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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Residues*

15 - 16 June 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/0f829378-55ec-4ec0-83a8-2b49cf50f96f*

SUMMARY REPORT

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table. One Member State commented on the entries in the table for thiophanate-methyl/carbendazim and pyrethrins. It regretted the procedural delay caused by the termination on request of one Member State of the written voting procedure on the non-renewal of thiophanate-methyl following the meeting of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF), section Phytopharmaceuticals – Legislation in May, which lead to delay for the follow up work on the maximum residue levels (MRLs) for carbendazim and thiophanate-methyl. The Member State had prepared a concern form for consideration by the FAO/WHO Joint Meeting on Pesticides Residues (JMPR) on carbendazim, benomyl and thiophanate-methyl for which the residue definitions are linked (see agenda item A.13).

2. Confirmatory data Art. 12 follow-up

3.a) Outcome of several confirmatory data evaluations by EFSA and proposed follow up

The Commission circulated a revised version of the table reporting certain proposed risk management decisions to be considered by Member States.

The Committee agreed on the following actions:

i. For spinosad, the Commission will submit a mandate to EFSA to carry out an exposure assessment of the existing maximum residue levels (MRLs) by considering the changed Acute Reference Dose (ARfD) established in the framework of the renewal of the active substance.

ii. For abamectin, summer and winter trials may be combined to set an MRL for dry beans and the value can be extrapolated to dry peas. As regards lettuces, a preliminary assessment shows that the MRL proposed by the Evaluating Member State may lead to an acute intake concern. It is therefore proposed not to increase the value for lettuces at this stage.

iii. For cymoxanil, the MRLs for pulses will be lowered to the relevant limit of quantification (LOQ). The footnotes for herbal infusions and hops will be maintained to remind Member States of the missing data when granting re-authorisations following the decision on the renewal of the active substance.

iv. For metazachlor, the MRL for turnips can be set at 0.9 mg/kg, based on 3 trials supporting the Northern European use and 3 trials for the Southern European use. The value can also be extrapolated to horseradishes and swedes.

v. For prothioconazole, the MRLs for onions, shallots, flowering Brassica, Brussels sprouts, head cabbages, leeks, barley, oats and pulses should be lowered to the LOQ. For products of animal origin, the MRLs should be lowered to the Codex maximum residue limits (CXLs) that were adopted in 2018 and were supported by the EU.

3.b) Follow up on Article 12 data gaps that were not filled

The Commission informed the Committee of its intention to follow up on substances with tentative MRLs for which confirmatory data following an Article 12 review had been requested. EFSA and Member States, in their function as Evaluating Member States, were invited to confirm whether or not such supporting data had been submitted for certain crop/pesticide combinations. Subsequently, the Commission intends to prepare a draft Regulation either proposing to lower the respective MRLs to the LOQ or, if the data gaps were fully addressed, remove the respective footnote requiring confirmatory data, to make the tentative MRLs permanent. The selection of substances for this draft Regulation took into account the due date of the confirmatory data, but also the timelines of the renewal of approval for each substance in order to avoid confusion due to overlapping processes.

Evaluating Member States and EFSA were invited to provide their feedback on the list of substances and to complete the information by 30 June 2020.

4. Residue definition for risk assessment

A Member State requested to discuss the procedural framework for amendments of the residue definition for risk assessment.

The Commission placed the request in the context of earlier discussions of this topic in the Committee. It agreed that clarification is desirable but identified several issues that need to be addressed, to ensure consistency between procedures under different legal acts, and between decisions taken by different sections of the Committee.

EFSA welcomed these discussions and reported on the difficulties in relation to provisional residue definitions for risk assessment.

A Member State acknowledged the complexities and enquired where the applicable residue definition for risk assessment is published. The Commission clarified that the relevant endpoints are found in the EFSA Conclusion on the peer-review of the latest assessment, once they are implicitly endorsed by risk managers when taking decisions on the renewal of approval of a substance. Another Member State suggested that the residue definition for risk assessment could be published in the EU Pesticides database, similar to the toxicological reference values.

The Commission invited Member States to submit comments by 17 July 2020.

5. Amended Commission Working Document for drafting Art. 12 proposals – for discussion

The item had been added to the agenda, since in the course of the discussions on several draft Regulations similar procedural questions had come up that needed clarification.

The Commission presented the amended Commission Working Document (CWD) for drafting Article 12 proposals in which it clarified the procedure for setting the MRLs for the product "others" within a group/subgroup of Part A of Annex 1 to Regulation (EC) No 396/2005.

The Commission recalled that the product "others" covers only those crops that are not explicitly mentioned in Part A or Part B of Annex 1. If there is no common MRL for a group/subgroup of products, or if the critical Good Agricultural Practice (GAP) leading to the MRL of a group/subgroup does not cover crops that fall under the category "others", the LOQ of the corresponding matrix for the group/subgroup applies, unless another relevant justification for setting a different MRL is available and agreed on a case by case basis.

A Member State commented that with a view to providing such justification, it would be appropriate to submit data on the respective GAPs to EFSA at the stage of drafting the reasoned opinion, and not at the moment of making risk management decisions in the Committee. EFSA confirmed that the Member State consultation step of the Article 12 review would be the appropriate moment.

EFSA asked for further clarification whether the intention of the Commission was to complete Part B of Annex 1 with as many specific crops as possible to avoid ambiguities.

The Commission and a Member State commented that full completion would be very difficult, if not impossible, and would require multiple and frequent changes to the Annex. The group "others" was meant to cover crops not explicitly mentioned and would continue to be needed, in particular for minor crops. This was supported by another Member State.

Member States were invited to submit comments by 7 July 2020.

A.02 Feedback from Legislation Committee:

The Commission informed that two active substances, lavandulyl senecionate and chloropicrin had been added to the agenda of the SCPAFF, Section Phytopharmaceuticals - Legislation since the last meeting of Residues Committee in February 2020.

A.03 Specific substances:

1. BAC/DDAC

In order to review the temporary MRLs for benzalkonium chloride (BAC) and didecyldimethylammonium chloride (DDAC) that had been established in 2014, and for which residues from biocidal uses can remain in foodstuffs, the Commission recently consulted the EU Reference Laboratories for pesticide residues (EU RLs) on the appropriate LOQs for both substances. The latter confirmed that there are analytical limitations to reach low values considering the existing residue definition comprising several isomers. Moreover, DDAC and BAC may be used as biocides for hygiene

purposes to prevent the presence of *Listeria monocytogenes* in food. Considering the impact that the COVID-19 situation may have on the use of these compounds, the Commission proposed to collect further monitoring data covering at least the year 2020 before reviewing the current MRLs.

2. Glufosinate ammonium

There was no news as regards this agenda item.

3. Glyphosate

The Commission informed the Committee about the adoption of Commission Decision C(2020) 2936, responding to a request for administrative review under Article 13 of Regulation (EC) No 396/2005.

4. Chlorpropham

In order to accompany the setting of a temporary MRL for chlorpropham in potatoes from storage facilities that were previously used for post-harvest treatments (see agenda item C.06) with measures aiming at bringing the levels down as quickly as possible, an annual reporting requirement about measured levels and progress with cleaning practices is proposed in the respective draft Regulation. Trade associations dealing with potatoes and potato products, have revised the guidelines on cleaning practices taking into account comments submitted by Member States. Moreover, other pieces of information were delivered to be used by farmers and food business operators such as an infographic, a grower self-checklist and visual inspection guidelines. Those documents are currently available on CIRCABC in English and a few other languages. Additional versions will be uploaded as they become available.

5. Methoxyfenozide

The Commission informed the Member States that it intends to send a mandate to EFSA asking to perform an exposure assessment on those crops that may pose acute concerns when considering the new acute Reference Dose (ARfD) established in the framework of the renewal of the active substance. The proposed deadline for the assessment is 31 December 2020.

6. Spinosad

The Commission informed the Member States that it intends to send a mandate to EFSA asking to perform an exposure assessment on those crops that may pose acute concerns when considering the ARfD that was established for the first time in the framework of the procedure for the renewal of approval of the active substance. The proposed deadline for the assessment is 31 January 2021.Since the renewal decision has not yet been taken, nor have the new endpoints been endorsed by risk managers, the Commission presented the draft mandate to the SCPAFF - section Phytopharmaceuticals – Legislation on 18/19. May 2020 and asked for feedback. No concerns were raised by Member States by the timeline indicated.

7. Indolylacetic acid (IAA)

The Commission informed the Member States that it had not received any new information since the last meeting. It proposed, not to include IAA in Annex IV to Regulation (EC) No 396/2005 despite the natural background levels as EFSA did not

recommend Annex IV inclusion in 2014 based on the toxicological properties of the substance. The Commission, however, acknowledged that enforcement action based on the default MRL is also difficult. A specific MRL based on realistic background data would in principle be the most appropriate solution. Since experience with other substances (e.g. dithiocarbamates) has shown that collection of specific background data requires substantial resources both from the Member States, EFSA and the EURLs, the Commission proposed that in a first step priorities would need to be established. The issue is well-known and common to several substances in the same situation.

A Member State informed about a request at national level to include the substance into Annex IV.

Another Member State agreed with the Commission that the issue would need to be dealt with more broadly and highlighted that in the near future when more and more low risk substances would be approved, the number of substances in the same situation is expected to increase.

The Commission proposed to make an inventory list of substances for which natural background levels exist, but which are not recommended to be included in Annex IV by EFSA, in order to have a general discussion in the future how to best address those. An amendment of the Guidelines for Annex IV inclusions could also be considered in this context.

Member States were invited to submit comments and inform of those substances by 17 July 2020.

8. Fosetyl-Al

The Commission presented the mandate to EFSA on the joint review of MRLs for fosetyl and phosphonates, which includes references to both the current Acceptable Daily Intake (ADI) for phosphonic acid and the new, lower ADI derived in the procedure for the renewal of approval of fosetyl. It had presented the mandate to the section Phytopharmaceuticals – Legislation of the Committee at its meeting on 18/19 May 2020 and indicated its intention, upon receipt of the reasoned opinion, to prepare a draft act modifying MRLs on the basis of EFSA's recommendation in the scenario with the new, lower ADI. Member States did not raise any concerns by the timeline indicated.

A Member State informed the Committee that it had received an application for a product containing phosphonates marketed as a biostimulant. The Commission referred to the requirements of the fertilising products Regulation (see Regulation (EU) 2019/1009, Annex I, Part II, Point 5, and Annex III, Part I, Point 3), and asked the Member State to encourage the applicant to contact the Rapporteur Member State (RMS) regarding a possible submission of relevant data on residues, as specifically provided for in the mandate to EFSA.

EFSA reported on the state of play for the update of the collection of GAPs for fosetyl and for the preparation of the Evaluation Report on phosphonates by the RMS.

9. Ethephon

The Commission made reference to EFSA's 2018 Annual Report for pesticide residues[1], where ethephon was identified among the substances for which in several commodities the ARfD was exceeded.

While in peppers in such cases also the MRL was exceeded, in table grapes this was not the case.

The Commission recalled that this phenomenon was well-known and related to the model to estimate acute exposure, therefore currently work is ongoing in Codex Alimentarius on the revision of the International Estimated Short-Term Intake (IESTI) model. The MRL for ethephon on table grapes was discussed in 2014, when Member States had agreed to set a value of 1 mg/kg[2], corresponding to the existing CXL.

EFSA indicated possible misuses of the substance that is a plant growth regulator, but also may have other effects (e.g. on the colour). The Commission invited Member States to be vigilant when checking the proper use of the substance in their enforcement actions.

10. Fluopyram

The Commission informed that the Reasoned Opinion on the modification of the existing maximum residue levels for fluopyram in herbal infusions from leaves, herbs and flowers will be addressed in the framework of the Article 12 review (SANTE/10044/2020).

11. Mancozeb

The Commission informed that the Reasoned Opinion on the modification of the existing maximum residue levels for mancozeb in various crops will be addressed only once the decision on the renewal of approval of the active substance will be taken. Since it is well known that the crops under consideration have high natural background levels of CS_2 and the available enforcement methods cannot distinguish between levels of naturally occurring CS_2 and those arising from the use of dithiocarbamates, mancozeb MRLs will be addressed in the forthcoming Article 12 review of the group of dithiocarbamates. In preparation for that review, background data have specifically been collected on organic crops over the last years in the framework of the "Pestipedia" project managed by the EURLs for pesticide residues.

12. Boscalid

The EFSA Article 10 Reasoned Opinion on boscalid outlined several risk management options for the setting of an MRL in honey. The Commission proposed to establish a permanent MRL at the level of 0.15 mg/kg based on field trials instead of a temporary MRL based on monitoring data and proposed that in case both field trials and monitoring data were available, the data from field trials should always prevail.

The Commission proposed that this principle could be established as a general principle in a forthcoming amendment of the Technical Guidelines on the MRL setting procedure (SANTE/2015/10595 Rev. 5.4).

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[1] https://www.efsa.europa.eu/en/efsajournal/pub/6057

[2] https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phytopharmaceuticals_sum_2014112425_ppr_en.pdf

One Member State supported this approach.

Member States were invited to provide their feedback by 17 July 2020.

13. Lambda-cyhalothrin

The Commission reported about an Article 10 draft Reasoned Opinion on lambda-cyhalothrin in spices for which a risk management decision was needed on whether footnotes on existing data gaps set in the context of the preceding Article 12 review process should be maintained. The application had been submitted to EFSA on 25 May 2018, just shortly before the entry into force (26 July 2018) of the respective Regulation setting the MRLs according to the Article 12 review. In the Article 12 review EFSA identified data gaps relating to certain metabolites for which confirmatory data are required by the deadline of 6 July 2020.

The Commission proposed to maintain the footnotes relating to confirmatory data in the draft Regulation that will be prepared, in line with Chapter 7 of the Technical Guidelines on the MRL setting procedure (SANTE/2015/10595 Rev. 5.4), which states that *"Article 6 applications need to comply with the data requirements that exist on the day of submission of the application to the Evaluating Member State. This means that new requirements set under Article 12 would trigger the stop-the-clock procedure only if the Article 12 Regulation already entered into force at the time of submission of the Article 6 application"*.

14. Maleic hydrazide/chicory roots – use of fast track procedure

A Member State made a request to use the fast-track procedure, foreseen by the Technical Guidelines on the MRL setting procedure (Chapter 3.6), to set an MRL in chicory roots based on the residue trials on carrots, which were assessed by EFSA in the framework of the procedure for the renewal of approval in 2016.

Member States were invited to signal whether they had any objections by 30 June 2020.

15. Imazamox

EFSA assessed an application for imazamox on soybeans that explicitly referred to the setting of a new (higher) MRL based on a new residue definition for enforcement proposed in the framework of the procedure for the renewal of approval of the active substance, but not yet legally applicable through any preceding MRL measure.

EFSA proposed two options using the existing residue definition for enforcement and the one proposed in the conclusions on the renewal assessment.

With the current residue definition, the proposed MRL is covered by the existing LOQ (at 0.05* mg/kg), while by changing the residue definition, a higher value of 0.07 mg/kg would need to be established. In the latter case, all existing MRLs for the substance would also need to be re-calculated.

The Commission proposed to follow the approach previously taken, not to change the residue definition for enforcement in an Art. 10 review, but to confirm with the applicant in advance that this approach was acceptable and make its decision transparent (e.g. though a recital in a legal act).

Member States were invited to provide their feedback by 17 July 2020.

16. 1,4-Dimethylnaphthalene

The Commission received information from some Member States in relation to the natural occurrence of 1,4-dimethylnaphthalene in plants and the possible contamination from solvents used in plant protection products. These Member States expressed concerns related of enforcement since the default value of 0.01 mg/kg applies for all commodities, except for potatoes. In parallel, the United Kingdom had informed the Commission about an ongoing risk assessment in relation to the findings of the substance in products of animal origin following the authorised use on potatoes showing that there might be a chronic intake concern. EFSA clarified that the United Kingdom proposed to submit this information to the Netherlands who acts as Evaluating Member State and EFSA for their possible consideration under the Article 12 review. In the context of the Article 12 review, all relevant aspects will be considered.

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 13 new question numbers were issued and 11 finalised since the previous meeting of this Committee in February 2020. 5 additional questions are at finalisation stage. Currently, 83 question numbers are at different steps of the procedure (out of which 29 relating to import tolerance applications and 11 to confirmatory data assessments) and 48 are under clock-stop (17 relating to import tolerance requests).

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

EFSA presented the state of play of the ongoing Article 12 reviews. 8 Reasoned Opinions were finalised since the previous meeting of this Committee. 35 active substances are currently under review and at different stages of the procedure.

EFSA informed that the Article 12 work instructions, agreed at the last Pesticides Steering Network meeting on 4-5 November 2019, were published on the EFSA website (https://www.efsa.europa.eu/en/topics/topic/pesticides) after having undergone a public consultation. They will become effective as from 1 July 2020 for all new or ongoing MRL reviews.

EFSA also informed about a new newsletter foreseen to be launched in July 2020 which will contain up to date information on the launch and status of Article 12 reviews. All interested parties (applicants, trade organisations, other stakeholders and public authorities (including from non-EU countries) can subscribe to that newsletter at the following website:

https://europa.us10.list-manage.com/subscribe?u=e6bc309c39d67dee1eb0bf114&id=7ea646dd1d

The Commission encouraged Member States and EFSA to use all available data to ensure that existing Codex MRLs are taken into account in the MRL review to the widest extent possible. It recognised that in some cases it may require flexibility in the separation of tasks agreed between Member States and EFSA, and stressed the need for good communication between (Rapporteur) Member States and authorisation holders on the one hand, and Rapporteur Member State and EFSA on the other hand.

One Member State would prefer that the EU Pesticides database would indicate whether a given MRL is set based on authorisations in EU Member States, an import tolerance request, or alignment to Codex MRLs. The Commission referred to the existing database of Codex MRLs on the website of the Food and Agriculture Organization of

the United Nations (FAO), and ongoing work by a Member State and the Commission services on an overview of import tolerances in the EU.

The Commission informed the Committee that in its view it was not appropriate for EFSA to carry out a review of the existing MRLs for methiocarb, in view of the concerns on genotoxicity of metabolites identified in the procedure for the renewal of the active substance, and referred to the draft Regulation presented under agenda item C.06, proposing to lower all MRLs for methiocarb to the LOQ. Moreover, the main authorisation holder informed the RMS that it will not invest in generating data to address those concerns. The Commission proposed to delete methiocarb from the 2020 work plan for MRL reviews, to which the Committee agreed.

Following the recent renewal of approval of the active substance pyriproxyfen, the renewal of authorisations of plant protection products containing it is expected to be completed by August 2021. In view of the available capacity of EFSA to carry out MRL reviews as well as the approval conditions that are not more restrictive than before the renewal of approval, the Commission proposed to launch the MRL review exceptionally even before completion of the renewal of authorisations.

The Commission invited Member States to submit comments on the possible launch of the MRL review for pyriproxyfen before completion of the renewal of authorisations by 7 July 2020.

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

EFSA reported that two requests of the Commission under Article 43 of Regulation (EC) No 396/2005 were finalised (temporary MRLs for chlorpropham on potatoes and for chlordecone on certain animal products). Furthermore a mandate on fosetyl and phosphonates had been accepted and a mandate on propoxur was in the acceptance procedure. New mandates are expected from the Commission on methoxyfenozide and spinosad. EFSA also informed about a mandate on copper that it had received from the Commission. The mandate will be dealt with by EFSA's Scientific Committee who has been requested to provide a scientific opinion on the Acceptable Dietary Intake (ADI) for copper and to perform a new intake estimation taking into account all sources of exposure by 31 December 2021. The requested opinion will also take into account the already existing outputs from specific EFSA Panels and units.

4. Update on the EFSA reports on cumulative risk assessment

EFSA reported that the final reports on the first two cumulative risk assessment of the thyroid and the nervous system groups had been published on the EFSA website in April 2020[3]. On request of the Commission, work on cumulative assessment groups for two new effects will now be carried out (chronic neurotoxic effect (acetylcholinesterase inhibition) in 2020 and cranio-facial malformation effects in 2021).

EFSA and the Commission will jointly prepare an implementation plan by end of 2020 as announced in the REFIT report on the evaluation of the pesticides legislation (see also agenda item A.19).

EFSA will continue to work with the Commission and Member States on developing an approach for using cumulative risk assessment in regulatory practice, i.e. for setting MRLs (see also agenda item A. 09).

[3] https://www.efsa.europa.eu/en/news/pesticides-first-cumulative-risk-reports-published

5. Implementation of the EFSA GD on stereoisomers

The discussion on this item was postponed to the next meeting of the Committee.

6. Discussion on rotational crops (Implementation of OECD Guidelines)

EFSA made a presentation on rotational crops and highlighted some issues frequently encountered when assessing pesticides in rotational crops. For the assessment of rotational crops so far EFSA has used Appendix C to the Guidelines for the generation of data concerning residues[4] - testing of plant protection products in rotational crops - 7524/VI/95, but since 2018 the new OECD Guidance Document on Residues in Rotational Crops (ENV/JM/MONO (2018)[5]) is available. EFSA compared both documents and highlighted some differences that may lead to different risk assessment outcomes. Member States and Commission were consulted on the necessity to maintain certain elements from one or both guidance documents and on the format and type of conclusions on rotational crops that would be considered useful for risk managers. Furthermore, EFSA requested input from Member States on possible existing risk management practices (e.g. use restrictions) at national level for rotational crops.

EFSA also asked for clarification whether there was a need for the Committee to formally take Note of the 2018 OECD guidelines.

A Member State pointed out that Appendix C was outdated (from 1995) and supported its deletion given that OECD Test Guidelines 502 and 504 and the new 2018 OECD guidance document were now available. In terms of risk management options, the Member State considered that use restrictions would not be the best option, as they would be more difficult to control, therefore it would prefer to set MRLs for the various rotational crops. Another Member State agreed that the preferred option would be setting MRLs as other options are not easily enforceable.

EFSA informed the Committee of setting up a focal group for drafting a technical report to facilitate the interpretation of the OECD Guidance Document on Residues in Rotational Crops and its associated Test Guidelines 502 and 504.

The Commission explained that OECD guidelines are not usually taken formally note of in the Committee, but that they are implemented in the EU via Commission Communications 2013/C95/01 and 2013/C95/02 supplementing the respective Regulations on data requirements. The Communications would need to be updated in this respect as the 2018 OECD Guideline is not yet included.

EFSA invited Member States to comment by 17 July 2020 to the EFSA functional mailbox at **pesticides.mrl@efsa.europa.eu** and to the Commission at the same time.

7. Other

No issue was raised under this agenda item.

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[4] Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (Document 1607/VI/97 - 10 June 1999)

[5] https://one.oecd.org/document/ENV/JM/MONO(2018)9/en/pdf

A.05 New Transparency rules:

1. EFSA and COM activities

EFSA made a presentation on horizontal Practical Arrangements (PAs) to be established by EFSA for the implementation of the Transparency Regulation with a focus on MRL issues. These PAs will cover public disclosure and confidentiality, pre-submission advice and public consultation and are relevant also for the MRL sector.

EFSA clarified that the Transparency Regulation also specifically covers data protection.

Once the EFSA draft PAs are in a more advanced stage, the Commission will review the existing Technical Guidelines on MRL setting to align the processes accordingly. If possible, a first draft could be submitted to the next meeting of this Committee in September 2020 in view of finalisation at the latest in the meeting of this Committee in February 2021.

2. IT tools

EFSA made presentation on IUCLID, which is intended to be used for all dossier submissions including MRL applications as from March 2021. The current MRL submission form in pdf format is planned to be abandoned then.

A Member State mentioned the letter submitted to the Commission on IUCLID, whereby a longer transitional period should be provided to adapt (the Member State considers the time until March 2021 as too short as further revisions may be necessary). From a technical point of view, the Member State has concerns for studies that cannot be linked to the relevant endpoints and is more comfortable using CADDY.

Member States were invited to submit comments by 7 July 2020 on the use of IUCLID and the planned replacement of the MRL application form by IUCLID.

A.06 Implementation of revisions of PRIMo model.

The Commission referred to the request of the Member States at the last meeting of the Committee to clarify which version of the PRIMo model should be used in national authorisation procedures. The Commission had proposed two options on which Member States had been asked to comment. All Member States who replied preferred the option to immediately implement the newest version of the PRIMo model (currently rev. 3.1.) also for PPP authorisations, in line with the approach agreed for MRL assessments at the meetings in November 2019 and February 2020. Clarifications were also provided as regards specific questions on mutual recognition. The outcome of these discussions will now be brought to the attention of the Legislation section of the SCPAFF Phytopharmaceuticals at its meeting in July for its endorsement and will subsequently be communicated to the Post Approval Issues Working Group under the same section of the SCPAFF.

A.07 Monitoring of pesticides residues.

The Commission informed of the United Kingdom's reaction following the recent publication of Regulation (EU) 2020/585[6] regarding the EU Multi-Annual Coordinated

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=urisery%3AOJ.L_.2020.135.01.0001.01.ENG&toc=OJ%3AL%3A2020%3A135%3ATOC

Monitoring Programme (EU MACP) for pesticide residues. In this Regulation, the number of samples allocated to the "UK in respect to Northern Ireland" remains the same as the number of samples assigned to the UK in the previous versions of the EU MACP. According to the UK, a new number of samples should be allocated to the "UK in respect of NI", proportionate to the size of that territory's population.

The Commission informed that it was currently preparing a mandate for EFSA to update its 2015 study on the design assessment of the programme[7] in order to update the number of samples allocated to the "UK in respect to NI". It was stressed that, in order to maintain the current margin of error (0.75%) by which an MRL exceedance rate of more than 1% can be determined, the total number of 683 samples should remain unchanged, as this number stems from the statistical model. This would mean a re-allocation of samples to other Member States. An updated version of the EU MACP for the years 2021-2022-2023 will be presented to this Committee at its meeting in September 2020.

Several Member States informed that they will most likely be able to complete their 2020 monitoring programmes, but possibly with slightly reduced sample numbers or changed sampling schedule, due to the current COVID-19 situation.

A.08 Foods for infants and young children.

The Commission provided an update on the on-going project for the development of analytical methods with lower LOQs for infant formulae and informed that the EURL for commodities of animal origin recently published on its website the validation study for those methods on milk-based infant formulae. The Commission also informed that the project for the alignment of the delegated Regulations of the baby food sector with Regulation (EC) No 396/2005 is on-going.

A.09 Next steps for cumulative risk assessment.

The Commission informed that a Working Group meeting on cumulative risk assessment (CRA) will be held on 29 June 2020 focusing on initial methodological approaches for the prospective (MRL-setting) scenario. Moreover, the Commission made reference to the on-going discussion within the Commission regarding the EU Chemicals Strategy and, specifically, to the Mixture Assessment Factor (MAF) that is currently under discussion for assessing exposures to multiple chemicals through various routes of exposure.

The Commission also informed the Committee that the SANTE webpage had recently been updated with regard to CRA.

A.10 Project on data collection dithiocarbamates.

The Commission informed that this task is on-going and the EURL on Single Residue Methods will re-allocate resources from events that are cancelled due to COVID-19 towards in-house CS2 analyses in an effort to provide EFSA with a complete data set at the time EFSA starts the Article 12 review of the dithiocarbamates group of substances. The review starts at the end of 2020 ad the data would be needed early 2021.

[7] https://www.efsa.europa.eu/en/efsajournal/pub/4005

A.11 New Official Control regulation and impact on pesticides legislation.

The Commission summarised the feedback it had received from Member States. According to the comments received the Commission concluded that there was no need to re-instate Articles 26 and 27(2) of the MRL Regulation which is considered to be fully covered by the general provisions of the Official Control Regulation (Regulation (EU) No. 2017/625 (OCR)).

However, some Member States see a need to re-instate Articles 27(1) and 30 of the MRL Regulation. This would mean that for Article 27(1) of the MRL Regulation a delegated act would be needed which then would cover a sufficient number and range of samples representative for the market, taking into account results of previous controls and close to the point of supply. For the Article 30 of the MRL Regulation an implementing act would be needed which then would cover e.g. risk based national programmes with the dual purpose of compliance check and exposure assessment and other more detailed elements supplementing the provisions of Article 110 of the OCR. A further Member State supported re-instating the Article 30 provisions to set out clearly the dual purpose of the monitoring programme.

Member States were invited to submit comments by 17 July 2020.

A.12 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2020-2021.

The Commission had prepared a revised version of the overview table with temporary MRLs that will expire in 2020-2021. EFSA had recently finalised the assessment on the occurrence of flupyradifurone and its metabolite difluoroacetic acid in rotational crops. The Committee was reminded of the MRLs for cyantraniliprole, which will expire automatically on 30 June 2021.

A.13 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission had shared with the Member States the Report on the Activities of the Residue Chemistry Expert Group (RCEG), where the main achievements and future steps in relation to the relevant OECD expert groups are outlined. This report was discussed in the framework of the OECD working group on pesticides, which was held on 11-12 June 2020. In that framework, it was proposed to also involve China as an observer to the OECD WG on the residue definition for risk assessment in order to ensure global harmonisation as China is currently re-assessing an extensive set of active substances.

1b) Honey guidelines- discussions in OECD

The item was added to the agenda by the Commission.

The Member State who attends the OECD WG on setting MRLs in honey gave an overview of the ongoing work. The working group has more than 25 members (OECD countries, industry representatives, EFSA and the Commission). The discussions on the honey guidelines have been ongoing about a year and the plan is to finish the guidelines in 2021. The EU Honey Guidelines were the basis for the discussion for the first 6 months but lately two working group members have made other proposals which are based on setting default values. At the last working group it was agreed to base the work on the EU Guideline. The first task is to list the plants which can cause residues in

honey and set criteria to decide in which cases specific MRLs are needed for honey from these crops.

The next meeting of OECD drafting group takes place mid-July 2020.

The Commission invited the Member State to report back at the next meeting of this Committee.

2. Codex Alimentarius/JMPR issues- future work organisation

The Commission informed the Committee that the 52nd session of the Codex Committee on Pesticide Residues (CCPR) was moved to 12-17 April 2021, Guangzhou.

Due to the impact of the Covid-19 pandemic on working arrangements, physical Council Working Parties will likely not take place in September or October 2020. The German Presidency in the second half of 2020 confirmed that it may be possible to hold a videoconference on 11 September but that the availability of facilities was subject to evaluation. The Commission suggested working through written procedures and hold a physical Council Working Party under Portuguese Presidency in early 2021.

a) Outcome of the second Council Working party meeting on 4 March 2020

The Commission reported from the Council Working Party on 4 March 2020, which focused on proposed draft Codex MRLs derived by the regular Joint Meeting on Pesticide Residues (JMPR) in September 2019.

b) CCPR 2020- working groups and substances

The Commission presented a draft EU position in response to Circular Letter CL 2020/05-PR(REV) from the CCPR electronic Working Group on Priorities. It thanked one Member State who had previously submitted detailed comments, which it had taken into account in the draft.

The Commission invited Member States to submit comments on the draft response by 23 June 2020.

One Member State informed about another extraordinary JMPR meeting, facilitated by the USA, planned to take place in 2021, with a focus on new use evaluations. It also drew attention to several amendments in the priority list, which did however not reduce the number of planned periodic reviews.

c) Planning of preparatory work for possible further Council Working parties in 2020

One Member State presented a draft concern form on benomyl, carbendazim and thiophanate-methyl, which have a combined residue definition at Codex level. Through the draft concern form, clarification is requested on the status of the substances and their MRLs at Codex level, and a periodic review of carbendazim is supported. The Commission thanked the Member State for drafting the concern form and suggested to await the decision-making on the approval of thiophanate-methyl in the EU before sending the concern form (see also agenda item A.01.01).

The Commission invited Member States to submit comments by 17 July 2020 on the concern form.

A.14 SANTE extrapolation guidelines (SANTE-2019-12750), replacement of existing guidance document SANCO 7525/VI/95 Rev. 10.3).

The Commission presented the new draft version of the extrapolation guidelines, highlighting the main differences with the previous version and the open points where further discussion is needed. Some Member States agreed with the proposal of setting a concrete distance between different sites that are considered to be "independent" for the performance of field trials. Other Member States pointed out weaknesses of this approach and proposed alternatives. Several Member States proposed to extend the limit of max. 50% of residue trials that may be performed outside the EU to all minor crops, not only to tropical minor crops. A Member State proposed to review the consumption data used to define major crops, replacing the Global Environmental Monitoring System (GEMS) food cluster diets with PRIMo data. The classification of indoor crops was also discussed. The use of the reference "hectare leaf wall area" for the application rate in tall crops was proposed by one Member State.

Member States were invited to submit comments by 17 July 2020.

A.15 Revision of GD SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1 - Analytical guidances.

This point was postponed to the next meeting.

A.16 Revision of RASFF WI 2.2.

Following the discussions under agenda items A.16 and A.20 at the Committee's meeting on 17/18 February 2020, the Commission had invited Member States to submit comments and concrete proposals, to decide whether and how to amend the current version of the Rapid Alert System for Food and Feed (RASFF) Working Instructions (WI) 2.2. The Commission thanked all Member States who had done so and concluded that different practices continue at Member State level as regards the application of measurement uncertainty to determine MRL exceedances in cases where also the ARfD is exceeded. The Commission acknowledged that the current wording provides less prescriptive guidance and thus more flexibility for Member States on purpose, and recalled it was a compromise reached. Based on recent comments from Member States, the Commission considers that a revision is unlikely to yield a different outcome.

As regards other suggestions (not related to the measurement uncertainty) to improve the WI 2.2, the Commission informed Member States that discussion on the RASFF Standard Operating Procedures (SOP) are planned for the second half of 2020, and that it was appropriate to await the outcome of those discussions first, before considering further changes to the WI 2.2.

A.17 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

Finland had made a notification under Article 18(4) to Reg. (EC) No 396/2005 for flonicamid on carrots. Finland explained that the residue data was already assessed in the framework of SANTE/11195/2018, which received an objection from the European Parliament and was not yet implemented. The Committee took note of the notification made by Finland.

A.18 Designation of Member States for maximum residue levels (MRL) applications.

The Netherlands had received an import tolerance request for bananas treated with isoprothiolane for which no RMS was attributed at EU level. The Committee agreed that the Netherlands acts as the Evaluating Member State.

The Commission informed that an applicant has submitted an MRL application for fenpropathrin in various crops together with new toxicological data. However, there is no RMS appointed for the substance at EU level nor is there any Member State who has evaluated the substance in the recent past. Member States were invited to volunteer to become evaluating Member States for fenpropathrin by 7 July 2020.

A.19 Farm to Fork Strategy and report to Council and Parliament on the REFIT evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The Commission presented the recently published Farm to Fork (F2F) Strategy and the outcome of the REFIT evaluation of the pesticides legislation for which a Report to Council and Parliament was published on the same day, together with the Biodiversity Strategy and the second Report on the Implementation of the Sustainable Use Directive. It highlighted the new focus of the F2F Strategy on sustainability next to food safety and its strong international dimension which is also reflected in the conclusions of the REFIT Report to Council and Parliament. The Commission also pointed out that one of the novelties was that environmental matters of global nature would in future be considered when assessing import tolerance requests for substances no longer approved in the EU while respecting WTO standards and obligations.

One Member State welcomed the new approach envisaged for import tolerances and suggested that import tolerance requests should be generally treated separately from other MRL applications.

Another Member States was critical of the approach taken and stated that a thorough assessment of all possible impacts should have been carried out first.

A third Member State informed about the dates for Council Working Groups under its forthcoming Presidency which will deal both with the F2F Strategy and the REFIT evaluation of pesticides legislation.

EFSA mentioned the need to reflect about a change of the existing data requirements in view of the envisaged future approach for import tolerances.

The Commission thanked the Member States for their initial views and invited those who might still wish to send comments to do so by 7 July 2020.

A.20 Info on Brexit and Northern Ireland Protocol.

The Commission informed that a new notice "Withdrawal of the United Kingdom and EU Rules on Plant Protection Products", dated 25 May 2020[8], had been made publicly available. This notice replaces the previous notice to stakeholders and the Questions and Answers document that had been drafted for the event of a "hard" Brexit. The new notice focuses more on plant protection products, including mutual recognition and parallel trade, than on MRL aspects. It includes a chapter on the applicable rules in Northern Ireland after the end of the transition period. It is expected that more detailed guidance will be released on the Protocol on Ireland/Northern Ireland towards the end

[8] https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/plant_protection_products_en.pdf

of the transition period. Both, Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 shall apply to and in the United Kingdom in respect of Northern Ireland, with some exceptions, in particular as regards the participation of the United Kingdom in decision-making and the possibility to act as lead authority for evaluation and assessments, including referrals under Article 43 of the MRL Regulation.

The Commission drew attention to Article 41 of the Withdrawal Agreement: As part of the so-called separation rules, all identifiable goods lawfully placed on the markets of the EU or the United Kingdom for the first time prior to the end of the transition period may be made further available on the EU or United Kingdom markets and circulate freely between the two markets until reaching the end users.

A.21 Other Information points:

1. Fee recovery by Member States for work on Article 12 and 43

The Commission gave an overview of the feedback it had received following the request for further information by a Member State at the last meeting. Only few Member States reported that they would have means in their national legislation to recover fees for Article 12 evaluations or for contributions to Article 43 scientific opinions prepared by EFSA based on a mandate from the Commission. Most Member States reported not to be able to recover fees, but clarified that they do charge fees when as a consequence of an MRL review, the national authorisations need to be changed.

One more Member States added that it would not charge fees for Article 12 reviews.

2. Enforcement for feed – Sharing of practices

The Commission gave an overview on the feedback it had received on Member States' practices for enforcement of feed MRLs, following a request for sharing information brought up by a Member State at the last meeting. Two detailed guidelines had been shared by two Member States which were considered very useful documents.

The Member state who had asked for the feedback welcomed the information received and supported the discussions with the aim to harmonise current practices.

3. Transitional periods MRL measures – Feedback from last meeting

The Commission informed the Member States about the feedback it had received after the last meeting of the Committee. Overall, it concluded from the reactions received that a further discussion on this issues was not considered as a priority at this point in time, but did not exclude the possibility to take this up again at a later stage.

One Member State reminded the Commission to share some additional information on CIRCABC that it had submitted earlier.

4. Mandate on copper to EFSA

The Commission referred to its recent mandate to the EFSA Scientific Committee on the Acceptable Daily Intake (ADI) for exposure to copper made available to Member States under this agenda item. The contents were however presented by EFSA under agenda item A.04.03. The Commission clarified that decisions on modifications of MRLs for copper compounds in the context of other pending procedures will only be taken after the mandate is addressed by EFSA.

The Commission informed the Member States about an application for "coffee leaves" as traditional food under the Novel Food Regulation. In this context a question came up about the applicable MRL for copper in coffee leaves. The Commission asked

Member States for feedback on its proposal to consider coffee leaves to fall under the subgroup "herbal infusions from leaves and herbs" – "other" (Code 0632990) of Annex 1 Part A to Regulation (EC) No 396/2005 and not to include this commodity specifically under Part B of Annex 1.

This would mean that currently a MRL of 100 mg/kg applies. The applicant for the traditional food was informed that if the MRL that is currently recommended by EFSA in the Art. 12 reasoned opinion would be implemented in the future, the MRL for this category would drop to the LOQ of 5mg/kg.

The Commission suggested that when Novel Foods get authorised following an EFSA opinion of EFSA's NDA Panel, the correct classification should already be provided in that scientific opinion. This was communicated to EFSA.

The Member States were invited to comment on the proposed classification by 7 July 2020.

5. Update on PRAC measures voted in February

The Commission gave an update on the situation of the draft Regulations on which the Committee had voted in its meeting in February. Procedures for most were progressing well, some of them were already adopted and published, while there were some procedural delays for others.

The Commission informed that the European Parliament's Environmental Committee had adopted a draft motion for resolution (uploaded on CIRCABC) opposing one of the draft Regulations and had asked the Commission to withdraw and re-submit the measure at a later stage, to allow making use of its right for scrutiny within the legal deadline of 2 months, which had not been possible due to COVID-19. The Commission had agreed to that and the measure will now be re-submitted and a vote will be tabled at a forthcoming Plenary meeting of the European Parliament with a view of deciding on a possible adoption or rejection of the motion objecting to the draft Regulation.

The Commission explained that it currently carefully analysed, which impacts the delay with this specific draft Regulation dealing with several substances will have on MRLs proposed in subsequent draft Regulations that are already under discussion and re-arrange the planning accordingly.

6. Dimethoate emergency measure taken by France

The Commission reported on the written consultation of the Standing Committee in April 2020 on the follow up to the 2020 French emergency measure on cherries treated with dimethoate[9]. In that framework, there was large support from Member States not to take further action for dimethoate/omethoate in cherries as the draft Regulation lowering MRLs for cherries had already been voted at that time. The Commission also informed on the publication of Regulation (EU) 2020/703, which will become applicable on 16 December 2020.

7. Notification of a national measure imposing testing requirements for certain agricultural products coming/originating from other Member States

The point was added to the agenda by the chair.

The Commission informed of a recent notification of a national measure – amended several times - taken by one Member State imposing a 100% testing requirement for

[9] http://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20200424_ppr_sum.pdf

pesticide residues for certain agricultural products originating from other Member States as pre-condition for placing them on its national market. The measure applies from 30 June 2020 until 1 October 2020. The Commission requested further information on the reasons for and background of this measure from that Member State and informed the Committee that this was now scrutinised by the Commission. The representative of the Member State in question agreed to forward the request to the relevant authority.

Section B Draft(s) presented for an opinion

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

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/…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 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, blood meal, chlorantraniliprole, chlormequat, cyprodinil, fluxapyroxad, fosetyl, , limestone, mandipropamid, pepper, pyridaben, seaweed extracts, spirotetramat and trimethylamine hydrochloride in or on certain products.

The Commission outlined the contents of the measure. Three substances were withdrawn from the measure as compared to the title in the agenda: fluxaproxad, spirotetramat and fosetyl. Fluxapyroxad and spirotetramat will be dealt with by the draft Regulation (SANTE/10032/2020) presented under Point C.03 of the agenda. Fosetyl will be added to a forthcoming draft Regulation in view of the procedural delay with another draft Regulation (SANTE/11822/2019) containing the same substance on which the newly proposed MRLs are based.

The draft Regulation confirms permanent inclusion in Annex IV for seven substances previously temporarily included pending the Article 12 review, several of them naturally occurring substances. A Member State requested that further general discussions would be needed for naturally occurring substances for which EFSA cannot perform a complete risk assessment in view of the available data (see also discussion under agenda item A.03.07 on indolylacetic acid).

One Member State signalled it would vote against the draft Regulation in view of the suggested MRL for chlorantraniliprole in palm fruits, referring to its national plan on reduction of the production of palm oil.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 directly after the meeting of the Committee.

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) No …/…amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products (SPS).

The Commission outlined some minor amendments that were brought to the draft Regulation following the consultation of other Commission services and comments submitted by Member States.

A Member State expressed concerns in relation to residues of 6-hydroxybentazone for which EFSA could not conclude on the toxicity. The Commission clarified that risk managers had concluded that the metabolite has a similar toxicity to the parent compound in the framework of the renewal of the active substance (see Review Report SANTE/12012/2015 Rev. 8). Following the comment from another Member State, the Commission had revised the Annexes to the draft Regulation setting the value for "other animal products" at the highest level between liver, kidney and edible offal, as defined in the relevant guidelines.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 directly after the meeting of the Committee.

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) No …/…amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council of the Committee as regards maximum residue levels for bupirimate, carfentrazone-ethyl, ethirimol and pyriofenone in or on certain products (Art. 12).

The Commission outlined some minor amendments that were brought to the draft Regulation following the Commission's internal consultation procedures.

In view of the discussion held under agenda item A.01.05, the MRLs for bupirimate and ethirimol in the subgroup "others" within the group of cane fruits were set at 0.7 mg/kg for bupirimate and 0.07 mg/kg for ethirimol, respectively, in line with the MRLs for blackberries and dewberries, as it was clarified that the national authorisation of bupirimate in blackberries and dewberries covers all *Rubus spp*.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 directly after the meeting of the Committee.

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 metam, dazomet, hexythiazox, clethodim and sethoxydim (Art. 12).

The Commission presented a new revision of the draft Regulation where, based on comments from the Member States, the MRL for hexythiazox in soyabeans was

modified. The applicant for clethodim had shared the detailed study protocol for the evaluation of the genotoxicity potential of clethodim metabolites, but results were not yet presented as the final audited report was not yet available. Once the report becomes available, the Commission will consider whether changes of the current draft Regulation are necessary and consult the Member States. No comments were received from Member States at this stage.

Member States were invited to submit comments by 17 July 2020.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for acequinocyl, cycloxydim, diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products.

The Commission presented a revised draft Regulation to the Committee. The Commission informed that MRLs for fluopyram were based on the option from EFSA's Reasoned Opinion[10] where no risk management measures were applied, apart from the restriction on the most critical indoor GAP on tomatoes (option two). A Member State informed that in line with its comments under agenda item A.04.06 it generally prefers this option of setting MRLs over the alternative option to propose risk management measures. Another Member State confirmed that this was also its view, but that in this specific case a risk management measure (setting of a plant-back interval) could be more appropriate. The Commission informed that the draft Regulation would be notified under the WTO SPS agreement directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in September.

Member States were invited to submit comments by 30 June 2020.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat.

The Commission presented a revised version of the draft Regulation which, inter alia, also includes MRLs for fluxapyroxad and spirotetramat that were based on applications under Article 6 of Regulation (EC) No 396/2005 and were taken out of the draft Regulation SANTE/10480/2020 (see agenda item B.01).

No comments were received from the Member States.

The Commission informed that the draft Regulation would be notified under the WTO SPS agreement directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in September.

Member States were invited to submit comments by 30 June 2020.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for benalaxyl, benalaxyl-M, dichlobenil, fluopicolide, proquinazid, and pyrdalyl.

The Commission presented revision 2 of this draft Regulation and informed the Committee that it is currently undergoing the Commission's internal consultation procedures.

[10] http://www.efsa.europa.eu/en/efsajournal/pub/6059

A discussion took place regarding the level of detail needed in the recitals on the rationale for risk management decisions taken by the Commission on each single MRL, in particular where MRLs were lowered.

Some Member States indicated that in view of transparency information should be more detailed to motivate the lowering of MRLs. The Commission reminded that the recitals already make reference to those MRLs which are recommended for lowering in the respective EFSA Reasoned Opinions and that the current template for draft Regulations on Article 12 reviews had been agreed with other Commission services previously. The Commission proposed that it would consider including some more general information on the approach used for all Article 12 draft Regulations in the Commission Working Document (CWD) that is currently already under revision (see agenda item A.01.05). Adding more details in the recitals would make the draft Regulations overly complex and might not contribute to clarity.

Regarding the MRLs for fluopicolide in the subgroup "Others" within the groups of 0220990-Bulb vegetables, 0242990-Head brassica, 0251990-Lettuces and salad plants, 0256990-Herbs and edible flowers, Member States were informed that, in line with the discussion held under agenda item A.01.05, a justification would be needed for substantiating any deviation from the general principles laid down in that document.

The Commission informed that the draft Regulation would be notified under the WTO SPS agreement directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in September.

Member States were invited to submit comments by 30 June 2020.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products.

The Commission introduced the draft Regulation and presented its content.

A Member State informed that modified MRLs for bixafen had not been considered in the draft Regulation due to some residue levels which were reported incorrectly and therefore had impacted the recommendations in the underlying EFSA Reasoned Opinion..

EFSA informed of a corrigendum of the Reasoned Opinion for bixafen that was imminent. (Post-meeting note: the corrigendum was published on 16 June 2020).

Member States were invited to submit comments by 17 July 2020.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products.

The Commission informed that, in line with the comments received from the Member States, the latest version of the draft Regulation proposes to set a temporary MRL for chlorpropham in potatoes at 0.4 mg/kg. This value is supported by both monitoring data and GLP trials investigating residue levels following storage in contaminated facilities and considers the possible formation of 3-chloroaniline, which is the metabolite driving the risk assessment. An annual reporting of measured levels and of progress with cleaning practices is also required (see agenda item A.03.04).

The Commission clarified that it will add a specific recital in the draft Regulation outlining the main health concerns identified by EFSA in relation to the substances contained in the draft Regulation, for which approval had recently no been renewed due to these concerns. This will provide further clarification on the rationale for not proposing transitional measures for those substances.

The Commission informed that the draft Regulation would be notified under the WTO SPS agreement directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in September.

Member States were invited to submit comments by 30 June 2020.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for chlordecone in or on certain products.

The Commission outlined the contents of the draft Regulation, which is currently undergoing the Commission's internal consultation procedures.

One Member State confirmed that it supports the draft Regulation, but that it had some reservations in relation to the rounded values for certain products of animal origin. The Commission re-iterated that EFSA has recommended values considering the existing guidelines on the OECD MRL calculator.

The Commission informed that the draft Regulation would be notified under the WTO SPS agreement directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in September.

Member States were invited to submit comments by 30 June 2020.