-up

Following the reminder letters to manufacturers regarding the commercial availability of analytical standards for cyflufenamid (E-isomer), fluroxypyr conjugates and spiroxamine carboxylic acid metabolite M06, the Commission informed of the response of a manufacturer to make the analytical standard of the E-isomer of cyflufenamid commercially available by 31/12/2022.

2. List of non-approved substances for follow-up

At the meeting of this Committee in September 2022, the Commission had proposed the inclusion of 10 non-approved active substances in a mandate to EFSA requesting a targeted review of their MRLs. These active substances were carbaryl, cyanides, dicloran, diquat, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, and saflufenacil. The proposed list received the support from Member States.

The Commission noted that, for cyanides, as these are also regulated under the contaminants legislation1, and in view of their natural occurrence, proposing the MRL at the Limit of Quantification (LOQ) of 0.01 mg/kg will not be appropriate for several crops, and highlighted that, before addressing this substance, internal discussion with the Commission services dealing with contaminants would be needed. Therefore, it proposed not to include this substance in the next mandate, which would then cover only nine active substances. One Member State supported this proposal. Due to EFSA's heavy workload, this targeted review will start in the second half of 2023.

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

The Commission presented a revised version of the draft general principles on setting footnotes for data gaps related to MRLs set at the LOQ. While the question when to set or not to set such footnotes arose for MRLs set under the Article 12 review procedure, it could also be applicable to other situations. Once agreed, the approach could be integrated into the Commission Working Document on drafting measures to amend pesticides MRLs following Article 12 of Reg. (EC) No 396/2005 (SANCO/11485/2012). The aim is to achieve consistency and harmonisation across draft Regulations, although it was acknowledged that special cases may arise which would then need individual considerations.

Possible scenarios were presented and discussed in the form of a table, considering the various types of data gaps (e.g. analytical methods for enforcement, residue trials, residue definition, metabolism, rotational crop studies) and various bases for setting MRLs (EU GAP, Codex MRL (CXL), third country GAP (import tolerances), no use). The Commission clarified that CXLs and import tolerances appear in the table as they can be indeed at LOQ, although it is rare.

Member States were invited to share their comments on the revised proposal by 15 January 2023.

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

The Commission provided an update on the table of active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon, and for which follow-up action was therefore needed.

[1] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

A.03 Specific substances:

1. Glufosinate ammonium

The Commission informed that there were no news on this substance. A Member State asked for more details on the reasons for the delays with the follow up on this substance. The Commission referred to ongoing internal consultations within the Commission.

2. Glyphosate

Following the announcement by EFSA and ECHA in May 2022 of delays in the assessment of glyphosate, the Commission proposed in October 2022 to extend the current approval of glyphosate for one year in accordance with Article 17 of Regulation (EC) No 1107/2009, in order to allow the ongoing peer review process to be completed and for EFSA to deliver its Conclusion in July 2023. . As "no opinion" on this proposed extension was delivered, the Commission referred the draft Regulation to the Appeal Committee for further deliberation, which convened on 15 November 2022. The Appeal Committee also deliver an "no opinion" vote. The Commission will adopt the draft act before 15 December 2022 to extend the deadline, as it is obliged under Article 17 of Regulation (EC) No 1107/2009.

3. Bacillus thuringiensis (Bt)

In the last meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation that took place on 13-14 October 2022, the Commission presented the draft renewal reports concerning the eight strains of Bt for which the process of renewal of approval is currently ongoing. Based on previous discussion it was proposed to Member States to consider the need for a Pre-Harvest Interval (PHI) for certain edible crops aiming at ensuring that the consumers' exposure to Bt remains below the threshold of 10^5 CFU/g for fresh consumption at the time of availability for consumers. The length of the PHI may vary among the 8 strains and the representative crops, based on the following data and assumptions:

- residue data provided in the dossier,
- a minimum of 1 day would be needed between harvest and availability on the market for consumers, and
- EFSA assumption that the half-life of Bt under greenhouse conditions is 24h.

If residues data, measured or estimated, do not show levels of Bt above 10^5 CFU/g at harvest, then, as recommended by EFSA, the PHI would not be required.

The Commission further informed that in the proposed renewal report applicants would be required to provide data in at least one representative edible crop (i.e. pome fruits or tomatoes) in order to determine the density of Bt from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10^5 CFU/g as recommended by EFSA. This would also include storage stability data of the micro-organisms between the sampling and the spore counting analysis.

In the SCoPAFF, section Phytopharmaceuticals – Legislation taking place in December the Commission will ask feedback from the Member States on the proposed renewal reports in a tour de table, as only few have provided input so far.

A Member State indicated that on the food hygiene side there were findings on products that did not correspond to 10^5 CFU/g for *Bacillus cereus* sensu lato and were therefore

taken off the market without specific identification of Bt strains as no specific analytical methods were used in this routine monitoring activity. Another Member State highlighted the importance of protecting the consumers and that, therefore, the level of 10^5 CFU/g should cover the whole *Bacillus cereus* group as stated in the EFSA opinion[2]. In addition, they questioned whether a residue decline study on only for one edible crop per Bt strain would be sufficient to ensure that all products on the market comply with 10^5 CFU/g. A Member State supported the Commission's proposal as a good way forward, but reminded that the aim was to make sure that wore data were received by the applicant. With regard to methods, it would be advisable to require data established in such a way as to differentiate individual strains.

The Commission clarified that Commission Regulation (EC) No 2073/2005[3] on microbiological criteria for foodstuffs only sets limits for *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age and highlighted that, if setting MRLs for Bt, this would seem a stricter approach than what the food hygiene Regulation provides for. In addition, the Commission explained that, in its opinion, the collection of the monitoring data for one edible crop is proportionate to what is needed.

The Commission asked the Member States to reflect whether the proposed PHI would provide sufficient guarantees that consumers would not be exposed to levels higher than 105 CFU/g and whether in that case Bt strains could be included into Annex IV to Regulation (EC) No 396/2005, or if a MRL would still be needed in Regulation (EC) No 396/2005 to reflect this level. A Member State replied that in its view the PHI would logically require the setting of an MRL as food business operators, farmers and control authorities should be aware of such a level and that Member States competent authorities would need to able to enforce it. Another Member State supported this point of view. On analytical methods the Member State stressed that by now differentiation between strains is well feasible. The Commission requested more information on those analytical methods from this Member State.

The Commission called for coordinated action among the Member States representatives attending the two sections of the SCoPAFF as to provide feedback from the Residues to the Legislation section in view of the meeting of the latter section on 9 December.

4. Acetamiprid

The Commission informed that EFSA had received a request for access to the data that were shared by Member States on the findings of unexpected levels of the acetamiprid metabolite N-desmethyl-acetamiprid (IM-2-1) in some food products. The Commission noted that, as the data are property of the Member States concerned, the requestor should address its request to the Member States owning the data.

5. Thiacloprid

The Commission informed of a draft mandate to EFSA according to Article 43 of Regulation (EC) No 396/2005 to perform a risk assessment considering the updated toxicological reference values (TRVs), the latest version of PRIMo and any relevant

[2] Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. Including *Bacillus thuringiensis* in foodstuffs. EFSA Journal 2016;14(7):4524

[3] Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1)

confirmatory data. Subsequently, based on the EFSA recommendation, the Commission will prepare a draft Regulation lowering certain MRLs to the LOQ.

6. Trimethyl-sulfonium (Trimesium) cation

As discussed in the previous meeting of the Committee, Member States should collect monitoring data. Stakeholders are also invited to provide further monitoring data enabling a better overview on the presence of trimesium in different foodstuffs. Meanwhile, the Commission will reflect with EFSA on possible options and terms of reference for further investigations on this substance.

7. Oxamyl

The Commission informed that, as announced at the last meeting of this Committee, the SCoPAFF, section Phytopharmaceuticals - Legislation endorsed the new TRVs at its last meeting on 13 October 2022. Thus, the Commission is in the process of sending a mandate to EFSA under Article 43 to perform a risk assessment of MRLs for oxamyl with the new TRVs in view of consumer protection, including investigating the need and feasibility of LOQs lower than 0.01* mg/kg. The EFSA statement is expected to be finalised by early February 2023, so that a preliminary discussion could be held at the next meeting of this Committee.

8. Sodium hydrogen carbonate

Currently two separate entries exist in the EU MRL database for this substance: one as basic substance listed in Annex IV to Regulation (EC) No 396/2005 for which no MRLs are required, and another one as low risk active substance for which the default MRL of 0.01mg/kg according to Article 18(1)(b) applies to all products. At the meeting of this Committee in September, the Commission had proposed to align those entries by including "Sodium hydrogen carbonate (low risk active substance)" in Annex IV as the substance, as confirmed by EFSA[4], fulfils the Annex IV inclusion criteria. The proposal was agreed by Member States.

One Member State noted that, according to Article 23(1)(d) of Regulation (EC) No 1107/2009, with the approval of an active substance according to Article 22 of that Regulation, the same active substance cannot be approved as a basic substance. The Commission informed the Member States that this issue is under discussion in the SCoPAFF, section Phytopharmaceuticals – Legislation.

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 3 processes[5] had been adopted since the last meeting of this Committee.

Currently, outputs addressing 47 such processes are at different steps of the procedure. Out of these, 14 are under scientific assessment (9 under Regulation (EC) No 396/2005 and 5 under Regulation (EC) No 1107/2009) and 33 under clock-stop as additional data had been requested (26 under Regulation (EC) No 396/2005 and 7 under Regulation (EC) No 1107/2009).

[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5407
[5] Each process receives a so called "EFSA question number".

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

EFSA presented the state of play of the ongoing Article 12 reviews. Since the last meeting of this Committee, 2 MRL reviews were finalised, 20 are on hold, 19 are currently being assessed at different stages of the procedure, while for 11 substances data is pending. The progress report table is available for interested stakeholders[6].

3. Update on other mandates

Adoptions since the last meeting

The following EFSA Reasoned Opinion was adopted by EFSA since the last meeting of this Committee:

- A targeted review of MRLs for haloxyfop-P under Article 43 of Regulation (EC) No 396/2005

Ongoing mandates

- Nine further mandates are currently ongoing relating to several substances or horizontal issues. Details can be seen on the dedicated page of the EFSA website[7].

Forthcoming mandates currently under discussion

Three mandates are currently being prepared:

- Mandate under Article 43 of Regulation (EC) No 396/2005 for a risk assessment of MRLs for oxamyl in view of consumer protection.
- Mandate under Article 43 of Regulation (EC) No 396/2005 for a targeted risk assessment and an evaluation of confirmatory data for certain MRLs for thiacloprid.
- Mandate under Article 43 of Regulation (EC) No 396/2005 for a targeted risk assessment for famoxadone.

Comments on the recent EFSA Statement on the short-term (acute) dietary risk assessment for the temporary MRLs for nicotine in rose hips, teas and capers[8]

The Commission informed that Tea & Herbal Infusions Europe (THIE) had sent letters to both the Commission and EFSA criticising the validity of EFSA's PRIMo data concerning tea consumption for children in one Member State, which led to the identification of an acute risk deriving from the existing temporary MRL (tMRL) for nicotine in teas. In the THIE's view, the draft Commission Regulation lowering that MRL that was voted by this Committee in September should be amended to maintain it. The Commission confirmed that the identified issue would need to be addressed, and that discussions have been already initiated with EFSA in that sense. Nevertheless, it also highlighted that the lowering of the tMRL was based on monitoring data, which still justify this lowering even if there is no risk for consumers.

EFSA commented that the existing data for tea consumption of children of the respective Member State may not be correct and that they will investigate with the Member State concerned. The latter confirmed that the consumption data need to be corrected, and that it would work as to provide the new data to EFSA. On a possible revision of PRIMo, EFSA noted that this will be time consuming and that alternative

[6] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf
[7] https://open.efsa.europa.eu/questions
[8] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7566

solutions may be explored, such as not considering the current consumption data for Irish children in the calculation but the second highest and perform a new calculation on that basis. This would allow the publication of a revised statement in a relatively short time. A Member State agreed with the proposed approach.

4. Other issues

Pesticides Steering Network (PSN)/Transparency/IUCLID[9]

EFSA informed that from the first 57 IUCLID post transparency MRL dossiers received, 22 are pending finalisation of the admissibility checks, 35 were declared admissible by Evaluating Member States. From the 35 admissible dossiers, 10 passed the confidentiality assessment.

Following the issues reported at the last meeting of this Committee, EFSA is working on improving efficiency of the confidentiality assessment and of the admissibility check, with 5 ad hoc teleconferences between EFSA and Member States held to-date to support Member States and anticipate issues encountered with the admissibility check.

The 5th meeting of the PSN-IUCLID subgroup will be held on 5 December 2022[10].

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

The JMPR held its annual meeting on 12-23 September 2022 and the summary report was recently published[11]. A mandate under Article 43 of Regulation (EC) No 396/2005 is under discussion for the yearly report on scientific support for preparing the EU position for the 54th Session of CCPR. The exact scope is currently still being discussed between EFSA and the Commission.

PRIMo rev 4

EFSA informed on the development of PRIMo rev 4, which is expected for final publication in November 2023. A public consultation is planned from March to end of May 2023. New features of Primo rev 4 will include: a refined IESTI assessment with standard unit data from Member States to allow for a more consistent approach among countries and surveys, an increased quality of consumption data with use of individual data from a comprehensive database allowing possible refinement for processed foods and minor crops, a refined definition of relevant subgroups of the population (including infants and young children), an improved consistency with other food sectors, and more transparency on intra- and inter- population variability.

EFSA 2021 Annual Report on Pesticide Residues

EFSA informed that the consultation of Member States on the draft Annual Report on Pesticide Residues, analysing the 2021 monitoring data, will be launched in January 2023.

[9] International Uniform Chemical Information Database
[10] https://www.efsa.europa.eu/en/events/5th-meeting-pesticide-steering-network-iuclid-sub-group
[11] https://www.who.int/publications/m/item/joint-fao-who-meeting-on-pesticide-residues-by-the-2022-meeting--13-22-september-2022

Cumulative Risk Assessment

The EFSA Scientific report on Retrospective cumulative dietary risk assessment of craniofacial alterations by residues of pesticides has been published[12].

Triazole Derivative Metabolites

EFSA informed that it is working on a draft document which will be presented at an upcoming meeting of this Committee.

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

The Commission presented an update on the harmonisation of MRLs for pesticides and veterinary medicinal products (VMPs). The working table was revised, prioritising substances based on the prioritisation principles agreed with the Member States at the meeting of this Committee in September. The work will continue according to the identified urgency and the availability of resources.

A Member State noted that some of the active substances present in the table are also used as food additives, and enquired whether this should also be considered. The Commission will reflect and report back at the next meeting of this Committee. Another Member State commented on the Commission's proposal that no alignment was needed in cases where MRLs for VMP are only set for fish, as no MRLs for pesticide are set for fish at this stage. In its view, as it is unknown at which level pesticides residues from fish feeding may occur in fish, those may contribute to higher residues of substances that are used both as pesticide and as VMP. Therefore, it proposed that monitoring data in fish should be carefully checked and every suspicious residue of the relevant active substances should be reported to this Committee and/or to the monitoring Working Group.

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

The Commission, based on the comments received from Member States, presented the first draft Regulation which includes *Bacillus amyloliquefaciens* strain AH2, *Bacillus amyloliquefaciens* strain IT-45, *Purpureocillium lilacinum* strain PL 11 to Annex IV of Regulation (EC) No 396/2005.

With regard to *Streptomyces lydicus* strain WYEC 108, the Commission proposed to wait until the renewal of approval process is finished.

As regards Beauveria bassiana strains and the possible concerns on the metabolite beauvericin, the Commission informed that beauvericin is a mycotoxin produced also by various *Fusarium* species and that in 2014 EFSA adopted an opinion on the risks of beauvericin and enniatins[13], concluding that acute exposure to both does not raise concerns for human health. With respect to chronic exposure, no firm conclusion could be drawn, thus relevant in vivo toxicity data were needed to perform a human risk assessment. The respective study was performed in 2018[14] and EFSA will follow up in January 2023 on whether the data from this study are sufficient for a risk assessment.

[12] https://www.efsa.europa.eu/en/efsajournal/pub/7550

[13] Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed. EFSA Journal 2014;12(8):3802

[14] In vivo toxicity and genotoxicity of beauvericin and enniatins. Combined approach to study in vivo toxicity and genotoxicity of mycotoxins beauvericin (BEA) and enniatin B (ENNB). EFSA Supporting publication 2018:EN-1406

A Member State is against of including *Purpureocillium lilacinum* strain PL 11 into Annex IV of Regulation (EC) No 396/2005 as leucinostatins should be considered as toxicologically relevant metabolites. It referred to the EFSA conclusion on the peer review[15] supporting its view. The Commission clarified that the substance's approval has very recently been renewed and this issue was not considered a human health concern.

Member States were invited to submit comments by 15 January 2023.

A.07 Monitoring of pesticides residues:

The Commission provided an overview of the discussion held during the meeting of the Working Group on the monitoring for pesticide residues on 17 October 2022, resulting in the update of the EU multi-annual control programme (see point C.01) and of the Working Document SANCO/12745/2013 (see point A.11).

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

1. General overview

The Commission provided an update on the state of play for the remaining substances listed in the overview table. The tMRLs for chlorpropham in potatoes will be reviewed based on monitoring data provided by food business operators by the end of 2022. Once received, the data will be shared with Member States. Subsequently, the Commission will propose a revision of the tMRLs, if appropriate, at the meeting of this Committee in February 2023.

Member States were invited to share their comments by 15 January 2023.

2. Chlormequat and mepiquat in cultivated fungi

The Commission informed that the European Group of Mushroom Growers shared the outcome of their studies investigating residues of mepiquat and chlormequat in cultivated fungi, including studies dedicated to Oyster mushrooms. However, the Commission concluded that no recommendation for modifying the existing tMRLs can be derived from the presented data, as they are unsuitable for statistical processing. EFSA will provide monitoring data in cultivated fungi (including Oyster mushrooms) for the period 2019-2021 and the Commission will consider possible revision of the existing MRLs at the meeting of this Committee in February 2023.

The same stakeholder also raised concerns for the potential exceedance of the existing MRLs for fosetyl-Al in cultivated fungi due to the recent increase16 of the MRL for that substance in wheat from 2 to 150 mg/kg. The studies that were presented also included trials on this active substance. The Commission will request EFSA to provide monitoring data for fosetyl-Al in wheat and cultivated fungi to investigate the situation. Nevertheless, if food business operators consider that a revision of the existing MRL in

[15] Peer review of the pesticide risk assessment of the active substance Purpureocillium lilacinumstrain PL11 EFSA Journal 2022;20(5):6393

[16] Commission Regulation (EU) 2021/1807 of 13 October 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products (OJ L 365, 14.10.2021, p. 1).

cultivated fungi is needed, they should submit an application according to Article 6 of Regulation (EC) 396/2005.

A Member State commented that, as the new MRL for fosetyl-Al in wheat became applicable only recently, it may not be possible to identify its impact on the levels for this substance on cultivated fungi yet. The Commission acknowledged this fact and noted that the data request from ESFA would allow setting a baseline for future analysis, but that, before any action on this MRL, an Article 6 application should be submitted.

Member States were invited to share their comments on the proposed approach by 15 January 2023.

A.09 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed that the working group received many comments and is currently working on addressing them. The guidance document is expected to be ready by the end of 2023.

2. OECD Honey Guidelines

A Member State that attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. The draft is ready but there is still discussion needed on the chapters of non-target plants and study design. The aim is to have the draft document ready by the end of year for comments from the working group. The guidelines are expected to be finalised by the end of 2023.

3. Codex Alimentarius/JMPR issues

a) Internal working procedures for drafting EU coordinated positions for CCPR

The Commission presented an updated draft of its internal working procedures that should assist Commission and Member States in their annual preparatory work for the Codex Committee on Pesticides Residues (CCPR). The working procedures were prepared based on a request of several Member States who asked for a document that would ensure consistency of decision making by risk managers over several years, also avoiding information loss due to normal fluctuations of staff, both in Member States and the Commission. The updated version considers comments received from Member States and EFSA and also contains an informative introductory chapter on Codex Alimentarius and its main procedures as well as the status and role of the EU and its institutions in Codex Alimentarius.

The Commission presented the various comments received from Member States and the main issues raised were discussed with the Committee.

Furthermore, the Commission informed that both EFSA and a Member State are working on the development of a table matching the food commodities from the Codex classification system with those from Annex 1 to Regulation (EC) No 396/2005 in order to facilitate the transposition of CXLs to EU MRLs where CXLs were accepted by the EU.

Member States were invited to submit their comments by 15 January 2023.

b) Issues arising from eWGs

The Commission confirmed that, following the finalisation of the EFSA Reasoned Opinion on an application under Article 6 of Regulation (EC) No 396/2005, and the

subsequent electronic consultation of Member States, the EU reservation on the CXL for pendimethalin on leeks introduced at CCPR53 had been lifted ahead of the annual meeting of the Codex Alimentarius Commission (CAC) on 21 November 2022.

The Commission informed of the Circular letter that is being finalised in the Electronic Working Group (eWG) of Enhancement of work management of CCPR and JMPR and invited the Member States to provide comments by 14 December 2022. A Member State suggested reporting back from all eWG as most of the issues are interlinked.

A Member State emphasised the importance of early preparation of some of the other Codex eWGs and would have wished to discuss the state of play of them as well. The Commission will put an update of the relevant eWGs on the agenda of the February meeting of this Committee.

4. Other

No issues were discussed under this point.

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

The Commission followed-up with EFSA and the French national food safety agency (ANSES) on speeding up the delivery of the mock assessment for the prospective scenario. The tasking grant for the chronic assessment will be launched by EFSA before the end of the acute exposure calculations, enabling ANSES to meanwhile start work on the chronic exposure, possibly delivering results ahead of the October 2024 deadline.

A.11 Endorsement by the Committee of the Working Document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin (SANCO/12745/2013, Rev. 14).

The Commission referred to the meeting of experts on the monitoring of pesticide residues held on 17 October 2022 and presented an overview of the updates of the working document. Mercury compounds are removed from Chapter 4, because in accordance with Regulation (EU) 931/2022[17], they are monitored under the official control framework for contaminants. Nevertheless, the situation as regards MRLs remains unchanged: MRLs set in Regulation (EC) No 396/2005 continue to apply alongside the specific maximum levels (MLs) set by Regulation (EC) No 1881/2006 for some foodstuffs. Zucchinis/courgettes are reinstated in Annex VIII concerning commodities of interest to be analysed under NCPs.

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

No issues were raised under this agenda item.

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

No issues were raised under this agenda item.

[17] Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food, OJ L 162, 17.6.2022

A.14 Update of the Technical Guideline on the Evaluation of Extraction Efficiency (SANTE/2017/10632 Rev. 4).

A Member State volunteered to present a draft update of the Technical Guideline at the next meeting.

A.15 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830 Rev. 1).

A Member State noted that paragraph *"2.3 Hazardous Reagents",* excludes compounds classified as carcinogenic, mutagenic and toxic for reproduction (CMP), category 1 or 2, excluding commonly used solvents such n-hexane or toluene. This classification was a carryover from the previous guideline SANCO/825/00 Rev.8.1, but meanwhile with the entry into force of Regulation (EC) 1272/2008[18] categories 1&2 should be replaced by categories 1A&1B. The amended text will be discussed for endorsement by the Member States at the next meeting.

A.16 Forthcoming draft Regulations (indicative only):

1. Potassium phosphonates

The draft Regulation reviewing the MRLs for this group of substances will be presented at the next meeting of this Committee and will be based on EFSA's Scientific statement[19] summarising the MRLs proposed in several EFSA outputs, while also taking into account the 2021 EFSA Reasoned Opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates[20].

2. Carbendazim, thiophanate-methyl

A draft Regulation lowering the existing MRLs for carbendazim in grapefruits, oranges, papayas and mangoes and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes to the LOQ, will be presented at the next meeting. It will be based on EFSA's Reasoned Opinion[21] identifying acute risk for consumers with the current MRL for these products. The measure will take into consideration the most recent TRVs derived by EFSA.

3. Deltamethrin, metalaxyl-M, trifloxystrobin

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for those substances based on the EFSA evaluation of confirmatory data following the Article 12 MRL review. This draft measure will take into account risk management decisions taken by this Committee in its previous meetings. The drafting of this Regulation will start at the first half of 2023.

4. Quinoxyfen, lufenuron

The Commission informed of a possible forthcoming draft Regulation reviewing the MRLs for quinoxyfen and lufenuron taking into account the Farm to Fork Strategy on environmental issues of global concern. The use of both substances is no longer authorised in the EU due to their persistent bioaccumulative and toxic (PBT), very

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

[19] https://www.efsa.europa.eu/en/efsajournal/pub/7400

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

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

persistent and very bioaccumulative (vPvB) and persistent organic pollutant (POP) properties. The Commission also presented data from the 2020 EU residue monitoring, indicating that from the samples analysed, most of them (99.9%) had values below the LOQ both for quinoxyfen and lufenuron.

5. Fenoxycarb, diethofencarb, pencycuron, flutriafol, myclobutanil

The Commission will include those substances in a new draft Regulation, which, following the expiry dates of their approvals and of their grace periods, will lower MRLs to LOQs in consideration of certain CXLs and/or import tolerances, where appropriate.

6. Measure addressing confirmatory data under Article 12

The new draft Regulation will update MRLs for 2,4-DB, iodosulfuron, mesotrione, methoxyfenozide and pyraflufen-ethyl.

For 2,4-DB, EFSA confirmed that the data gaps for barley, oats, rye and wheat were addressed in the EFSA Conclusions of the peer review of the substance and therefore MRLs can be maintained. However, the data gap on analytical methods for animal products is still valid and MRLs should be lowered to the LOQ. For iodosulfuron and mesotrione, the applicant did not submit any data to address the data gaps and MRLs are proposed to be lowered to the LOQ.

For methoxyfenozide, no data was submitted by the applicant to address the missing information for aubergines. This MRL will also proposed to be lowered to the LOQ. For the data gap for the analytical methods on animal products, EFSA confirmed that it was addressed in the peer review of the substance, therefore those MRLs can be maintained. For pyraflufen-ethyl, EFSA confirmed that the data gap on the analytical method for hops remains, thus the MRL will be proposed to be lowered to the LOQ.

Member States were invited to submit their comments by 14 December 2022.

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

The Commission informed the Committee that after the consultations on the draft Communication on Part A of the data requirements, around 200 additional comments were received. After processing this information Member States will be invited to endorse the final version on the draft Communication in the SCoPAFF, section Phytopharmaceuticals - Legislation. The Commission is reflecting how to organise the compilation of guidance documents, test methods and supportive documents identified during the preparation of this document.

A Member State requested the inclusion of the data requirements for fish in the Communication document in order to gather information of consumer exposure to pesticide residues via fish. The Commission stated that it was not in favour of this inclusion and referred to the extensive and repeated discussions from the past on this issue. It reminded Member States about the decision of this Committee in the meeting that took place in February 2021 where it was agreed to maintain the status of the documents on fish as Commission staff working documents. Inclusion in the Communications on data requirements was considered premature given that MRLs for fish had not yet been established and the setting of such MRLs was not identified as a priority in the REFIT exercise. Nevertheless, monitoring data on fish are available, showing the generally low incidence of findings, except findings of some specific

substances (DDAC, BAC and chlorate) for which the Commission and Member States agreed on specific follow up action.

One Member States strongly opposed to the non-inclusion of the guidelines on fish in the Commission Communications, others concurred with the Commission's views. The Commission invited Member States to share their opinions on this point with a view to assessing the need for a possible renewed discussion.

A.18 Other Information points:

1. Update on PRAC measures/objections

No issue was raised under this point.

2. Brexit

No issue was raised under this point.

3. Commission Directive 2002/63/EC on sampling

Following the comments from Member States, the Commission will prepare a draft Regulation for discussion at the next meeting.

4. Future organisation of PAFF meetings

The Commission informed about the feedback received from the Member States after the last meeting. All Member States that expressed their views were in favour for a mix between hybrid and virtual meetings, one Member State asked for a full physical meeting with all Member States present once a year. The Commission explained that it had been decided to always offer the possibility for hybrid meetings and that therefore a "physical only" meeting could not be organised. It concluded that it envisages to alternate between hybrid and fully virtual meetings in 2023 but that the decision on the format should remain flexible and would also depend on the agenda. Member States welcomed this proposal. One Member State stated that it had agreement to attend physically 50% of the meetings, in line with this schedule.

5. Planned working group with Member States on genotoxic carcinogens

Following the announcement at the last meeting of this Committee, the Commission informed that a joint working group meeting with Member States on genotoxic carcinogens, including also Member States' representatives from the contaminants sector, is now scheduled for 19 January 2023 in the morning. It will be held virtually. Following this wider discussion on the approach for genotoxic carcinogens, a more specific discussion on RASFF procedures could be organised as follow up, if needed. This Committee will be subsequently invited to review and endorse the final approach.

Member States were invited to nominate Experts for the meeting by 30 November 2022. The draft agenda and background documents will be send out in December 2022, with the possibility for Member States to comment on them in advance of the meeting.

6. Inclusion of mukunuwenna (Alternathera sessilis) in part B of Annex I to Regulation (EC) No 396/2005

The Commission informed of a request from a Member State to include mukunuwenna (*Alternathera sessilis*) in part B of Annex I to Regulation (EC) No 396/2005, indicating that it believes that the MRL for spinaches applies. Currently mukunuwenna is not explicitly mentioned in Annex I to Regulation (EC) No 396/2005 but due to its close

similarity to spinaches, the Commission considers that the MRLs for the group "others" within the group "spinaches and similar leaves" (Code 0252990) apply The Commission indicated that in a future revision of Annex I, the possible inclusion of this product, e.g. in Part B will be considered, and shared a compilation of products for which classification in Annex I has recently been discussed. Several Member States provided their views on the complexity of this review and on the inclusion of numerous very minor crops in Part B of the Annex instead of using the category "others" in different groups or subgroups of products.

7. Fertilisers WG – Phosphonates as plant biostimulants

A Member State shared the comments it made to the Commission's Directorate-General in charge of fertilisers (DG GROW), which has received a request to amend the Fertilising Products Regulation (FPR)22 as regards EU fertilising products (FP) containing phosphonates in view of their placing on the market as EU plant biostimulants.If pursued, this would be in the form of a delegated act (DA). The current FPR bans the intentional addition of phosphonates in EU fertilisers. It also provides for a limit for the unintentional presence of phosphonates in EU FP (maximum 0,5 % w/w). The possibility to adopt such a DA was discussed at the FPs expert meeting in October 2022.

The discussion was initiated by some new evidence submitted by a stakeholder organisation, the European Biostimulants Industry Council (EBIC23), claiming that phosphonates would be able to improve the plants' nutrition efficiency and hence would fall under the definition of plant biostimulants. A representative of DG GROW presented a discussion paper explaining the contents of a possible DA which would allow the intentional addition of phosphonates to EU plant biostimulants only. He explained that the proposal would fit with the objectives of the Farm to Fork Strategy to minimise nutrient losses resulting in reducing the use of fertilisers by 2030.

The Member State having submitted comments expressed concerns about the validity of the studies proving the bio-stimulant effect of phosphonates and in particular about the absence of appropriate studies to refute any possible antifungal effect of this active substance at the proposed application rate and plant growth stadium where the plant biostimulant effect is supposed to occur. If an antifungal effect were to be present, the product must first be authorised as plant protection products and the plant biostimulant effect could only be considered as additional claim after the compliance check in accordance with the FPR.

More importantly, the Member State noted that the use of phosphonates as plant bio-stimulant may cause problems with the compliance of food/feed with the existing MRLs for fosetyl/phosphonates.

The representative of DG GROW clarified that in some cases a substance for which MRLs are set in Regulation (EC) No. 396/2005 can be used in an EU FP, provided that the use of the FP, as specified in the use instructions does not lead to the exceedance of those MRLs. Currently, the FPR has set a maximum concentration (0,5 % w/w) for the non-intentional presence of phosphonates in FPs, and their intentional addition is forbidden. The discussion paper suggests to allow the intentional addition of

[22] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).
[23] https://biostimulants.eu/

phosphonates to EU plant biostimulant. EBIC's request refers to application of phosphonates as plant biostimulant at an early plant growth stage with an indicative maximum application rate of 450g/ha. The discussion paper further suggests that the EU FPs should be duly labelled to inform on the phosphonate content with a precautionary phrase addressed to the final user regarding the risk of exceedance of the existing MRLs.

A Member State noted that the use of phosphonates as bio-stimulants may pose a high risk of MRL exceedances, due to their stability that could lead to accumulation in soil and subsequently in crops in case of combined uses both as a plant biostimulant and as a PPP. This is particularly true in case of use on those crops for which MRLs are set at the LOQ where no authorised PPP uses exist. In such cases, the Member State was concerned that the risk of MRL exceedances will be shifted to the farmer, who will not have all the information needed to avoid the risk of exceeding the MRLs. Another Member State supported this conclusion, and noted that adding a warning on the label would not help farmers if it does not include details on the use (e.g. dosage). One Member State mentioned that it had found residues of phosphonic acid also in organic products, for which the source was not identified. A reason may be the accumulation of this substance in the soil. An observer from a third country commented that, while appreciating the intention behind using phosphonates as biostimulants to improve plant nutrient efficiency in agriculture, such effect must be proven by solid scientific evidence. Another Member State mentioned that the studies presented to support the PPP claim are not published in a peer-reviewed scientific journal. This Member State proposed requesting an independent assessment of the bio-stimulant effect claim.

According to the representative of DG GROW, no confirmation or peer review assessment of the studies by any independent Agency is foreseen in the context of the FPR. The scientific information is assessed by the Commission and its Commission expert group on fertilising products. He also confirmed that industry was aware of the possible risk of MRL exceedances and of the need to provide more substantial information on expected residues.

One Member State enquired if labelling requirements as regards the protection of water, the environment etc. would also be included. The representative of DG GROW informed that the manufacturer of an EU plant biostimulant needs to prepare a dossier, including efficacy data, which will be checked by a notified body (an independent 3rd party certifying the compliance with essential requirements defined by the FPR) that will issue a conformity certificate. The label will indicate both the crop and the GAPs and a statement that the plant biostimulant contains phosphonates and that special care to comply with existing limits is needed. As phosphonates are substances (falling under component material category 1 of the FPR), the manufacturer will need to provide in the REACH registration dossier a justification that the use is also safe from the view of occupational and environmental exposure. These aspects will also be checked by the notified body.

On the further time planning the Commission informed the Committee that a public consultation on a draft DA may be launched in spring 2023, and that a DA may be adopted by the end of the first half of 2023. The Commission will keep the two sections of this Committee (Phytopharmaceuticals – Legislation and Pesticides Residues)

informed about the ongoing process. All documents from the CIRCA BC folder of the expert group on FPs are publicly accessible[24].

The Commission mentioned that a new draft Commission Regulation proposing modifications to the existing MRLs for phosphonates based on some recent EFSA outcomes is in the pipeline. As several of the MRLs are set at the LOQ, authorising the use of phosphonates as a FP could indeed pose enforcement issues for many crops.

Member States were invited to submit their comments by 14 December 2022.

8. Anthraquinone in smoked tea

A Member State requested the opinion of the other Member States on the application of the MRL for anthraquinone in smoked tea leaves, consisting of smoked black tea. The Member State applies the existing MRL for anthraquinone in tea (0.02 mg/kg) to smoked tea and considers that exceedances of this MRL in the final product would render it possibly unsafe. Several Member States indicated that they take the same approach.

9. Update on chlorate

In light of the 2017 update of the EFSA guidance[25] on the application of the Benchmark Dose (BMD) modelling in risk assessment, recent studies concluded on Tolerable Daily Intake (TDI) values for perchlorate significantly diverging from the TDI included in the 2014 EFSA opinion[26]. As the TDI for chlorate in the 2015 EFSA opinion[27] came as a read across from the TDI for perchlorate, in the forthcoming review of the MRLs for chlorate in June 2025, EFSA will consider those evaluations, along with the monitoring data on food and in water.

Section B Draft(s) presented for an opinion

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

(PLAN/2022/2334)

The Commission outlined the draft Regulation and its contents. The following MRL applications had been submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 in support of new and/or confirming existing uses in the EU:

- pyridate on chives;
- pyriproxyfen on apricots and peaches;
- triclopyr on oranges, lemons and mandarins.

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[24] https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f
https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/06d5fd29-fdb8-4eb3-b429-82afff9d7253/details
https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/4348d413-7498-4c45-a476-ae0407c7f689/details

[25] European Food Safety Authority, 'Update: use of the benchmark dose approach in risk assessment', EFSA Journal 2017;15(1):4658

[26] European Food Safety Authority, 'Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables'. EFSA Journal 2014;12(10):3869

[27] European Food Safety Authority, 'Risks for public health related to the presence of chlorate in food', EFSA Journal 2015;13(6):4135

In addition, an MRL application for modifying the MRL for pyridaben in grapefruits had been submitted in accordance with Article 6(2) and (4) of that Regulation in support of import tolerances requested by the United States.

EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers. In addition, for pyridate, EFSA noted that the data gap concerning analytical methods, identified in the framework of the MRL review, was addressed in the Conclusions on the peer review of the substance. Therefore, the draft Regulation proposed deleting the respective footnotes in Annex II to Regulation (EC) No 396/2005. For triclopyr in oranges, lemons and mandarins, EFSA noted that the submitted data were sufficient to derive a lower MRL proposal of 0.07 mg/kg based on the intended use. Nevertheless, as confirmatory data supporting the existing MRL of 0.1 mg/kg are still pending, it was decided to reconsider it in the framework of the Article 12 confirmatory data assessment.

One Member State asked if information was available on the status of the Article 12 confirmatory data assessment for triclopyr. The Rapporteur Member State informed that no information had been received yet from the applicant.

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

(SANTE/10108/2022)

(PLAN/2022/1062)

The Commission presented an overview of the draft Regulation and the modifications made since the last meeting of this Committee taking into account the comments received from the Member States and those received by a third country following the consultation with trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organisation (WTO).

For isoxaben, the Member States agreed that the MRL for dewberries would be set at 0.01* mg/kg based on extrapolation from raspberries, and that there was sufficient evidence of a "no residue" situation for sage, rosemary, thyme, basil and edible flowers so that the MRLs for these products could be set at the LOQ of 0.01* mg/kg without footnotes. In addition, an application was submitted for modifying the MRL for peas (fresh, without pods) using the fast-track procedure to set a MRL at 0.02 mg/kg based on extrapolation from beans (fresh, without pods), which the Member States agreed on.

For novaluron, the Member States agreed to change the residue definition for clarity from "Novaluron" to "Novaluron (sum of constituent isomers)", based on a proposal from the EURLs. Additionally, as all MRLs for novaluron are set at the specific LOQs, they should be moved to Annex V.

For tetraconazole, the Member States agreed to change the residue definition for clarity from "Tetraconazole" to "Tetraconazole (sum of constituent isomers)" based on a proposal from the EURLs. For products for which there are use authorisations but no residue trials available, i.e. peppers and cereals except wheat and rye, the Member States agreed that MRLs should be lowered to the LOQs. The Commission informed

that a typo in the MRLs for bovine and equine muscle had been corrected and that the value for these MRLs is 0.015 mg/kg, as per the EFSA Reasoned Opinion.

The Commission informed of the comments received from a third country following the consultation with trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organisation (WTO).

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 cyantraniliprole and folpet in or on certain products (Art. 10):

(PLAN/2022/1666)

The Commission had informed the Committee in advance of the meeting that the vote on this draft measure would be postponed, as additional discussion was needed to take appropriate risk management decisions for the MRLs for the products covered by the import tolerance application for cyantraniliprole.

While this draft Regulation intended modifying existing MRLs for both cyantraniliprole and folpet, it was decided to remove folpet and create a separate draft Regulation for this substance, to avoid potential delays for setting the new MRL for folpet in lettuces. Therefore, a new revision (Rev. 1) of the draft Regulation PLAN/2022/1666, excluding folpet and taking into consideration the comments from Member States, was presented for discussion. The most relevant changes are the following:

- a MRL of 15 mg/kg was proposed for cyantraniliprole in lettuces (0251910), based on the open leaf trials only, as it would not be appropriate to pool the open leaf lettuce and head lettuce trials as the two datasets are not homogeneous, and the open leaf trials were the most critical;
- the current MRL for other lettuces and salad plants (0251990), set at the LOQ, was proposed to be maintained as EFSA concluded that some information on the magnitude of residues and on the formation of cyantraniliprole degradation products in processed products were not available, and some of the products belonging to this category may undergo processing.

The Commission recalled that, for potatoes, tropical root and tuber vegetables, cucurbits with inedible peel, Chinese cabbages/ pe-tsai, other leafy brassica, escaroles/broad-leaved endives, spinaches and similar leaves, and parsley, this draft Regulation proposed not to modify the existing MRLs based on the import tolerance application, as some information on the magnitude of residues and on the formation of cyantraniliprole degradation products in processed products were not available. The current revision of the draft still contains this proposal. Nevertheless, the Commission highlighted that some Member States had commented that, since the genotoxicity of the cyantraniliprole degradation products was ruled out and since they would have a low contribution in the dietary burden, they should be disregarded from the residue definition for risk assessment. Those Member States also recalled that EFSA concluded that the calculated exposure still has a wide margin of safety.

Member States were invited to share their views by 14 December 2022.

Vote postponed.

B.04 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 bromopropylate, chloridazon, fenpropimorph, imazaquin and tralkoxydim in or on certain products.

(SANTE/10644/2021)

(PLAN/2021/11187)

The Commission presented an overview of the draft Regulation and the modifications made since the last meeting of this Committee taking into account the comments received from one Member State. No comments were received from third countries following the consultation with trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organisation (WTO). The draft Regulation proposes to lower all the MRLs for the listed active substances, with the exception of certain MRLs for fenpropimorph which were based on data from import tolerances and Codex MRLs recently reviewed by EFSA, concluding that they were safe for consumers.

A Member State requested clarifications on the criteria to maintain certain MRLs for fenpropimorph and more generally for non-approved active substances for which the toxicological classification has not been updated and the assessment for endocrine disruption has not been conducted. Another Member State indicated that it is not in favour of maintaining import tolerances for non-approved substances. The Commission indicated that on the criteria for maintaining CXLs and/or import tolerances further discussion was necessary.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) .../... correcting Commission Regulation (EU) 2022/1363 of 3 August 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb and silthiofam in or on certain products.

Regulation (EU) 1363/2022 erroneously omitted footnote (A) for fluroxypyr as regards the commercial non-availability of the analytical standard for fluroxypyr conjugates. The Commission prepared a draft correcting act to reinstate this foonote. However, the voting on this point was postponed as the internal discussions within the Commission services on the proposed draft regulation had not yet been finalised.

The Commission will provide an update in the next meeting.

On this occasion, a Member State commented whether, in general, the conjugates of a substance should be included in the residue definition of that substance and which those conjugates should be. As this topic requires a more general approach, the Commission concluded that it could be discussed in the next Working Group for the monitoring of pesticide residues.

Vote postponed.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation as regards a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin:

(PLAN/2022/2309)

Following the meeting of the Working Group with Member States' representatives on the monitoring of pesticide residues held on 17 October 2022, the Commission presented revision 1 of the draft Regulation. It now includes product codes in Parts A and B of Annex I and new substances are included in Part C (clopyralid, copper compounds, flupyradifurone, nicotine, triflumizole, zoxamide) and Part D (chlormequat, copper compounds, mepiquat).

For pyrethrins, comprising 6 compounds, while the participants of the WG suggested their inclusion in Part C, the EURLs and a Member State indicated the calibration challenges due to the variability in the composition of each of those compounds in the available analytical standards. Therefore, pyrethrins will be excluded from Part C, but remain in Chapter 4 and Annex II of SANCO/12745/2013, Rev.14.

As nicotine and copper compounds are amenable to single residue methods (SRM), a Member State stressed the high financial burden for Member States and official control laboratories (OfLs) to develop them and suggested including them on a voluntary basis under national control programmes. In the same sense, another Member State noted that they don't have the sufficient capacity to analyse clopyralid.

The Commission recalled that these are not new substances, they were included in Chapter 4 of SANCO/12745/2013 in 2018 for nicotine, in 2019 for copper compounds and in 2021 for clopyralid and that Member States should already have done preparatory work on them since their first inclusion in that working document. As they will be analysed under the EU coordinated programme starting in 2025 only, official control laboratories will have time to develop the methods with the help of the EURLs. In addition, for nicotine and copper compounds, monitoring data is needed to enable risk management decisions regarding their tMRLs and, therefore, those substances should be included in the EU-coordinated programme. Another Member State supported this view, but added that for copper compounds it would be appropriate to focus on specific products of the programme.

Member States were invited to submit their comments by 14 December 2022.

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

(PLAN/2022/2311)

The Commission presented an overview of the draft Regulation reviewing the MRLs for phosmet and pyriproxyfen under Article 12 of Regulation (EC) No 396/2005.

For phosmet, the Commission informed that the data gap on the toxicity of the metabolite phthalic acid had been addressed by EFSA in its Reasoned Opinion on the review of MRLs for dithianon under Article 12, of which phthalic acid is also

a metabolite, and that the TRVs are lower than those of phosmet. However, the data gap on the toxicity and genotoxicity of the metabolite phosmet-oxon remains. A Member State commented that in view of health concerns this draft Regulation should progress and apply as soon as possible, and that the LOQs for some products might not be protective enough so that lower values should be set. This was supported by another Member State. Since there are CXLs for phosmet, a Member State commented that a concern form should be lodged to the JMPR ahead of the next CCPR meeting.

For pyriproxyfen, the Commission shared a letter from industry requesting to maintain the MRL for bananas at 0.7 mg/kg until an import tolerance request could be submitted with the supporting residue trials. The MRL had been proposed to be lowered to the LOQ as there is no authorised use in the EU anymore, there is no CXL, and no fall-back GAP had been received by EFSA during the review of the MRLs.

Member States were invited to submit their comments by 14 December 2022.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for Denatonium benzoate, diuron, etoxazole, methomyl and teflubenzuron in or on certain products:

(PLAN/2022/2310)

The Commission presented an overview of the draft Regulation as regards the MRLs for the non-approved substances denatonium benzoate, diuron, methomyl and teflubenzuron, and for etoxazole, renewed on 1 February 2021 with a restriction to ornamental plants in greenhouses, for which the EFSA Conclusions on the peer review revealed data gaps with regard to the toxicity of metabolites.

Member States were invited to submit their comments by 14 December 2022.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for carbetamide, carboxin, fenbuconazole and triflumuron in or on certain products:

The Commission introduced the draft Regulation as regards the MRLs for the non-approved active substances carbetamide, carboxin, fenbuconazole and triflumuron. Regarding famoxadone that was initially included in the draft Regulation, the Commission explained that the MRLs based on CXLs would need to be reviewed by EFSA which will take some time. In order not to delay the overall process it was decided to remove this substance from the draft Regulation. Carbetamide, carboxin, triflumuron will be moved to Annex V of Regulation (EC) No 396/2005. For fenbuconazole, the MRLs based on CXLs and import tolerances are proposed to be maintained in its Annex II.

With regard to fenbuconazole, a Member State indicated that CXLs were set in different years (1999-2014). The last full evaluation was done in 1999. The Codex Alimentarius Commission procedural manual[28] on risk analysis indicates that the evaluation on toxicology data after 25 years is obsolete.

Member States were invited to submit their comments by 14 December 2022.

[28] The Codex Alimentarius Commission procedural manual. Twenty-fifth edition (2016) https://www.fao.org/3/i5995e/i5995e.pdf

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenazate in or on certain products:

(PLAN/2022/2307)

The Commission introduced the draft Regulation which proposes to lower all the MRLs, including the ones which are based on CXLs to the LOQ following the recent use restrictions for bifenazate to non-edible crops. The use was restricted because the risk assessment for edible commodities could not be finalised due to a number of data gaps that could have an impact on the assessment of residue levels in the different crops and due to missing toxicological reference values for metabolite D3598 (bifenazate-diazene) included in the residue definition for both monitoring and risk assessment.

Member States were invited to submit their comments by 14 December 2022.