EUROPEAN COMMISSION



Health and Food Safety Directorate General

sante.ddg2.g.5(2019)8542342

Standing Committee on Plants, Animals, Food and Feed Section *Phytopharmaceuticals – Pesticide Residues* 25 - 26 November 2019

CIRCABC Link: https://circabc.europa.eu/w/browse/ee829df7-83ec-4f3b-9b0c-1a53d8760a75

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 enquired about the state of play regarding pyrethrins, in view of its request at previous meetings that a decision on the confirmatory information submitted under Regulation (EC) No 1107/2009 for pyrethrins had been taken before the renewal decision, to allow initiation of the maximum residue level (MRL) review as soon as possible.

The Commission reiterated its explanation that a decision on pending confirmatory information under Regulation (EC) No 1107/2009 should be taken first because that information pertains i.a. to the residue definition.

2. Confirmatory data Art. 12 follow-up

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

The Commission prepared a revised table on the agreed risk management decisions that were taken on the basis of several Reasoned Opinions. Most of the substances were included in draft measure SANTE/12092/2019, which was discussed under Agenda Point C 10.00.

3. Follow up on EFSA statement on substances for which no Art. 12 review is required

The Commission presented the table with follow up actions by the Commission on the substances in the statement.

No action is required for linuron, buprofezin, orthosulfamuron and Bacillus thuringiensis subsp. Tenebrionis (NB 176 (TM 14 1)) as specific limits of quantification or the general default level according to Article 18(1)(b) of Regulation (EC) No 396/2005 already apply.

For imazaquin and maltodextrin further discussion is needed, therefore they will be taken out of this statement. The Rapporteur Member State (RMS) for imazaquin highlighted the existence of an import tolerance for imazaquin, covered by the current MRL of 0.05* mg/kg which would need to be considered if the limit of

quantification (LOQ) was lowered. The EU Reference Laboratories (EU RLs) would first need to be consulted.

Inclusion of limestone, pepper dust extraction residue (PDER), sea-algae extract and trimethylamine hydrochloride to Annex IV will be made permanent by removing the footnote indicating the temporary nature of Annex IV inclusion in a forthcoming routine MRL proposal.

For sodium aluminium silicate, 1-4 diaminobutane and ammonium acetate permanent inclusion into Annex IV could be an option. 1,4-diaminobutane shows high background levels in food. It was clarified that ammonium acetat is no longer used as a food additive.

One Member State asked for clarification on the residue definition that should be looked at for sodium aluminium silicate.

Member States were invited to submit comments by 31 December 2019.

A.02 Feedback from Legislation Committee:

1. New active substances currently under discussion in the Legislation Committee

The Commission informed that only one active substances, pydiflumetofen, was added to the agenda of the Standing Committee on Plants, Animals, Food and Feed – Section Phytopharmaceuticals Legislation since the last meeting of this Committee.

A.03 Specific substances:

1. Copper MRLs

The Commission thanked Member States for their responses to the action points from the last meeting and provided an overview of the information. Overall, some delays in the renewal of authorisations are expected. The Commission proposed to take stock in advance of the meeting of this Committee planned for June 2020 to allow an informed discussion at that time.

EFSA pointed out that there is an Article 6 application ongoing for copper compounds, which may have an impact on the overall MRL setting.

A Member State asked whether the contribution of copper compounds in fertilisers will be taken into account. Another Member State expressed their expectation that the contribution from fertilisers will not have a strong effect.

2. *BAC/DDAC*

EFSA had extracted data for benzyldiammonium chlorid (BAC) and dodecyl diammoniumchlorid (DDAC) from its database on the national monitoring programme covering 2014 to 2017. A Member State had submitted its national data for 2018 and beginning of 2019. Relevant stakeholders recently informed the Commission that they would provide further data within the deadline of 31 December 2019.

The Commission will analyse all data received and discuss the possible way forward at the meeting of this Committee in February 2020.

3. Cyantraniliprole

The Reasoned Opinion for cyantraniliprole in Chinese cabbages, blackberries and raspberries was published on 22 November 2019. EFSA concluded that, although cyantraniliprole is hydrolytically stable under pasteurisation and sterilisation conditions, under boiling conditions it converts to two degradation products (IN-F6L99 and IN-N5M09) for which the toxicological profile is unknown and for which additional data have been requested in previous MRL applications submitted by the same applicants.

One Member State recently carried out a risk assessment where the Threshold of Toxicological Concern (TTC) approach was used and submitted an updated evaluation report to EFSA. EFSA noted that there are still some issues to be addressed.

The Commission informed the Committee that the Reasoned Opinion will be put on hold until it is clarified whether the two metabolites might pose a concern to consumers.

4. Glufosinate ammonium

There were no news as regards this agenda point.

5. Glyphosate

The Commission referred to the publication on 31 October 2019 of the EFSA Reasoned Opinion on the review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 – revised version, to take into account omitted data. The changes compared to the previous version are limited to 12 commodities or groups thereof, mostly affecting the information identified previously as missing, and in few cases the level of the derived MRL.

A Member State pointed out that the extraordinary JMPR meeting in May 2019 proposed draft Codex MRLs for glyphosate.

6. Anthraquinone

The Commission shared recent information received from the association of Tea & Herbal Infusions Europe (THIE) on an ongoing research project on anthraquinone and its possible environmental sources carried out together with a research institute on meteorology. Some data on smoked salmon had also been received from the EU Reference Laboratories showing lower than the LOQ analytical results. However, in dried mushrooms, levels above the LOQ were found in 22% of the samples, while fresh mushrooms did not contain such levels, confirming that drying methods may play a role. The Commission informed that the planned audit in China of its audit and inspection services was postponed to 2020 and that the Commission's Directorate-General for Agriculture had been in touch with third countries on the issue of anthraquinone in organic products.

7. Triazole Derivative Metabolites (TDMs) – update from the Commission

The Commission informed that toxicological endpoints and residue definitions for TDMs, will be presented for endorsement at the meeting of the SC PAFF – Section Phytopharmaceuticals, Legislation on 6 December 2019. Following the experts' meeting on the monitoring of pesticides residues in October 2019, the EU Reference Laboratories informed that isotope labelled standards exist for all 4 TDMs.

8. Dimethenamid-P

At the last meeting, Member States were invited to comment as to whether they would be in favour of changing the residue definitions in a routine MRL measure, considering that the Article 12 review had already been carried out in the past.

A Member State clarified that the analytical standards for the metabolites M26 and M31 were currently not available and these should therefore not be included in the residue definition for enforcement purposes. The Commission will confirm with EFSA whether those metabolites should be included in the provisional residue definition. In case the metabolites are relevant for the intended uses, the Commission will investigate with the applicant on the missing analytical standards.

9. Fenpropathrin

Fenpropathrin is an active substance that was never approved in the EU. MRLs for citrus fruits, melons, strawberries and tea, which correspond to import tolerance requests made in the past, were kept on a provisional basis in Regulation (EC) No 396/2005 pending the re-assessment by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). In 2015, the EU made a reservation in the Codex Committee on Pesticide Residues (CCPR) due to the lack of data on the technical specifications of the active substance used to derive the reference values and the residue definition.

The Commission proposed to lower the remaining MRLs to the relevant LOQs in a future measure.

10. Chlorpropham

The Commission gave an update on the state of play.

The relevant stakeholders submitted some additional data at a late stage, which is currently being assessed by the Evaluating Member State (EMS) who will submit an updated evaluation report to EFSA. The Commission noted that this will delay the publication of the Reasoned Opinion, but asked EFSA to share its preliminary assessment by January 2020 to enable a first discussion on a possible measure at the next meeting of this Committee in February 2020.

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 in 2019, 39 Reasoned Opinions were issued so far and 10 new question numbers addressed since the last meeting of this Committee. Although clarifications or additional data for several long lasting clock-stops had been received and had led to a certain reduction of the number of clock-stops, the overall number is still high (45 questions).

Some assessments under Article 10 of Regulation (EC) No 396/2005 are merged with the assessment under the peer review process of Regulation 1107/2009, but can be separated if the peer review results in a clock-stop (e.g. on endocrine properties). EFSA asked the Evaluating Member State to notify EFSA whether in such cases the Article 10 assessment should be performed separately or only under the peer review procedure (this could be significantly later due to the clock-stop).

EFSA also reported some practical difficulties with combined applications for Article 12 confirmatory assessments and new MRL applications and estimated that procedures would run smoother if such applications were kept separately.

EFSA reported about its pilot project on Excel tables for Good Agricultural Practice (GAP) for residues which was also discussed in the Pesticides Steering Network (PSN) meeting of 4/5 November 2019. A more comprehensive GAP table that will also comprise information from the peer review process will be presented in both sections of the SC PAFF, Phytopharmaceuticals, in the beginning of 2020 for commenting by Member States.

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

EFSA presented the state of play of the ongoing Article 12 reviews. 37 active substances are currently under review, 36 under the new procedure and one under the interim procedure. Out of these 36, 16 are at finalisation stage with the Member States consultation period already closed. EFSA is also at finalisation stage for a new statement on active substances that do not require an Article 12 review.

Instructions for Article 12 work aimed at improving transparency and clarifying roles and responsibilities of all actors were discussed at the EFSA PSN meeting.

EFSA also reported about its first experiences with a pilot project on substances for which the Article 12 review process runs in parallel with the renewal of approval process concerning active substances temporarily included into Annex IV of Regulation (EC) No 396/2005.

The Commission presented the draft 2020 work programme for reviews of existing MRLs under Article 12 of Regulation (EC) No 396/2005 for 2020. It was amended based on Member States' feedback during the meeting. The Commission thanked Member States for their constructive attitude and indicated that it will make the revised version available on CIRCABC after the meeting.

The Committee agreed on the work programme, pending final confirmation from the designated rapporteur for one substance, and with the understanding that the order of substances in the second half of 2020 may need to be adjusted at a later stage to take into account ongoing decision-making on the approval of some of those substances.

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

Two mandates under Article 43 were recently accepted by EFSA: a mandate on chlorpropham with a deadline of 4 January 2020 and a mandate on chlordecone with a deadline of 31 January 2020. Study reports from the applicant on chlorpropham are still missing, therefore an extension of the deadline will likely be needed.

4. Outcome of public consultation of the EFSA reports on cumulative risk assessment

EFSA reported that the public consultation on the reports for cumulative risk assessment was closed on 15 November and that a stakeholder meeting took place in Brussels on 22 October 2019. An overview had also been presented at the last EFSA PSN meeting. The final reports are expected to be adopted by EFSA in March 2020 and published in April 2020.

5. Annual monitoring report

EFSA informed that the deadline for publishing the 2018 Annual Report is 29 February 2020. A public consultation will be launched mid-January 2020 on the draft report, there will be no second commenting period on the final report as was

previous practice. All Member States' comments on the draft report will be published alongside the final report. EFSA informed that data analysis for data collected under Regulation 669/2009 as regards the increased level of official controls on imports of certain feed and food of non-animal origin will no longer be carried out as EFSA does not receive the entire set of data (data are collected by Commission). The Commission clarified that this would still need to be discussed and agreed with all responsible units in the Commission.

Further, EFSA announced that national summary reports will no longer be presented in the Annual Report as many Member States have delayed submission of their reports to EFSA. The Commission expressed its concerns as it considers these reports to provide useful information and suggested that this should be further discussed. The views of the Commission where supported by several Member States. EFSA clarified that it would re-consider its position on this point and invited Member States to submit their national reports by 5 December 2019. The Commission underlined the importance for Member States to submit their reports by the deadline of 1 September to enable EFSA to integrate them.

6. Outcome of Pesticides Steering Network Meeting (PSN)

EFSA gave an overview of the topics discussed at the dedicated PSN meeting on MRL procedures and residue assessment held on 4-5 November 2019. In that framework, there were discussions on the official Note Taking of new and/or provisional residue definitions for risk assessment.

The Commission clarified that discussions on the residue definition for risk assessment are currently underway in the SC PAFF, Section Phytopharmaceuticals –Legislation in the context of an update of the guidance document on "the evaluation of new active substance data post (renewal of) approval" (SANCO/10328/2004), which addresses the Note Taking procedure in relation to residue definitions for risk assessment. The guidance will be discussed at the Standing Committee on 5-6 December 2019 under Agenda Point A 08.07.

A.05 Implementation of revisions of PRIMo model.

As a follow-up to the discussion in the meeting of this Committee in September 2019, when several Member States had voiced concerns about the prolonged use of the Primo model revision 2, the Commission proposed a compromise solution in which the newest revision of the Primo model (rev. 3.1.) would be used across all procedures as from 1 January 2020 while still providing an opportunity to the applicants to provide additional information (e.g. fall-back GAPs) in specific cases.

Three Member States supported the Commission's proposal.

A Member State suggested that where an exceedance is identified EFSA should first carry out a refined calculation and only then investigate potential fall-back GAPs. EFSA clarified that this is already current practice and that fall-back GAPs would only be considered where the refined assessments would show problematic exposure.

Fluopyram and tefluthrin are the only Article 12 substances that fall in the transition period with a planned adoption or Reasoned Opinions by EFSA by end of 2019. EFSA clarified that there might be an exceedance of the ADI for fluopyram when also considering the Codex limits for products of animal origin when using Primo rev. 3.1. but not with Primo rev. 2. Risk management options will be provided in the relevant Reasoned Opinion for this Committee to decide.

The Commission will circulate the proposed approach in writing and invited Member States to send comments by 29 November 2019.

A.06 Foods for infants and young children.

The Commission informed about the ongoing method developments carried out by the EU Reference Laboratories (EURLs). Methods have been validated for liquid milk and infant formulae. The EURLs have already collected several samples of liquid full-fat milk and of various types of infant formulae which they will start analysing by end of 2019, starting with the liquid milk samples followed by infant formulae. Preliminary analytical results for the liquid milk samples will be available at the next meeting of this Committee.

A.07 Next steps for cumulative risk assessment.

Following EFSA's publications on the pilot assessments for the cumulative risk of multiple pesticides residues on the thyroid and the nervous system, the Commission expressed its commitment to progress with further developments, exploring the possible integration of the currently developed methodology of retrospective assessments into practice, while at the same time pursuing the development of the methodology for prospective assessments. To this end, the Commission announced that an Expert Group meeting is foreseen to take place in the first half of 2020.

In commenting on EFSA's "EU Roadmap on the Assessment of Human Health Risks from Combined Exposure to Multiple Chemicals", the Commission stressed that it welcomes reflections on a broader range of chemical mixtures that would also cover non-dietary routes of exposure and coverage of all types of chemicals. The Commission, however emphasised that this should not delay the already ongoing work on pesticides residues. The Commission announced that it would also comment in this way in the forthcoming EFSA Advisory Forum and invited Member States to do the same.

Furthermore the Commission explained that the broadening of the scope from pesticides to other types of chemicals, would mean that a broader consultation of other Commission services and related agencies would become necessary. The Commission also invited EFSA to prepare a more detailed implementation plan related to pesticides in 2020.

A Member State raised its concern that including other chemicals, such as contaminants, in the assessment would delay the process as often the toxicological package for such substances would be incomplete.

A.08 Project on data collection dithiocarbamates.

The Commission informed that the EURL on Single Residue Methods (SRM) managing the project, had already collected data for approximately 10.000 organic samples, which include data up to 2017, data from official laboratories for 2018-2019 and data from private institutions. The EURL SRM is currently compiling the data. It already suggested commodities for which no organic samples are currently available and which should therefore be sampled with priority. Those commodities were included in Annex X of the Working Document SANCO/12745/2013, Rev.11(3) (for Note Taking under agenda item A.16.

A.09 New Official Control regulation and impact on pesticides legislation.

The Commission presented the changes that will be brought to Regulation (EC) No 396/2005 with the application of the new Official Control Regulation as from 14 December 2019. It explained which of the Articles to be deleted would need to be reinstated by delegated and which by implementing acts. The biggest impact is that Article 27(2) and 28 of Regulation (EC) No 396/2005 will be deleted as from 14 December 2019 and Articles 26, 27 (1) and 30 will have to be replaced by an implementing and/or delegated act before 14 December 2022. The Commission invited Member States to start reflecting whether any additional issues would need to be considered when re-instating the existing provisions.

A.10 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2019-2020.

There were no news as regards this agenda point.

A.11 Outcome of the Expert Working Group on Monitoring and other issues related to monitoring.

The Commission informed that a meeting of the Working Group on Monitoring was held on 14 October 2019 and that its outcome is reflected in the minutes uploaded on CIRCABC. The Commission further updated on a follow-up of the "annual survey on analytical coverage" that was conducted by the EURL SRM. In this follow-up survey, the control laboratories indicated that the main reasons for their narrow analytical scope for commodities of animal origin are associated with the lack of resources, but that in case such analyses would become a regulatory requirement resources would be allocated to include them in their scope.

A.12 International Matters:

1. OECD ongoing work - Guidance document on the definition for risk assessment

The Commission followed up on the request of a Member States to share the collected and summarised EFSA monitoring data on honey presented at the last meeting of this Committee with OECD who is working on a guideline for honey. The Member States agreed that the data that they had previously submitted to EFSA could be shared with OECD. EFSA will organise the technical transfer. The Commission reminded of the importance to take new confidentiality rules into account.

The Member State who attends the OECD working group on honey proposed to be the contact point for the Commission and Member States with OECD.

The Commission also gave an update on the on-going work of the OECD Residue Chemistry Expert Group (RCEG) on the guidance document on the definition of residues. The group was divided into two teams for the purpose of addressing pesticide exposure and toxicological issues. Discussions are currently taking place on the metabolite toxicological evaluation in a platform where all members can contribute. The group aims at delivering a first draft by January 2020. A face-to-face meeting will be held on 9-11 March 2020 in the premises of the French risk assessment body ANSES to address the outstanding issues. The OECD guidelines on honey will also be discussed.

The Commission will upload new documents on CIRCABC as soon as they are available for Member States to provide their feedback.

2. Codex Alimentarius/JMPR issues- future work organisation

The Commission called on Member States to act as rapporteur for substances that do not have a Rapporteur Member State (officially designated: methoprene, fluensulfone, omethoate, pyflubumide, and pyrifluquinazon). A Member State volunteered for afidopyroben and tolfenpyrad shortly after the meeting.

A Member State asked who should support the CCPR preparation for substances where the designation as rapporteur has changed, and the new rapporteur does not yet have in-depth experience with the substance. The Commission clarified that EFSA would start from the official designations at the time of preparation. Alternative arrangements are possible where Member States mutually agree, however it is the responsibility of the rapporteur originally designated to identify such situations at an early stage and proactively discuss with another Member State who could take over.

The Commission thanked the Member State who agreed to follow the work of the electronic working group on the management of unsupported compounds.

Member States and EFSA reported on the work in various electronic working groups:

- Revision of the classification of food and feed: useful comments were received in the first commenting round. Revised draft documents are currently on the platform for a second round of commenting by 13 December 2019.
- National registrations database: low activity so far in spite of high number of registered participants.
- Substances with low public health concern: a revised draft document is currently on the platform for a second round of commenting by 10 January 2020.
- Review of the International Estimated Short Term Intake (IESTI) equation: a draft document is currently on the platform for commenting by 2 December 2019. A teleconference with registered participants is planned for 10 December 2019.

The Commission thanked Member States and EFSA for the reports and the work invested. It called on all Member States to engage actively in the work of the electronic working groups.

The first Council Working Party to prepare for the Codex Committee in 2020 is scheduled for 20 January 2020, with the focus on substances which were assessed by the extraordinary JMPR meeting and other agenda items, if documents are already available. The second and third Council Working Parties are scheduled for 4 March and 16 March 2020, respectively, with the focus on substances which were assessed by the regular JMPR meeting and other agenda items.

The Codex Committee on Pesticides Residues will take place in Guangzhou from 30 March to 4 April 2020.

A.13 SANTE extrapolation guidelines (SANTE-2019-12750), replacement of existing guidance document SANCO 7525/VI/95 Rev. 10.3).

The first draft of the extrapolation technical guidelines document was presented, highlighting elements that still require further discussion. Some Member States proposed to allow the use of data from trials performed outside the Union for certain tropical minor crops since there is not enough economical interest to carry out trials in the EU.

Member States were invited to send comments by 15 January 2020.

A.14 Revision of GD SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1 - Analytical guidances.

The Member State working on the revision of the guidance documents provided an update of the ongoing work and presented a first draft merging the two existing guidance documents. The draft includes new paragraphs to include, among others, updates on analytical techniques, hydrolysis and enantioselective methods. The draft contains an Appendix allocating commodities to their respective crop groups.

Member States were invited to send comments by 31 January 2020.

A.15 Update of the Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed (SANTE/11813/2017) (new version SANTE/2019/12682) for Note Taking.

A Member State indicated that the possible use of an expanded measurement uncertainty with a lower confidence level in cases where an exceedance of an MRL is also an exceedance of the acute reference dose had not been included in the proposed revision. The Commission clarified that this risk management option was described in the Rapid Alert System for Food and Feed (RASFF) working instruction 2.2 (https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_reg-guid_sops_wi-2-2_en.pdf), hence a duplication in the Analytical Quality Control Guideline would not be required. However, the RASFF working instructions 2.2 may also need to be reviewed in light of the discussions held at the Pesticides Steering Network on 4-5 November 2019.

The Committee took note of the updated guidance document SANTE/2019/12682.

A.16 Working document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin (SANCO/12745/2013 rev. 11) for Note Taking.

The Commission presented revision 11(4) of the working document and informed that in that revision, an Annex XI was added to include triazole derivative metabolites (TDMs) among the substances recommended for inclusion in national monitoring programmes. Although the Commission clarified the non-mandatory character of this document, two Member States expressed their concerns for taking up TDMs in the document. The Commission therefore proposed to include TDMs under Annex II regarding substances for which further support is needed from EURLs.

The Committee took note of the guidance document.

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

No issues were raised under this agenda item.

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

No issues were raised under this agenda item.

A.19 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The Commission informed that the draft Report to the Council and the Parliament on the REFIT evaluation of pesticides legislation was in the process of finalisation. It could possibly be adopted in spring 2020 and subsequently be presented to the Member States. The Commission informed that since the contents were still under internal discussion, detailed feedback could not yet be given.

A.20 Amendment of the General Food Law by Regulation 2019/1381 (Transparency Regulation).

The Commission presented the recent amendments to the General Food Law and the impact they have on the current procedures and legislation in the area of pesticides.

In particular for pesticide residues, the Commission reminded Member States that supporting dossiers should be submitted to EFSA in accordance with Regulation (EC) No 396/2005 and the guidance document on the MRL setting procedure (SANTE/2015/10595). Evaluation Reports will no longer be assessed by EFSA if the supporting information is missing.

As a result of the need for more transparency, public consultations will be carried out in relation to MRL applications. EFSA still has to define further how this will be carried out and will provide some feedback at the Standing Committee in February 2020.

A.21 Other Information points:

1. Indolylacetic acid

The Commission followed up on this issue which was brought up by a Member State at the meeting of this Committee in September 2019. The Member State had found levels of indolylacetic acid in rice at levels well above the current MRL of 0.1 mg/kg. Such findings in rice were confirmed by two other Member States and two trade associations which had sent comments/data to the Commission on rice and corn. In the EFSA Article 12 review, background data for rice were taken into account. However, according to the more recent information provided by Member States and stakeholders, the level of indolylacetic acid may be higher, around 0.9-4.2 mg/kg. This needs to be further investigated.

2. BAC and chlorate in fish

A Member State reported on recent findings of benzylammonium chloride (BAC) and chlorate in fish of Vietnamese origin, which would lead to an exceedance of the MRL/acute Reference Dose (ARfD). Follow-up measures are being considered by the relevant services in the Commission. A Member State asked whether other Member States had similar experience and/or data to be shared. At the meeting, two other Member States confirmed that they had also found such levels in fish from Vietnam.

The Commission referred to existing Codex standards and cleaning practices in third countries with chlorinated water which could be at the origin of the problem. It also referred to 2018 monitoring data provided by a Member State showing that both substances occur in fish.

EFSA confirmed that data on fish are available in its data collection and will provide some assistance to Member States to carry out risk assessments.

3. Carbon tetrachloride

The Commission wondered why MRLs were set at EU level for cereals at 0.1 mg/kg and whether such MRLs are still needed.

EFSA clarified that the MRLs had been set by Council Directive 86/362/EEC on the fixing of maximum levels for pesticide residues in and on cereals.

Member States were invited to submit comments by 20 December 2019.

4. Matrine - Document from THIE

The Commission informed of the concerns of Tea and Herbal Infusion Europe about matrine findings in liquorice roots as a result of cross-contamination with co-harvested plants containing high levels of matrine. It was clarified that the default level of 0.01 mg/kg applies to matrine in liquorice roots regardless of its origin as a cross-contamination from co-harvested other plants. Harvesting practices would need to be improved to avoid such excessive levels.

5. Clarification on criteria to select measures to be adopted within the current Commission

On request of a Member State the Commission explained that those draft Regulations on MRLs that had been under increased political scrutiny had been put on hold in the transition between the current and future Commission and were now waiting for validation by the new Commission. They could possibly be voted in the next meeting of the Committee in February 2020.

C.01 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for dimethoate and omethoate in or on cherries.

The item was not discussed as the technical discussion was finalised in the meeting of this Committee on 26-27 September 2019.

C.02 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for chlorate

The item was not discussed as the technical discussion was finalised in the meeting of this Committee on 26-27 September 2019.

C.03 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for cycloxydim, flonicamid, haloxyfop, mandestrobin, mepiquat, Metschnikowia fructicola strain NRRL Y-27328 and prohexadione in or on certain products.

The item was not discussed as the technical discussion was finalised in the meeting of this Committee on 26-27 September 2019.

C.04 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for sintofen, myclobutanil and napropamide

A Member State requested to review the myclobutanil MRLs on beans with pods, based on data from an import tolerance request with missing information (metabolism study and number of trials).

For napropamide, a Member State requested to maintain an MRL of 0.05 mg/kg for napropamide for herbs and edible flowers (on the basis of monitoring data) and another one requested to maintain the existing MRL of 0.05 mg/kg for napropamide on Chinese cabbage, kale and kohlrabi. The Commission will look into both issues.

Member States were invited to comment by 13 December 2019.

C.05 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products.

The Commission had prepared a new revision of the draft Regulation following comments submitted by Member States. The Committee was informed that the substance sulfoxaflor will be addressed in a separate measure. Moreover, the Commission clarified that in the current measure, specific Codex limits are being implemented for products of animal origin and that it would be inappropriate to set higher values for edible offal in this framework.

A Member State commented that for kresoxim-methyl the Codex limit for the subgroup "Barley, similar grains and pseudocereals with husks" should also apply to canary grass. It further stressed that canary grass is an important novel food in some third countries. The Commission found it inappropriate to modify the MRL for kresoximmethyl in common millet, which covers several very minor crops among which canary grass, since the latter crop is not representative of the group and the impact on EU consumption of millet was not assessed by EFSA.

Member States were invited to submit comments by 13 December 2019.

C.06 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for chromafenozide, fluometuron, pencycuron, sedaxane, tau-fluvalinate and triazoxide in or on certain products.

The Commission presented revision 4 of the draft Regulation along with an explanatory note, which had been uploaded on CIRCABC. For fluometuron the draft Regulation considers only the parent compound in the residue definition as the complex residue definition including free trifluomethylaniline (TFMA) would lead to higher LOQ values, which indicated concerns in chronic exposure assessment.

Member States were invited to submit comments by 13 December 2019.

C.07 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for metam, dazomet, hexythiazox and clethodim in or on certain products.

In the last commenting round a Member State had proposed to maintain the MRL for hexythiazox on soybeans based on data recently received from the applicant. The

Commission rejected this proposal and clarified that new data can only be taken into account by means of a new MRL application under Article 6 of Regulation (EC) No 396/2005.

Information from applicants and other stakeholders related to clethodim had been received and shared on CIRCABC. A Member State informed that sethoxydim was also on the agenda of the 2020 CCPR and supported the option to separate the residue definitions for clethoxydim and sethoxydim in the draft Regulation. The applicant for sethoxydim had informed the Commission that it no longer plans to submit an import tolerance request. The Commission informed that it sees a need for a joint meeting between all relevant parties (applicants, RMS and EMS for clethodim) as well as EFSA early in 2020 to take stock of the situation and define the next steps.

Member States were invited to send comments by 13 December 2019.

C.08 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for chlorpyrifos and chlorpyrifos-methyl.

The Commission had prepared a draft Regulation lowering the MRLs for chlorpyrifos and chlorpyrifos-methyl to 0.01 mg/kg. The EURLs confirmed that the value can be achieved for all products by enforcement laboratories across the EU. In view of the serious health concerns identified by EFSA, the draft Regulation does not allow transitional measures and following comments from Member States, it was agreed that a shorter deferred period of three months instead of the usual six months should be applied.

At the meeting, two Member States reacted by supporting the draft Regulation and urged the Commission to schedule the proposal for a vote at the meeting of this Committee in February 2020.

Member States were invited to submit comments by 29 November 2019 to allow the Commission to notify the draft Regulation under the WTO/SPS agreement swiftly.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation regarding a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

The Commission presented revision 1 of the draft Regulation, which reflected the outcome of the experts meeting on monitoring of pesticide residues that was held in October 2019. The Commission referred to the minutes of that meeting uploaded on CIRCABC under Pt. A 11.00 detailing the changes compared to the previous version.

Member States were invited to send comments by 13 December 2019.

C.10 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products.

For bentazone, dimethomorph, fludioxonil, pyraclostrobin and teflubenzuron, MRLs had been set earlier as temporary MRLs due to some data gaps identified by EFSA in the review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005. EFSA had assessed additional confirmatory data submitted by the applicants in

response to these data gaps. Based on this new information EFSA now recommended lowering these MRLs.

The approval of the active substance oxadiazon expired on 31 December 2018. Regulation (EU) 2017/1125 and Regulation (EU) 2017/1186 withdrew the approval of tall oil pitch and tall oil crude respectively, because the information submitted by the applicants had not been sufficient to conclude on the toxicological profile of the substances. As a consequence, Member States had to revoke existing authorisations for plant protection products (PPPs) containing those substances. All grace periods set by Member States will have expired by the time this MRL Regulation will become applicable. The proposed Regulation will lower the MRLs for those substances to the limit of quantification (LOQ), in line with Article 17 of Regulation (EC) No 396/2005.

Flufenoxuron was initially on the list for a full review of MRLs under Article 12, but due to the overall delays of the exercise, it was not yet assessed. However, given that the substance was not approved through Regulation (EC) No 942/2011, all MRLs are proposed to be lowered to the LOQ, except for tea, for which the current MRL is safe to consumers and corresponds to an import tolerance request from Japan.

For azinphos-methyl and phosalone, the CCPR recently withdrew the Codex limits for all products except for spices, noting that these were derived from monitoring data and that the dietary exposure was extremely low (REP19/PR). Since the two substances are no longer approved in the EU and the authorisations had been revoked more than ten years ago, the draft Regulation will lower the MRLs for those substances to the LOQ, except for spices.

At the meeting, the Commission clarified that the following Article 6 applications will be addressed in the draft Regulation, for the sake of efficiency, as the substances and the relevant recitals are already reported: bentazone in poppy seeds and soya beans, fludioxonil in rhubarbs and pyraclostrobin in sweet corn.

Member States were invited to submit comments by 20 December 2019.

C.11 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for chlordecone in or on certain products.

The Commission had forwarded the assessment carried out by ANSES to EFSA who accepted to deliver a statement by 31 January 2020. The Commission intends to discuss a draft Regulation lowering the MRLs for chlordecone in several products of animal origin at the meeting of this Committee in February 2020.

C.12 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for acequinocyl, acibenzolar-S-methyl, Bacillus subtilis strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products.

The Commission had prepared a new revision of the draft Regulation following comments submitted by Member States.

A Member State re-iterated its intention to abstain in the vote on the proposed Regulation as it does not support the inclusion of *Bacillus subtilis* strain IAB/BS03 in Annex IV to Regulation (EC) No 396/2005.

Member States were invited to submit comments by 13 December 2019.

C.13 Exchange of views of the Committee on a draft Commission Regulation regarding maximum residue levels for bupirimate, carfentrazone-ethyl, emamectin and pyriofenone in or on certain products.

The Commission introduced the draft Regulation and presented its content.

Member States requested clarification on LOQ values below the default for emamectin. A Member State indicated that the proposed LOQ is too low for complex residue definitions. The Commission clarified that these values were proposed due to a very low Acceptable Daily Intake (ADI).

Member States were invited to submit comments by 20 December 2019.