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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Residues*
11 - 12 April 2022

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SUMMARY REPORT

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table.

2. Confirmatory data Art. 12 follow-up

In its Reasoned Opinions on the assessment of Article 12 confirmatory data for deltamethrin, metalaxyl-M and trifloxystrobin, the European Food Safety Authority (EFSA) reported the need for some risk management considerations.

For deltamethrin, Member States agreed that, even if there is a difference between the residue definition (RD) for enforcement and risk assessment (RA), the latter including the alpha and trans-isomers, a conversion factor (CF) of 1 could be used, as the isomers are unlikely to occur. Using this calculation, the data gap concerning the number of trials could be addressed. Therefore, the Committee decided to accept the CF of 1 (or a higher CF, when suggested by EFSA) for crops where a risk management decision is required. In case safe Codex MRLs (CXLs) exist, it was agreed to maintain/modify the existing MRL as to equal the CXL despite the wider RD for enforcement for the CXLs. For pears, as the newly derived MRL would be very close to the current one, for which an acute risk for consumers was identified by EFSA with the Pesticide Residues Intake Model version 3 (PRIMo 3.1), it was agreed to lower the MRL to the limit of quantification (LOQ).

For metalaxyl-M, for MRLs for which data gaps were not addressed, Member States agreed to accept alternative MRLs in case fall back Good Agricultural Practices (GAPs) are available, or otherwise to lower MRLs to the LOQ. One Member State noted that for several products (e.g. apples, pears) new CXLs will be discussed this year by the Codex Committee on Pesticide Residues (CCPR53) which are acceptable according to EFSA's preliminary assessment. The Commission proposed to wait for a decision on the final EU positions to be agreed with the Member States before presenting a draft measure for the review of the MRLs for metalaxyl and metalaxyl-M. For soyabeans, as the proposed fall back GAP is not in line with the use restrictions, the Commission proposed to lower the MRL to the LOQ. For herbs and edible flowers, the Commission asked to confirm if the newly proposed indoor GAP has been authorised in any of the Member States. One Member State confirmed having authorised an indoor use on herbs

and edible flowers (except sage) for the treatment of seeds. However, the data gap identified during the Article 12 review concerns the lack of trials for a GAP relating to foliar treatment. Therefore, the Commission noted that the trials relating to the GAP for seed treatment cannot be used to address the original data gap, as the difference in application of the pesticide (foliar vs seed treatment) has not been assessed and may lead to different MRL values. Thus, the Commission proposed to lower the existing MRL for herbs and edible flowers to the LOQ.

For trifloxystrobin, the Member States agreed lowering the MRLs to the LOQ for all products for which data gaps were not addressed (i.e. passion fruits/maracujas, Chinese cabbages/pe-tsai and other leafy brassica), with the exception of cucumbers and gherkins, for which they agreed to maintain the current MRL of 0.3 mg/kg as it reflects the CXL for cucurbits. One Member State informed of an authorised use on Chinese cabbages/pe-tsai, and asked whether the proportionality principle had been applied. EFSA informed that the adjusted GAP on which the new MRL for kales is proposed was authorised only for kales and that no alternative use on Chinese cabbages/pe-tsai had been reported to EFSA or to the Evaluating Member State in the framework of the confirmatory data assessment process. The respective Member State informed it will provide further information while assessing the possibility of extrapolating data from kales. The Commission noted that for escaroles, EFSA identified an exceedance of the Acute Reference Dose (ARfD) for some consumer groups[1] and, therefore, proposed lowering the current MRL to the LOQ.

Member States were invited to submit their comments by 13 May 2022.

3. List of non-approved substances for follow up

The Commission recalled that at the meeting of this Committee in February 2022, a decision was taken to mandate EFSA to address a first batch of non-approved substances (azocyclotin, bifenthrin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin, and profenofos) for which potential consumer risks were identified. The Commission shared a draft mandate with Member States for their comments.

The mandate concerns a targeted review of the MRLs for all ten substances according to Article 43 of Regulation (EC) No 396/2005 with an overall tentative deadline of 11 months, but EFSA will be invited to deliver gradually separate Reasoned Opinions for each substance.

The Commission clarified that for substances that are non-approved in the EU for a long time, old toxicological reference values (TRVs) might be outdated and more recent studies might not be available. It was clarified that for those substances EFSA will examine the best possible information available in order to screen the existing TRVs, provide feedback on missing information and related uncertainties to support a risk management decision.

A second mandate to EFSA is planned for a next batch of non-approved substances, but its drafting has not started yet.

One Member State supported the proposed mandate and reiterated the importance of considering the validity of TRVs. EFSA highlighted that, as the substances covered by this mandate are non-approved, there will be no applicants who could provide such

[1] European Food Safety Authority, "Modification of the existing maximum residue levels for trifloxystrobin in various crops", EFSA Journal 2018;16(1):5154

additional data. EFSA confirmed that in screening TRVs it will assess if they were established according to current scientific standards, thus allowing informed risk management decisions. A similar approach will be followed for the residue definition for risk assessment.

The Commission asked Member States to provide comments on the proposed approach by 22 April 2022.

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

The Commission proposed to define a refined approach on setting footnotes under Article 12 for MRLs set at the LOQ. According to the Commission Working Document on reviewing MRLs following Art. 12 of Regulation (EC) No 396/2005 "[…] for tentative MRLs that have been set at the LOQ, the Commission may set a footnote requiring confirmatory data aiming at completion of the data package. While non-submission of such data within the foreseen time span would not lead to a change of the existing MRL (which is set already at the LOQ), the completeness of the data package should nevertheless be considered by the Member States when granting national authorisation."

The Commission explained that it would be beneficial to further define this approach and apply it consistently in Article 12 measures. Some possible scenarios were presented and discussed.

Several Member States supported the initiative, and all Member States were invited to share their views by 13 May 2022.

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

The Commission provided an overview of the main outcomes of the last meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation held on 30-31 March 2022.

A draft measure restricting the use of bifenazate to greenhouses and non-edible crops was voted by the Committee and obtained a favourable opinion. In addition, a draft measure proposing the restriction of use for sulfoxaflor to greenhouses was presented to the Appeal Committee on 31 March. As the vote by written procedure ended with a no opinion, the Commission will now proceed to adopt the Regulation[2].

A.03 Specific substances:

1. Glufosinate ammonium

The Commission informed that there were no further news on this substance.

2. Glyphosate

The Commission informed that there were no further news on this substance.

3. Ethylene oxide

EFSA published its Statement on the opinion of the Bundesinstitut für Risikobewertung (BfR) regarding the toxicity of 2-chloroethanol[3].

[2] Post meeting Note: The Regulation was in the meantime adopted and published: OJ L 126, 29.04.2022, p. 18.
[3] https://www.efsa.europa.eu/en/efsajournal/pub/7147

The Commission informed that the SCoPAFF – Section Novel Food and Toxicological safety of the food chain of 24 March 2022 gave a favourable opinion for the draft Regulation amending the Annex to Commission Regulation (EU) No 231/2012 as regards the presence of ethylene oxide in food additives. According to the draft Regulation *"no residue above 0.1mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide) shall be present in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives"*.

4. Bacillus thuringiensis

The Commission informed that discussions on the possibility to mandate EFSA and the European Centre for Disease Prevention and Control (ECDC) to improve clarity on horizontal issues concerning dietary exposure for consumers linked to Bacillus thuringiensis strains are still ongoing. In addition, the Commission highlighted that since 2016 when EFSA published the scientific opinion on Risks for public health related to the presence of *Bacillus thuringiensis* in foodstuffs[4], no Member State had reported any case to the EFSA Zoonosis database[5], hence, there is no information in the EFSA Zoonoses report on *Bacillus thuringensis*. Should Member States have data, it should be submitted officially, as only then EFSA can take it into account.

5. Fosetyl/phosphonates

Between June 2021 and January 2022, EFSA published one Reasoned Opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005, one Scientific Report providing scientific support for preparing an EU position for the 52nd Session of the CCPR and four Reasoned Opinions on the modification of MRLs for potassium phosphonates based on applications received in accordance with Article 6 of Regulation (EC) No 396/2005. Since several evaluations were based on different uses and different data sets, sometimes relating to the same products, diverging MRL values were proposed for the same products in different outputs (e.g. citrus fruits).

The Commission informed of a mandate to EFSA, with a 3 months deadline, to deliver a consolidated statement recommending which MRLs should be considered in these cases. According to the mandate, EFSA will express MRLs referring to the residue definition for enforcement proposed in its Reasoned Opinion on the joint review, while providing reference to the respective scientific output on which each MRL was based. EFSA will provide an updated consumer risk assessment, based on the consolidated list of MRLs for potassium phosphonates.

6. Cyanantraniliprole

Further to the discussion of this Committee in February 2022, where the Commission concluded that it would not be appropriate to apply the fast-track procedure to establish further temporary MRLs for cyantraniliprole in raspberries, blackberries and leeks, one Member State asked whether it is possible to establish a permanent MRL in raspberries/blackberries via the fast-track procedure following

[4] European Food Safety Authority, "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

[5] https://www.ecdc.europa.eu/en/all-topics-z/food-and-waterborne-diseases-and-zoonoses/surveillance-and-disease-data/eu-one-health

EFSA's recent Reasoned Opinion[6]. The Opinion rules out the previously identified data gap on genotoxicity concerns with regard to metabolites IN-N5M09 and IN-F6L99 and concludes that the estimated exposure related to these degradation products is unlikely to pose safety concerns for the crops under assessment. The Commission reiterated that permanent MRLs should be based on an application submitted in accordance with Article 6 of Regulation (EC) No 396/2005 and that the use of the fast-track procedure was not appropriate.

7. Prosulfocarb

At the previous meeting of this Committee, a Member State had informed of occurrences of prosulfocarb in apples due to cross-contamination from authorised uses on neighbouring crops. Monitoring data were collected from EFSA and Member States, who also shared information about mitigation measures being implemented in the different countries.

EFSA shared monitoring data from 2019-2020, which included more than 93,000 samples analysed for prosulfocarb residues. Of those, 17 samples exceeded MRLs and were non-compliant considering measurement uncertainty (MU) and another 14 samples exceeded MRLs, but were compliant considering MU. For apples, more than 4,000 samples were analysed; prosulfocarb was quantified in 143 samples and MRLs were exceeded only for seven samples, four of which were still compliant considering MU.

Several Member States reported cases of cross-contamination of prosulfocarb in various crops and provided information about the mitigation measures that they had put in place. While those mitigation measures are not always effective to obtain a 'no detection' situation, they contribute in keeping the level as low as possible and the MRL exceedances are rare. A Member State is currently developing a concept for the monitoring of airborne transport of pesticides from treated areas and will share the outcome of this study, when available.

The Commission reiterated that the submission of an application for setting an MRL at a level higher than the LOQ for prosulfocarb in apples would not be appropriate, as there are no authorised GAPs for this substance on apples. The use of monitoring data to establish a temporary MRL according to Article 16 of Regulation (EC) No 396/2005 would not be appropriate since there are risk mitigation measures available to Member States to address the situation. Moreover, the monitoring data do not justify such an action. The Commission invited Member States to continue sharing best practices, as to expand the toolbox of mitigation measures. The Member State that had raised the issue initially, informed the Committee that its chemical agency is looking into strategies to strengthen the risk mitigation measures currently put in place.

8. Haloxyfop-P

The approval of haloxyfop-P expired in December 2020 and the grace period for use and sale of this active substance will expire on 30 June 2022.

A draft measure aiming to set import tolerance for haloxyfop-P used in Australia on linseeds and rapeseeds/canola seeds based on an application under Article 6 of Regulation (EC) No 396/2005 was presented for vote at the meeting of this

[6] European Food Safety Authority, "Modification of the existing maximum residue level for apricots and setting of import tolerances for cyantraniliprole in various crops", EFSA Journal 2022;20(3):7219

Committee in March 2021. During that meeting, a Member State had provided information suggesting that, performing a preliminary risk assessment with PRIMo 3.1, the current MRLs might lead to an exceedance of the Acceptable Daily Intake (ADI). Due to this concern, the written procedure for the vote on the draft measure was not launched and the Commission requested EFSA to carry out a targeted review of all MRLs for haloxyfop-P according to Article 43 of Regulation (EC) No 396/2005.

The Commission shared a draft mandate with Member States for their comments, according to which, EFSA will perform a preliminary chronic and acute consumer risk assessment based on the latest PRIMo version and using the TRVs set by Commission Implementing Regulation (EU) 2015/2233 considering several possible exposure scenarios. Member States were invited to submit their comments by 22 April 2022.

9. Terbufos

Terbufos was included in Annex IIIA of Regulation (EC) No 396/2005 through Regulation (EC) No 149/2008, which updated that Annex with temporary national MRLs for substances that were not included in Annex I of Directive 91/414/EEC. This was done following a Reasoned Opinion from EFSA, published in 20077.

The Reasoned Opinion mentions that exposure calculations were performed based on the ARfD and the ADI used for the JMPR evaluation of this substance (which was carried out in 2003). Thus, the Codex residue definition should be considered (i.e. sum of terbufos, its oxygen analogue and their sulphoxides and sulphones, expressed as terbufos), instead of the EU residue definition "terbufos".

In addition, in its evaluation EFSA identified chronic risks for 24 diets and health concerns for children. Therefore, all MRLs were proposed to the LOQ. However, the MRL for bananas was not set at the LOQ but at 0.05 mg/kg, which corresponds to the CXL value, even though for that MRL EFSA's assessment indicated a possible health risk for children.

Therefore, the Commission proposed to urgently address this issue in an upcoming measure amending the current residue definition for terbufos in Regulation (EC) No 396/2005 and lowering the MRL for bananas to the LOQ (0.01*mg/kg). One Member State supported this proposal and agreed with the rationale provided.

Member States were invited to submit their comments by 13 May 2022.

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

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

EFSA reported that outputs addressing 5 processes[8] 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, 4 are to be started, 5 are under scientific assessment (3 under Regulation (EC) No 396/2005 and 2 under Regulation (EC) No 1107/2009), and 38 are currently under clock-stop as additional data had been requested (27 under Regulation (EC) No 396/2005 and 11 under Regulation (EC) No 1107/2009).

[7] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2007.32r
[8] Each process receives a so called "EFSA question number".

4 new mandates have been received in March 2022, related to flonicamid, oxathiapiprolin, pyriproxyfen, and copper hydroxide.

Member States were reminded to use the new address FDP@efsa.europa.eu for any communication on dossiers.

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, 25 MRL reviews are on hold, 16 are currently being assessed at different stages of the procedure, while for 14 substances data is pending.

The progress report table with the overview of the progress under Article 12 of Regulation (EC) No 396/2005 was recently updated on 24 March 2022 and is made publicly available for interested stakeholders [9].

Dithiocarbamates

EFSA reported on the ongoing work. The reviews for different substances are at different stages of the process. EFSA is currently performing the data analysis to calculate MRLs. If there is a sufficient number of results for a given commodity (≥ 61), the MRL proposal will be derived at the 95th percentile, otherwise it will reflect the highest statistically reliable percentile. If needed, EFSA may propose MRLs for crop groups with similar characteristics. For commodities without any data, EFSA will propose MRLs derived by extrapolation, if feasible. EFSA's Reasoned Opinion will be shared with Member States for consultation around May 2022.

Complexity evaluation of forthcoming Article 12 evaluations

As agreed at the meeting of this Committee in November 2021[10], the evaluation of the complexity calculator started with the support of a Member State, acting as Evaluating Member State (EMS) for phosmet. The GAP collection was immediately launched and EFSA, the Commission and the EMS met to discuss identified issues, re-estimate the complexity and agree on the timelines. The EMS provided comments on the calculator and the procedure. After the GAP collection, EFSA, the Commission and the EMS had a trilateral meeting and agreed that one week is a sufficient timeline for providing feedback on the preliminary complexity before initiating the process, and that a trilateral meeting after the GAP collection stage should be included in the procedure for establishing the work program.

The revised procedure is consequently as follows: 1) EFSA completes a checklist to estimate the complexity of the Art. 12 MRL review before the initiation of the process; 2) EFSA shares the completed checklist with the EMS for comments with a deadline of 1 week, also informing the Commission; 3) after the GAP collection, a trilateral meeting of EFSA, the Commission and the EMS is held to agree on the timelines, taking into account the complexity of the assessment.

3. Update on other mandates

The Commission mandated EFSA to perform a targeted review of MRLs for indoxacarb. EFSA screened existing MRLs (focusing only on import tolerances and CXLs), considering the new toxicological reference values established in the EFSA Conclusions on the peer review of indoxacarb to identify crops which may pose

[9] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf
[10] https://ec.europa.eu/food/system/files/2021-12/sc_phyto_20211122_ppr_sum_0.pdf

a health concern. EFSA requested Member States to submit fall-back GAPs for import tolerances and requested input from the EU Reference Laboratories (EURLs). The draft Reasoned Opinion will be circulated to Member States and EURLs for consultation, with the aim to deliver it by 18 August 2022.

An Article 43 mandate for an updated consumer exposure assessment for haloxyfop-P is being finalized (cf. point A. 03.08). Another Art. 43 mandate for a targeted review of MRLs for 10 non-approved a.s. (azocyclotin, bifenthrin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos) is under discussion (cf. point A.01.03).

The Commission is finalizing a mandate under Article 31 of Regulation (EC) No 178/2002 for a statement summarising the different MRL proposals for potassium phosphonates made by EFSA in the Art. 43 MRL review and the latest Art. 10 Reasoned Opinions for which risk management decisions are still pending (cf. agenda item A.03.05). A mandate under Art. 31 of Regulation (EC) No 178/2002 for exposure assessment concerning the risks for public health related to the presence of benzalkonium chloride (BAC), didecyldimethyl ammonium chloride (DDAC) and chlorates in/on fish and fish-products is under discussion (cf. point A.15.03).

A mandate under Art. 29(1) of Regulation (EC) No 178/2002 is under discussion for a scientific opinion on the risks for human health related to the presence of bromide ion in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed.

Another mandate will be issued for a technical report presenting EFSA's analysis to support discussions held by the Commission and Member States regarding the establishment of national temporary MRLs under Article 18(4) of Regulation (EC) 396/2005 to address possible shortages of feed supply as a consequence of the interruptions of imports from Ukraine (cf. agenda item A.10.00).

4. Other issues

International – EFSA Report on scientific support for preparing the EU position for the 53rd Session of CCPR

Following the publication of the summary report[11] of the Joint Meeting of the Food and Agriculture Organisation of the World Health Organisation (FAO/WHO) on Pesticides Residues (JMPR) held extra-ordinarily in May 2021, where 27 substances are assessed, and the report[12] of the regular JMPR meeting (September/October 2021), where 19 active substances are assessed, EFSA shared with Member States its draft report covering all active substances, and invited them to provide comments by 25 March 2022. 6 Member States submitted comments, and a revised draft report will be made available to Member States and the Commission at the beginning of May 2022.

The new version of the report will also contain EFSA comments on 'General considerations' of JMPR: feedback on virtual Extra JMPR meetings, benefits and challenges of virtual JMPR meetings, the international estimate of short-term

[11] https://www.who.int/publications/m/item/joint-fao-who-meeting-on-pesticide-residues-may-and-june-2021-summary-report
[12] https://www.who.int/publications/m/item/joint-fao-who-meeting-on-pesticide-residues-september-and-october-2021-summary-report

intakes (IESTI) equation, first considerations on a possible need for amendments to the Environmental Health Criteria (EHC) 240 guidance on the appropriate use of toxicological historical control data (HCD), guidance on the assessment and interpretation of non-linear dispositional kinetics, recommendations for use of leafy vegetables to extrapolate residues to the Subgroup 027A (herbaceous plants).

EFSA Guidance on Rotational Crops

EFSA received a mandate from the Commission for the preparation of a Guidance document on the assessment of studies concerning pesticide residues in rotational crops. The document will describe under which circumstances studies investigating the nature and magnitude of residues in rotational/succeeding crops are required, will provide details on the study design and guidance on the interpretation of the studies for consumer risk assessments and risk mitigation measures and will derive recommendations for the development of tools necessary to perform the assessment in line with the Guidance Document[13] of the Organization for Economic Cooperation and Development (OECD). The draft document will be submitted to the Member States and public consultation prior to its finalization, which is expected by end of January 2023.

Pesticides Steering Network/Transparency/IUCLID

On 25 February 2022, the updated International Uniform Chemical Information Database (IUCLID) 6.6 Microbial Active Substances Manual was published[14]. On 6 April 2022, the updated IUCLID 6.6 Basic substance Manual was published[15]. On 25 March 2022, EFSA published its User Guide on Confidentiality (including "How to submit confidentiality requests via IUCLID")[16]. On 4 May 2022 the Pesticide Steering Network –IUCLID sub-group will hold its 3rd meeting.

From the first IUCLID MRL dossiers received, 10 dossiers were declared admissible by EMSs, 3 public consultations are finished, with no comments received so far, and the first post-Transparency Regulation assessment, which concerns copper-hydroxide, is ongoing.

The 29th meeting of the Pesticide Steering Network (PSN) on residues will be held on 28 April 2022. This PSN meeting is open to external and registered observers. Registration details and the agenda are available by EFSA[17].

Following the discussion of this Committee in February 2022 regarding personal data in IUCLID dossiers[18], EFSA shared a guidance document for Member States through the Pesticides Steering Network IUCLID Teams channel. The document clarifies that disclosure of personal data is a joint responsibility shared between the applicant, the Rapporteur Member State/Evaluating Member State and EFSA, and defines the roles of the actors. It describes how to perform the light check on confidential-personal data during the admissibility phase and provides standard text that can be used by a Member State for contacting the applicant and requesting to amend a dossier. The document will be discussed at the next IUCLID PSN meeting on 4 May 2022 together with practical experiences and examples. Member States

[13] https://www.oecd.org/chemicalsafety/guidance-document-on-residues-in-rotational-crops-99457f3f-en.htm
[14] https://zenodo.org/record/6281523#.Yl65q9tBzcs
[15] https://zenodo.org/record/6418582#.Yl65P9tByUk
[16] https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf
[17] https://www.efsa.europa.eu/it/events/3rd-meeting-pesticide-steering-network-iuclid-sub-group
[18] https://ec.europa.eu/food/system/files/2022-03/sc_phyto_20220222_ppr_sum.pdf

are invited to contact EFSA (FDP@efsa.europa.eu) for any question and for getting further support during their admissibility check. EFSA recommends discussing issues at an early stage to ensure correct publication of the dossiers.

EFSA re-organisation

EFSA reminded of its organisational changes effective as of 1 January 2022. The unit dealing with MRLs is now the Pesticides Residues & Plant Health (PLANTS) unit which is part of the Risk Assessment (ASSESS) department. The Data Management System (DMS) structure and pesticides residues mailbox have not been changed.

EFSA conference 2022

EFSA reminded that the "ONE – Health, Environment, Society – Conference 2022", co-organised by EFSA, the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Medicines Agency (EMA) and the European Commission's Joint Research Centre (JRC), will take place in Brussels and online on 21-24 June 2022. Registration is now open and will close, for physical participation, on 29 April 2022.

EFSA 2022 Annual Report on Pesticide Residues

EFSA provided an overview of its 2022 monitoring report[19], showing that, overall, the pesticide residues situation is under control. Annex I of the report[20] includes the data visualisation of both the EU multi-annual control programme (EU MACP) and the National Control Programmes. EFSA invited Member States to provide comments for its improvement by 30 June 2022.

EFSA reported that some countries were unable to meet the sampling targets required by the EU MACP Regulation due to the COVID-19 pandemic. Among its recommendations for the future, EFSA highlighted the need for reassessing TRVs for bromide ion, suggested that Member States should try to elucidate the higher quantification rate of residues in organic animal products compared to conventional production and stressed the need for improving the reporting of the samples' country of origin even though the percentage of samples of unknown origin decreased compared to the previous year. For certain substances amenable to Single Residue Methods (SRMs), EFSA recommended further integration of such analytical methods by Member States' laboratories. In view of performing probabilistic assessments, EFSA also recommended a future review of the commodities included in the EU MACP.

For bromide ion, the Commission recalled that a mandate to EFSA is being prepared (see point A. 04.03; on bromide see also points A.05.00 and A.06.00).

According to a Member State, there are very limited findings of residues on certain products and their sampling might no longer be necessary. EFSA recalled that Member States should review their sampling programmes based on risk assessment, while also considering the recommendation for further integration of SRMs. In explanation of the higher quantification rate of residues in organic animal products, a Member State suggested that in organic farming, animals stay longer on outdoor

[19] https://www.efsa.europa.eu/en/efsajournal/pub/7215
[20] https://www.efsa.europa.eu/en/microstrategy/annual-pesticides-report-2019

fields, thus they are susceptible to higher bioaccumulation of substances compared to conventional farming which is typically indoors. With reference to its importance for the methodology on Cumulative Risk Assessment, another Member State noted that EFSA's past recommendation for laboratories to report Limits of Detection in addition to LOQs was not included in EFSA's report this year. According to EFSA, there is no harmonisation among official laboratories to report the limits of detection and, therefore, it was decided not to list it among its suggestions, considering that the CRA methodology uses 1/2LOQ for left-censored data.

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

The Commission presented an update of the ongoing work on the harmonisation of MRLs for pesticides and veterinary medicinal products (VMPs). A Member State had provided new data confirming the findings of bromide in products of animal origin (chicken eggs, bovine liver, chicken fat, milk, and honey). While the number of samples is still low (103 in total), a prevalence of MRL exceedance was observed for all samples and especially for milk (94%), bovine liver (77%) and chicken eggs (64%). The Commission noted that the sample size is still not large enough to provide a robust statistical evaluation for eggs, and called on Member States to collect additional data to assess the need for establishing MRLs for bromide in eggs and potentially for other products of animal origin.

The Commission informed that thiabendazole is included in the draft Regulation SANTE/10090/2022, which proposes the alignment of all MRLs between Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005 for this active substance. Cyfluthrin is included in the draft Regulation SANTE/11128/2021, which proposes the alignment of MRLs for cattle and goat muscle. The discussion concerning the alignment of MRLs for chlorocresol are still ongoing between the Commission services in charge of VMPs and biocides, and with Member States.

A.06 Multiple source substances for which Annex IV inclusion is not recommended:

The Commission recalled that the draft mandate on bromide ion is still under discussion with EFSA, but the following main items for assessment were already agreed: assessment of the general toxicity for human and animal health based on the available data, including, if appropriate, derivation of TRVs for human and animal dietary risk assessment; comparison of the existing MRL with the available monitoring data from 2012 to 2021; and a screening of the safety of those MRLs, provided that TRVs can be derived. In addition, the risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed, in particular in algae and seaweed and derived products, will be assessed.

A.07 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2022-2023:

The Commission provided an update on the state of play for the remaining substances listed in the overview table. The table was updated to include information about the extension of validity of, and changes to, the existing temporary MRLs that are proposed by draft Regulations SANTE/11466/2021 and SANTE/10090/2022.

A.08 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed about the progress made in the OECD expert group. There are still some issues that need to be considered and reviewed (e.g. review of the schemes and certain definitions used in the document). A draft Guidance document is expected by summer 2022 and will then be circulated to the Member States.

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. Progress has been made in the subgroups working on the study design and the non-target plants. The draft Guidelines document is expected by summer 2022 and will then be circulated to the Member States.

3. Codex Alimentarius/JMPR issues

The Commission informed of the EU reply submitted to the "Coordination Committee for Latin America and the Caribbean Part" providing information on notifications for non-compliances with MRLs for the products listed in group 14 (Assorted fruits – inedible peel) of the Guideline (CXG 41-1993) and on the EU reply to CL202197-PR requesting information on national registrations. The Commission provided an update on the developments of different electronic Working Groups (eWG). A Member State co-hosting the eWG on the Revision of the Classification of Food and Feed invited Member States to submit comments on edible animal tissues and the definition of edible offals, even though the deadline of the commenting period has already passed.

The Commission and a Member State gave an overview of the Crop Life International's global workshop on Codex CCPR/JMPR enhancement held on 31 March 2022.

A.09 State of play on Cumulative Risk Assessment (CRA):

The Commission informed of a presentation regarding "Prospective Cumulative Exposure Assessments" that was shared by the national food safety authority of a Member State in the frame of its participation in the 2022 Fresenius Conference on "Food Safety and Dietary Risk Assessment".

A.10 Follow up on the Extraordinary SCoPAFF meeting of 11 March 2022:

At the meeting of this Committee on 11 March 2022[21], the Commission and Member States discussed on measures with regard to expected shortages of feed supply in some Member States due to Russia's invasion of Ukraine. Article 18(4) of Regulation (EC) No 396/2005 enables Member States to set national temporary MRLs (tMRLs) in exceptional circumstances to authorise the placing on the market and/or the feeding to animals within its territory of non-compliant food or feed, provided that such food or feed does not constitute an unacceptable risk. Such national measures must be immediately communicated to the Commission, EFSA and the other Member States.

The Commission invited Member States to give an update of the situation in their countries, particularly those that had previously signalled that they might face feed supply shortages. Two Member States had already informed the Commission and the other Member States in March of the national measures they took under Article 18(4), two others informed that they are foreseeing supply issues for maize for feed in the coming weeks and are also considering taking national measures under Article 18(4).

[21] https://ec.europa.eu/food/system/files/2022-03/sc_phyto_20220311_ppr_sum.pdf

Those two Member States that had taken temporary national measures under Article 18(4) for maize for a period of 6 months presented their measures already and answered questions from other Member States. They clarified that to date, increased imports from other third countries than Ukraine had not yet materialised, so that the measures taken were not yet applied in practice. Earlier in March, both countries had shared detailed risk assessments and information on control measures in place on their territory. According to those risk assessments no residues are expected on products of animal origin. Even if imported feed would contain residues between the EU MRL and the higher national tMRLs, this is not expected to lead to non-compliant products of animal origin (for which the MRL is established at the Limit of quantification (LOQ)). Maize, for which higher tMRLs apply, is mixed into composite feed at a maximum percentage of 45%. Control programmes are implemented in both countries. Imports of feed are systematically controlled at the border by checking each consignment. Traceability is ensured through the Trade Control and Expert System (TRACES) and controls are implemented to ensure that feed that is not compliant with the lower EU MRLs does not leave the national territory. Additionally, both countries take regularly samples of plant and animal origin under the coordinated EU programme. The commodity milk, which is relevant for children, will be controlled throughout the year 2022. The other Member States did not object to these measures, which, given the assurances provided, are not expected to raise any consumer health concerns.

Additionally, both Member States informed that they had already imported some consignments of maize from third countries other than Ukraine in the past and shared control data showing only few findings for the substances of concern. One of the two Member States informed that they intend to remove the tMRL for dichlorvos from their national measure. Correspondingly, the Commission advised the other Member State to also review their tMRL for dichlorvos. The Commission invited both Member States to align their approach for the tMRL for pirimiphos-methyl to 1.1mg/kg and emphasized that in this emergency situation there is a need to be flexible and to align/update measures as more information becomes available.

As increased imports from other third countries had not yet materialised, the Commission emphasized that both countries should immediately inform the Commission and other Member States when such imports start and that they should immediately signal any change of the situation, e.g. unexpected findings in feed/food of animal origin.

The Commission recalled that, in line with Article 18(4) of Regulation (EC) No 396/2005, national measures and risk assessments supporting them remain the responsibility of the Member States. The Commission is examining the measures and EFSA is working in an advisory function, but not performing a full risk assessment of the national measures. However, it is important that assurances are given to all Member States that those measures will not lead to a lower level of consumer protection in the EU and thus all Member States taking national measures should share the necessary detailed documentation as soon as possible. All such measures must be notified to the Commission, EFSA and the other Member States and also be uploaded in the specific section of CIRCABC (see point A.15.02) for information of the UK on behalf of Northern Ireland. Any other Member State that considers taking similar measures could perform similar risk assessments, if relevant, when considering the same substances, but should adapt them to their national characteristics, e.g. maximum percentage in feed and dietary burden calculations, as well as its own controls and traceability systems.

The Commission will mandate EFSA for technical assistance to support discussions with Member States on national risk management measures addressing possible shortages of food and feed supply as a consequence of the Russian invasion of Ukraine. This mandate will include the publication of a Technical Report on the results of EFSA's analysis performed in preparation of the extraordinary meeting of this Committee on 11 March 2022, explaining the methodology used and also deal with possible further flexibilities for Member States taking national measures.

A.11 Notifications under Article 18(4) to Reg. (EC) No 396/2005:

No issues were raised under this agenda item.

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

A Member State informed that it is acting as Rapporteur Member State for the assessment of both the confirmatory data under Article 12 and the confirmatory data submitted within the renewal of approval procedure of penconazole.

A.13 Feedback from Working group on RASFF procedures as regards pesticides residues:

The Commission informed of the outcome of the meeting held on 28 March 2022 of the technical working group on RASFF procedures as regards pesticide residues. This working group was convened following a request from Member States for a harmonised approach in evaluating and notifying risk and in determining compliance with MRLs. In particular, such a uniform approach described in the Work Instruction (WI) 2.2[22] should account for the use of Measurement Uncertainty (MU) and for performing consumer exposure assessments in case of substances with no TRVs, e.g. genotoxic carcinogens.

At the technical meeting, the Commission provided clarifications on RASFF risk evaluations and outlined the key parameters enabling risk decisions labelled as "no risk", "not serious risk", "undecided risk" and "serious risk". In particular, the Commission clarified that "undecided risk" is a risk for which it is not possible to decide and prove beyond doubt that it is serious, therefore it should be understood as "potentially serious risk".

The Member States then discussed on a list of criteria and considerations for taking risk decisions for samples exceeding MRLs in RASFF, related to various aspects including TRVs, residue definition for risk assessment and hazard classification. The Commission also recalled the recently endorsed Information Note on Article 20 of Regulation (EC) No 396/2005 on Processing Factors[23] and suggested to include a cross-reference in the WI.

The Commission explained that, in line with the current RASFF procedures, two pre-conditions should be respected for their harmonised application:

(i) The residue level must be non-compliant with the MRL. This means that in all cases the MRL must be exceeded taking into account the MU, which can be either the default value of 50% or, in cases of serious risk or potentially serious risk, a MU with a lower confidence interval as a precautionary measure in accordance with the Guidance on Analytical Quality Control

[22] https://ec.europa.eu/food/system/files/2022-03/rasff_reg-guid_sops_wi-2-2_en.pdf
[23] https://ec.europa.eu/food/system/files/2022-02/pesticides_mrl_guidelines_proc_imp_sante-2021-10704.pdf

(SANTE/11312/2021[24]). Compliant samples are considered to be safe as per Article 14(7) of Regulation (EC) No 178/2002.

(ii) New MRLs only apply as from their date of application.

Diverging views were expressed with regard to the use of MU, in particular in cases of substances with no TRVs and no threshold. The Commission invited Member States that had not yet done so to send their further comments by 6 May 2022.

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

The Commission updated on the expert nominated by Member States to contribute to the translation of the codes used by the Codex Classification of Foods and Feeds to EU Codes of Annex I to Regulation (EC) No 396/2005. A Member State requested clarification on the harmonization with other classification systems (e.g. the FoodEx 1 and 2 systems). EFSA clarified that, currently, several classifications systems are taken into account, but that due to the complexity of the project it would be necessary to clearly define the scope of the work. In a second step, the food consumption data used in PRIMo model could be included.

The Commission informed about a stakeholder request to review the existing classification in Annex I to Regulation (EC) No 396/2005 for tiger nuts (*Cyperus esculentus*) and invited Member States to provide their comments by 13 May 2022.

The Commission provided an update on the opinions received on how to deal with applications for MRLs for radish leaves when these are higher than the ones for kales. In view of the divergent options, the Commission proposed that, on a temporary basis, in cases where an MRL different than the one for kale is required for radish leaves, then this information would be included in a footnote on kales indicating the specific value for radish leaves. In addition, before 1 January 2025 (as it was set by Commission Regulation (EU) 2021/1771), the classification of radish leaves will be re-discussed taking into account the data generated in field trials.

A.15 Other Information points:

1. Update on PRAC measures/objections

The Commission informed of the outcome of a motion for resolution that was presented during the scrutiny period for the draft Regulation SANTE/11282/2021 setting MRLs for flutianil to address an import tolerance request, for which this Committee had given a favourable opinion after the meeting of November 2021. The motion for resolution was voted in the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament on 15 March, and was adopted (47 in favour, 38 against and 1 abstention). The European Parliament voted in plenary on the ENVI objection on the 24 March. The objection was rejected as no absolute majority was achieved (310 votes in favour were received while 353 would have been needed to adopt it). The draft measure is now published[25].

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

[24] https://ec.europa.eu/food/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf
[25] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0566

The Commission recalled that according to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union[26] and in concern of its Protocol on Ireland/Northern Ireland, it is necessary to exchange information on implementing measures relating to the Union acts listed in the Annexes to this Protocol. For this purpose, the Commission has created a special folder in CIRCABC[27], where Member States must place their national measures regarding temporary MRLs under article 18(4) of Regulation (EC) No 396/2005.

3. Guidance values for fish – update

The Commission informed that a draft mandate to EFSA for the collection of data for residues of pesticides on fish and the assessment of consumer exposure has been prepared, is available on CIRCABC and invited Member States to provide comments by 22 April 2022.

4. IESTI equation

The Commission acknowledged the information provided by Member States giving practical examples illustrating the problems with the current International Estimated Short Term Intake (IESTI) equation. Based on this information, the Commission intends to prepare a mandate to EFSA to compile all the existing knowledge on IESTI and prepare a scientific output consolidating the existing work. Member States were invited to provide comments on the elements to be included in this mandate by 13 May 2022.

5. MRL application form

The point was discussed on request of a Member State on whether an applicant still needs to submit an application form for a new MRL according to Article 6 of Regulation (EC) No 396/2005 or when applying for Article 12 confirmatory data. The Member State noted that both the Commission document on the evaluation of data submitted to confirm MRLs[28] (SANTE/10235/2016 Rev. 4.1) and the Commission guidance for setting MRLs[29] (SANTE/2015/10595 Rev. 6.1), while mentioning IUCLID, still makes reference to the application form. On the other hand, EFSA's administrative guidance[30] does not contain such reference and EFSA had proposed in June 2021 not to use the application form any longer. Some applicants claim that the application form is no longer needed, but some Member States continue to require it.

One Member State commented that Regulation (EC) No 396/2005 makes clear reference to the need of submitting an application, and opined that the submission of a notification via IUCLID only may not satisfy the legal obligations set under Article 6. The Commission observed that, in this transition phase, application forms may still be needed for some specific cases, but that this would need to be reviewed in future.

Member States were invited to submit their comments by 13 May 2022.

6. Question on acetamiprid-spinach

A Member State informed that it detected high levels of N-desmethylacetamiprid (IM-2-1, a metabolite of acetamiprid) in spinaches. According to the Member State, the

[26] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12019W%2FTXT%2802%29
[27] /CircaBC/SANTE/Future with United Kingdom and Northern Ireland/Library/ or https://circabc.europa.eu/w/browse/ef176857-d202-40a3-8c83-1934a8665735
[28] https://ec.europa.eu/food/system/files/2021-03/pesticides_mrl_guidelines_sanco-10235-2016_v4-1.pdf
[29] https://ec.europa.eu/food/system/files/2022-01/pesticides_mrl_guidelines_mrl-setting-proc_v6-1.pdf
[30] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6464

levels of this metabolite in spinach samples are often higher than the parent compound, but it is not included in the residue definition for acetamiprid in products of plant origin. Some of the analysed samples contained acetamiprid levels below MRLs but, if residues from IM-2-1 were also to be considered, the MRL would be exceeded leading to an acute risk for consumers.

According to a metabolism study included in the Renewal Assessment Report for acetamiprid (2018), the parent compound is the main residue in cabbage (80% of the total), while IM-2-1 only accounts for about 5% of the total. While, based on this study, it would be reasonable not to include IM-2-1 in the residue definition for risk assessment in plants, the data collected by the Member State suggests that this may not be the case for spinaches.

The Commission invited Member States to consult with their national laboratories and asked EFSA to investigate if similar findings have occurred in other countries, and to share the information with the Commission.

Member States were invited to submit their comments by 13 May 2022.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate in or on certain products (Art. 10).** (SANTE/10182/2022)

The Commission provided clarifications on Revision 2 of the draft Regulation and its Annexes, which contain some minor amendments following the comments received by other Commission services during the internal consultation procedures and by Member States.

The draft Regulation proposes implementing into EU legislation the CXL for cypronidil in soyabeans, since EFSA concluded it is safe for consumers and the EU had not expressed any reservation at the CCPR.

The draft Regulation also proposes retaining permanently the active substances calcium carbonate, carbon dioxide and potassium hydrogen carbonate in Annex IV to Regulation (EC) No 396/2005.

Outcome of the vote by written procedure: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) …/… as regards maximum residue levels for beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products (Art. 12). (SANTE/11128/2021)

The Commission provided clarifications on Revision 1 of the draft Regulation and its Annexes. This version contains editorial changes and corrections of the footnotes.

For cyflumetofen, it proposes the same residue definition for enforcement for both plant and animal commodities.

For cycloxydim, it maintains the current residue definition for enforcement. In the forthcoming procedure on the renewal of the approval of the substance, a simplified residue definition should be considered, as the complexity of the current one is challenging for enforcement laboratories.

For penthiopyrad in animal commodities, two residue definitions for monitoring are proposed as recommended by EFSA: 1) Penthiopyrad and 2) 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM). As PAM was only proposed for animal commodities, the respective entries for plant commodities in the respective column listing the MRLs in Annex 2 to Regulation (EC) No 396/2005 would remain empty which means implicitly that the default MRL of 0.01 mg/kg would apply automatically. However, in plant products PAM may occur naturally at higher levels (the EFSA Reasoned Opinion mentions levels around 0.1 mg/kg), so that such a default MRL may pose a problem. It is therefore proposed to accompany plant commodities by a footnote which indicates that at this stage the default MRL of 0.01 mg/kg for PAM will not apply to those products.

Member States were invited to submit their comments by 13 May 2022.

C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) …/… as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products. (SANTE/10090/2022)

The Commission provided clarifications on the draft Regulation and its Annexes in consideration of comments provided by the Member States.

For benzalkonium chloride (BAC), no lowering of any temporary MRL is proposed while for didecyldimethylammonium chloride (DDAC) the draft Regulation proposes lowering the temporary MRLs for products of plant origin to 0.05 mg/kg, based on monitoring data, and to maintain the existing ones for products of animal origin. All the temporary MRLs for BAC and DDAC should be re-assessed in 7 years.

For chlorpropham in potatoes, the draft Regulation intends to lower the current temporary MRL to 0.35 mg/kg, based on monitoring data provided by the industry, and to re-assess this MRL based on new monitoring data by the end of 2022.

For flutriafol, this draft Regulation intends to increase MRLs for cucurbits with inedible peel following an Article 6 application for setting an import tolerance, to implement EFSA recommendations following confirmatory data assessments and to maintain the MRL of 0.06 mg/kg in beetroots since an extrapolation from sugar beets is possible.

The approval of flutriafol expired in 2021, but grace periods are still ongoing. Therefore, the current draft Regulation does not intend to lower all MRLs based on EU uses to LOQ. These changes will be addressed by another measure following the expiry of the grace periods for this substance.

For nicotine, this draft Regulation implements the decisions of this Committee in November 2021[31] concerning the lowering of current temporary MRLs for nicotine in rose hips, herbs and edible flowers, wild mushrooms (fresh), teas, herbal infusions and seed and fruit spices. It proposes re-evaluating these MRLs in 7 years and updating the relevant footnotes accordingly. As recommended by one Member States, as SANTE/11466/2021 extended the validity of the temporary MRLs for wild fungi (dried ceps and dried wild mushrooms other than ceps), for the sake of harmonisation, the MRL for wild fungi should be revised 7 years after publication of that measure. For all products for which no specific MRL is indicated under Regulation (EC) No 396/2005, for the sake of completeness and transparency, this draft Regulation clarifies that the specific LOQs apply. Some Member States proposed to keep the current MRL for tea, if there are no risks for consumers, as there could be natural levels occurring in some specific regions. The Commission reiterated its intention to lower the MRL, as monitoring data suggests that a reduction is possible and temporary MRLs should only be maintained for as long as necessary. A Member State commented that with the current temporary MRL of 4 mg/kg, PRIMo 3.1 indicates exceedance of the ARfD for capers. Thus, this MRL should be lowered to 3 mg/kg. Another Member State supported this view and noted that ARfD exceedances were also indicated for other commodities (e.g. oranges, potatoes, and milk) with the current LOQ values. The Commission took note of the comments and informed the Committee that it would consult EFSA and the EU Reference Laboratories (EURL) in this regard.

For metazachlor, this draft Regulation follows up the risk management decision taken by this Committee in June 2020, for lowering existing MRLs for radishes, flowering brassica and kales, while confirming the MRLs for head cabbages and kohlrabies. In addition, it proposes lowering the MRL for swine liver based on the updated livestock dietary burden calculation.

For profenofos, this draft Regulation implements the decisions taken during the meeting of this Committee in November 2021 concerning the lowering of current temporary MRLs for profenofos in herbs and edible flowers, re-evaluating them in 7 years and updating the relevant footnotes accordingly.

For quizalofop-P, this draft Regulation intends to lower the existing MRLs in caraway based on an application for an EU use, in accordance with EFSA's conclusion.

For sodium aluminium silicate, as its approval expired on 31 August 2019, this draft Regulation intends to lower all existing MRLs to the LOQ and to move this substance from Annex IV to Annex V. Some Member States suggested keeping it in Annex IV due to lack of analytical methods. However, due to the toxicity of aluminium and in accordance with a recent decision for food additives based on an EFSA Opinion[32] concluding that the safety of this substance could not be assessed, the Commission confirmed its intention to move this substance to Annex V. Several Member States commented that the EURLs should be consulted on the analytical method to be used.

[31] https://ec.europa.eu/food/system/files/2021-12/sc_phyto_20211122_ppr_sum_0.pdf

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

A Member State noted that the decision to move this substance to Annex V due to the presence of aluminium should be specified in the draft Regulation. EFSA noted that, as aluminium could be derived from several sources, an appropriate risk definition for enforcement should be defined (i.e. this should not only target aluminium). The Commission confirmed that it would consult with EURLs on these topics.

For thiabendazole, this draft regulation intends to modify existing MRLs for products of animal origin based on an EFSA Opinion. The draft Regulation proposes to lower to the LOQ those MRLs for which CXLs exist but are not sufficiently supported by data and to lower the current MRLs for cattle and goat products (including milk) as to align them with the MRLs set by Regulation (EU) No 37/2010.

For triadimenol, as its approval expired on 31 August 2019, this draft Regulation intends to lower all MRLs to the LOQ, except for the CXL for grapes. The draft also intends to lower to LOQ the existing CXL for cucurbits with inedible peel and globe artichokes, as in its Reasoned Opinion on the Art.12 review for the substance, EFSA noted that those uses werenot fully supported by data. The Commission highlighted that in the same Reasoned Opinion, EFSA concluded that the CXL for grapes was also not fully supported by data, but in preparation of CCPR (also in 2015), EFSA did not identify a risk for consumers for that CXL. Therefore, the Commission invited Member States to share their view on maintaining the CXL for grapes. A Member State suggested that the CXL for grapes should not be kept as it is not sufficiently supported by data and it should be lowered to the LOQ.

Member States were invited to submit their comments by 13 May 2022.

C.03 Exchange of views of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for for abamectin in or on certain products (Art. 43). (SANTE/11316/2021)

The Commission presented an overview of the draft Regulation and clarified that the MRL for the subgroup "Others" of the product category "cucurbits with edible peel" is maintained as the authorisations granted by Member States also cover that subgroup. The Member States requested to lower the currently proposed MRL of 0.01*mg/kg for apples to 0.006*mg/kg as it was proposed for pears, because the level of 0.01*mg/kg might not be protective enough.

The Commission also shared a letter from EU Focus proposing to wait with the lowering of MRLs for abamectin until new residue trials were made available. The Commission stated that it was not possible to postpone lowering those MRLs as there is an acute risk for consumers.

Member States were invited to submit their comments by 13 May 2022.

C.04 Exchange of views 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 bifenthrin, bromopropylate, chloridazone, fenpropimorph, imazaquin and tralkoxydim in or on certain products. (SANTE/10644/2021)

Following the request from some Member States and further information received from EFSA, the Commission proposed to take out bifenthrin from the draft Regulation under discussion as a new risk assessment from EFSA was required to consider further scientific data. The Commission proposed to prepare a separate draft Regulation as

regards MRLs for bifenthrin once EFSA has concluded its risk assessment. The details on the mandate for this risk assessment were discussed under point A01.03.

For the rest of the active substances, the Commission presented an overview of the modifications of the draft Regulation compared to previously discussed versions. The Commission proposed revised MRLs for the active substance fenpropimorph and transition measures for food placed on the market before this Regulation will become applicable.

Member States were invited to submit their comments by 13 May 2022.

C.05 Exchange of views of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. (SANTE/11226/2021)

The Commission presented the contents of the draft Regulation lowering the MRLs for clothianidin and thiamethoxam. However, the details of this draft are still under internal discussion and the Commission will distribute it to Member States only once this procedure is concluded. In parallel, the draft Regulation will be submitted for consultation to trading partners under the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO). The vote on the draft measure will be scheduled once all procedures have been concluded. The Commission also informed about a letter from a stakeholder association (Crop Life Europe) indicating their concerns on the proposed measure.

C.06 Exchange of views 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 isoxaben, novaluron and tetraconazole in or on certain products. (SANTE/10108/2022)

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for isoxaben, tetraconazole and novaluron under Article 12 of Regulation (EC) No 396/2005. The Commission highlighted the specific situation of novaluron, which was non-approved in the EU in 2012 further to a voluntary withdrawal of the application by the applicant and before EFSA could finalise its assessment at the time. MRLs are currently set in Annex IIIA to Regulation (EC) No 396/2005 based on CXLs and import tolerances and EFSA's assessment identified various data gaps.

Member States were invited to submit their comments by 19 April 2022.

C.07 Exchange of views of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium phosphide, cyromazine, topramezone and triflumizole in or on certain products. (SANTE/10088/2022)

The Commission introduced the draft Regulation lowering the MRLs for the substances calcium phosphide, cyromazine, topramezone and triflumizole following the non-renewal of their approvals. The Commission informed that all the existing MRLs for these active substances are based on EU uses and no CXLs or import tolerances exist for any of them. Therefore, it is appropriate to lower all MRLs to the LOQ, except for the MRL of 0.3 mg/kg of cyromazine in bovine products (except milk) that was set to cover its use in veterinary medicine.

Member States were invited to submit comments by 13 May 2022.

C.08 Exchange of views of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for acequinocyl in or on certain products (Art. 10). (SANTE/10180/2022)

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

Acequinocyl was included in SANTE/11314/2021 which received a favourable opinion in February 2022, therefore the vote for this draft will be planned after the entry into force of SANTE/11314/2021.

Member States were invited to submit their comments by 13 May 2022.

C.09 Exchange of views of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for benalaxyl, bromoxynil, chlorsulfuron, fenamiphos and epoxiconazolein or on certain products.

Following the expiry of approval and of the grace periods granted for those substances, the draft Regulation proposes lowering their MRLs where appropriate.

Benalaxyl shares the same residue definition with benalaxyl-M, therefore, MRL modifications in Annex II to Regulation (EC) No 396/2005 should consider benalaxyl-M's legitimate uses and existing CXLs. With reference to EFSA's 2019 Reasoned Opinion regarding benalaxyl-M[33], the draft proposes maintaining the MRLs for table grapes, wine grapes, potatoes, garlics, onions, shallots, melons, watermelons, lettuces and leeks, while lowering MRLs for aubergines and tomatoes. For peppers and rapeseeds, no authorised uses for benalaxyl-M nor CXLs or import tolerances exist, hence those MRLs should be lowered to the LOQ.

For fenamiphos, according to EFSA's 2009 Reasoned Opinion, the import tolerances for table grapes and wine grapes were safe for consumers, therefore those MRLs should be maintained. All other MRLs should be lowered to the LOQ.

For bromoxynil, chlorsulfuron and epoxiconazole, in the absence of CXLs and import tolerances, MRLs will be lowered to the LOQ in Annex V to Regulation (EC) No 396/2005.

Member States were invited to submit their comments by 13 May 2022.

[33] European Food Safety Authority, 'Review of the existing maximum residue levels for benalaxyl-M according to Article 12 of Regulation (EC) No 396/2005', EFSA Journal 2019;17(9):5818