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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Residues*
17 - 18 February 2020

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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.

2. Confirmatory data Art. 12 follow-up

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

      The Commission outlined the Reasoned Opinions that were recently published by the European Food Safety Authority (EFSA), where risk management decisions had been proposed. The Commission will update the follow-up table accordingly and invite Member States to provide their comments by 13 March 2020.

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

   The Commission presented an updated table with comments received from the Member States after the last meeting on the proposed follow-up action for substances for which no Article 12 review was needed. This was based on an EFSA statement published in December 2019. Several Member States proposed to make the inclusion of sodium aluminium silicate, 1-4 diaminobutane and ammonium acetate permanent in Annex IV by removing the footnote indicating the temporary nature of the Annex IV inclusion. A Member State proposed to indicate in the respective draft Regulation that ammonium acetate and sodium aluminium silicate were no longer used as plant protection products. One Member State proposed to consider the setting of a maximum residue level (MRL) for Bacillus thuringiensis and express it in “Colony Forming Units” (CFU). A Member State announced that a study by its national risk assessment body was currently under review and would be published soon. The Commission referred to the outcome of the Committee’s meeting of 12/13 June 2017 where it was decided to await the outcome of the renewal exercise for all Bacillus thuringiensis strains before taking a risk management decision.

   The Commission Member States were invited to provide their comments by 13 March 2020.

4. Substances covered by forthcoming Article 12 draft Regulations

   The Commission presented an initial overview of the substances covered by three forthcoming draft Regulations. Explanatory Notes and an overview of achievable limits of quantification (LOQs) from EFSA and the EU Reference laboratories (EURLs) were shared with the Member States. The following substances will be covered:

   - acequinocyl, cycloxydim, diclofop, fluopyram, ipconazole and terbuthylazine (SANTE 2020/10044),
   - fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat (SANTE 2020/10032), and
   - benalaxyl, benalaxyl-M, dichlobenil, fluopicolide, proquinazid and pyridalyl (SANTE/2020/10034)

   Member States were invited to provide comments by 28 February 2020 on the proposed residue definitions for enforcement and the LOQs in view of the preparation of the respective texts for draft Regulations, which will be shared with the Member States for a first commenting round in March 2020.

A.02 Feedback from Legislation Committee:

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

   The Commission informed that two active substances, ferric pyrophosphate and dimethyl disulphide were added to the agenda of the Standing Committee on Plants, Animals, Food and Feed (SCPAFF), Section Phytopharmaceuticals - Legislation since the last meeting of this Committee in November 2019.

A.03 Specific substances:

1. Benzalkoniumchloride (BAC) and Didecyldimethylammonium chloride (DDAC)

   Temporary MRLs were set for BAC and DDAC by Regulation (EU) No 1119/2014 pending the submission of new monitoring data by 31 December 2019. EFSA gathered data from the monitoring programme covering 2014-2017. Some Member States recently shared their national monitoring data up to 2019. Most of the samples (95-99%) showed no findings or findings at levels close to 0.01 mg/kg. Moreover, there is a trend showing that the levels are decreasing over time. Overall, findings are similar in all products, with the exception of some products of animal origin in two Member States where higher occurrences were identified. Also stakeholders provided data specifically on fresh products and dairy products confirming the high compliance rate.

   Based on the available data, the Commission proposed to lower the temporary MRLs for products of plant origin to the relevant Limit of Quantification (LOQ) and asked Member States to provide feedback on whether an intermediate MRL for products of animal origin should be set in view of the few positive findings between 0.01 and 0.05 mg/kg. Some Member States suggested that the EURLs for pesticide residues should be consulted on the appropriate LOQs given that the proposed MRLs would represent a sum of isomers.

   Member States were invited to provide comments by 31 March 2020.

2. Glufosinate ammonium

   There were no news as regards this agenda item.

3. Glyphosate

   There were no news as regards this agenda item.

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

   The Commission informed that on 6 December 2019, the SCPAFF, Phytopharmaceuticals – section Legislation, took note of the toxicological reference values and of the residue definitions for enforcement and for risk assessment for TDMs. Those values and the residue definitions are included in an Appendix that will be attached to the Review Report of each active substance of the triazole group. The update of individual reports is currently ongoing. A Member State commented on the use of those toxicological reference values and of the residue definitions in the frame of national authorisations of plant protection products containing triazole compounds.

5. Dimethenamid-P

   The Commission referred to the Reasoned Opinion on the evaluation of the confirmatory data following the Article 12 review. In that framework, EFSA clearly acknowledged that a comprehensive revision of the existing MRLs would be required in case risk managers decided to endorse the residue definition for enforcement proposed in the peer review.

   The Commission considered that it was not appropriate to amend the residue definition in the framework of a routine MRL measure. Based on the comments received and the absence of a health risk, it was concluded that a further revision of the MRLs for dimethenamid-P was not a priority.

6. Chlorpropham

   EFSA shared an advanced copy of the Reasoned Opinion on the setting of a temporary maximum residue level for chlorpropham in potatoes. In that framework, three possible risk management options are reported based on the different methodologies used to derive temporary MRLs. In the Conclusion and Recommendation section of the Reasoned Opinion, EFSA clarified that the monitoring data were obtained exclusively from potato storages where chlorpropham had been used in previous seasons and where effective cleaning practices had not yet been fully applied, since the research in this area was still ongoing.

   In view of the above, the Commission proposed to set a temporary MRL at the lowest proposed level of 0.3 mg/kg. The Commission further stressed that extensive cleaning should be carried out to minimise the contamination from storage facilities. The draft guidelines on cleaning practices developed by the potato sector were shared with the Member States. The Commission will have a meeting with the trade associations of the potato sector to discuss on cleaning practices in March 2020.

Member States were invited to provide comments by 28 February 2020.

7. Methoxyfenozide

   In the framework of the assessment of an application for an import tolerance, the Evaluating Member State identified exceedances of the Acute Reference Dose (ARfD) established in the peer review of the active substance. The Commission intends to ask EFSA to carry out an exposure assessment of the existing MRLs in light of the new toxicological reference values.

8. Tebuconazole

   In the framework of the Article 12 review carried out in 2013, the EU agreed to maintain on a temporary basis the MRL for tebuconazole in beans with pods at 2 mg/kg, which was based on an EU Good Agricultural Practice (GAP) that was not sufficiently supported by data, pending the submission of an import tolerance request from Kenya.

   In 2017, EFSA published a Reasoned Opinion on the setting of an import tolerance for tebuconazole in beans with pods. In that framework, EFSA concluded that an MRL of 3 mg/kg would address the import tolerance request. However, several uncertainties were identified, such as the lack of the establishment of an MRL in Kenya, the pending assessment of the TDMs, the need for clarification on the ratio of isomers, which may lead to an exceedance of the ARfD in a worst case scenario. Moreover, the residue trial data contained one high residue level, statistically identified as an outlier, driving the MRL calculations upwards.

   For the reasons above, the Commission proposed not to increase the current MRL of 2 mg/kg to 3 mg/kg and to review it together with the remaining MRLs for which the Article 12 review identified missing confirmatory information.

   The Committee agreed to the approach proposed by the Commission.

9. Spinosad

   In the EFSA Conclusion of the peer review a new acute ARfD for spinosad of 0.1 mg/kg body weight was proposed and a consumer intake concern identified.

   Furthermore, the applicant was requested to submit additional data concerning the endocrine disrupting properties of spinosad. This may delay the overall renewal process up to 18 months. In view of the consumer intake concerns, the Commission intends to ask EFSA to carry out an exposure assessment of the existing MRLs in light of the new toxicological reference value.

10. Pyridate/pyridafol

    The Commission informed the Committee about a modification of the entry for the active substance pyridafol in the EU Pesticides database, to address an apparent contradiction. The reference to the default value of Article 18(1)(b) of Regulation (EC) No 396/2005 was replaced by a reference to the MRLs for pyridate, as pyridafol is included in the residue definition of pyridate, where pyridafol is referred to as CL 9673 (6-chloro-4-hydroxy-3-phenylpyridazin).

11. Indolylacetic acid

    The Commission informed the Committee on a literature review and the monitoring data on wheat, maize, oilseeds and crude vegetable oils sent by a stakeholder

organisation. According to their monitoring data, high levels of indolylacetic acid (IAA) were found with average content in maize (2.4 mg/kg) and crude coconut oil (0.2 mg/kg). In addition, literature review showed high natural content of IAA in cereals, legumes, fruits and seeds. The Commission reminded that in the Art 12 review EFSA did not suggest to add the substance into Annex IV as the full toxicological properties of IAA remained unknown and teratogenic effects were found. A Member State felt that nevertheless, given that IAA was a natural plant hormone, a risk management decision could be taken to include IAA in Annex IV of Regulation (EC) No 396/2005. The Commission asked the Member States to consider all the elements and proposed to re-discuss the issue at the next meeting.

12. Carbon tetrachloride

    Based on the comments sent by Member States, the Commission proposed lowering the temporary MRLs that are currently set for cereals in the framework of an MRL measure to be notified under the WTO-SPS notification procedure.

13. Fosetyl-Aluminium (in the following text referred to as "fosetyl")

    The current residue definition of fosetyl for enforcement and risk assessment in all plant and animal commodities is "sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl". MRLs for fosetyl are set taking into account uses of this active substance as well as of the active substances disodium phosphonate and potassium phosphonate.

    At its meeting of 24/25 February 2014, the Committee had agreed that the residue definition of fosetyl for enforcement and risk assessment in all plant and animal commodities should be set as "phosphonic acid and its salts", following a review of MRLs for fosetyl taking into account also contributions from other uses than those of the active substance fosetyl.

    However in 2018, the peer review of the pesticide risk assessment of fosetyl in the context of the procedure for renewal of approval of fosetyl concluded that the residue definition for enforcement and risk assessment in all plant commodities should be set as "sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid", and for all animal commodities as "phosphonic acid".

    In view of the already complex task of reviewing contributions from multiple sources, EFSA requested a clarification on the residue definition to be used in the review.

    The Commission reminded the Committee that expert meetings in 2012 and 2018, as well as the Committee itself during the discussions of 2013/2014, recognised that all different options for residue definitions had advantages and disadvantages. A Member State mentioned the issue of alignment to Codex MRLs.

    The Committee confirmed its decision of 2014 that the residue definition of fosetyl for enforcement and risk assessment in all plant and animal commodities should be set as "phosphonic acid and its salts". The Commission will prepare the mandate to EFSA accordingly.

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, 53 Reasoned Opinions were finalised and 15 new question numbers addressed since the last meeting of this Committee. 92 question numbers are at different steps of the procedure and 51 under clock-stop.

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

   EFSA presented the state of play of the ongoing Article 12 reviews. 16 Reasoned =pinions and one statement containing 11 active substances for which no Article 12 review is needed, were finalised since the previous meeting of this Committee. 41 active substances are currently under review and at different stages of the procedure.

   EFSA informed that the Article 12 work instructions, agreed at the last Pesticides Steering Network meeting on 4-5 November 2019, were expected to be published in March 2020. For a list of active substances temporarily included in Annex IV of Regulation (EC) No 396/2005 a pilot project had been agreed with the Commission previously, aiming at their assessment in parallel with the peer review process. EFSA clarified that in those cases the data requirements laid down in Regulation 283/2013 would apply.

   EFSA asked the Member States to verify the completeness of an updated overview Excel sheet on confirmatory data (placed on their Document Management System (DMS)) and, if necessary, to update the information by 23 March 2020.

   The Commission presented a revised 2020 work programme for reviews of existing MRLs under Article 12 of Regulation (EC) No 396/2005 for 2020, which had become necessary due to delays in the decision-making on approvals for several active substances. The Committee agreed on the revised work programme.

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

   EFSA had shared the draft Reasoned Opinions on chlorporpham on potatoes and on chlordecone in certain products of animal origin with the Committee prior to the meeting. The reasoned opinions will be approved by EFSA soon. EFSA also informed that a draft mandate on fosetyl was currently under discussion with DG SANTE (see agenda item A.03.13).

4. Update on the EFSA reports on cumulative risk assessment (CRA)

   EFSA informed the Committee about the state of play on CRA and the next steps, referring also to the "EU Roadmap on the Assessment of Human Health Risks from Combined Exposure to Multiple Chemicals" presented at the last EFSA Advisory Forum. EFSA's Scientific Committee is currently working on criteria which would make the cumulative assessment groups leaner and allow better prioritisation. In the meantime, on request of DG SANTE, work on cumulative assessment groups for two new effects will go on. An assessment is planned for 2020 on a chronic neurotoxic effect (acetylcholinesterase inhibition) and another one for 2021 on cranio-facial malformation effects.

   EFSA will also work jointly with the Commission and Member States on developing an approach for using cumulative risk assessment in regulatory practice, i.e. for setting maximum residue levels (MRLs) (see also agenda item A. 08).

5. Presentation of draft Annual Monitoring Report for 2018

   EFSA made a presentation on the main findings of the draft annual monitoring report 2018 for which publication is planned for March 2020 and which shows that overall the pesticide residues situation is well under control. For the first time,

EFSA will include an on-line data visualisation system providing users an enhanced overview of the results and options for tailor made data presentation.

A Member State indicated a delay in transmitting some of its monitoring data due to a technical problem. EFSA clarified that the delayed data could be acknowledged in the annual report without being considered for data analysis as the process was already finalised.

A Member State remarked that the EFSA report did not sufficiently explain the reasons for findings of non-compliances, which very often would be well known (e.g. chlorate). EFSA replied that it would appreciate the Member States' input on such background information during the public consultation period in order to be able to integrate it. Comments were also made regarding the assessments of the presence of multiple pesticide residues. EFSA clarified that the annual report will not address CRA at this stage, but that after the publication of its reports on the cumulative risk assessment of pesticide residues on the thyroid and the nervous system in April this year, EFSA will publish a statement on the main risk drivers, analysing the 2018 monitoring data in this respect. A Member State requested clarifications on the MRLs used for goji berries. EFSA explained that the values used are based on the MRLs for tomato considering processing factors.

EFSA clarified that, following the discussion held during the previous meeting, the Member States' national summary reports will continue to be compiled and published. On request of the Commission, the data collected under Regulation (EC) No 669/2009 will also continue to be presented until those data can be fully integrated in the Commission's TRACES system. As EFSA is moving away from the current documentation management system (DMS), a discussion took place regarding alternative tools, e.g. the use of CIRCABC for data sharing: Data provided by a given Member States will continue to be visible for all data submitters, as currently already the case.

6. Outcome of Pesticides Steering Network Meeting

   No issues were raised as an update had already been given at the last meeting of the Committee.

7. EFSA informed the Committee about its Guidance on stereoisomers, adopted by EFSA in July 2019, and presented to the SC PAFF, section Phytopharmaceuticals - Legislation in October 2019. The Commission asked the Member States to closely look at it and provide comments by 13 March 2020, in particular with a view to its possible impacts on the parallel discussions on the residue definition for risk assessment, currently ongoing in OECD, and thus possibly also on the acceptance of Codex MRLs (CXLs). Feedback from the Committee can then be given to the SC PAFF section Phytopharmaceuticals- Legislation before its March 2020 meeting.

A.05 Implementation of revisions of PRIMo model.

The Commission referred to the agreed approach in the last meeting of the Committee as regards the use of the new version (revision 3.1.) of the PRIMo model for exposure assessment as from 1 January 2020. The agreed approach was presented in a short document that will be uploaded on the SANTE webpage at:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_primo-imp.pdf

Two Member States asked for further guidance on the approach for national authorisations after 1 January 2020 and the revision of PRIMo to be used in cases where an older PRIMo tool was used in the EFSA risk assessment. The Commission clarified that the issue of national authorisations would not be dealt with in its document. However, the Commission will facilitate discussion among Member States aimed at finding a harmonised approach and outlined two possible options. Member States were invited to comment or propose other suitable options by 13 March 2020.

One Member State commented that it would generally refuse authorisations if the use of revision 3.1. of the PRIMo tool would result in exceedances of toxicological reference values during the authorisation procedure, regardless of the revision that had been used by EFSA in their earlier risk assessments.

A.06 Update of the Commission working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs (SANTE/10235/2016).

The agreement on the approach to implement the new PRIMo (see agenda item A.05) made it necessary to amend Commission working document SANTE/10235/2016 accordingly. The Commission presented a draft revision as well as comments received from EFSA.

The revision also clarified that the Rapporteur or Evaluating Member State submits not only the Pesticide Residue Overview File (PROFile) and the supporting Evaluation Report but also the dossier to EFSA. A Member State expressed concerns about uploading the dossier on the EFSA DMS because of the size of the data and proposed to send information on a CD instead.

The Committee took note of the new revision (rev. 4) of Commission working document SANTE/10235/2016, which applies to MRL applications submitted from 1 January 2020.

It is available on the SANTE website:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

A.07 Foods for infants and young children.

The Commission presented an overview of the project which is performed by both the EU Reference Laboratory for commodities of animal origin (EURL AO) regarding substances amenable to multi-residue methods (MRMs) and the EU Reference Laboratory for Single Residue Methods (EURL SRM) regarding SRM amenable substances.

The EURL AO focused on approximately 60 MRL amenable active substances with very low accepted daily intakes (ADIs) and developed an analytical method for liquid milk reaching to very low LOQs accordingly. The EURL AO sampled and analysed 54 samples of liquid milk using this new analytical method and all results were below these LOQs. The EURL AO will continue the method development on infant formulae and will then proceed with analysing infant formulae samples. Preliminary results are expected before the June 2020 meeting of the Committee.

Regarding SRM amenable substances, the EURL SRM developed the analytical method to achieve very low LOQs on both liquid milk and infant formulae and will soon publish a method validation report. The initial results indicate that the achieved

LOQs are sufficiently low. Meanwhile, it has already published on its website a report on analytical observations and will soon start analysing liquid milk and infant formulae samples, however, preliminary results are not expected before the September 2020 meeting of this Committee.

A.08 Next steps for cumulative risk assessment.

Following EFSA's publications expected for April 2020 regarding the retrospective[1] cumulative risk assessment (CRA) of the effects of pesticide residues on the thyroid and the nervous system, the Commission informed that it intends to continue the work for expanding the CRA methodology towards the prospective [2](MRL-setting) scenario and announced that a working group meeting with Member States' experts will be held in Brussels on 24 April 2020.

Member States were invited to nominate their Experts by 6 March 2020.

A.09 Project on data collection dithiocarbamates.

The Commission informed that the project is ongoing and that the EURL SRM managing the project had collected sufficient data to establish background levels for some commodities, but that more samples would still be required for a large number of other commodities. More data are already available from the 2018 monitoring exercise from EFSA. On request of the Commission, the EURL SRM will analyse approximately 100 additional samples (150 had already been analysed) to fill the gaps.

A.10 New Official Control Regulation (OCR) and impact on pesticides legislation.

The Commission presented an overview of those Articles of Regulation (EC) No 396/2005 which will be deleted as from 14 December 2022 when the transitional period given in the new Official Control Regulation (Regulation (EU) 2017/625 – (OCR)) is over. It presented its initial analysis of correspondence to already existing provisions in the OCR - while emphasising that only the European Court of Justice has the power to rule on the interpretation of EU law and that the views expressed were not necessarily the final views of the Commission.

The Commission clarified that Member States had to provide an annual report to the Commission under Article 113 of the OCR by 31 August each year for all areas falling under the OCR. On this basis the Commission has to publish a more comprehensive annual report by 31 January each year covering those different sectors (Article 114 of OCR). At the same time the Member States will remain obliged under Article 31 of Regulation (EC) No 396/2005 to submit their detailed annual reports (and data in the standard format as set out by EFSA) on pesticides residues, which will then be the basis for EFSA to draw up the specific annual report on pesticides residues according to Article 32 of Regulation (EC) No 396/2005. Although Member States have to provide two separate reports, some information may overlap as some of the provisions from Regulation (EC) No 396/2005 will in future be covered by the corresponding articles in the OCR.

[1] The retrospective scenario looks at human exposure using monitoring data collected in past years under the existing monitoring programmes.

[2] The prospective scenario looks at human exposure in the context of future regulatory decision making, e.g. approval/authorisation procedures or the setting/modifying of MRLs following applications.

EFSA switches from their Document Management System (DMS) system to the Advanced Records System (ARES), therefore, CIRCABC as a possible data sharing platform was discussed.

Member States were invited to provide their comments by 3 April 2020.

A.11 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2019-2020.

This item was covered by Agenda Point A 03.01.

A.12 International Matters:

1. OECD Guidance document on the definition for risk assessment

   The Commission shared the draft revision of the OECD guidance document and outlined those issues, which still need to be addressed by the subgroups on toxicology and residue exposure at the meeting of the OECD Residue Chemistry Expert Group (RCEG) in Paris on 9-11 March 2020.

2. Codex Alimentarius/JMPR issues - future work organisation

   - Outcome of the first Council Working party meeting on 20 January 2020

     The Commission reported from the first Council Working Party (CWP) meeting on 20 January 2020, which focused on proposed draft CXLs from the extraordinary JMPR meeting in May 2019.

   - Codex Committee on Pesticides Residues (CCPR) 2020- working groups and substances

     Working group on the review of the Internationally Estimated Short Term intake (IESTI)

     EFSA presented an overview of the activities and achieved outcomes of the electronic working group (eWG) on the review of the IESTI equations. Following several rounds of written commenting and two web conferences, the final discussion document was sent to the CCPR and Codex Secretariats on 10 February 2020. EFSA presented the recommendations derived by the eWG.

     The Commission thanked EFSA for the excellent work in the context of the EU's chairmanship of this eWG. It also thanked Member States who were actively involved and engaged.

     The Commission provided an outlook on possible next steps on the IESTI file.

     Mass spectrometry – comments from MS in preparation of 2nd CWP

     The Commission informed of the state-of-play regarding the eWG on Mass Spectrometry and informed that the EURLs will provide their comments on the draft update of CXG 90-2017 by 28 February 2020 in view of the preparations for the CWP.

     Concern forms

     At the first CWP, it was agreed that the relevant Rapporteur Member States would prepare concern forms for the following substances: chlormequat, chlorpyrifos, chlorpyrifos-methyl, imazalil and propiconazole.

The draft concerns forms were shared prior to the current meeting. The Commission explained that it intends to put on hold the concern form on imazalil, pending the on-going evaluation of an import tolerance request, which may address the concerns raised by the EU at CCPR concerning post-harvest uses. The remaining forms will be submitted to JMPR in the coming months for its consideration and possible re-evaluation of the substances.

Member States were invited to provide comments by 28 February 2020.

- Planning of preparatory work for Council Working parties in 2020

  The Commission indicated that the second and third CWP on 4 and 16 March 2020 will focus on proposed draft CXLs from the regular JMPR meeting in September 2019, and the remaining agenda items of the CCPR. As for those agenda items, there were no documents available yet (with the exception of the general section of the JMPR Report), the Commission suggested to start preparations based on the latest draft documents available from the eWGs.

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

The Commission presented a brief update on the progress on the Extrapolation Guidelines. Comments had been received from 7 Member States and were assessed and summarised in a document that was circulated, alongside a revised version of the Extrapolation Guidelines. Areas for further discussions were highlighted. The Commission clarified once again, that the focus of this revision – unlike several rounds in the past – was the main text and its alignment to e.g. the OECD guidelines, and not the Annexes with specific extrapolations.

Given the complexity of the issue, the Commission proposed to arrange an expert working group with Member States, most likely in spring 2020. The Commission will get back to the Member States with a proposal for a concrete date.

In the meantime Member States were invited to comment on the presented version by 20 March 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 draft document merging the two guidance documents received a large amount of comments, but will nevertheless consider them in a revised draft that will be presented in a forthcoming meeting in 2020.

A.15 Working documents on fish.

A Member State had substantially revised and further developed the 2013 working document on the nature of residues in fish (fish metabolism studies) and prepared two additional documents, a document on the magnitude of pesticides residues in fish (fish feeding studies) and a document on dietary burden calculations in fish. An overview was presented to the Committee. In 2013, the working document on the nature of pesticides residues in fish had not been finalised due to a lack of suitable methodology.

Member States were invited to comment by 30 April 2020 directly to the Member State drafting the documents.

The Commission clarified that technical discussions could continue, but that questions such as the follow up to be given as regards the use and implementation of the documents would need to be discussed in the context of the overall priorities. This should be done in the context of discussions on follow up to the REFIT exercise which are still to come.

In order to prepare possible future discussions, and given that monitoring data on fish in the EFSA monitoring database are very scarce, the Commission invited the Member States to send available monitoring data covering the years 2017, 2018 and 2019 to the Commission by 30 April 2020.

A.16 Revision of RASFF WI 2.2.

Discussion of this agenda item was postponed to the next meeting. See also the point on the sampling Directive under agenda item A.20.

The Commission invited the Member States to submit comments and concrete proposals on the wording of RASFF WI 2.2, e.g. as regards the analytical uncertainty, by 13 March 2020.

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

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

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

The Netherlands received an import tolerance request for tolfenpyrad, which is a substance for which no application for approval had ever been submitted under Regulation (EC) No 1107/2009. The Committee agreed that this Member State acts as RMS for this substance.

Germany had received an MRL application for diquat in several crops. The former Rapporteur Member State for diquat was the United Kingdom. The Committee agreed that Germany evaluates the application.

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

The Commission informed that the Report to the Council and the European Parliament on the REFIT evaluation of the pesticides legislation was expected to be published on 25 March 2020, at the same time as the Farm to Fork Strategy and the second report on the implementation of the Sustainable Use Directive (SUD).

A.20 Other Information points.

- Ukraine/cereals

  The Commission informed of the information received from a Member of the European Parliament regarding possible residues of non-approved substances in cereals imported from the Ukraine. Member States were encouraged to include the substances atrazine, EPTC, carbofuran, linuron, propachlor and simazine in their national control programmes for cereals imported from third countries.

- Fenpropathrin – import tolerances

  The Commission informed that the applicant still supports the existing import tolerances and intends to submit the relevant information, including the missing data on the technical specifications of the active substance by August 2020, at the latest. The Commission proposed to wait for the assessment of the additional data, instead of immediately lowering the MRLs as announced in the previous meeting.

- Fee recovery by MSs for work on Article 12 and 43 of Regulation (EC) No 396/2005

  A Member State requested feedback from the other Member States on whether or not they would charge fees for Article 12 and Article 43 evaluations. Several Member States replied. Practices among the Member States were different. Some Member States reported having a legal basis in their national legislation to require fees from applicants. Member States who would still like to comment were invited to do so in writing.

- Sampling Directive (Directive 2002/63)

  A Member State requested to amend Directive 2002/63 and insert more concrete provisions on analytical uncertainty in regulatory decision making. The Commission highlighted that in its view there was no need to review the sampling Directive, as provisions are already available in the Analytical Quality Control Guidelines updated regularly by the EU RLs and in the Working Instructions of the Rapid Alert System for Food and Feed (RASFF WI). Concrete proposals would be needed from Member States in order to decide whether and how to amend the current version of the RASFF WI 2.2.

  A Member State supported the Commission's view that a review of the sampling Directive was not needed. The Member State clarified that at national level the relevant authorities apply the analytical uncertainty only for enforcement, whereas the actual value is used for risk assessment. Another Member State confirmed this practice at national level.

  The Commission invited the Member States to submit comments and concrete proposals by 13 March 2020.

- Transitional periods in MRL measures

  The Commission invited the Member States to reflect, whether a discussion on clarification of the wording related to the Article dealing with transitional periods in Regulations lowering MRLs could be taken up again, in order to respond to criticism voiced mainly by third countries. Two Member States already gave their initial views that this might be difficult for them to support.

  Member States were invited to comment by 31 March 2020.

- Enforcement question on MRLs for feedingstuffs

  The point was added to the agenda on request of a Member State who reported about some enforcement questions on feed that came up recently and asked the other Member States to share their experiences and practices. Feedback was received from several other Member States. One Member State prepared a guideline on enforcement issues for feedingstuffs which will be shared with the other Member

States. Member States who would still like to comment were invited to do so in writing.

- Residue definition for risk assessment

  A Member State reminded the Commission that it had expected to discuss a procedural question related to the residue definition for risk assessment as agreed in the November meeting of the Committee. The Commission apologised and explained that this was an oversight. The issue will be put on the agenda of the next Committee meeting in June.

- Fluopicolide in poppy seeds

  The Netherlands reported on recent findings in untreated poppy seeds.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for myclobutanil, napropamide and sintofen in or on certain products (Art. 12).

Minor modifications on footnotes and proposed MRLs for one crop group were agreed before voting.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products (CXLs).

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

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chromafenozide, fluometuron, pencycuron, sedaxane, tau-fluvalinate and triazoxide in or on certain products (Art. 12)

The Commission presented the updated version of the draft measure which included an additional clarification on a footnote for tau-fluvalinate on poultry edible offals.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products

The Commission outlined the recent amendments brought to the measure in its latest revision, following the Commission's internal consultation procedures.

The Commission clarified that the main content was unchanged: the draft measure still proposes lowering all MRLs for the two substances with a three months deferred application date and no further transitional measures in view of the serious concerns identified by EFSA. The measure was notified to WTO via the SPS procedure. Several third countries and international food business operators reacted to the measure indicating that a longer transition period should be granted to allow for the normal marketing, processing and consumption of products that were produced before the new MRLs apply. A set of countries from Latin America made a joint declaration specifically on chlorpyrifos in bananas requesting the EU to maintain the current CXL set at 2 mg/kg.

All comments received were shared with the Committee who took note of the concerns expressed by the various actors involved in the food business. Two Member States did not support the current measure as they still use chlorpyrifos-methyl at national level and believe that a six months deferred application date would have been appropriate for that substance. Another Member State abstained to the measure in consistency with its position in relation to the non-approval decisions. Other Member States provided explicit support to the draft measure as it was presented. A Member State supported the draft measure, although it stated that a longer transition period should have been provided.

Two Member States proposed to modify the current wording in Article 2 to distinguish between fresh and processed products in relation to the deferred application date. The Commission clarified that this would affect the contents of the measure and that it would delay the decision making process as other services of the Commission would need to be re-consulted, as well as third countries via the WTO-SPS notification procedure.

Request of two Member States to clarify the use of the Rapid Alert System for Food and Feed (RASFF) in case of findings of chlorpyriphos

One Member State had made repeated information notifications in the Rapid Alert System for Food and Feed (RASFF) on levels of chlorpyriphos in citrus complying with existing MRLs, but exceeding the future MRL of 0.01 mg/kg. This had been contested by the Member State of origin of the citrus consignments. The Commission presented initial views - while emphasising that only the European Court of Justice has the power to rule on the interpretation of EU law and that the views expressed were not necessarily the final views of the Commission – and noted that this practice seems doubtful, as all Member States had already been aware of the risks related to chlorpyriphos and that risk management measures had already been taken by the Commission (non-renewal decision already applicable, draft Regulation lowering the MRLs to be voted at this Committee). Hence, there was no element of a new previously unknown risk necessitating quick communication via RASFF.

Part of the non-renewal decision was the explicit granting of a very short grace period of 3 months (until end of April 2020), supported by the Member States, which implicitly means that products should be still considered compliant during this period and until the application date of lowered MRLs. Nevertheless, the Commission also highlighted that Article 14(8) of the General Food Law allowed Member States in certain circumstances to withdraw compliant products from the market, based on case by case decisions.

The Member State having notified in RASFF explained that its notification was based on the health risks identified by EFSA, while the Member State of origin thought that, since risk management measures were underway and at an advanced stage, the RASFF system should not have been used. The latter was supported by another Member State. A fourth Member States supported the view expressed by the Commission that use of Article 14 (8) should be carefully considered case by case and in view of the length of the decision making process. The Commission offered that specific cases could be discussed in this Committee in order to define a common line. One Member State requested clarification in relation to the criteria for the use of the RASFF notification system in case of genotoxic substances. The Commission proposed to discuss this issue separately.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a coordinated multiannual control programme of the Union for 2021, 2022 and 2023 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 informed that the draft measure was currently under internal consultation of the other Commission services and that the final version will be tabled for vote during the meeting of the SCPAFF, Phytopharmaceuticals – section Legislation on 23-24 March 2020.

Vote postponed.

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

The Commission clarified that no changes were brought to the draft measure, which still proposes a deferred application date of six months in line with the wording used in the notification submitted the WTO-SPS notification system.

Vote taken: Favourable opinion.

B.07 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 chlorate.

The Commission proposed a new version of the draft measure including an update of the MRL value for kales. Some Member States expressed their surprise at this last moment change but considered it relevant and that it should be taken on board. One Member State abstained, raising concerns regarding the consumer exposure from the proposed values overall, while another Member State voted against the draft measure in concern of the MRL value for milk and the resulting levels of consumer exposure.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, flonicamid, haloxyfop, mandestrobin, mepiquat, Metschnikowia fructicola strain NRRL Y-27328 and prohexadione in or on certain products (Art. 10).

The Commission clarified that the draft measure had already been translated and that it was planned to be published before the draft measure discussed under Agenda Point B.9. The Commission drew the Member States' attention to the fact that the two measures contain the same substance flonicamid.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, Bacillus subtilis strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products (Art. 10).

The Commission outlined some minor amendments that were brought to the measure following the Commission's internal consultation procedures. A Member State confirmed its reservations in relation to the inclusion of *Bacillus subtilis* strain IAB/BS03 in Annex IV to Regulation (EC) No 396/2005.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for metam, dazomet, hexythiazox, clethodim and sethodydim in or on certain products (Art. 12).

A revised draft text was presented to the Committee. A discussion took place whether the existing MRL for hexathiazox could be tentatively maintained for soyabeans with a footnote requesting confirmatory data within two years. Member States agreed that this was appropriate in this specific case. The Commission shared the information received from the applicant for clethodim who intends to present preliminary study results to the Commission prior to the next Committee meeting in June 2020. A discussion on the follow up is scheduled for this meeting. Sethoxydim, a metabolite of clethodim and included in the current residue definition for enforcement, is proposed to be taken out of the residue definition and will be regulated separately in Annex V of Regulation (EC) No 396/2005.

Member States were invited to provide their comments by 13 March 2020.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products.

The Commission recently finalised the internal consultation procedures and shared its intention to launch the SPS-WTO notification in the coming weeks aiming at presenting a draft measure for the opinion of the June 2020 meeting of this Committee.

A Member State informed the Committee that it had overlooked the fact that a less critical GAP led to higher residue levels in fresh beans and peas (with pods) and that the residues of bentazone exceed the current EU MRLs for these commodities. The Commission suggested that the Member State submits a new MRL application in accordance with Article 6 of Regulation (EC) No 396/2005.

Member States were invited to provide their comments by 13 March 2020.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for chlordecone in or on certain products.

EFSA shared an advanced copy of the statement on the dietary exposure assessment for the temporary MRLs for chlordecone in certain products of animal origin. EFSA recommended lowering the existing MRLs to the values identified by the French risk assessment body (ANSES), which were rounded according to the guidelines on the OECD MRL calculation. The Commission intends to draft a measure in the coming weeks and circulate it to Member States for a commenting period before launching the WTO-SPS notification. The Commission aims at presenting a draft measure for a vote in September 2020.

The Committee agreed on the proposed approach. However, France expressed some reservations on the rounding of the values in terms of communicating the inconsistency to the general public, but will address this issue at national level. Another Member State enquired whether products of plant origin could also be revised at this stage. France clarified that on the basis of the available monitoring data it would be too premature to take action on crops as there are still occurrences due to the persistency of the substance in soil.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bupirimate, carfentrazone-ethyl, emamectin, ethirimol and pyriofenone in or on certain products (Art. 12).

The Commission introduced the draft Regulation and gave an overview of the comments received.

On emamectin two Member States indicated that MRLs lower than the default value of 0.01 mg/kg should be used in only very exceptional cases, reasoning with the low contribution of various products to the ADI and analytical difficulties. EFSA clarified that the recommended lower than the default values for specific commodities were needed, because the use of default values would have led to exceedance of the ADI. In addition, EFSA clarified that its calculations only considered the parent compound while metabolites would provide an additional contribution to the overall exposure, and that the existing CXLs were also lower than the default value.

Member States were invited to provide their comments by 13 March 2020.