EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)6451974

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
28 - 29 September 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/d42302cf-a9b1-4d88-a0a4-4576aaa900e7*

SUMMARY REPORT

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

1. **Priorities under Art. 12 – updated table:**

The Commission presented the updated table.

The Commission informed the Committee that due to the recent withdrawal of the application for renewal of approval of thiophanate-methyl by the applicant, it will present a draft Regulation on the non-renewal of approval for an opinion of the Committee in its section Phytopharmaceuticals – Legislation. The Commission set out the next steps of the follow-up work on the maximum residue levels (MRLs) for carbendazim and thiophanate-methyl.

A Member State requested to swiftly start the MRL review under Article 12 of Regulation (EC) No 396/2005, in view of the concerns identified in the EFSA conclusions of the peer review.

2. **Confirmatory data Art. 12 follow-up**:

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

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

As regards abamectin, EFSA indicated in the conclusions of the peer review that there might be acute risks in relation to some commodities and that a review of the MRLs is necessary in view of the lowered toxicological reference values (TRVs). The Commission proposed to take note of the changed TRVs in advance of a decision on the possible renewal/non-renewal of the substance at the section Phytopharmaceuticals - Legislation of the Committee and ask EFSA to assess the safety of the existing MRLs also considering the ones that were proposed in a recent Reasoned Opinion, which were not yet implemented in EU legislation.

As regards azoxystrobin in products of animal origin, risk managers are to decide whether the low exposure would justify waiving the submission of data on the general toxicity of the metabolites L1, L4 and L9 as was proposed by the

Rapporteur Member State in the context of the Reasoned Opinion on the Evaluation of confirmatory data following the Article 12 MRL review. The MRLs for liver, kidney and other edible offal should be set at the LOQ (0.01* mg/kg), in line with the EU dietary burden calculated under the current assessment.

Member States were invited to submit comments on abamectin by 7 October 2020 and axozystrobin by 23 October 2020.

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

The Commission informed that it was currently preparing a draft Regulation regarding MRLs for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb, prothioconazole and silthiofam to follow up on the submission or non-submission of Article 12 confirmatory data. A first draft Regulation is expected to be presented at the next meeting of the Committee.

The Member States and EFSA were invited to provide further input and clarifications in particular on 2,4-DB, ethofumesate, fenhexamid, pyridate and sulfosulfuron by 23 October 2020. Upon consideration of the comments those substances will be included in a future draft measure.

3. **Residue definition for risk assessment**

The Commission referred to the discussions at the meeting of this Committee on 15/16 June 2020 and thanked Member States and EFSA for the written feedback received. It explained that further coordination among different Commission services is necessary, before it will be able to present concrete suggestions to the Committee.

4. **Added: amended Commission Working Document (CWD) for drafting Art. 12 measures** – for Note Taking (SANCO/11485/2012 – Rev. 8)

The Commission presented the amended CWD for drafting Article 12 measures (revision 8) and outlined the main changes compared to the last version of the document. The procedure for setting MRLs at the Limit of Quantification (LOQ) was clarified: in order to avoid putting an unnecessary burden on the enforcement authorities, in general lower LOQs than the default value of 0.01 mg/kg should not apply, except in particular cases, where a risk has been identified in relation to the default value of 0.01 mg/kg (e.g. warfarin, fipronil, carbofuran) for specific commodities of concern, provided that such low levels can be achieved by enforcement laboratories across the EU. In addition, roundings of certain MRLs were aligned with the OECD MRL Calculator[1]. For the subgroup "others" of specific commodity groups, the Commission highlighted the importance of following the ALARA ("As Low As Reasonably Achievable") principle. According to the Working Document the LOQ should be set at the default unless a good justification to deviate was provided by a Member State (e.g. in case that a national authorisation covers the subgroup "others").

The Committee took note of revision 8 of the CWD for drafting Article 12 measures.

[1] OECD MRL Calculator User Guide (Series on Pesticides, No. 56); OECD MRL Calculator Statistical White Paper (Series on Pesticides, No. 57, www.oecd.org

5. **Overview on import tolerance requests since 2009**:

   The Commission had prepared an overview table on import tolerances granted since 2009 as a result of an access to document request. The table was reviewed with assistance of a Member State. After a further review by the Member States the table will be published on the webpage of the Directorate-General for Health and Food Safety.

   Member States welcomed the initiative and proposed to integrate information on import tolerances in the EU Pesticides Database.

   The Commission clarified that, while it thinks that this would be a good idea, it currently lacks the resources to extend this task any further.

   Member States were invited to submit comments on the overview table by 23 October 2020.

6. **OECD calculator:**

   The Commission informed the Committee of the new revision of the OECD MRL calculator, which was recently released to address a mistake that had been encountered when sorting values for residue trials. The Commission asked the Member States whether the EFSA MRL calculator reporting also the old methodology (Rber/Rmax) is still needed. Some Member States stated that the old methodology would no longer be needed for evaluations, as in 2012 it was agreed that only the OECD calculator would always be used, therefore a reference to it on the DG Health and Food Safety webpage might no longer be needed. Nevertheless, some Member States considered it a useful tool for internal use for comparison of non-standardised datasets as it would provide a better understanding of the residue behaviour. Member States were invited to submit comments by 16 October 2020.

A.02 Feedback from Legislation Committee:

1. New active substances currently under discussion in the section Phytopharmaceuticals – Legislation of the Committee

   The Commission informed about three new active substances added to the agenda of the section Phytopharmaceuticals - Legislation of the Committee since the last meeting of this section of the Committee in June 2020:

   – 24-Epibrassinolide

   – Bacillus amyloliquefaciens strain AH2

   – Aqueous extract from germinated seeds of sweet Lupinus albus

A.03 Specific substances:

1. Glufosinate ammonium

There was no news as regards this agenda item.

2. Glyphosate

There was no news as regards this agenda item.

3. Indolylacetic acid

The Commission recalled that based on the discussion on indolylacetic acid in the meeting of this Committee in June, it had been agreed to reflect on a way forward for substances for which natural background levels exist, but which are not recommended to be included in Annex IV of Regulation (EC) No 396/2005 by EFSA (no MRL necessary). The Commission had started gathering information on such substances and is in the process of making an inventory. In a next step the criteria to be used for prioritisation of substances should be defined in view of possible future collection of background data for these substances. The Commission intends to present an initial list to the Member States at the next meeting of this Committee.

4. Mancozeb

There were no updates on this agenda item as a vote had not yet taken place in the section Phytopharmaceuticals – Legislation on the possible (non-)renewal of approval of the active substance.

5. Imazamox

On the basis of an EFSA Reasoned Opinion under Article 10 of Regulation (EC) No 396/2005 and the comments submitted by Member States after the last meeting of this Committee, the Commission concluded that it is not necessary to amend the residue definition for monitoring to include metabolite CL 263284. The Commission will inform the applicant accordingly and propose to address the MRL application for soya beans in a future measure lowering the existing MRL from 0.05* mg/kg to 0.03 mg/kg.

6. Kresoxim-methyl

On the request of a Member State, the Commission clarified that the correct residue definition for monitoring for kresoxim-methyl in animal products is "metabolite BF 490-9, expressed as kresoxim-methyl". This was agreed by risk managers in the framework of the Article 12 review. However, Regulation (EU) 2016/486 reported the old residue definition by mistake, which was also reflected in a Reasoned Opinion (EFSA, 2018) and this created some confusion. The correct residue definition was then re-instated by Regulation (EU) 2019/1015 and reflected in Regulation (EU) 2020/856. Also the EU Pesticides Database reports the correct residue definition that was agreed in the Article 12 review.

7. Chlorothalonil

The Commission outlined the contents of a recently adopted EFSA Reasoned Opinion on the confirmatory data following the Article 12 MRL review for chlorothalonil, including assessments for import tolerances for banana, papaya and peanuts. EFSA concluded that the residue trials supporting the MRL for peanuts do not lead to a change of the existing MRL, the MRL for papaya leads to an acute concern and the MRL for bananas leads to a slightly higher LOQ proposal at 0.02 mg/kg accompanied by a number of uncertainties. Moreover, the latter use relates to bagged bananas only. EFSA confirmed that studies investigating the effect of high temperature processing on the magnitude of SDS-3701 in processed products are not available. For the metabolite SDS-3701 the toxicological profile is not fully elucidated and therefore toxicological reference values could not be derived. Hence, for this metabolite the consumer risk assessment cannot be finalised.

In view of the above, the Commission intends to move ahead with lowering all MRLs for chlorothalonil to the LOQ, as proposed in the draft Regulation discussed under Agenda Point B.05.

8. Ethirimol – correction of MRL

The Commission informed that a Member State had noticed that the residue value for ethirimol in cucumbers had by accident been wrongly reported in the Evaluation Report. As a consequence, potential unjustified MRL exceedances could result from this mistake. The Commission had asked the Evaluating Member State to urgently send a corrected Evaluation Report to EFSA, who then swiftly corrected the Reasoned Opinion (published in the EFSA Journal on 30 Sep 2020[2]).The correct MRL can be re-instated by the next draft Regulation setting MRLs following applications.

9. Carbendazim, benomyl, and thiophanate-methyl: Discussion under agenda item B.1 of the agenda of the section Phytopharmaceuticals, Legislation of 29 September 2020

See also agenda item A.01.1.

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 35 question numbers had so far been addressed in 2020, 19 since the previous meeting of this Committee in June 2020.

Currently, 75 question numbers are at different steps of the procedure. Out of these, 21 relate to import tolerance applications, 15 to confirmatory data assessments and 8 to applications dealt with in the context of the renewal of approval process. 48 question numbers are currently under clock-stop. Out of these, 13 relate to import tolerance requests, 8 to confirmatory data assessments and 6 to applications dealt with in the context of the renewal of approval process.

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

EFSA presented the state of play of the ongoing Article 12 reviews. 30 active substances are currently under review and at different stages of the procedure, including one statement that is under preparation for substances that do not require an MRL review.

EFSA informed the Committee about various points concerning the group MRL review for dithiocarbamate substances, planned to start in November/December 2020, to promote a common understanding of the specificities of this review with Member States, EU Reference Laboratories for Residue of Pesticides and the Commission.

The Commission presented an updated work programme for 2020 with minor changes. The Committee agreed with the revisions as presented.
The Commission presented a draft work programme for 2021. It asked Member States to submit comments in writing by 16 October 2020, with a view to agreeing

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for bupirimate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17 (7):5757.

the 2021 work programme at the next meeting of this Committee on 23/24 November 2020.

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

EFSA reported that four specific requests of the Commission for assessments under Article 43 of Regulation (EC) No 396/2005 were currently ongoing:

- Two draft reasoned opinions on fosetyl / phosponates and spinosad expected to be circulated to the Member States consultation step in October 2020;
- one draft reasoned opinion for methoxyfenozide expected to be adopted by 31 October 2020;
- one draft reasoned opinion on propoxur expected to be adopted by 20 December 2020.

EFSA also informed about progress with the mandate on copper dealt with by EFSA's Scientific Committee for which a first working group meeting had already taken place in September 2020. The deadline for the EFSA scientific opinion is 31 December 2021. The requested opinion will also take into account the already existing outputs from specific EFSA Panels and units.

4. Implementation of the EFSA guidance document (GD) on stereoisomers

The Commission circulated the draft cover page for the EFSA guidance document and the proposed implementation plan in both the sections Phytopharmaceuticals - Legislation and Pesticides Residues. EFSA presented the main features of the detailed flow charts for Article 10 and Article 12 MRL processes. The Commission also informed about further information material uploaded on CIRCABC and the planned process for taking note of the document in the October meeting of the section Phytopharmaceuticals - Legislation of this Committee (post-meeting note: taking note of the document will be postponed to the meeting of that section in December 2020).

The Commission asked for comments by 7 October 2020 on the cover page in view of its finalisation.

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

EFSA gave an overview of the feedback received from the Member States. The risk mitigation measures for rotational crops vary in the Member States. Most of Member States that took the floor supported setting somewhat higher MRLs that would take into account residues from rotational crops instead of taking other risk mitigation measures as they consider this would be easier to enforce.

EFSA invited the Member States to participate in a new working group for the development of a technical report to support the interpretation of the OECD Guidance document in rotational crops.
Member States were requested to signal their interest to EFSA by 9 October 2020.

6. Other

No items were raised under this agenda item.

A.05 New Transparency rules:

The Commission clarified that it no longer intends to review the existing Technical Guidelines on the MRL Setting Procedure (SANTE/2015/10595 Rev. 5.4) to reflect the amendments brought by the new Transparency rules. These new aspects are sufficiently

outlined in the horizontal Practical Arrangements (PAs) and the relevant guidance document, which are currently being prepared by EFSA.

EFSA gave an update on the state of play of the development of the PAs and guidance.

A.06 Update of the Communications on data requirements:

The Commission informed the Committee of the planned update of two Commission Communications supplementing Regulations 283/2013 and 284/2013 on data requirements to reflect current scientific and technical knowledge. The Communications will provide a consolidated list of internationally validated test methods and guidance documents which will become mandatory once they feature on the lists. The project, initiated in 2018, was recently resumed. Member States and stakeholders will be consulted on a draft version, most likely by end of 2020, before the Commission launches the adoption procedure.

A.07 Monitoring of pesticides residues:

The Commission reminded of the e-mail circulated to the members of the Committee concerning the planned Working Group meeting in preparation of the Union monitoring programme for 2022, 2023 and 2024 to be held on Friday 9 October 2020. Member States were reminded of the deadline to nominate experts by 30 September 2020.

A.08 Foods for infants and young children:

Member States were invited to review the draft measures amending Delegated Regulations (EU) No 2016/127 and No 2016/128 with regard to the requirements on pesticides for infant formulae and follow-on formulae and food for special medicinal purposes, respectively and provide their comments to their colleagues participating in the expert group on food intended for infants and young children for which the unit dealing with food information and composition in DG Health and Food Safety is in charge.

The Commission provided an update on the project for the development of analytical methods with lower LOQs for infant formulae and informed that both the EURL for single residue methods and for commodities of animal origin had concluded their work. Both laboratories, having shared the workload on the substances with very low health-based guidance values[3], developed sensitive analytical methods[4,5] and analysed 54 liquid milk samples from 21 countries and 80 samples of infant formulae from 25 countries. Results were re-assuring as none of the substances of concern (fluquinconcazole, alpha-cypermethrin, ethoprophos, gamma-cyhalothrin, emamectin and chlorpyrifos) were detected in the samples analysed.

A.09 Next steps for cumulative risk assessment:

EFSA provided an update on its work regarding CRA and clarified that even though this project extends beyond pesticides, its priority is on pesticide residues. EFSA envisions that by 2030 the routine implementation of human health risk assessment to multiple chemicals will be possible across EFSA´s domains of activity. This will

[3] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5286
[4] https://www.eurl-pesticides.eu/docs/public/tmplt_article.asp?LabID=300&CntID=1153&Theme_ID=1&Pdf=False&Lang=EN
[5] https://www.eurl-pesticides.eu/docs/public/tmplt_article.asp?LabID=200&CntID=1151&Theme_ID=1&Pdf=False&Lang=EN

include work on the combined exposure to multiple chemicals, on human health risk assessment and on dietary and non-dietary exposure.

EFSA focuses its work on four main work packages: in the field of **methods' development** emphasis is given to harmonised grouping criteria of substances, while concerning the development of tools, efforts address an **open source Monte-Carlo Risk Assessment (MCRA) software** on the basis of a modular platform. EFSA will seek further **data consolidation**, expanding its OpedFoodTox Database and including chemical occurrence in non-food media. The **application work** will initially focus on the dietary exposure to multiple pesticides, then on the aggregate exposure to multiple pesticides and finally on the aggregated exposure to multiple chemicals.

In the frame of the REFIT evaluation of pesticides legislation, the Commission and EFSA committed to developing an action plan on CRA by end of 2020. EFSA plans to work on the validation of the prioritisation method for Cumulative Assessment Groups (CAGs) and apply the method to deliver the first batch of new CAGs in 2022. Meanwhile, in 2020 EFSA will perform retrospective CRA on the chronic effects of pesticide residues on the nervous system and in 2021 on the acute effects on cranio-fascial malformations.

At the same time, EFSA is also working on prospective (pre-marketing) CRA, currently working on the development of prospective scenarios. To this end, EFSA developed a protocol for performing case studies, which was discussed during an experts meeting held by the Commission in June 2020 and which, following the comments from the experts, was finalised and circulated to the Member States. This protocol forms the basis for the case studies calculations that will be performed by the Dutch national institute for public health and the environment (RIVM). The results of those calculations will be discussed during an Expert Group that is expected to take place early 2021.

A.10 Project on data collection dithiocarbamates:

The EU Reference Laboratory on Single Residue Methods (EURL SRM) provided a list of commodities for which the number of samples collected is sufficient for statistical evaluation and identified commodities for which data is still missing. The list will be updated to include the data collected by EFSA from Member States in 2018. The data collected will feed into the planned review of the group of dithiocarbamates under Article 12 of Regulation (EC) No 396/2005 (see also pt. A.04.02).

A.11 New Official Control Regulation – delegated and implementing acts:

The Commission informed the Committee on its plan to set up a separate expert group dedicated to the discussion on a delegated act to re-establish the provisions of Article 27(1) of Regulation (EC) No 396/2005. A meeting, which still needs to be confirmed, is intended to take place in connection with the next meeting of this Committee in November, with a separate agenda.

The Commission introduced a draft Implementing Regulation, which covers provisions of Article 30 of the MRL Regulation. A Member State asked for explanation on the removal of the phrase "compliance with current legislation". The Commission clarified that this is covered in Recitals 2 and 3 but that further discussion is needed.

Member States were invited to submit comments by 23 October 2020.

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

There were no news as regards this agenda item.

A.13 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission gave an update on the state of play. Meetings are held on a regular basis on residue exposure and toxicology. Progress is being made in drafting the new revision and the expectation of the working group is to finalise the document in the first half of 2021. Discussions are also on-going on possibly considering biocidal products in relation to dual uses.

2. OECD Honey Guidelines

The Member State who attend the OECD working group on setting MRLs in honey gave an overview of the ongoing work. The working group is in the process of drafting the first version of the guidelines expected to be ready at the beginning of next year. There were discussions on the use of monitoring data, on which the working group concluded that they would not be sufficient to set MRLs. Other aspects discussed were the list of the crops that would trigger the need to set MRLs and the criteria to be used to take a decision on whether or not an MRL would be needed. Countries have different practices compared to the EU Member States. For example honey in Australia and New Zealand is produced in areas where there is almost no treatment. So they would prefer not to set MRLs, where not needed.

The next meeting of the OECD working group takes place on 6 October.

3. Codex Alimentarius/JMPR issues - future work organisation

- CCPR 2021 - working groups and substances

The Commission informed the Committee that the videoconference to prepare the EU position originally planned to take place in September 2020 had been cancelled, as sufficient progress was achieved through written procedures, which will continue in the weeks ahead. It thanked Member States for their active contribution to develop coordinated replies to various Circular Letters.

The Commission referred to the recent publication of a scientific article on a probabilistic acute exposure assessment in relation to Codex MRLs, led by WHO. The Commission asked Member States to share any comments or observations on the relevance of this publication with regard to the work of the electronic Working Group on the IESTI equations by 23 October 2020.

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

The Commission acknowledged all the contributions to the revision of the extrapolation guidelines and presented the proposed way forward for the points discussed in the last meeting of this Committee in June 2020. EFSA presented an Excel tool providing specific information on the number of residue trials and on recommended extrapolations. The tool will be used by EFSA internally but may also be useful for Member States as supplement of the guidelines. The Commission thanked EFSA for this work and considers this a very valuable practical addition to the guidelines. The

Commission plans to finalise the extrapolation guidelines and take note of the document in the next meeting of this Committee on 26/27 November 2020. The suggested application date is 1 December 2020.

Member States were invited to provide their last comments on the document and on the proposed application date by 23 October 2020.

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

The Member State working on the update of the analytical guidelines provided an overview of the new draft document which is based on the above mentioned documents, along with an overview of the comments received. Member States were invited to submit their comments by 30 November 2020 directly to that Member State.

A.16 Notifications under Article 18(4) to Reg. (EC) No 396/2005:

There were no notifications under 18(4) of Regulation (EC) No 396/2005.

A.17 Designation of Member States for maximum residue levels (MRL) applications:

At the meeting of this Committee in June 2020, Member States had been asked whether they would be willing to become the Evaluating Member State in relation to an MRL application covering a set of import tolerance requests for fenpropathrin. The Netherlands had informed the Commission that it would take the lead in assessing the MRL application. The Committee agreed on this and took note of the decision. The Commission thanked the Netherlands for their support.

A.18 Farm to Fork Strategy/REFIT:

The Commission informed the Committee about the ongoing discussions in the Council in view of adopting Council Conclusions under the German Presidency on the Farm to Fork Strategy and the REFIT evaluation of pesticides legislation and gave the floor to the German delegation for further details on the outcome of the Council working group that took place on 18 September 2020. The German delegation informed that the discussions were not yet finalised and that Member States had been given a deadline of 9 October 2020 to comment to the Council secretariat. The Commission highlighted that careful reflection about priorities would be necessary in view of the long wish list of Member States on the follow up to the REFIT evaluation, and the resources available, both in the Commission and in Member States.

<u>REFIT follow-up actions already started:</u>

The Commission informed about the progress with certain commitments made in the REFIT report on the evaluation of pesticides legislation. It is planned to give some guidance to Member States in respect of enforcement action on <u>processed products.</u> A document will be prepared, but its format is not yet decided, as it will depend on many factors such as the content, size, etc. The aim of this document is not to establish harmonised processing factors or to work towards specific MRLs for all processed products. The intention is rather to use the flexibility given by Article 20 of Regulation (EC) No 396/2005 and give some guidance to Member States how to apply processing factors using the best information available, in order to ensure a more harmonised procedure among Member States.

The Commission intends to present a first version of the document at the next meeting of the Committee in November 2020.

A.19 Overview on substances in forthcoming Art. 12 draft Regulations:

The Commission presented an initial overview of the substances covered by forthcoming draft Regulations:

- Imidacloprid (Article 12 review);
- Glyphosate (already mentioned under A.03.2);
- 6-benzyladenine, aminopyralid and chlorantraniliprole;
- Meptyldinocap, flubendiamid, metaflumizone, amisulbrom and propineb.

A.20 Other Information points:

1. Classification of coffee leaves as (novel food) under Annex 1 to Reg. (EC) No 396/2005

Based on the comments received from Member States after the meeting of this Committee in June 2020, the classification of coffee leaves should be in the category "others" of the group 0632990 "Herbal infusions from leaves and herbs".

2. Update on measures with regulatory scrutiny (PRAC measures) voted in February

The Commission gave an update on the state of play of the draft Regulations that had received favourable opinions by this Committee in its meeting in February 2020.

The Commission informed that the European Parliament, in its plenary session on 17 September 2020, had adopted with majority a motion for resolution opposing the draft Regulation containing MRLs for a range of different substances, including haloxyfop, mandestrobin and flonicamid, which were the substances of concern to the Parliament. An earlier version of that draft Regulation had already received an objection by the Parliament in November 2019, as it contained at the time an import tolerance for clothianidin in potatoes, which had been subsequently removed from the draft Regulation before it was re-submitted for vote in this Committe. At that time the Parliament had not raised any concern with regard to haloxyfop, mandestrobin and flonicamid.

The Commission explained that it was currently carefully analysing the options how to proceed, including reflections on how to deal with MRLs already proposed in subsequent draft Regulations that are impacted by the objection as they contain partially the same substances. It added that the objection had also already resulted in delays with several routine applications (flonicamid, fosetyl and oxathiapiprolin) which had been put on hold awaiting the Parliament's vote.

Two Member States voiced their strong disagreement with this objection by the European Parliament and their concern about the arguments that had been used to motivate this objection. One Member State indicated that the delay with the regular setting of MRLs for flonicamid had already forced it to grant emergency authorisations for this substance in carrots. The other Member State added that decisions should continue to be taken on the basis of science.

Another Member State requested to get the link to the texts of the 2019 and 2020 objections as regards that particular draft Regulation. The Commission provided the links to the Parliament's webpage:

https://www.europarl.europa.eu/doceo/document/B-8-2019-0138_EN.html

https://www.europarl.europa.eu/doceo/document/B-9-2020-0245_EN.pdf

3. Readiness and preparedness for the end of the transition period of the UK Withdrawal agreement

The Commission recalled that a readiness note was available on its website for the area of plant protection products (https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/getting-ready-end-transition-period_en) and informed that there were no new developments.

4. Chlorate in white peppercorn

The Commission informed of a letter from the European Spices Association (ESA) concerning elevated levels of chlorate residues in white pepper. According to ESA the current MRL of 0.07 mg/kg for chlorate on this commodity cannot be met and suggested that an alternative regulatory approach should be considered, due to the introduction of chlorate residues during production via potable water.

The Commission reminded that footnote (A) of the Annex of Regulation (EU) 2020/749 provides the basis for taking into account the additional contributions of chlorate residues for processed food products when determining the permitted content of chlorate in food and in accordance with paragraph (1) of Article 20 of Regulation 396/2005.

5. Questions from a Member State on analytical issues

A Member State requested information from the other Member States on how to deal with analytical uncertainly in the context of official controls and a company's own checks and with analytical problems in case of analysis for residues of dithianon. Several Member States gave feedback on the question. While it was clear that for official controls the analytical uncertainty (default 50%, or lower, if appropriate) was always taken into account, there were diverging views on whether this should also apply to a company's own checks. Some Member States were of the view that for own checks the exceedance of the MRL without taking into account uncertainty would be more appropriate. The Commission stated that company's own checks were the responsibility of business operators who had to ensure that they acted in due diligence and that it would refrain from interfering with their responsibility.

6. Question from a Member State on how other MSs deal with chlorate residues on processed food

A Member State raised the question on which level of chlorate content should be considered for water used in processing, the WHO guideline value[6] of 0.7 mg/L or the level provided by the Food Business Operator (FBO). Another Member State informed that there is an on-going discussion in a working group of official laboratories and private laboratories exchanging information regarding chlorate

[6] https://www.who.int/water_sanitation_health/dwq/chemicals/chlorateandchlorite0505.pdf

levels in water. Another Member State highlighted that a harmonised approach would be challenging and that similar issues will come up in the future.

7. Info from BE on ethylene oxide in Indian sesame seeds

Belgium informed the Committee of their recent findings of ethylene oxide in sesame seeds imported from India at levels vastly exceeding the MRL. It referred to the pertinent RASFF notification for further information. The Committee agreed that all Member States should be vigilant and take this information into account in their ongoing monitoring and control activities.

8. The Multi Annual National Control Plan (MANCP) 2021 for pesticide residues

The Commission reminded on behalf of EFSA the Member States who had not yet sent their MANCP of 2021 to EFSA to do so through Teams by end of September.

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) No …/… amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, cow milk, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products (Art. 10).

The Commission outlined the draft Regulation and its contents.

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

- Boscalid for the use on pomegranates and to increase the existing MRL in honey and other apiculture products following the use on rapeseed;
- Etofenprox for the use on plums;
- Lambda-cyhalothrin for the use on seed and fruit spices;
- Maleic hydrazide for the use on chicory roots;
- Mefentrifluconazole for the use on pome fruits, apricots, cherries, peaches, plums, grapes, potatoes, sweet corn, maize, sunflower seeds, rapeseeds/canola seeds and sugar beet roots;
- Sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate for the use on grapes, strawberries, raspberries, currants, maize/corn, rice, wheat and hops;
- Triclopyr for the use on kiwi fruits.

The draft Regulation also proposes the inclusion of the active substance ferric pyrophosphate and the basic substances L-cysteine and cow milk into Annex IV to Regulation (EC) No 396/2005.

As regards the occurrence of nitro-phenolates in hops, EFSA highlighted that there is a mistake in the relevant Reasoned Opinion, which is the process of being corrected. The

correct value for hops is 0.3* mg/kg instead of 0.03* mg/kg. The Commission had prepared a new revision (Rev. 3) to address this mistake.

During the meeting, one Member State indicated that the MRL for boscalid in honey and other apiculture products should reflect the monitoring data from official controls rather than the residue trials, the latter resulting in a higher MRL proposal. Another Member State reacted by stating that residue trials would be the most appropriate way to reflect residues in honey. If using monitoring data in addition, data from official control would not be sufficient to have a clear understanding on the occurrence, and further data from stakeholders would be required.

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 on the proposed draft as presented.

Austria asked for the following statement to be recorded in the minutes of the meeting:

"Austria favors lower temporary MRLs based on monitoring data. Austria does not agree with a permanent MRL of 0.15 mg/kg due to field trials".

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 diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products (Art. 12).

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.

The Commission pointed out that for fluopyram in the subgroup "others" of other small fruits and berries, other root and tuber vegetables except sugar beets, bulb vegetables, flowering brassica, head brassica and leafy brassica two Member States had requested to deviate from the standard approach established in the Working Document for drafting Article 12 measures (see discussion under Point A.01.04) and use the MRL of a certain commodity of the group instead of the LOQ. This was agreed since relevant justifications were provided.

A Member State expressed some concerns in relation to fluopyram and the contribution of certain Codex maximum residue levels (CXLs) (mango, soybeans, potatoes and peanuts) to the overall chronic exposure. The CXLs had been taken over in EU legislation last year. EFSA clarified that they had verified the information received from the applicant and as the chronic risk remained too high, the CXLs for these commodities were not proposed to be maintained. The Commission proposed to lower the MRLs for these commodities as suggested by EFSA.

A Member State stated that it would prefer a separate draft Regulation on fluopyram alone, instead of a multi-substance measure due to its concerns with fluopyram as regards existing import tolerances and the contribution from rotational crops that would lead to exposures close to the ADI. It announced it would abstain if fluopyram stayed in the current draft Regulation.

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 on the proposed draft as presented.

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 as regards maximum residue levels for fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat (Art. 12).

The Commission explained the changes made in Revision 3 related to the MRLs for fluxapyroxad for the group garlic, onions and shallots (to cover values from rotational crop field studies) and of oil palm fruit, kapok and some animal commodities (to cover existing CXLs). The Commission outlined the amendments to be included in revision 4, following the discussions of the Committee, to include the MRL for apricots to cover the CXL adopted in Regulation (EU) 2017/626 and the MRL for the group of lettuce and salad plants to cover authorised uses of a Member State that had provided an evaluation report with the pertinent information. The Commission informed about a Corrigendum that EFSA is preparing with corrections of mistakes in fluxapyroxad levels on several crops, e.g. apricots, mangoes, tomatoes, sweet peppers, aubergines/eggplants okra/lady's fingers, globe artichokes, poultry muscle.

The Commission outlined the amendments for metamitron in Revision 3 which included values for thyme to cover the less critical Good Agricultural Practice (GAP) reported by a Member State.

One Member State reminded that fluxapyroxad is persistent and believed that appropriate risk mitigation measures for rotational crops should be applied.

A Member State announced the intention to vote against the proposal due to values derived from import tolerance applications for fluxapyroxad in "other root and tuber vegetables (except sugar beets)" as the EU uses would lead to lower MRLs.

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.04 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 benalaxyl, benalaxyl-M, dichlobenil, fluopicolide, proquinazid, and pyrdalyl (Art. 12).

The Commission reported on the comments received by Member States and provided Revision 3 of the draft Regulation. This version had been notified to the members of the World Trade Organisation (WTO) via the Sanitary and Phytosanitary (SPS) notification procedure and the Commission reported on the comments received.

Regarding the comments received from the German Hops' Association which questioned the proposed level for hops, it was clarified that the MRL for fluopicolide on hops, proposed at the level of 0.15 mg/kg, was derived from EU GAP-compliant

trials, whilst Codex CXLs do not exist for this crop/pesticide commodity. On this matter, a Member State reminded that the previous reported GAP was based on a 2-times application, while the current GAP includes only one application.

Another Member State commented that in view of the non-renewal of approval of benalaxyl, its MRLs will need to be reviewed again after the expiry of any grace periods that Member States may have granted.

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.05 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 carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products.

Following the notification of the draft Regulation to the members of the World Trade Organisation (WTO) via the Sanitary and Phytosanitary (SPS) notification procedure, the EU had received comments from third countries and stakeholders' associations. The Commission went through the various concerns expressed in relation to the lowering of MRLs for several substances in various commodities.

A Member State raised some concerns in relation to the applicability of Article 17 of Regulation (EC) No 396/2005 in relation to the lowering of MRLs, which correspond to import tolerance requests or CXLs. The Commission clarified and confirmed that this had been investigated and confirmed internally several times as being the appropriate legal basis.

On the request of another Member State, the Commission clarified that due to the various procedural steps and the deferred application date, the new MRLs will not become applicable before the end of summer 2021. A Member State announced that it would not support the current measure in line with its earlier position in relation to the non-renewal of approval of the active substance fenamidone.

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.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlordecone in or on certain products.

The draft Regulation had been revised to reflect the outcomes of the internal consultation between Commission services. The wording was further improved to clearly indicate that EFSA considered the OECD MRL calculator rounding rules, which lead to MRL proposals, which are slightly different from the ones recommended by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).

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 Draft(s) presented for discussion

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 informed the Committee that it had received a report submitted by the applicant of clethodim containing study results intended to clarify the open questions on the possible genotoxic potential of 3 chloro-allyl-alcohol. Two Member States and EFSA had already looked at the report and had given their preliminary views that based on the results it was not possible to conclude on the genotoxic potential of 3 chloro-allyl alcohol due to shortcomings in the studies and deviations from the OECD protocols. The Rapporteur Member State in charge of the forthcoming renewal of approval of the substance presented a summary on its initial conclusions. In view of this, the Commission proposed to lower all clethodim MRLs to the LOQ considering however the possibility of setting a transition period for products placed on the market before the application date.

Several Member States supported the Commission's proposal. The Commission asked Member States for their feedback by 23 October 2020.

After that, the draft Regulation would be notified to third countries through the WTO/SPS notification procedure in view of a vote in the meeting of this Committee in February 2021.

C.02 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 (Art. 12).

The Commission introduced the draft Regulation and gave an overview of the comments received. The Commission informed the Committee of the concerns of one Member State on the MRLs of spinetroam in cresses and other sprouts and shoots and land cresses. The MRLs had been established in Commission Regulation (EU) 2017/1777[7] after a favourable assessment by EFSA[8]. However, since authorisations had not yet been granted at the moment of launching the Article 12 MRL review, no GAPs were reported to EFSA at that moment. Given that authorisations were now granted in that Member State and a safe MRL was very recently established, the Commission considered it appropriate to maintain those MRLs. A short evaluation report was requested from the Member State for transparency, including information on the GAP,

[7] Commission Regulation (EU) 2017/1777 of 29 September 2017 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 Bacillus amyloliquefaciens strain FZB24, Bacillus amyloliquefaciens strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and Urtica spp. in or on certain products , OJ L 253, 30.9.2017, p. 1–31

[8] Reasoned opinion on the modification of the existing maximum residue levels for spinetoram in various crops. EFSA Journal 2017;15(5):4867

reference to the already existing EFSA Reasoned Opinion covering this use and an updated PRIMO calculation, if appropriate.

The Commission informed that the draft Regulation would be notified to third countries through the WTO/SPS notification procedure directly after the end of the commenting deadline in view of the planned vote in the meeting of this Committee in February 2021.

Member States were invited to submit comments by 23 October 2020.

C.03 Exchange of views of the Committee on a draft Commission Regulation adapting the coordinated multiannual programme for pesticides residues for the years 2021, 2022 and 2023 in view of the withdrawal of the United Kingdom from the Union – adaptation of minimum sample numbers to be taken and analysed by Member State.

Following the withdrawal of the United Kingdom from the Union, the Commission had mandated EFSA to re-calculate the samples to be taken by Member States and the UK in respect of Northern Ireland (NI) based on the EU's new population distribution and considering the much smaller population of NI compared to the United Kingdom.

EFSA presented its recently published study on the re-calculation of samples following Brexit[9], indicating that statistical bias could be introduced in the case of discrepancies between the numbers calculated in the study, the numbers included in the draft measure and the number of samples actually provided by the Member States.

The Commission reminded of the discussion held in the Experts Meeting on the monitoring of pesticide residues in October 2015, where it had been agreed for specific practical reasons that each Member State would provide a minimum number of 12 samples per commodity per year. A Member State supported this view. The Commission suggested to further discuss this issue during the upcoming Experts Meeting on 9 October 2020 and invited EFSA to evaluate the possible bias introduced over the past 3 years.

Member States were invited to provide their comments by 2 October 2020. It is planned to vote on this draft Regulation in the meeting of the Committee, Section Phytopharmaceuticals – Legislation in its meeting on 22-23 October 2020 in view of the urgency of adopting this Regulation before the end of this year.

[9] European Food Safety Authority, "Pesticide Monitoring Program: Re-allocation of number of samples considering population changes", doi: 10.2903/sp.efsa.2020.EN-1933