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

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table. The Article 12 maximum residue level (MRL) review for difenoconazole was launched in September 2021 and the one for phosmet is scheduled to be launched in January 2021 as agreed with the Evaluating Member State (EMS) (see point A.04.02).

2. Confirmatory data Art. 12 follow-up

The Commission referred to the decisions taken at the last meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Pesticides Residues on 14/15 June 2021 and recalled the decisions taken for flutriafol and bifenthrin (see point C.04.00).

3. Residue definition for risk assessment (RD for RA)

The Commission provided an overview of the key changes made to the paper following the comments received after the last meeting of SCoPAFF, Section Phytopharmaceuticals–Legislation on 5/6 July 2021 and explained that some late comments submitted by EFSA were still to be considered.

The Commission recalled that the paper/document:

- sets out a common understanding of how residue definitions for risk assessment (RD-RA) will be agreed and reported and how changes can impact application processes;
- does not constitute a formal guidance or other binding set of rules (but noted that in the future changes could be made to relevant guidance documents, if necessary);
- clarifies some questions raised by Member States, allowing for smoother downstream processes following setting of RD-RAs, and about how provisional definitions are agreed and to be used;
- can be updated based on experience gained.

The Commission explained that it considered the document was ready to be finalised pending a consideration of the late comments from EFSA.

Member States were invited to consider the updated version and make any final remarks or comments by 1 October 2021.

The Commission explained that it intends to ask Member States to agree on the document at the next meeting of SCoPAFF, Section Phytopharmaceuticals – Legislation on 21/22 October 2021.

4. List of non-approved substances for follow up

The Commission thanked two Members States for their thorough analysis of the list of non-approved substances as extracted from the EU pesticides database, which allowed identifying potential issues with existing MRLs. Substances that were not approved before 2008, and therefore do not fall within the scope of the review under Article 12 of Regulation (EC) No 396/2005, were also considered. Based on these analyses, the Commission conducted a prioritisation exercise to identify substances for which existing MRLs would need to be reviewed with priority. The Commission proposed substances for which a potential risk for consumers was identified to be addressed first, and noted that this could be done with current resources. Addressing the other issues identified will require additional resources, or de-prioritising some of the activities that are currently ongoing. Member States were invited to comment on the proposed prioritisation.

One Member State agreed on the proposed prioritisation, and concurred that the review of existing Limits of Quantification (LOQ) to adapt them to technical progress should be given a low priority. One of the Member States had carried out a screening for possible acute risks with PRIMo and noted that it had used the MRL as input value and not the highest residue as required by the current International Estimate of Short-Term Intake (IESTI) methodology. The other Member State having initiated the analysis expressed support to the Commission's further work and underlined that for substances not approved in the EU MRLs should be set at the LOQ, to ensure a level playing field between producers in third countries and EU farmers. It announced further written comments and suggested not to focus on the risk from PRIMo only, but also on the decision taken at the Codex Committee for Pesticides Residues (CCPR) on MRLs that were set a long time ago (e.g. methoprene and dicloran).

The Commission confirmed that any future more detailed prioritisation would need to take into account the situation at CCPR (including unsupported compounds and CXLs withdrawn by the Joint WHO/FAO meeting on Pesticides Residues (JMPR)), but re-iterated that current resources did not allow to do this in the near future. Lowering all MRLs of non-approved substances to the LOQ without checking for existing safe import toleances and CXLs would be against the principles of Regulation (EC) No 396/2005 and not in compliance with the EU's obligations under the WTO/SPS agreement. The Commission thanked Member States for their input, and proposed to further discuss this issue at a forthcoming meeting.

Member States were invited to submit comments by 15 October 2021.

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

The Commission summarised the Regulations voted by written procedure after the last meeting of SCoPAFF, Section Phytopharmaceuticals – Legislation held on 5/6 July 2021.

A Member States asked the Commission to communicate upcoming changes with potential relevance for MRL setting earlier than at or after the decision-making stage (e.g. on expected changes of toxicological reference values (TRVs)).

The Commission agreed to consider this request, but invited the Member States to also regularly liaise with their counterparts attending the Section Phytopharmaceuticals - Legislation of the Committee to receive timely and updated information.

A.03 Specific substances:

1. Glufosinate ammonium

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

2. Glyphosate

EFSA provided an updated on the status of the import tolerance application for glyphosate on genetically modified soybeans from the United States. In its Reasoned Opinion (RO), which will be published in October 2021, EFSA will propose maintaining the existing level of 20 mg/kg considering the current residue definition.

3. Ethylene oxide – update on the state of play

The Commission reminded Member States of a joint meeting of experts on pesticide residues and additives that will take place on 4 October 2021 to provide clarifications and assist Member States with the application of the conclusions that the Crisis Coordinators reached during their meeting on 13 July 2021[1]. It was clarified that the purpose of the meeting was not to re-open the debate on the risk management conclusion reached, but to clarify and provide answers to technical and legal questions received following the Crisis Coordinators meeting.

4. Bacillus thuringiensis

The Commission informed the Committee that at the meeting of SCoPAFF, Section Phytopharmaceuticals – Legislation held on 5/6 July 2021, a discussion took place, in which the Commission summarised the comments received from Member States, applicants, and other stakeholders, on horizontal issues concerning dietary exposure for consumers. The Commission highlighted that internal reflections are on-going on how to increase clarity on a possible link between Bacillus thuringiensis strains and food intoxication outbreaks.

Further discussion on the next steps will take place in the next meeting of the Section Phytopharmaceuticals - Legislation of the Committee on 21/22 October 2021.

5. Cyantraniliprole

The Commission informed that MRLs for cyantranilipole on olives and berries would be included in forthcoming draft Regulations, since concerns on genotoxicity with two metabolites had been recently ruled out by EFSA. The MRL for berries had dropped to the Limit of Quantification (LOQ) in June 2021. The Commission informed that a fast-track procedure could possibly be used for berries as described in the MRL Technical Guidelines (on MRL setting (SANTE/2015/10595). A Member States asked whether the same procedure could also be applied for the temporary MRL for leeks. In reply to

[1] https://ec.europa.eu/food/system/files/2021-07/rasff_ethylene-oxide-incident_e410_crisis-coord_sum.pdf

that another Member State informed that this was not possible as the application on leeks was currently under clock-stop by EFSA due to a lack of data on rotational crops.

6. Clethodim

The Commission informed the Committee that the adoption procedure for the draft Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 as regards maximum residue levels for clethodim, dazomet, hexythiazox, metam and sethoxydim in or on certain products (SANTE/11220/2019), which had been voted in this Committee in February 2021, could not go ahead as planned due to administrative reasons.

In view of new studies that had become available in the meantime, the Commission had decided to delete the substance clethodim from the draft Regulation. Instead, an evaluation under Article 21 of Regulation (EC) No 1107/2009 is planned, in order to enable EFSA to evaluate the new studies with a view to elucidating the concerns identified in the EFSA Reasoned Opinion on clethodim[2]. An MRL review might become necessary thereafter. The Commission indicated that further details would be given in the next meeting of the Section Phytopharmaceuticals – Legislation of the Committee on 21/22 October 2021. One Member State regretted the delay in the proposed lowering of MRLs.

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 12 processes[3] had been adopted since the previous meeting of this Committee in June 2021. Of these, 3 relate to import tolerance applications and 9 to uses in the EU.

Currently, outputs addressing 59 such processes are at different steps of the procedure. Out of these, 16 are under scientific assessment and 42 are currently under clock-stop (29 under Regulation (EC) No 396/2005 and 13 under Regulation (EC) No 1107/2009), and one additional mandate had just been received by EFSA. 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

Dithiocarbamates

EFSA reported about the ongoing work on dithiocarbamates. The different substances are at different stages of the process. As for some commodities data is insufficient, EFSA presented the different steps of its stepwise approach to complete the datasets. It will also launch an additional call for data to all Member States. As a fall back option, in case sufficient data are not made available, EFSA will calculate MRL proposals with alternative methodology requiring less data.

Complexity evaluation of forthcoming Article 12 evaluations

EFSA informed that it intends to evaluate the complexity of forthcoming Article 12 assessments to allow better predictability of time and resource needs. This will be done via a checklist which will be shared with the Evaluating Member States for commenting within one week. The outcome will then be used in discussions with the Commission

[2] EFSA Journal 2019;17(5):5706)
[3] Each process receives a so called "EFSA question number".

on the timelines. A Member State commented that the deadline of one week might not be long enough. EFSA clarified that this step will be before the launch of the Article 12 review and would not diminish the agreed timelines for the other steps.

Two Member States opposed EFSA's proposal. They noted that the proposed one week deadline would be too short as different bodies would need to be involved within the Member States and that the assessment would be complex. EFSA stated that the checklist is very basic, but robust and proposed to share the checklist with Member States to allow them to familiarise themselves with it and evaluate it, noting that a strict deadline would not be needed for the first assessment.

Article 12 Work programme 2021/2022

The Commission presented an updated work programme for 2021. The launch of the MRL review for difenoconazole was confirmed for September 2021. The MRL review for phosmet will start in January 2022. The Committee agreed with the revision as presented.

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

EFSA reported about the state of play of recent mandates under Article 43 of Regulation (EC) No 396/2005.

All Art. 43 mandates were finalised and the relative Reasoned Opinions (ROs) adopted. The RO for the joint Article 43 review of fosetyl, disodium phosphonates and potassium phosphonates and the RO on the review of the toxicological properties and MRLs for thiophanate-methyl and carbendazim were adopted in July. The focussed assessment on certain MRLs of concern for abamectin was adopted in September 2021. A new output (statement on the lack of confirmatory data following Article 12) was agreed with EFSA and is currently under finalisation following a Member States consultation. This will allow to proceed in future with the follow up on Article 12 confirmatory data.

4. Other issues

Pesticides Annual Monitoring Report

EFSA presented an update on other ongoing mandates and activities. With regard to the Pesticide Residue Annual Report (ARPR) 2020, EFSA reminded Member States to formally accept their data sent to the Scientific Data Warehouse using the new format by 30 September 2021. Member States consultations on the ARPR 2020 will take place in the last two weeks of January 2022.

International

The Joint FAO/WHO Meeting on Pesticides Residues (JMPR) summary report for their extraordinary meeting in May 2021 was published and EFSA has started working on their scientific report. As for four of the substances assessed by JMPR (i.e. ethion, ethiprole, isoprothiolane and methoprene) there is no Rapporteur Member State (RMS) assigned under Regulation (EC) No 1107/2009, EFSA asked for volunteers. A Member State volunteered to take ethiprole and isoprothiolane, another one signalled it would reflect on the two other substances and confirm its decision after the meeting[4].

[4] Post-meeting Note: the Member State informed after the meeting not to be able to deal with the substances ethion and methoprene.

Pesticides Steering Network/Transparency/IUCLID

EFSA provided an update on MRL applications in IUCLID and informed about a meeting of the IUCLID sub-group of the Pesticides Steering Network (PSN) that will take place on 1 October 2021, while the PSN main meeting will take place on 13 October 2021. The last session of the Hypercare Programme, which was established to support applicants and Member States in their submission of dossiers under IUCLID, will be held in November 2021. Then the PSN IUCLID subgroup will take over this support function. A training for Rapporteur Member States dealing with admissibility checks under IUCLID is planned for 19 October 2021. In addition, a range of supporting materials is available on the EFSA website. Lastly, EFSA informed the Committee that, in order to comply with the new transparency provisions, the minutes of the PSN will in future be published within 15 days from the end of the meeting.

Extraction efficiency guidelines

EFSA referred to the discussion in the previous meeting of this Committee on the question whether the lack of data on extraction efficiency is sufficient to invalidate residue trials or not. The issue was further discussed under point A.14.00 of this meeting.

Good Agricultural Practice(GAP) overview file

EFSA announced that a revised GAP overview file, including new features, is available. A dedicated tutorial will also be distributed. A pilot phase will be launched.

A Member State informed EFSA that it has regular IT problems with features included in the GAP overview file (i.e. EXCEL macros are blocked as they are recognised as malicious by their national systems), and invited EFSA to consider this type of issues when developing systems to be used by the Member States.

EFSA draft Technical Report on Rotational Crops

EFSA presented the ongoing work on the development of a Technical Report for rotational crops to support the harmonised interpretation of the relevant OECD Guidance Documents and Test Guidelines. During the summer, EFSA had consulted Member States on seven questions on the proposed tiered approach to enable EFSA to propose further refinements. EFSA had received replies from 13 Member States and presented an overview. EFSA will prepare a revision of the Technical Report to consider the comments from the Member States.

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, based on the input received from Member States. One Member State commented that, when MRLs are lower in Regulation (EC) No 396/2005 than those set in Commission Regulation (EU) No 37/2010 on residues for veterinary medicinal products, MRLs are not enforceable, and asked that this issue should be addressed. The Commission considered that, if the higher levels set by one of the two Regulations were confirmed by EFSA in a Reasoned Opinion to be safe for consumers, they could in principle be taken over in the other Regulation. However, in any such cases, a Reasoned Opinion from EFSA would be necessary. The Commission recalled one earlier case (oxytetracycline) where EFSA had concluded that the alignment with the higher levels set in Commission Regulation

(EU) No 37/2010 was not safe. Thus, the responsible service in the Commission dealing with veterinary medicines was contacted to discuss potential solutions.

Member States were invited to submit comments by 15 October 2021.

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

The Commission recalled that it had asked EFSA to provide further statistics on the monitoring data for bromide ion. The Commission had extracted those commodities with less than 59 samples and invited Member States to focus on those when drafting their national monitoring programmes. More data is needed in order to set MRLs at a realistic level for bromide ion.

A.07 Next steps for cumulative risk assessment.

The Commission reminded of the "Proposed prospective scenarios for cumulative risk assessment of pesticide residues" published by EFSA and the Dutch Institute for Public Health and the Environment (RIVM), which followed the discussion held during the Working Group meetings of Experts earlier this year. This scientific report provides a good basis for further reflections towards agreement of the methodological approach to be used for the MRL setting scenario, but also gives incentives for further thoughts on the risk management options that would follow.

A.08 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 on the remaining substances listed in the overview table. The Commission had asked EFSA to extract monitoring data for chlormequat, mepiquat, nicotine and profenofos on those products for which temporary MRLs had been set in the past. These data, together with additional data and/or studies submitted by Member States and trade associations, were analysed and presented to the Member States.

2. Data analyses for decisions on temporary MRLs (t-MRLs) for chlormequat, mepiquat, profenophos and nicotine

The Commission presented its proposals as to whether the existing temporary MRLs (t-MRLs) should be maintained or lowered based on data extracted by EFSA from the monitoring database for the years 2018-2019 and the calculations of the highest reliable percentiles. Due to the different numbers of samples for the different commodities these highest reliable percentiles can be different for each commodity.

Several Member States supported the proposal to reassess t-MRLs for chlormequat and mepiquat on oyster mushrooms only in 2022, and one Member State proposed to keep the existing t-MRL for chlormequat in cultivated fungi, too, and to reassess it in 2022.

One Member State disagreed with the proposal of lowering t-MRLs for chlormequat in pears, and presented data from residue trials performed on orchards that were legally treated with this substance before 2000. These studies show that residues are still found, and that MRL levels are very unpredictable across the years. The Member State highlighted that EFSA monitoring data are based also on data from trees that were never treated, and noted that, according to SANTE/2015/10595 Technical Guidance Rev. 6, "where both field trials and monitoring data are available, the data from field trials

should prevail". Another Member Sate supported this position, and provided field data to support maintaining the existing t-MRLs.

EFSA asked for clarifications concerning the data analysis at the basis of the Commission's proposals, noting that in the past the 95th percentile was used for this purpose, and expressed its availability to discuss further with the Commission to harmonise the approach. The Commission noted that a case by case approach was used in the past for setting t-MRLs, with different percentiles being used in different situations, and agreed to discuss further with EFSA for ensuring consistency of the work done.

Member States were invited to submit comments by 15 October 2021.

A.09 International Matters:

1. OECD Guidance document on the residue definition for risk assessment

The Commission informed about the progress made in the OECD expert group. The aim is to finalise the technical work on the draft guidance document by the end of this year and to aim at adoption by OECD in early 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. The work is still done in several subgroups.

As a result of the call for data early in the year, the OECD working group on honey received data on more than 300 trials which were analysed in the summer.

The Member State recalled that at the last meeting of this Committee, Member States were invited to send comments on the implementation of the "EU Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey" (SANTE/11956/2016) which was used as a starting point for the discussions in the OECD.

The Member State summarised the comments received from three Member States and presented these at the last meeting of the OECD expert group which took place on 22 September 2021. The Member State asked whether the comments could be distributed to the OECD expert group with the names of the countries. The Member States who had sent comments agreed to that. The work in OECD is delayed compared to the initial timelines (finalisation was planned for early 2022). The first draft of the guidelines is currently expected to be ready by mid of 2022, finalisation by end of 2022.

3. Codex Alimentarius/JMPR issues

The Commission provided a brief summary of the main points discussed during the 52nd Session of the Codex Committee on Pesticides Residues (CCPR) held virtually from 26 -29 July and on 3 August. One Member State commented on the agenda point of "Unsupported Compounds" and proposed to consider the option of lowering the MRLs of those Codex MRLs (CXLs) which are no longer supported. The Commission indicated that this is considered in the context of the discussions on agenda item A.01.05. Another Member State requested information on the next steps on the "International Estimate of Short-Term intake (IESTI)" equation at EU level for which the Commission provided some clarifications on the state of play.

A.10 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 informed the Committee of the outcome of the stakeholder consultation that took place at the beginning of September 2021. In total, the Commission had received 26 replies from stakeholders, Member States and a third country. In the light of the comments received, the Commission will revise the document and will then consult the Member States with the aim of finalising the document in the meeting of this Committee scheduled for February 2022.

A.11 Note Taking of the revised Technical Guidelines for MRL setting as regards the clarification of "Exceptional circumstances" under Article 16 of Regulation (EC) No 396/2005 (SANTE/2015/10595 Rev. 6).

The Commission provided an overview of the main changes to the document and the comments received. It clarified that rev. 5.4 continues to apply for applications submitted before 27 March 2021.

The Committee took note of the Document in its revision 6.

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.

Greece as the previous Rapporteur Member State (RMS) for fenazaquin proposed to evaluate a new import tolerance application for fenazaquin on hops (expected to be received in September-October 2021) instead of the new RMS Germany. This was agreed by all Member States.

A.14 Questions related to the implementation of the Extraction Efficiency guidelines (SANTE/2017/10632 Rev. 3).

According to EFSA, the Technical Guidelines SANTE/2017/10632[5] on the Evaluation of Extraction Efficiency of Residue Analytical Methods is intended to provide guidance to applicants on how to perform new studies. They complete and further specify the provisions laid down in chapter 6.2 of the data requirements (Regulation (EU) No 283/2013). Therefore, EFSA suggested that the guidelines should be updated and their scope limited to new active substance approvals and renewals of approvals. They should not be used for MRL review processes such as those carried out under Article 12 or Article 43 of Regulation (EC) No 396/2005.

EFSA suggested the following procedure: in the case of assessments according to Article 10 of Regulation (EC) No 396/2005, the respective Evaluating Member State (EMS) should check with the applicant for availability of additional data. If data were available, they would be evaluated, if not, this would not lead to a stop-clock procedure, but would be highlighted in the EFSA Reasoned Opinion as lack of data on extraction efficiency for further consideration by risk managers. In the case of Article 12 reviews, the absence of such data would not lead to a data gap established by a footnote to a tentative MRL, unless the same data gap was previously already identified in the EFSA Conclusion on the peer review of that active substance during the renewal of approval procedure.

[5] https://ec.europa.eu/food/system/files/2017-11/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf

A Member State shared the views of EFSA regarding the proposed procedure and added that the Guidelines should serve in providing guidance on how to conduct studies and supported the review of Chapter 7, suggesting that it should apply for approvals, renewals and zonal approvals. Another Member State supported this view.

The Commission invited Member States to provide their comments by 15 October 2021.

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

The Commission acknowledged the comments received from Member States regarding the questions on Annex I of Regulation (EC) No 396/2005 discussed in the previous meeting of this Committee on 14/15 June 2021.

For the novel food *Synsepalum dulcificum* (miracle berry plant) the Commission clarified that in its view it falls under Code number 0820990 ('others' in the group of fruit spices) of Annex 1 to Regulation (EC) No 396/2005. On chia seeds, Member States supported maintaining its current classification, i.e. under the group of cereals (buckwheat/pseodocereals) consistent with the classification of Codex Alimentarius. Since the MRLs for copper are currently under evaluation by EFSA's Scientific Committee, the background levels on chia seeds could be addressed within this task. The Commission shared the letter from a stakeholder organisation requesting to review the classification of grape seeds. Member States supported maintaining the current classification as it is in line with the Codex Alimentarius classification. One Member State explained that this approach is the same than the one for many products in Annex I where different parts of the plant are consumed separately. The Commission requested the opinion of the Member Stated on the classification of the aquatic plants *Wolffia arrhiza* and *Wolffia globose* which are under evaluation as Novel Foods. The Commission indicated that the option of classifying both plants in the group 290000 (Algae and prokaryotes organisms) is currently considered.

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

The Commission shared information on the developments under the Farm to Fork strategy directly affecting pesticides no longer approved at EU level and the consideration of environmental issues when assessing import tolerances for such substances. The Commission clarified that the focus will be on those environmental issues that are matters of global concern and that cannot be addressed through action in the EU alone. Such environmental issues of global concern are for example the worldwide decline of pollinators or the contamination of the environment with bioaccumulative, toxic and persistent chemicals. The Commission provided some information on the outreach activities conducted to inform third countries and announced that it will now start preparing a draft Regulation lowering the existing MRLs for the neonicotinoid substances clothianidin and thiamethoxam to the LOQ. It is also intended that new import tolerances for those substances will not be granted. The Commission responded to questions from Member States about procedural and legal aspects.

A.17 Info on a Corrigendum to Commission Regulation (EU) 2021/1110 of 6 July 2021 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 ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products (SANTE/10946/2021).

The Commission informed the Committee of a mistake in Article 2 of Commission Regulation (EU) 2021/1110 with regard to the date of application which should be 27 January 2022 and not the date of entry into force (27 July 2021). This will be corrected by a corrigendum which will be published soon after this meeting of the Committee.

A.18 Info on a Draft Commission Delegated Regulation (EU) supplementing Regulation (EU) 2017/625 as regards additional requirements related to the use of relevant substances in food-producing animals and residues arising therefrom, for the entry into the Union of such animals, products of animal origin and composite products.

The Commission informed about the state of play of the above draft Regulation under discussion with Member States under the lead of the Commission service responsible for Food Processing Technologies and Novel Foods. Since reference is made to the EU monitoring programme on pesticides residues, Member States were invited to comment by 27 September 2021.

A Member State pointed to an inconsistency between a recital and the respective Article as regards the scope (national monitoring programmes versus the EU coordinated monitoring programme). The Commission thanked the Member State and announced it would follow up with the responsible Unit to clarify this.

A.19 Other Information points*:*

1) Update on PRAC measures/objections by the European Parliament (EP)

As a follow up to the objections of the European Parliament (EP) in April 2021 against two draft Regulations setting MRLs for flonicamid and lufenuron, respectively, the Commission updated the Committee on the state of play. An amended draft Regulation for flonicamid is on the agenda for this meeting under point B.02 for vote in written procedure after this meeting. In this draft Regulation some new information has been taken into account, confirming once again that all MRLs are safe and fully supported by data. Another draft Regulation containing the substances to which the EP had not objected is also re-submitted for vote under point B.03 of the agenda for this meeting. The substance lufenuron will be dealt with in the context of a forthcoming draft Regulation lowering MRLs after withdrawal of all authorisations following the expiry of the approval of the substance.

2) Brexit

No issues were raised under this agenda item.

3) Peeling factor/consumption of unpeeled food

With reference to agenda item A.16.4 of the agenda of the previous meeting of this Committee on 14/15 June, EFSA and the Commission both confirmed that no comments from Member States had been received. EFSA repeated its request to Member States to send information on commodities with new consumption trends (e.g.

on commodities which are now consumed with peel, while previously they were consumed without peel) and consumption data for such commodities by 15 October 2021.

Several Member States took the floor and asked question on how the current PRIMo rev. 3.1 addresses this. EFSA clarified that the tool by default calculates with the edible portion for commodities that are usually eaten peeled only (melons, bananas, citrus fruits). If in the edible portion the residues are lower compared to the whole product, the exposure calculation can be refined either be inserting the risk assessment values (HR/STMR) for the edible portion or by inserting the risk assessment values for the whole product but including a peeling factor. The commodities for which the refinement with a peeling factor is allowed had been discussed with Member States in the course of the PRIMo development. However, this refinement is not mandatory; calculations can be also performed based on consumption of the unpeeled commodity. If peel only is eaten, this would need to become a new commodity in PRIMo with associated consumption data to it. A Member State asked whether cooked peels would be included. EFSA replied that cooked (processed) peels should be covered by the consumption data on peel.

4) Matrine/Oxymatrine

The Commission recalled that during previous meetings of this Committee it had been concluded that the default level of 0.01mg/kg was the applicable MRL for matrine and oxymatrine.

However, the Chinese authorities had sent a letter concerning findings of matrine and oxymatrine in honey, claiming that these levels would lack a scientific basis and would be disruptive for trade. A relevant research report mentioned that both substances would naturally occur in plants of the Sophora species and would not be artificially added in the honey-making process. Those plants blossom at the same time as the flowers of the black locust (Robinia pseudoacacia, Fabaceae) and acacia (Acacia spp., Fabaceae), thus when producing honey, bees collecting nectar from the Sophora flowers, contaminate the robinia and the acacia honeys with those substances.

A Member State proposed that the Chinese Authorities can submit an important tolerance request in accordance with Article 6 of Regulation (EC) 396/2005 and if, following an assessment from EFSA the proposed MRLs are safe for consumers, a MRL higher than the default MRL could be established. EFSA suggested to also check the EU monitoring data on honey to see whether the substances would also be found in honey in the EU, which could be assumed in case of their natural occurrence. The Commission invited the Member States to provide analytical data for potential findings of matrine and oxymatrine in honeys by 15 October 2021.

5) Acceptance of UK Trials

The Commission shared some information exchange with the Post Approval Issue Working Group (PAI) of the Section Phytopharmaceuticals – Legislation of the Committee on the acceptance of residue trials performed in the UK. The Commission indicated that according to Regulation (EC) No 283/2013 the evaluation of intended uses within the EU should be based on residue trials mainly generated within the EU. The data requirements state that part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical good agricultural practices and that the production conditions (such as cultural practices, climatic conditions) are comparable. At least 50% of the trials must be generated in the EU.

More guidance on the application of this principle is given in the Technical Guidelines on Extrapolation (SANTE/2019/12752).

6) Fluopyram in soybeans and peanuts - request from a Member State

A Member State requested feedback from the other Member States on an MRL application related to the substance fluopyram. Since the consumer exposure with current MRLs is >100% of the Acceptable Daily Intake (ADI), 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. The Member State requested feedback on the rationale used by the applicant by 15 October 2021.

7) Definition of a "lot" in the context of import controls– request from a Member State

A Member State requested feedback from the other Member States on the definition of a "lot" (e.g. of tea), controlled at import into the EU with increased frequency and comprising different varieties, but accompanied by only one "Common Health Entry Document" (CHED). The Commission suggested that this type of question should be raised in the appropriate forum, i.e. the working group on import control in the context of Regulation (EU) No 2017/625 on Official Controls. A Member State gave an example of how it would deal with such a situation: if a consignment would consist of 4 lots per variety and of 2 different varieties, the Member State would consider this to be 8 different "lots".

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, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acrinathrin, fluvalinate, folpet, fosetyl, isofetamid, *'Pepino Mosaic Virus, EU strain, mild isolate Abp1', 'Pepino Mosaic Virus, CH2 strain, mild isolate Abp2',* spinetoram and spirotetramat in or on certain products (SANTE/10884/2021).

The Commission provided clarifications on revision 2 of the draft Regulation which contains some drafting modifications arising from the consultation of the Commission services concerned.

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:

- Acrinathrin for the use on peaches and sweet peppers/bell peppers;
- Fluvalinate for the use on tomatoes and watermelons;
- Folpet for the use on barley, oat and rye;
- Fosetyl for the use on lemons, limes, mandarins and herbal infusions from leaves and herbs, following the use of potassium phosphonates;
- Isofetamid for the use on cane fruits;
- Spinetoram for the use on purslanes;
- Spirotetramat for the use on leeks, spring onions/green onions and Welsh onions and honey and other apicultural products.

The draft Regulation also proposes the inclusion of the active substance *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2in Annex IV to Regulation (EC) No 396/2005.

On folpet, EFSA had sent a written comment noting that the EFSA Reasoned Opinion also covers wheat and contains information that would support the deletion of current footnotes for wheat and poultry. The Commission explained that this information was disregarded as all confirmatory data will be addressed in the future by another dedicated draft Regulation.

On spinetoram, EFSA noted that a fast-track procedure had been used to derive the MRL for purslanes based on residue trials performed on lettuces, even if the GAP used for these two commodities are not identical. The Commission highlighted that the use of the fast-track procedure had been discussed at the meeting of this Committee in June and agreed on by Member States. Moreover, it noted that the purpose of this procedure is to support plant protection for minor uses, as in this case, where investment on additional residue trials would be unlikely. The Member States confirmed their support to the use of the fast-track procedure for spinetoram in purslanes.

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 flonicamid in or on certain products (SANTE/10892/2021).

The Commission introduced the draft Regulation, which contains all MRLs from applications for flonicamid that had been included in previous draft Regulations to which the European Parliament had objected. In addition, this draft Regulation also contains confirmation of several existing MRLs, which had been set previously on a tentative basis due to some minor data gaps which had now been filled.

The Commission provided clarifications on revision 2 of the draft Regulation, which contained some drafting modifications arising from the consultation of the Commission services concerned.

One Member State commented that it is reviewing, as Rapporteur Member State, the effect of flonicamid on bees as part of the renewal assessment of this substance. Preliminary results from studies on pollen and nectar, performed in accordance with the EFSA 2013 Bee Guidance Document, seem to indicate that there is an acceptable risk for bees if flonicamid is applied in accordance with the authorised GAPs. Data are not yet publicly available, and the Renewal Assessment Report is expected by 2022.

Outcome of the vote by written procedure: Favourable opinion.

B.03 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 acequinocyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flutolanil and imazamox in or on certain products (SANTE/11822/2019).

Following the recent objection by the European Parliament against a draft Regulation setting MRLs for these substances and flonicamid, the Commission had prepared an amended draft Regulation by removing acibenzolar-S-methyl, fosetyl, oxathiapiprolin, and flonicamid. The first three substances had been included in a draft Regulation

(SANTE/10518/2021) that had already been submitted to a vote via written procedure after the meeting of this Committee in June. Flonicamid was included in a separate draft Regulation to be voted under Point B.02.00 in written procedure after this meeting.

EFSA had sent a written comment proposing to delete the current footnote for flutolanil in peppers highlighting missing residue trials. The Commission noted that one of the first risk management decisions taken in 2019 while discussing the earlier draft Regulation for the first time, was to keep this footnote, as the re-authorisation of EU uses will lead to the submission of the missing data.

One Member State commented that acequinocyl is fat soluble and proposed this to be noted in a footnote (F). The Commission replied that the substance is in Annex IIIA and the MRLs will be reviewed under the Article 12 review procedure. The EU Reference Laboratories will then be consulted and the information on the substance can be updated, if needed.

One Member State noted that, for acequinocyl, the footnote on horseradish should be deleted. The Commission informed Member States that appearance of the footnote is due to a problem in the database, and proposed to address this in the upcoming draft Regulation reviewing the MRLs for acequinocyl under Article 12 of Regulation (EC) No 396/2005.

The Commission explained that due to an administrative maximum delay between the consultation of the relevant Commission services and the adoption date by the Commission of a draft Regulation, adoption of this draft Regulation had to take place before 17/12/2021, otherwise a new consultation and vote would become necessary. Due to this urgency, the vote took place in the virtual meeting of this Committee on 24 September 2021.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dazomet, hexythiazox, metam and methylisothiocyanate in or on certain products (SANTE/10942/2021).

The Commission provided some clarifications on the draft Regulation that had been prepared to replace draft Regulation SANTE/11220/2019 (see point A.03.06 on clethodim) with minor changes besides the inclusion in the title of the metabolite methylisothiocyanate.

Outcome of the vote by written procedure: Favourable opinion.

Section C <u>Draft(s) presented for discussion</u>

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 there are no changes in the current draft Regulation compared to the earlier version, as for those substances for which no confirmatory data had been submitted by the applicant, the Commission is expecting an output from EFSA

(e.g. a statement) to make this more transparent and will resume work on this draft Regulation after adoption of the statement.

Member States were invited to provide comments by 15 October 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/10218/2021**).**

The Commission informed the Committee on the developments on this draft Regulation and the related information received. The footnotes for sulfuryl fluoride and fluoride ion were reviewed to include the data gaps identified in the EFSA Reasoned Opinion. THIE, the European trade association for tea and herbal infusions, had provided additional information on the background levels of fluoride ion in herbal infusions and requested to set an MRL of 10 mg/kg in herbal infusions and of 5 mg/kg in rosehips, elderberries, basil and edible flowers to cover natural occurring levels of fluoride ion. As EFSA had indicated that the proposed values will not change the general conclusion of the risk assessment, the Commission proposed to set those values as tentative MRLs with a footnote requiring further monitoring data.

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)**.**

According to a Member State, MRLs for propoxur should be set at levels lower than the LOQ of 0.01*mg/kg currently proposed in the draft Regulation due to the toxicity of the substance.

Another Member State questioned the validity of the acute reference dose (ARfD) of 0.1 mg/kg body weight used in EFSA's focused assessment for the spinosad[6], and the fact that the new toxicological reference value had not yet been endorsed by the Section Phytopharmaceuticals - Legislation of the Committee (assessment of endocrine disrupting properties still ongoing). The Commission reminded the Member States of the procedure it had followed: a draft mandate to EFSA for an updated exposure assessment for spinosad considering the acute reference dose (ARfD) of 0.1 mg/kg bw had been presented to Member States at the meeting of the *Standing Committee for Plants, Animals, Food and Feed – Section Phytopharmaceuticals, Legislation of 18-19 May 2020*[7]. At that meeting, the Commission had 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[8], the *Standing Committee for Plants, Animals, Food and Feed – Section Phytopharmaceuticals, Pesticide Residues* 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. 0.1g/kg bw).

[6] https://www.efsa.europa.eu/en/efsajournal/pub/6404
[7] https://ec.europa.eu/food/system/files/2020-07/sc_phyto_20200518_ppl_sum.pdf
[8] https://ec.europa.eu/food/system/files/2020-07/sc_phyto_20200615_ppr_sum.pdf

On the question if a lower than the 0.01 mg/kg default level should be established, the Commission recalled its earlier compromise proposal, not to set MRLs below the default MRL 0.01 mg/kg, but to apply 0,01 mg/kg for all commodities with no multiplication factors for difficult matrices.

Member States were invited to provide comments by 15 October 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/10644/2021)**.**

The Commission informed the Committee on recent developments related to the draft Regulation and the information received. LOQs had been updated based on the information received form the EU Reference Laboratories. Monitoring data on the levels of bifenthrin in herbal infusions are still under evaluation, therefore specific MRLs for herbal infusions had not yet been proposed.

Member States were invited to provide comments by 15 October 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 (SANTE/10776/2021).

The Commission provided an overview of the text and annexes of this new draft Regulation and referred to the accompanying Explanatory Note.

For 1,4-dimethylnaphthalene (1,4-DMN), the EFSA Reasoned Opinion proposed a new residue definition for animal commodities. As 1,4-DMN is a naturally occurring substance, in a previous EFSA assessment an MRL of 0.1 mg/kg had been proposed to cover the natural background levels in plants. As monitoring results from the last three years suggested that for most of the crops the default MRL of 0.01 mg/kg would be appropriate, this level was proposed in the draft Regulation for all crops, except for potatoes.

For 8-hydroxyquinoline, EFSA did not propose changes to the residue definition, but the EU Reference Laboratories had suggested to include ‘chelates’ into the residue definition for plant commodities. MRLs at the LOQ were proposed for all crops. The Commission highlighted that, even if a LOQ of 0.01 mg/kg was proposed, the EU Reference Laboratories had expressed concerns whether this could be attained by all official control laboratories as different methods are applied.

For pinoxaden, EFSA had proposed 2 different residue definitions for plant commodities. The EU Reference Laboratories had confirmed that both would be technically feasible. The Commission proposed using the definition including conjugates, as this provides a more robust residue definition. A new residue definition had also been proposed for animal commodities. MRLs corresponding to CXLs were recommended for barley, rice, and wheat, and MRLs at LOQ were proposed for all other crops, as well as for animal commodities.

For valifenalate, the ESFA Reasoned Opinion had proposed a change in the residue definition for animal commodities (valifenalate and valifenalate acid). However, no analytical method for valifenalate acid nor an analytical standard are available. MRLs were proposed for table grapes, wine grapes, and aubergines (eggplants). Data gaps had been identified for tomatoes, thus a tentative MRL was proposed for this commodity.

MRLs at LOQ were proposed for all other commodities. An LOQ of 0.03 mg/kg was proposed for all commodities of animal origin.

Two Member States supported maintaining 0.1 mg/kg as LOQ for 1,4-DMN, noting that monitoring data are limited and that levels above LOQ were observed in certain crops. One Member State noted that a more in-depth investigation into monitoring data could be performed, and that this could be addressed by the monitoring Working Group of this Committee. The Commission proposed to ask EFSA to provide monitoring data for this substance to investigate further this issue.

One Member State had sent a written comment noting that the LOQ for 8-hydroxyquinoline in dry commodities should be 0.02 mg/kg. The Commission took note and indicated that it will amend the proposed levels accordingly.

Concerning valifenalate, EFSA noted that new CXLs were proposed during the last meeting of the Codex Committee on Pesticide Residues (CCPR), and that the EU raised no objections to them, but these had not been included in the EFSA Reasoned Opinion as it had been published earlier. The Commission replied that a new measure implementing CXLs will be drafted later this year, and that it will make sure that those measures will not contradict each other.

Member States were invited to submit comments by 15 October 2021.