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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
22 - 23 November 2021

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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

No issues were raised under this agenda item.

3. List of non-approved substances for follow up

The Commission presented an updated prioritisation of the list of non-approved active substances for which existing MRLs would need to be reviewed. The update was based on comments received from one Member State, who proposed criteria for assigning priorities to substances that had never been approved in the EU.

One Member State proposed attributing the highest priority to further substances and asked the Commission to develop a time schedule for the follow-up work. The Commission clarified that further discussion on prioritisation would be needed to rationalise workload, but reminded that this would need to take into account existing resources.

Member States were invited to submit comments by 22 December 2021.

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

The Commission gave an overview on the outcome of the last meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation held on 21-22 October 2021. It informed that two Member States had requested to terminate the written procedure for vote on the proposed non-renewal of phosmet without results. The vote will now take place in the meeting scheduled for 1-2 December 2021 of that section of the Committee. This will, however, not change the planned Article 12 review for phosmet scheduled to be started still in the second half of 2022.

The Commission recalled that at the last meeting of this Committee, Member States had asked the Commission to communicate upcoming changes with potential relevance for MRLs at an earlier stage (e.g. upcoming non-renewal decisions, withdrawals of

approvals or expected changes of toxicological reference values (TRVs)). The Commission agreed to regularly inform about such cases, but also called on Member States to bring such cases to the attention to the Committee if identified by them.

As a further follow-up to this request, the Commission presented the table on active substances the approval of which had not been renewed, for which grace periods had expired or will expire soon and for which follow-up action was needed. The Commission informed that it will update the table periodically. The Commission invited the Member States to notify any substances that might need to be added to the table. A Member State asked when the Commission plans to take action on indoxacarb, as according to them, an Art. 43 assessment should be launched already before the grace period ends. The Commission agreed to look into the matter but indicated that the grace period will expire already mid-2022 and that the fastest option would be to prioritise it then. A Member State asked for feedback on a low risk substance *Bacillus amyloliquefaciens strain AH2*, which had not been included in Annex IV to Regulation (EC) No 396/2005. The Commission explained that the presented table only displays substances which were not approved/renewed, for which approvals had been withdrawn or expired, or for which use restrictions with potential impact on MRLs were set. Follow-up on approved substances would continue to be done through routine MRL proposals. As regards the specific case of *Bacillus amyloliquefaciens strain AH2*, EFSA did not recommend inclusion into Annex IV to Regulation (EC) No 396/2005. Further discussions on the appropriate follow-up for this substance will be needed.

A.03 Specific substances:

1. Glufosinate ammonium

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

2. Glyphosate

The Commission informed that on 28 October 2021, EFSA published a Reasoned Opinion for the setting of an import tolerance for glyphosate on soybeans.

3. Ethylene oxide – update on the state of play

The Commission informed that a mandate to EFSA is currently being prepared concerning the review of studies evaluated by the German risk assessment body (BfR) relating to 2-chloroethanol and announced that a second technical meeting of experts would take place on 20 January 2022.

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 continue. Currently internal consultation and consultation with the Rapporteur Member States are ongoing to collect robust scientific inputs as a basis for drafting appropriate terms of reference for a mandate to EFSA.

5. Clethodim

The Commission updated the Committee on the discussion on the way forward for clethodim that took place in the meeting of the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals - Legislation held on 21 - 22 October

2021. As new studies are available on the metabolite 3-chloroallylalcohol, one of the options discussed is a possible review of the approval of the substance under Article 21 of Regulation (EC) No 1107/2009. The Rapporteur Member State (RMS) highlighted the importance of avoiding parallel evaluations that could reach contradictory conclusions. It signalled its preference to take the new studies submitted – or still to be submitted in early 2022 - into account in the context of the already ongoing procedure for the renewal of approval. The Commission considered that this would be the fastest way of dealing with that substance. It also stressed the importance for the RMS to signal without delay to the Commission if there were still indications that a genotoxic potential of the clethodim metabolite 3-chloroallylalcohol could not be excluded. Depending on the information and the outcome of the renewal procedure, a review of MRLs may still be needed in a second step. The Commission also informed that an application under Article 6 of Regulation (EC) No 396/2005 for clethodim MRLs had been rejected by the Evaluating Member State as it was not considered acceptable.

6. Fluopyram

- The Commission explained that Regulation (EU) 2021/1807 corrects the fluopyram maximum residue level (MRL) for soybeans and establishes the same date of application as in Regulation (EU) 2021/618. However, it does not specifically repeat the transitional period granted in the original Regulation for foods lawfully placed on the market before the application date. The Commission clarified that for soybeans these transitional measures also still apply as set in the original Regulation.

- Following the first discussion that took place at the meeting of this Committee in September 2021, the Evaluating Member State (EMS) for the active substance fluopyram reported about the feedback received from the other Member States. The applicant had applied for lower MRLs for pome fruits, wheat and sorghum, while applying for an increase of the MRLs for soybeans and peanuts given that chronic exposure was already at 100%. A Member State commented that according to the Technical Guidelines on the MRL setting procedure (SANTE/2015/10595), an application for lowering MRLs can be submitted based on consumer concerns and should be justified by the applicant. The Commission confirmed this. However, several Member States were critical as to the justification given by the applicant which they considered not sufficient and they had questions and doubts requiring further clarifications. Some Member States also raised a question whether lowering the values would have an impact on possible competitors of the applicant.

  The EMS will get back to the applicant with a request for further clarifications and will give an update at the next meeting of this Committee.

7. Matrine/oxymatrine

The Commission informed of a meeting with the Chinese customs authorities concerning matrine/oxymatrine, where China reiterated the natural occurrence of these substances in plants of the Sophora species and confirmed that the substance is used as a pesticide in China with MRLs established for head cabbages and cucumber at 5 mg/kg and for citrus fruits at 1 mg/kg and an Acceptable Daily Intake (ADI) set at 0.1mg/kg bodyweight/day (bw/d). The Commission recalled that in the EU the default value of 0.01 mg/kg applies according to Article 18(1)(b) of Regulation (EC) No 396/2005, but

that according to Article 6 of that Regulation, operators from China (or the Chinese authorities) could apply for an import tolerance.

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[1] had been adopted since the previous meeting of this Committee in September 2021. Of these, 2 relate to import tolerance applications and 3 to uses in the EU.

Currently, outputs addressing 58 such processes are at different steps of the procedure. Out of these, 13 are under scientific assessment and 42 are currently under clock-stop as additional data had been requested (29 under Regulation (EC) No 396/2005 and 13 under Regulation (EC) No 1107/2009). EFSA reiterated its invitation to Member States to provide expected timelines for submission of the additional information required during clock-stops.

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

EFSA presented the state of play of the ongoing Article 12 reviews. Reviews for 26 active substances are currently on hold as other processes are currently ongoing which need to be finalised first, for 14 data is pending, and 26 are currently being assessed at different stages of the procedure. Since the last meeting, 1 further review of all existing MRLs has been finalised.

Dithiocarbamates

EFSA reported about the ongoing work on dithiocarbamates. The reviews for different substances are at different stages of the process. EFSA analysed the monitoring data shared by the EU Reference Laboratories (EURLs) in March 2021 for possible grouping and extrapolations and complemented the datasets considering the data submitted in the Evaluation Reports/Draft Assessment Reports/Renewal Assessment Reports supporting the existing uses/previous MRL applications/peer review and the data available in the RUEDIS database (with the support of the German Federal Institute for Risk Assessment (BfR)). The Commission and EFSA had agreed not to launch an ad-hoc data call to all Member States for additional results in control samples. In case insufficient data are made available (<59 samples), EFSA will calculate MRL proposals with alternative methodology requiring less data.

Complexity evaluation of forthcoming Article 12 evaluations

During the meeting of this Committee in September 2021, EFSA had informed that it intended to evaluate the complexity of forthcoming Article 12 reviews via a checklist to be shared with the Evaluating Member States for commenting within one week. That proposal was further discussed with the Commission and it was agreed to pilot the complexity calculator with the Member State acting as Evaluating Member State (EMS) for phosmet. The procedure will be initiated soon.

<u>Article 12 Work programme</u>

The Commission presented an updated work programme for 2022. The launch of the MRL review for zoxamide was confirmed for September 2022 by the EMS. For 2022, for the moment phosmet and zoxamide will be the only substances to be reviewed under Article 12. The Committee agreed with the revision as presented.

[1] Each process receives a so-called "EFSA question number".

3. Update on mandates under Art. 43 of Regulation (EC) No 396/2005

All Art. 43 mandates were finalised and the relative Reasoned Opinions (ROs) adopted. The Statement on the lack of confirmatory data following Article 12 reviews (according to Art 31) for 2,4-D, fenhexamid and iprovalicarb was adopted on 29 September 2021.

4. Other issues

Pesticides Annual Monitoring Report

EFSA communicated that the work on the Pesticides Residues Annual Report (ARPR) 2020 was progressing as planned.

International

The full Joint FAO/WHO Meeting on Pesticides Residues (JMPR) summary report for their extraordinary meeting in May 2021 had recently been published[2] and EFSA had started working on their scientific report. JMPR assessed 27 substances in total. Rapporteur Member States (RMSs) will be consulted bilaterally in the course of the next weeks on the draft EFSA comments. A draft interim report on all 27 active substances is expected to be ready and shared with all Member States and with the Commission before the end of December 2021.

The JMPR summary report[3] for their regular meeting (September/October 2021) had been published while the full JMPR report is expected to be published only at the beginning of January 2022. Fifteen compounds were assessed and, among other topics, the International Estimated Short Term Intake (IESTI) was also discussed. EFSA plans to have bilateral consultations with the respective RMSs in January/February 2022 and to share a draft report covering all active substances with all Member States by mid-February 2022.

Cumulative risk assessment

The work on the cumulative risk assessment for craniofacial malformations is ongoing. Due to issues with input data the deadline for publication was postponed to the end of May 2022.

No proposals had been submitted for the EFSA call for proposal 'Cooperation with EFSA in area of cumulative risk assessment from dietary exposure to pesticides', which closed on 24 September 2021. A market analysis is now ongoing in order to understand factors causing the failure, and the call will be re-launched between the end of December 2021 and the beginning of January 2022.

Pesticides Steering Network/Transparency/IUCLID

EFSA provided an update on MRL applications in IUCLID: up to date, 5 dossiers had been declared admissible by Evaluating Member States (EMS). The public consultation on the first dossier (Copper hydroxide in small fruits) ran from 20 October to 3 November 2021, and no comments were received. EFSA informed that in accordance with the Transparency Regulation, the comments received during a public consultation are compiled by EFSA and shared with the respective EMS. In accordance with the EFSA administrative guidance, the EMS evaluates the comments during the risk assessment. Specifically, the Evaluation Report should clearly report in a dedicated

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

Annex how each comment received was considered for the risk assessment. Even when no comments are received, the EMS has to report the public consultation and its outcome when drafting the Evaluation Report.

EFSA informed that a meeting of the IUCLID sub-group of the Pesticides Steering Network (PSN) took place on 1 October 2021, and the PSN main meeting on 13 October 2021. An update of IUCLID (6.6) was released on 27 October 2021 and the revision of the related manuals is on-going. The last session of the Hypercare Programme, which had been established to support applicants in their submission of dossiers in IUCLID and Member States in evaluating such dossiers, was held in November 2021. Then the PSN IUCLID subgroup will take over this support function. A range of supporting materials is also available on the EFSA website.

EFSA invited Member States to verify the sanitisation of personal data and the inclusion of confidential version of attachments/reports during the admissibility phase of submitted dossiers and reminded them that they must notify (via email) all Member States, EFSA, the Commission (at SANTE-MRLs-applications@ec.europa.eu), and the applicant of the decision on admissibility of a dossier. The EFSA APDESK Unit is available to provide further support or advice in relation to performing the admissibility check in IUCLID.

Extraction efficiency guidelines (SANTE 2017/10632 Rev. 3)

EFSA provided an update on the discussion on whether the lack of data on extraction efficiency is sufficient to invalidate residue trials or not and summarised the comments received from Member States on the question how to handle Article 10 and Article 12 MRL assessments when information on extraction efficiency is lacking.

EFSA informed that several Member States supported the proposal of revising Chapter 7 of the Technical Guidelines providing more clarity on its applicability and scope. However, there were somewhat diverging views on the follow up to be given within the Article 10 or Article 12 risk assessment procedures when information on extraction efficiency is not provided. Different views were also expressed by Member States on the applicability of the Technical Guidelines regarding the assessment of extraction efficiency during authorisation of plant protection products at Member State or zonal level.

Further reflections by Member States are needed to decide on the approach (see also discussion under point A.14).

EFSA draft Technical Report on Rotational Crops

EFSA had discussed its draft Technical Report on Rotational Cropsthe Commission in preparation of the meeting of this Committee. It was agreed that an EFSA guideline would be more appropriate than a Technical Report to provide the necessary clarifications on the assessment of rotational crops. EFSA will prepare a "charter" to start work under a self-mandate. Details on timelines and procedure will be communicated to this Committee at its next meeting in February 2022. The discussion covered also legal and procedural aspects for which risk management input is required and approaches to deal with data gaps. The document is currently being revised, implementing the feedbacks from Member States and the Commission.

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

The Commission presented an update on the ongoing work on the harmonisation of MRLs for pesticides and veterinary medicinal products. The Commission reiterated its previous proposal to include ammonium sulphate in Annex IV to Regulation (EC) No 396/2005. In fact it noted that, while toxicology concerns were raised for 'aluminium ammonium sulphate', this was not the case for 'ammonium sulphate', which on the contrary does not raise a safety concern. A Member State pointed out that residues of bromide from its potassium and sodium salts in eggs frequently exceed the existing MRL set by Regulation (EC) No 396/2005. The Commission noted that current monitoring data on bromide in eggs are scarce, and called on Member States to collect additional data to assess the need of establishing MRLs for bromide in eggs. The Commission informed the Committee that, for phoxim and oxytetracycline, coordination was sought with the responsible service in the Commission dealing with veterinary medicines to discuss potential solutions, and that the work on these substances was temporarily put on hold. One Member States pointed out that phoxim is also in the list of non-approved substances for follow-up and recommended to ensure coordination on the activities on this substance as to avoid duplication of work. One Member State noted that an MRL for imidacloprid in fin fish had been established in Regulation (EU) No 37/2010, and recommended adding imidacloprid to the list of substances that will need harmonisation. Lastly, the Commission informed Member States that thiabendazole will be included in a forthcoming draft Regulation, which will propose the alignment of all MRL values among Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005 for this active substance.

One Member State commented that the EURL Single Residue Methods expressed difficulties in enforcing the current residue definition for amitraz, and asked the Commission what procedure could be followed to amend it, as amitraz is a non-approved substance and then no re-evaluation is foreseen. The Commission noted that, as this substance is also a veterinary medical product, coordination will be needed with the responsible Commission service to ensure alignment and that the issue could be taken up in that context. One Member Sate suggested checking monitoring data as to make sure that residues of amitraz are found before starting to address any issue on this substance.

Member States were invited to submit comments by 22 December 2021.

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

The Commission informed that it had extracted from the database received from EFSA (covering a time span of 10 years) those commodities with less than 59 samples and requested the Member States to specifically collect more data on those commodities. In order to support such an activity at Member State level, bromide was also included in Annex 1 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. 13)" which was scheduled for endorsement at this meeting of the Committee (cf. agenda item A.10).

Data had also been received by the trade association Tea and Herbal Infusions Europe (THIE) and had been shared with Member States on CIRCA BC. The Commission summarised the data received and stated that for some commodities the data showed

much lower levels than the current MRLs. However, for most commodities (except camomile and hibiscus flower) data are still not sufficient.

The Commission announced that as next step it would analyse the overall data package with regard to those commodities where changes of MRLs may be required.

A.07 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2021-2022:

1. General overview

The Commission gave an update on the state of play for the remaining substances listed in the overview table. As regards the existing temporary MRLs (t-MRLs) for chlormequat in cultivated fungi (including oyster mushrooms), monitoring data were insufficient to allow revising the t-MRLs and new data from the industry will become available in early 2022, therefore, the Commission reiterated its proposal to re-evaluate the situation by December 2022 together with the data on mepiquat which are expected to be submitted by that date. On chlormequat in pears, residue trials performed on orchards that were legally treated with this substance before 2000 support the existing t-MRL, and the Commission proposed to keep the current t-MRL and to review it after a period of 7 years.

The t-MRLs for chlorpropham in potatoes and benzalkonium chloride (BAC) and didecyldimethylammonium chloride (DDAC) in all commodities need to be reassessed. To this end, the Commission will ask EFSA to extract monitoring data, and will present them at a forthcoming meeting of this Committee.

Member States were invited to submit comments by 22 December 2021.

2. Data analyses for decisions on t-MRLs for profenofos and nicotine

The Commission presented its proposals as to whether the existing t-MRLs for nicotine and profenofos should be maintained or lowered based on data extracted by EFSA from the monitoring database for the years 2016-2019 or, in cases where such data were insufficient, monitoring data provided by the industry covering the period 2016-2020.

An upper bound approach was used for performing all calculations. In accordance with Commission Regulation (EU) No 283/2013 on data requirements for dossiers for the approval of active substances, the revised t-MRLs are proposed based on monitoring data, covering the 95th percentile of the data population (p95) at the 95 % confidence level. In one specific case, the decision was taken to use p99 instead of p95 (i.e., nicotine in herbs and edible flowers) in a first step and re-evaluate whether further reductions would be possible at a later stage.

The Commission presented the following proposals based on the 95th percentile, 95% confidence interval (where not indicated differently) and to combine this with a review after a period of 7 years:

- for nicotine on rose hips to lower the current MRL to 0.2 mg/kg,
- for nicotine on herbs and edible flowers to lower the current MRL to 0.1 mg/kg (corresponding to the 99th percentile, 95% confidence interval),
- for nicotine on wild mushrooms (fresh) to lower the current MRL to 0.02 mg/kg,
- for nicotine on teas, to lower the current MRL to 0.4 mg/kg,
- for nicotine on herbal infusions to lower the current MRL to 0.3 mg/kg,

- for nicotine on seed and fruit spices to lower the current MRL to 0.01 mg/kg,
- for profenofos on herbs and edible flowers, a large set of official monitoring data had been collected between 2016 and 2019. While the findings in the vast majority of samples were below the MRL, a very limited number of samples (n=5) presented very high values (i.e., above 10 mg/kg). The Commission proposed removing these outliers and, based on this new dataset, lowering the current MRL to 0.03 mg/kg,
- for profenofos on rose petals and for nicotine on wild mushrooms (ceps dry and other dry mushrooms), and spices (other than seed and fruit spices), official and industry monitoring data did not allow deriving any proposal for lowering existing t-MRLs. The Commission proposed maintaining current t-MRLs and to review them after a period of 7 years.

The Member States were invited to submit comments by 22 December 2021.

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 related to e.g. stereoisomers, conjugates/bound residues and metabolites with different mode of action to the parent compound that need to be considered and included in the draft.

The timeline was also re-discussed and a more realistic timeline for the finalisation of a draft document by the working group set for mid-2022. After peer review by the Pesticide Residue Chemistry Expert Group finalisation is planned by the end of 2022.

2. OECD Honey Guidelines and Member States' experiences with the EU guidelines

One of the Member States who attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. Currently the work is done in two subgroups: one works on the general decision tree and the other on the study design. The aim is to finalise the draft guideline by mid-2022.

3. Codex Alimentarius/JMPR issues

The Commission provided an update on the 44th session of the Codex Alimentarius Commission (CAC) held virtually on 8-13, 15, 17 and 18 November 2021. The standards and texts agreed during the 52nd Codex Committee on Pesticide Residues (CCRP) were adopted, including the correction on the MRLs for metaflumizone for mammalian fats (0.15 mg/kg) and for milk fats (0.6 mg/kg) suggested by the EU. A more detailled summary of the outcome of the meeting was circulated among the Member States.

The Commission indicated that further information on the venue and dates for the next CCPR meeting was not yet available and that under these circumstances it proposed to start working under the assumption that CCPR 2022 would take place in spring 2022 and that preparatory Council Working Parties would be needed in advance.

EFSA provided more information in their presentation under agenda item A.04.4.

A.09 Information Note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed (SANTE/10704/2021):

The Commission presented the revised draft Information Note. The Commission highlighted that the aim is to endorse the Information Note at the next meeting of this Committee in February 2022. A Member State commented that the definitions provided in Regulation (EC) No 852/2004[4] would not be line with definitions provided in the EU pesticides legislation and that it would provide further comments on that. A Member State asked whether the document could be shared with stakeholders. The Commission clarified that the Member States can consult their stakeholders but that the Commission itself does not foresee another stakeholder consultation round. Few Member States proposed to have one joint platform with an inventory of processing factors. The Commission clarified that such a project was already ongoing within EFSA jointly with the German Federal Institute for Risk Assessment (BfR). A Member State asked whether in the light of the recent findings of ethylene oxide (ETO) handling genotoxic substances will be captured in the document. The Commission clarified that the document lays down a standard approach. ETO is a specific case which is being dealt with separately. A Member State asked about options of sharing the useful information that will be gathered when implementing the procedures with the other Member States. The Commission specified that after some time of implementation of the Information Note there will be further discussion on practical issues such as sharing of information and experiences.

Member States were invited to submit comments by 22 December 2021.

A.10 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. 13) for endorsement by Member States:

The Commission referred to the meeting of experts on the monitoring of pesticide residues held on 15 October 2021 and presented an overview of the updates of the working document. Ethylene oxide including 2-chloroethanol and bromide ion were included in its Annex I, while matrine including oxymatrine were included in addition in Annex VII and Chapter 4.

The Committee endorsed the working document SANCO/12745/2013, revision 13(4).

A.11 Update of the Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed (SANTE/2019/12682) for endorsement by Member States:

The Commission had submitted an updated version of the document which included two changes: the addition of a footnote in paragraph C7 to make reference to SANTE/2017/10632 on the evaluation of extraction efficiency and additional wording in paragraph E12 to reflect that in justified cases, for the purpose of official controls, deviations from the default 50% uncertainty value could be considered, if supported by sufficient intra- and inter-laboratory evidence.

Two Member States questioned the reasoning for inclusion of this sentence in the document. The Commission clarified that such clarification is science-based and

[4] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1–54)

supportive to the document RASFF WI 2.2[5]. Another Member State commented that the time for considering those changes was too short and that it needed more time to reflect on them.

Endorsement of this document was postponed to the next meeting of the Committee.

Member States were invited to submit their comments by 10 December 2021.

A.12 Notifications under Article 18(4) to Reg. (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.

A.14 Implementation of the Extraction Efficiency guidelines (SANTE/2017/10632)):

EFSA provided an overview of the comments received on an update of the Technical Guidelines on Extraction Efficiency (SANTE/2017/10632). Overall, there is support for a revision of Chapter 7 of the Technical Guidelines to provide more clarity on its applicability and scope. However, EFSA requested further clarification on the actions to be taken for Article 10 and Article 12 evaluations in the case where data for extraction efficiency are not available. The Commission suggested that following further comments from the Member States an updated version of the TG would be prepared for the next meeting of this Committee.

Member States were invited to submit their comments by 22 December 2021.

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

The Commission thanked Member States for having provided feedback on the potential classification of the water plants *Wolffia arrhiza* and *Wolffia globose* in Annex I to Regulation (EC) No 396/2005. All comments had been forwarded to the Commission Working Group on Novel Food who is dealing with the authorisation of the *Wolffia spp* as Novel foods. The Working Group concluded that the most appropriated approach would be to cover those water plants by the MRLs set for the Subgroup (d) watercresses (Code 0254000) in Annex I to Regulation (EC) No 396/2005 as the growth conditions and the uptake of active substances (by spray drift or overhead spraying) and the occurrence of residues are expected to be similar.

A.16 Update on Farm to Fork/REFIT actions:

The Commission informed Member States about the initial steps in the preparation of the draft Regulation to lower the MRLs of the neonicotinoid substances clothianidin and thiamethoxam. This will be the first draft Regulation enacting the new policy announced in the Green Deal and in the Farm to Fork Strategy. The environmental aspect that this Regulation will target is the protection of pollinators worldwide. The Commission informed about its plan to present the draft Regulation for vote in this Committee in the meeting scheduled for 21 - 22 February 2022. The draft will be shared with Member States for commenting and simultaneously be notified to trading partners under the Sanitary and Phytosanitary (SPS) agreement to the World Trade Organization (WTO). Comments received within the 60-day deadline will be considered.

[5] https://ec.europa.eu/food/system/files/2017-02/rasff_reg-guid_sops_wi-2-2_en.pdf

The Commission informed about a communication received by a group of Non-Governmental Organisations that was distributed among Member States and clarified once again that its intention is not to reject all import tolerances for substances not approved in the EU, as requested by this group. Instead, and in line with its obligations under the WTO/SPS agreement, it will focus on substances of global environmental concern.

A.17 Forthcoming draft Regulations:

The Commission informed about forthcoming draft Regulations reviewing the MRLs for:

a) acequinocyl, chlorantraniliprole and emamectin;

These substances had already been discussed previously in different draft Regulations (acequinocyl (SANTE-2020-10044), chlorantraniliprole (SANTE-2020-12030) and emamectin (SANTE-2019-12558)), but had been put on hold as for all of those substances delays with earlier draft Regulations were experienced during the scrutiny periods. The substances had already been notified under the SPS agreement to the WTO, therefore the draft Regulation will not be notified again.

b) abamectin, fosetyl, disodium phosphonate and potassium phosphonates following the EFSA reviews under Article 43 of Regulation (EC) No 396/2005.

A.18 Other Information points:

1. Update on PRAC measures/objections

The Commission informed about an announced motion for resolution in the Committee on the Environment, Public Health and Food Safety of the European Parliament during the scrutiny period for the draft Regulation setting MRLs for flonicamid, for which this Committee had given a favourable opinion after the meeting in September 2021. It informed about its intentions as regards outreach activities to raise awareness of the objectives of the draft Regulation and the consequences of not setting the proposed MRLs.

2. Brexit

No issues were raised under this agenda item.

3. Peeling factor/consumption of unpeeled food

Neither the Commission nor EFSA had received any additional comments from Member States. The Commission concluded therefore that the discussion on this topic would be considered closed at this point in time.

4. Chlorpropham in cereals

The item was put on the agenda on request of a Member State.

The Member State informed having been contacted by the national association on feeding stuffs about the possibility to request a temporary higher MRL for chlorpropham in cereals to cover minor cross-contamination occurring in practice through the use of possibly contaminated storage facilities. Such facilities were previously used for potatoes but were partially turned into storages for cereals. After some discussion the Commission and Member States concluded that this would not be appropriate as the situation was not comparable to the situation previously discussed for potatoes. The level for potatoes was considerably lowered from previously 10 mg/kg

to 0.4 mg/kg after the non-renewal of approval of chlorpropham (based on a consumer health risk) and the intention is to lower it further after the annual review of MRLs that will take place based on the data and the assurances on good cleaning practices that are expected to be received by 31 December 2022. The existing MRLs for cereals are at the Limit of Quantification (LOQ) of 0.01 mg/kg, in place since 2014, and did not pose major problems so far. Higher levels than the LOQ can be avoided by good practices and application for higher MRLs should therefore not be encouraged. Furthermore, a Member States remarked that monitoring data alone would not be sufficient for such an assessment.

5. Radish leaves

The item was put on the agenda on request of a Member State in view of the application of MRLs for kales to radish leaves as from 1 January 2025.

The Member State requested additional clarifications on the way to handle applications for MRLs on radish leaves when the values are higher than the ones for kales to which radish leaves are currently associated in part B of Annex 1. Some examples, such as ongoing applications for mandipropamid and oxathiapiprolin were discussed. While a full overview on whether or not MRLs on kales are appropriate also for radish leaves for specific active substances will only be available when all residue trials will have been submitted and assessed, the Commission recommended to the Member States to assess the already submitted trials as soon as possible in view of their legal obligations. Since radish leaves may require some more specific MRLs that could be different from those needed for kales, the option of including specific MRLs for radish leaves in a footnote to the MRLs for kales (if diverging) was discussed. While this would be the best option in terms of keeping levels as low as reasonably achievable, clear disadvantages were highlighted by the Member States as regards extractability of such levels from the Pesticides Database and transparency. The Commission agreed to investigate this matter further with the DG Health and Food Safety IT specialists with a view of finding a satisfactory solution.

6. Karanjin

The item was put on the agenda on request of a Member State who asked the Commission to include karanjin in the EU Pesticide Database in order to clarify that karanjin is a non-approved substance under Regulation (EC) No 1107/2009 (it was never evaluated in the EU) and that the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005 applies. The Member State explained that there have been notable findings of the substance karanjin in food.

Karanjin is a bioactive compound, a furanoflavonoid, present in oil from seeds and leaves of *Pongamia pinnata (L.)* (Family Fabaceae Karanjin and has been reported to have inter alia pesticidal, insecticidal, acaricidal, antifungal and antibacterial properties).

A Member State pointed out that this substance could be helpful to meet the goals of the Farm to Fork Strategy. Another Member State highlighted that all substances including naturally occurring substances have to be assessed for their safety as some naturally occurring substances can be very hazardous. A Member State informed that Karanjin is used in the organic supply chain and asked for clarification of its legal status. The Commission clarified that Karanjin is considered as a non-approved substance under Regulation (EC) No 1107/2009, therefore the default MRL of 0.01 mg/kg applies even if it is a naturally occurring substance. If there was an import tolerance application

for that substance, it would be assessed according to the normal procedures and, if such assessment was favourable specific MRLs could be set.

Member States were invited to submit comments by 22 December 2021.

7. Rapid Alert System for Food and Feed (RASFF) Work Instructions (WI's) – clarifications

The item was put on the agenda on request of a Member State.

The Commission clarified that in cases of notifications where a risk is identified as "undecided", then this means that a decision cannot be made as to whether a risk is serious or not, but without questioning that there is a risk. The options "serious", "not serious" and "undecided" help to determine whether there should be an Alert notification or not, but from the moment that a notification is placed on the Rapid Alert System for Food and Feed (RASFF) there is a risk and, thus, Member States are aware and can take action.

The Commission clarified that in accordance with Work Instruction (WI 2.2) on the RASFF the first assessment step concerns the evaluation of the analytical result with the MRL in consideration of the 50% default measurement uncertainty (MU) value. Deviation from this default value is possible in case there is an exceedance of the Acute Reference Dose (ARfD). However, the WI does not provide clear guidance as regards the use of the MU when no toxicological reference values are available, e.g. in cases of substances that are genotoxic carcinogens.

Member States shared their views on how they would proceed in such cases, but called for a harmonised approach through an update of the relevant WI's in the near future. A Member State recalled that the RASFF Standard Operating Procedure (SOP) was the result of a discussion in which Member States had to compromise for the purpose of consensus, it is therefore appropriate to be re-discussed.

The Commission announced that further discussion will take place in Q1 2022 in a dedicated meeting and invited Member States to provide comments and submit cases/issues that would contribute towards this meeting by 22 December 2021.

Section B Draft(s) presented for an opinion

The Commission informed the Member States that its intention was to finalise the technical discussion on points under section B of the agenda and that voting would take place by written procedure after the meeting. It asked the Member States to signal whether they had any objections as regards a vote by written procedure. None of the Member States had any objections.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… 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 acetic acid, azoxystrobin, benzovindiflupyr, cyantraniliprole, cyflufenamid, emamectin, flutolanil, lime sulphur, maltodextrin and proquinazid in or on certain products (Art. 10). (SANTE/11280/2021)

The Commission provided clarifications on revision 1 of the draft Regulation. This version contains last drafting clarifications that were suggested by the other Commission services concerned. In addition, the substance *Gliocladium catenulatum* strain J1446 was deleted from the draft Regulation as it was noticed that this substance was already addressed by a previous Regulation, and that its name was modified due to changes in the taxonomic rules into *Clonostachys rosea* strain J1446. The EU Pesticides Database was also updated as to make clear that the substance now called *Clonostachys rosea* strain J1446 was previously called *Gliocladium catenulatum* strain J1446, and to associate the two residue definitions to the active substance.

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:

- benzovindiflupyr on 'herbs and edible flowers', spring onions/green onions, Welsh onions and leeks;
- cyantraniliprole for table olives and olives for oil production;
- cyflufenamid for blackberries and raspberries (red and yellow);
- emamectin for apricots, cherries (sweet), 'spinaches and similar leaves' and 'herbal infusions from leaves and herbs';
- proquinazid for blueberries and cranberries.

The following MRL applications had been submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 in support of import tolerances:

- azoxystrobin used in Brazil on mangoes and in Colombia on oil palm fruits;
- flutolanil used in the United States on peanuts/ groundnuts.

The draft Regulation also proposes retaining permanently the active substances acetic acid, lime sulphur, and maltodextrin in Annex IV to Regulation (EC) No 396/2005.

One Member State highlighted that currently no MRL is set for cyantraniliprole in other fruiting vegetables (0239000), and suggested setting this MRL at 0.01* mg/kg. As this is in line with Commission Working Document SANTE.E4.11485/2021 - Rev. 8, the Commission proposed implementing this value in the draft Regulation.

One Member State commented that the MRL for emamectin in herbal infusions from leaves and herbs recommended in the EFSA Reasoned Opinion was not correct, as it did not take into account the dehydration factor of 10 for this commodity. The draft Regulation was amended adding the correct value (i.e. 2 mg/kg), and EFSA agreed to publish a corrigendum for its opinion.

One Member State noted that EFSA indicated that a confirmation that the analytical method using LC-MS/MS is capable of detecting emamectin B1a in herbal infusions at the Limit of Quantification (LOQ) of 0.001 mg/kg would be desirable, and asked if this would qualify for a footnote requiring confirmatory data. EFSA replied that, while filling this minor gap may be desirable, no footnote would be needed as methods are existing for other matrices.

One Member State raised attention on issues it experienced deriving from the inclusion of *Clonostachys rosea* strain J1446 in Annex IV to Regulation (EC) No 396/2005, as data gaps still exist for this substance and authorised uses are limited, making it difficult for Member States to authorise plant protection products containing this substance. The Commission will take up this issue internally.

Austria submitted a declaration for the Summary report relating to points B.01 and B.02 which is presented below after Point B.02.

Outcome of the vote by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for flutianil in or on certain products (Art. 10). (SANTE/11282/2021)

The Commission provided clarifications on revision 1 of the draft Regulation, which contains last drafting clarifications that were suggested by other Commission services concerned.

The Commission outlined the draft Regulation and its contents. An MRL application in support of import tolerances for flutianil uses on apples, cherries (sweet), strawberries, cucumbers, and courgettes in the United States had been submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005. EFSA had confirmed that the proposed MRLs are fully supported by data and safe for consumers.

Outcome of the vote by written procedure: Favourable opinion.

Austria submitted the following written declaration in relation to points B.01 and B.02:

"Please note the following advice from Austria: As Ministry of Health, we strive to keep consumer exposure to pesticide residues as low as possible, also in view of the wide variety of plant protection products used. As there is as yet no suitable cumulative risk assessment method to evaluate acute and chronic exposure to multiple substances for setting MRLs, we are very concerned to minimize exposure to pesticide residues in food. Therefore, in principle, we would like to express our concern about the increase of the MRLs."

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb, and silthiofam following the evaluation of Article 12 confirmatory data. (SANTE/12078/2020)

The Commission informed that it had re-launched the consultation procedure of the other Commission services concerned (after availability of the new EFSA statement on confirmatory data), following which the draft Regulation will be submitted for consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO).

The Commission provided an overview of the comments received and presented in the draft Regulation SANTE/12078/2020 in its revision 5. For fluroxypyr, reference to EFSA's Reasoned Opinion on the modification of MRLs for thyme[6] was added in recital 6, thus modifying its wording to reflect the value presented in the Annex.

A Member State further noted that for garlics, shallots, leeks, cereals, herbal infusions from flowers and sugar canes the recital reflects the EFSA Reasoned Opinion for lowering MRLs to the Limit of Quantification (LOQ) in the absence of confirmatory data, while the Annex actually maintains the existing values. The Commission referred to the table mentioned under Agenda item A.01.02. of the meeting of this Committee of 28-29 September 2020. Based on document SANCO/11019/2011 rev. 5 of 23 March 2017 risk managers had considered that the data gap for analytical methods had been addressed, while EFSA's views included in its more recently published Reasoned Opinion on the evaluation of confirmatory data[7] point to the opposite conclusion.

Member States were invited to submit their comments by 10 December 2021.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fluoride, oxyfluorfen, pyroxsulam, quinmerac and sulfuryl fluoride in or on certain products. (SANTE/2021/10218)

The Commission informed that it had launched the consultation of the other Commission services, after which the draft Regulation will be submitted for consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO).

Regarding quinmerac, the Commission proposed to follow the EFSA recommendations and maintain the levels for beet roots and sugar beet roots at the specific Limit of Quantification (LOQ) of_0,15*mg/kg as this is based on 8 trials on sugar beets with residues lower than 0.15 mg/kg. The Commission also informed on the notification from the applicant about the commercial availability of the analytical standards for the quinmerac metabolite BH 518-4. Footnote (A) was therefore deleted from the draft Regulation.

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[6] EFSA, "Reasoned Opinion on the modification of maximum residue levels for fluroxypyr in chives, celery leaves, parsley, thyme and basil and edible flowers", EFSA Journal 2020; 18(10):6273

[7] EFSA, "Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for fluroxypyr", EFSA Journal 2019;17(9):5816

For sulfuryl fluoride and fluoride ion the Commission thanked EFSA for its revision of the footnotes to cover all the data gaps reported in the EFSA Reasoned Opinion[8]. One Member State requested to set the MRLs for 'Rose hips', 'Elderberries', 'Basil and 'edible flowers' (in particular peppermint) at the current level of 2 mg/kg and not at 5 mg/kg as requested by the trade association Tea and herbal Infusions Europe (THIE). The Commission agreed that in order to introduce higher MRLs a new application should be submitted in accordance with Article 6 of Regulation (EC) No 396/2005.

One Member State requested to set 0.05* mg/kg as LOQ for cocoa beans, instead of the proposed MRL 0.03 mg/kg for sulfuryl fluoride. (Post meeting Note: The Commission evaluated this request after the meeting and will propose to maintain the MRL at 0.03 mg/kg as this is based on field trial data as was proposed in the EFSA Reasoned Opinion. From the analytical point of view the EU RLs confirmed its achievability).

Member States were invited to submit their comments by 10 December 2021.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for methoxyfenozide, propoxur, spinosad and thiram in or on certain products. (SANTE/10552/2021)

The Commission informed that it had launched the consultation of the other Commission services concerned, after which the draft Regulation will be submitted for consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO).

Regarding propoxur, in response to comments of some Member States that the default MRL value of 0.01 mg/kg might not be sufficiently protective for consumers given the low toxicological reference values established by Health Canada (and used by EFSA in their assessment), and following input from the EURL Single Residue Methods on the lowest achievable Limits of Quantification (LOQ), this revision proposes a MRL of 0.005 mg/kg for high water, acidic and dry commodities and 0.01 mg/kg for high oil matrices. For more complex matrices, such as coffee, teas, hops and spices, the level of 0.01 mg/kg is proposed. A Member State commented that levels should not be lower than 0.01 mg/kg if it is not really necessary, since certain laboratories might not be able to achieve them. Another Member State commented that in the past five years only two results were quantified between 0.05 mg/kg and the actual MRL and that lower MRLs would not necessarily provide more findings. Another Member State suggested that for laboratories in their country a LOQ of 0.001 mg/kg would be feasible.

For spinosad, some Member States indicated their concerns on the lowering of MRLs for sweet peppers/bell peppers, lettuces, escaroles/broad-leaved endives, spinaches, chards/beet leaves and witloofs/Belgian endives based on the new Acute Reference Dose (ARfD) of 0.1 mg/kg body weight (bw) established during the peer review of the substance, but which has not been formally endorsed by risk managers.

The Commission explained that the renewal process for the substance is currently under clock-stop for further data generation regarding its endocrine disrupting properties, but given the acute health risk identified from its MRLs on certain crops, swift action had to be taken, until its review of endocrine disrupting properties is completed.

[8] EFSA "Review of the existing maximum residue levels for sulfuryl fluoride according to Article 12 of Regulation (EC) No 396/2005" EFSA Journal 2021;19(1):6390

At the meeting of the Standing Committee for Plants, Animals, Food and Feed – Section Phytopharmaceuticals, Legislation of 18-19 May 2020[9], the Commission had presented a draft mandate to EFSA for an updated exposure assessment for spinosad considering the ARfD of 0.1 mg/kg bw, which had been proposed by EFSA in the peer review in the framework of the renewal of the active substance. At that meeting, the Commission clarified that the new endpoints had not yet been endorsed by risk managers, but also asked Member States to raise any concerns they may have within a specific deadline (5 June 2020) indicating that otherwise a tacit agreement would apply. No comment had been received by the deadline, therefore the tacit agreement applied for the mandate, which considered the ARfD of 0.1 mg/kg bw for spinosad.

Additionally, at its meeting of 15-16 June 2020, the Standing Committee for Plants, Animals, Food and Feed – Section Phytopharmaceuticals, Pesticide Residues[10] agreed on the submission by the Commission of a mandate to EFSA to carry out an exposure assessment of the existing MRLs by considering the changed ARfD established in the framework of the renewal of the active substance (i.e. 0.1mg/kg bw).

Therefore, the Commission confirmed that the new ARfD of 0.1 mg/kg bw is considered to have been endorsed by risk managers previously and that the EU MRL database will be updated once the renewal procedure of the active substance is finalised.

For thiram, the Commission referred to the comments received by the applicant requesting to allow a transitional period of 6 months for the implementation of the lowered import tolerances on avocados and bananas. According to the applicant, EFSA did not identify a consumer risk for avocado and banana, despite the existing data gaps, and the transitional period would allow non-European producers to prepare for this change.

The Commission reiterated that according to EFSA, for metabolite M1 in the absence of toxicological reference values, a consumer exposure could not be performed and that, for thiram, the overall risk assessment is indicative and should be considered on a tentative basis. Therefore, while the deferred application date of 6 months is provided, given the identified health risk, transitional measures for products lawfully placed on the market before the application date cannot be granted in order to ensure a high level of consumer protection according to Article 49(2) of Regulation (EC) No 396/2005. A Member State commented that the endocrine disrupting properties of the substance are of additional concern.

Member States were invited to submit their comments by 10 December 2021.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenthrin, bromopropylate, chloridazone, imazaquin, fenpropimorph and tralkoxydim in or on certain products. (SANTE/2021/10644)

The Commission informed that it had launched the consultation of the other Commission services concerned, after which the draft Regulation will be submitted for consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO).

[9] https://ec.europa.eu/food/system/files/2020-07/sc_phyto_20200518_ppl_sum.pdf
[10] https://ec.europa.eu/food/system/files/2020-07/sc_phyto_20200615_ppr_sum.pdf

For bifenthrin, the Commission proposed to maintain the MRL for herbal infusions at 0.1 mg/kg based on the analysis of the monitoring data extracted by EFSA and to delete the existing footnote. The Commission asked the Member States to comment on whether transitional measures would be appropriate for bifenthrin, except for strawberries. For strawberries the existing level is based on a Codex maximum residue limit (CXL) that is not supported by a good agricultural practice and therefore health concerns cannot be excluded.

A Member State requested to maintain the existing MRL for maize at 0.05 mg/kg as EFSA indicated that the available data were sufficient and there was no concern for consumers.

Another Member State requested to set the LOQ for fruit spices at 0.05* mg/kg instead of the proposed level of 0.03* mg/kg. (**Post meeting Note:** The Commission evaluated this request after the meeting and will propose to maintain the proposed MRL at 0.03 mg/kg as this level is based on a Codex MRL and was agreed in the context of the discussions in CCPR. From the analytical point of view the EURLs confirmed its achievability.)

Member States were invited to submit their comments by 10 December 2021.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate in or on certain products (Art. 12). (SANTE/10776/2021)

The Commission presented the latest revision of the draft Regulation highlighting the modifications in the text, and made reference to the accompanying Explanatory Note.

For 1,4-dimethylnaphthalene, the footnote for potatoes was amended to clarify that data gaps are related to the residue trials and the nature of the residues in processed commodities. As there is evidence that 1,4-dimethylnaphthalene could naturally occur in some plant compounds, and taking into account available monitoring data and the comments received by Member States, the Commission proposed setting a temporary MRL of 0.05 mg/kg for all plant commodities (except potatoes), pending the submission of further monitoring data to confirm this.

For 8-hydroxyquinoline, taking into account comments from Member States, the Commission proposed not to modify the residue definition for plant commodities following the EURLs suggestion, as adding chelates would complicate the residue definition without adding much value. The proposal to add oxine copper was also discarded as this may be misleading, given that oxine copper is not an approved active substance itself. As the Limit of Quantification (LOQ) for dry commodities is 0.02 mg/kg, the MRLs proposed for cereals and pulses were raised to 0.02 mg/kg, as recommended by Member States.

For pinoxaden, after consultation with Member States, the Commission proposed adopting the residue definition presented as Option 1 in the EFSA Reasoned Opinion, as omitting the conjugates would imply having a less robust residue definition. Moreover, this would better align the definition with the one used by Codex Alimentarius, as Codex maximum residue limits (CXLs) are also based on a residue definition including conjugates (though only for M4 and not M6). For the residue definition for commodities of animal origin, the Commission proposed adopting the one proposed by EFSA. The EURLs were consulted to update information about

availability of a commercial standard for M5, and Member States were consulted on the need to add a footnote, in case of a negative answer from the EURLs. In accordance with comments received from a Member State and the EURLs, the Commission decided to set the LOQ for animal tissues and bird eggs at 0.02* mg/kg to avoid validation of M4 at levels ≤ 0.0083 mg/kg. This proposal will also align MRLs for some commodities (poultry muscle poultry fat, poultry liver and birds eggs) with the CXLs.

For valifenalate, it was decided to keep the default LOQ of 0.05* mg/kg for honey, even if a lower LOQ can be achieved, as no consumer risk was identified for this value and this would allow applying a more harmonised approach. The previously proposed LOQ of 0.03 mg/kg was maintained for all other commodities of animal origin. The Commission recalled that, during the meeting of this Committee in September 2021, EFSA had noted that CXLs for grapes, onions, shallots, aubergines/eggplants and tomatoes were proposed during the last meeting of the Codex Committee on Pesticide Residues (CCPR52), and that the EU raised no objections to them. The Commission informed Member States that these will not be addressed in the current draft Regulation but in a following one dedicated to implementing CXLs.

Member States were invited to provide comments by 30 November 2021 prior to the launch of the consultation of the other Commission services concerned, followed by submission of the draft Regulation for consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO).

Post-meeting Note: The EURLs informed the Commission that the M5-metabolite has been synthesised, but it is has not yet completely passed good laboratory practices controls for certification. Thus, the Commission proposes adding a footnote about the lack of the analytical standard for pinoxaden.

Member States were invited to submit their comments by 30 November 2021.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, isopyrazam, metobromuron and penthiopyrad in or on certain products (Art. 12). (SANTE/11128/2021)

The Commission introduced the substances that will be covered by the draft Regulation which is still in an early stage of preparation. As the Commission was waiting for the feedback on the Limits of Quantification (LOQs) from the EURLs, the draft Regulation with Annex could not yet be presented.

For isopyrazam the Commission informed that after a review under Article 21 of Regulation (EC) No 1107/2009 a decision withdrawing the approval might be taken in a forthcoming meeting of the Section Legislation of the Committee. After expiry of grace periods a further MRL review may then become necessary.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation as regards a coordinated multiannual control programme of the Union for 2023, 2024 and 2025 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. (SANTE/11190/2021)

The Commission referred to the meeting of experts on the monitoring of pesticide residues held on 15 October 2021 and provided an overview of the updated EU multi-annual control programme (EU MACP).

While including courgettes/zucchinis as proposed by EFSA and to maintain the same number of commodities in the programme, following the discussion and comments of the experts meeting, the Commission proposed to maintain both cauliflowers and broccolis in the EU MACP as Flowering Brassicas at a 50:50 sampling proportion indicated in footnote 3 of the Annex of document SANTE/11190/2021. A Member State suggested that 'courgettes/zucchinis' should be included as 'courgettes' and that among cauliflowers and broccoli the latter should be maintained as occurrences are more frequent. EFSA commented that the inclusion of both broccolis and cauliflowers could have an impact on the margin of error of 0.0075 with which the EU MACP assesses MRL exceedances[11].

The substances to be monitored were updated to include maleic hydrazide for onions and potatoes in 2023 and ethylene oxide for beans (dried), rye and rice in 2023, for wheat in 2024 and for barley and oats in 2025.

Member States were invited to submit their comments by 31 December 2021.

C.08 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for acetamiprid in or on certain products (Art. 10). (SANTE/11278/2021)

As the consultation of the other Commission services concerned was not yet completed at the time of the meeting, no draft Regulation was distributed under this agenda item. Discussion and possible vote will be deferred to a forthcoming meeting of this Committee. The Commission announced it would distribute the draft Regulation to Member States for commenting as soon as possible and set a commenting deadline only then.

[11] EFSA, "Scientific Report on the Pesticide Monitoring Programme: Design Assessment", EFSA Journal 2015; 13(2):4005