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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Residues*

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SUMMARY REPORT

A.01 Note Taking of 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.10 (3)).

The Commission informed the Committee of the outcome of the Expert Working Group Meeting on Pesticides Residues Monitoring (Expert WG) held on 12 October 2018 and presented Revision 10(3) of the Working Document (WD) SANCO/12745/2013 which integrates the conclusions of the Working Group. Some substances for analysis on animal commodities were maintained in Chapter 4 (substances to be included in national programmes) instead of moving them to Annex IV (substances with low amount of findings). It was proposed to discuss the issue of low findings in animal products in the next Expert WG meeting together with the EU Reference Laboratories (EURLs) since this could be due to the low analytical capability of official control laboratories for this matrix and therefore presents a systematic problem.

The Committee took note of Working Document SANCO/12745/2013, Rev 10(3) and the Commission will publish the document on the DG SANTE webpage under the section on analytical guidelines.

A.02 Art. 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12 – updated table

The Commission updated the table on substances prioritised under the Article 12 MRL review process and gave an overview on the state of play to the Committee.

2. Confirmatory data Art. 12 follow-up

a) Note Taking of Working Document 10235/2016 - Rev. 3

The Commission introduced a revised draft Working Document and the key comments it had received from Member States and EFSA, highlighting points for consideration by the Committee.

The Committee discussed the draft in detail with a view to establishing the right level of detail to be useful and instructive, while preserving sufficient flexibility to efficiently deal with individual applications.

The Commission presented a draft that was amended on the basis of this discussion.

The Committee took note of Revision 3 of Commission Working Document SANTE/10235/2016. It will be published on the SANTE website on MRL guidelines and apply to applications submitted from 01 March 2019.

b) Overview on footnotes A expiring in 2018

The Commission presented an overview of substances for which in the Article 12 review exercise it had been found that analytical standards were not available (marked as "footnote A" in the respective Regulations establishing MRLs). Follow up is foreseen with the manufacturers of the concerned substances.

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

EFSA had published a first set of Reasoned Opinions on the assessment of the confirmatory data requested under the Article 12 process. The Commission prepared a table identifying those cases for which risk management decisions will need to be taken. In particular, for pyraclostrobin in table grapes new data on residue trials became available indicating a possible risk for consumers. In order to enable the Commission to follow up swiftly on this, Member States were requested to verify whether there is a fall-back GAP in support to the use on grapes.

Member States were invited to provide their comments by 31 December 2018.

A.03 Feedback from Legislation Committee:

1. New active substances currently under discussion in the Standing Committee on Plants, Animals, Food ad Feed, section Phytopharmaceuticals - Legislation (SC PAFF) - section Legislation

The Commission informed about three new active substances currently under discussion in the SC PAFF – Phytopharmaceuticals Section Legislation: (EZ)-1,3-dichloropropene, Napropamide-M and ABE-IT 56.

2. Update on Brexit

The Commission reported from the discussions on Brexit preparations at the meeting of the PAFF Committee – Phytopharmaceuticals Section Legislation on 23/24 October 2018 (agenda item A.30 of that meeting). It referred to the technical expert seminar (EU27) on plant protection products and pesticide residues related to matters of the UK withdrawal, scheduled for 12 December 2019. The Commission urged Member States to have a well-prepared and internally coordinated position on the proposed re-allocation of assignments, and to signal any issues to the Commission well in advance of the technical expert seminar.

Member States were invited to internally coordinate their position for the technical expert seminar that will be held on 12 December 2018.

3. ***Update on discussion on grace periods in the October SC PAFF – section Legislation meeting***

The Commission reported from the discussions on grace periods following restriction of approval or non-approval of active substances under Regulation (EC) No 1107/2009 at the meeting of the SC PAFF Phytopharmaceuticals – Section Legislation on 23/24 October 2018 (agenda item A.29 of that meeting). It elaborated on the Commission services' efforts to ensure alignment of the level of stringency applied in decisions on approval and on MRL setting for the same substance. The Commission asked Member States to support such efforts and coordinate their positions taken in the sections Legislation and Residues accordingly.

A.04 Specific substances:

1. Propoxur

The Commission referred to the issue raised by a Member State at the meeting of the SC PAFF Phytopharmaceuticals – Section Residues on 20/21 September 2018 (Point A.04.03) and additional comments from that Member State since then, regarding the need to establish an acute reference dose (ARfD) for propoxur, which has not been approved as active substance in the EU since 2002. EFSA is in contact with Health Canada who established a low ARfD to see which information could be shared by the Canadian authorities.

One Member State supported the proposed way forward, and pointed out that instead of reviewing the MRLs under Art. 43 of Regulation (EC) No 396/2005, MRLs could also be deleted based on Article 17 of that Regulation since EU uses no longer exist and no Codex maximum residue limits (CXLs) were established for the substance.

2. Chlormequat in Capsicum – data submitted by the European Spices Association (ESA)

ESA informed the Commission about the recent findings of chlormequat in paprika spice (dried capsicum) originating from China. China provides around 75% of the EU supply of paprika, only around 10% is produced in the EU. According to the data presented by ESA, most of the paprika imported from China would not be compliant with the current EU MRL of 0.01 mg/kg (i.e. 0.1 mg/kg when applying a dehydration factor). A similar pattern occurs also for other capsicum species. ESA explained that the problem was only recently discovered, because chlormequat was not included in their monitoring screening method as it requires a single residue method, which is carried out by laboratories only on demand.

Several Member States confirmed that they do not screen systematically for chlormequat due to the single residue method. A Member State pointed out that according to the data shared by ESA, there are a significant number of findings also above the old MRL of 0.05 mg/kg that was applicable before the Article 12 review. Another Member State reported that it had performed analysis of the substance on a regular basis, but had not found exceedances of the MRLs. That Member States suggested that if there was an authorised use in China an import tolerance request could be made. A Member State reported that batches from China are often mixed with batches originating in EU Member States.

Member States were invited to share data on findings of chlormequat in capsicum species and report back to the Commission by 31 December 2018.

3. Mandipropamid (TTC approach)
   The Commission informed that the assessment of two MRL applications for mandipropamid had been put on hold by EFSA pending confirmation that a specific metabolite was not genotoxic. The two evaluating Member States had originally proposed to use the Threshold of Toxicological Concern (TTC) approach in view of the fact that the metabolite occurred at extremely low levels and in the absence of more specific data which was controversially discussed with EFSA. The use of the TTC approach was discussed with EFSA who raised concerns about its use. In parallel, the applicant had submitted further data and an expert meeting had been organised by EFSA. The experts confirmed that the metabolite was not genotoxic and not relevant in the crops under consideration, the use of the TTC approach was no longer necessary and the assessment of the two applications was therefore resumed.

4. Propyzamid (stop-the-clock)
   The Commission informed that the assessment of an MRL application concerning propyzamide in oilseeds had been put on hold by EFSA, pending the assessment of the confirmatory information that was recently submitted in the framework of Regulation (EC) No 1107/2009.

5. Tricyclazole/India
   The Commission updated the Committee on tricyclazole-related developments. This included an import tolerance request, currently pending at EFSA level awaiting submission of additional data by the applicant; RASFF notifications in 2018 on Basmati rice from India in which tricyclazole was quantified above the MRL; and a recent audit of SANTE Directorate F to India with a focus on pesticides in food of plant origin. The Commission invited Member States to be vigilant in their control activities and to share data on findings of tricyclazole in rice by 31 January 2019. A Member State commented that a listing in Regulation (EC) No 669/2009 should be considered to have a more systematic data collection. One Member State reported that it had analysed tricyclazole on rice systematically but that the majority of samples (80%) had been negative.

A.05 News from the European Food Safety Authority:

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

   EFSA gave an update on those Reasoned Opinions that were recently published and those that are about to be finalised. Overall, the "interim process" is almost completed. The reviews for dazomet, metam, imidacloprid and hexythiazox will be finalised by the end of this year leading to a total of 25 Reasoned Opinions adopted in 2018. For etridiazole, EFSA clarified that a statement will be published as the substance is no longer supported.
   One Member State asked to clarify how the voted renewal of approval decision for copper compounds, containing use restrictions, would affect the Article 12 review. As the Article 12 Reasoned Opinion was already published, it needs to be carefully checked whether a review becomes necessary. Details will first need to be discussed bilaterally between EFSA and the Commission.

2. Progress under Article 10 of Regulation (EC) No 396/2005

   54 Reasoned Opinions were published in 2018.
   54 MRL applications are currently under the stop-the-clock procedure. EFSA started a pilot project to collect the information on Good Agricultural Practices (GAP) in an Excel table format instead of pdf files which should help to reduce the number of clock-stops related to unclear information provided to EFSA on existing GAPs

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

   There are currently no EFSA mandates ongoing under the Art. 43 procedure.

4. Other information

   EFSA report on processing factors (PFs)
   EFSA made a presentation on their report on PFs, which had been published on 26 November 2018. The report was welcomed by the Member States and the Commission.
   EFSA explained that the report compiles those PFs that were established in EFSA risk assessments but does not currently take into account other PFs established in national databases. EFSA stated that it would be open to bilateral discussions with the respective Member States to explore the options for further harmonisation.
   One Member State asked EFSA and the Commission to clarify whether the compiled PFs could also be used for enforcement action taken by Member States or as a basis for establishing the missing Annex VI to Regulation (EC) No. 396/2005.
   One Member State highlighted that in its view the use of legally binding processing factors could pose problems as such factors would not take into account the particularities of specific processing operations and therefore not be robust enough. Enforcement action based on raw products would therefore be preferable. Another Member States enquired how the compilation of PFs would be updated in view of new information coming through the review process.
   The Commission suggested to have a more thorough discussion in a forthcoming meetings on the potential use of PFs by national authorities allowing Member States more time to familiarise themselves with the report.

   EFSA report on proportionality
   EFSA presented a technical report on proportionality, which had been published on 14 November 2018. A revised version will be published soon to amend some errors. The report is based on the agreement reached with Member States on the use of the proportionality principle in the SC PAFF Phytopharmaceuticals – Section Residues in September 2013 which in turn was based on the EU's earlier agreement on the approach at international level (Codex Committee on Pesticides Residues (CCPR) 2013).

   Minor amendment to PRIMo model (rev 3.1)
   EFSA had prepared a minor amendment of the PRIMo model (rev 3.1) addressing some editorial issues and some errors in consumption factors that were brought to its attention by Member States.

A.06 Discussion on possible follow up to the EFSA opinion on food for infants and young children.

The Commission recalled the discussion in previous meetings of the SC PAFF Phytopharmaceuticals – Section Residues and its request to Member State to highlight substances for which further analytical development work would be needed to achieve low Limits of Quantification (LOQ) in foods for infants and young children.

Member States commented on the list of substances with low Acceptable Dietary Intakes (ADIs) suggesting to add or remove substances in view of recently proposed changes of the ADIs in the renewal exercise. One Member State had proposed a list of active substances for which a potential carry-over from feed to milk could not be excluded and hence suggested their prioritisation for further analytical research.

The Commission updated Member States on the discussion that had taken place during the Working Group Meeting of Experts on Monitoring of Pesticide Residues in October 2018, where diverging opinions were expressed by Member States' experts on the Commission's proposal for inclusion of a small scale project on this matter within the 2019-2020 Work Programme of the EURLs. Following up on this proposal, the EURL on Single Residue Methods (SRM) proposed 6 substances (chlorpyrifos, emamectin, ethoprophos, fluquinconazole, gamma-cyhalothrin, alpha-cypermethrin) for further analytical investigation towards lowering LOQs.

Member States expressed diverging views, questioning on the one hand the usefulness of such a project given its high costs that were seen as disproportionate to the rather low risk that this type of well-controlled products present and on the other hand the need to make sure that robust analytical methods are available to ensure comprehensive controls by national authorities.

The Commission concluded that in view of the comments it would consider including a limited project in the EURL Work Programmes (WPs) for 2019. Member States were invited to provide their comments by 4 January 2019 on the possible short list of substances.

A.07 Transitional periods – follow up from September meeting.

Following Article 49 of Regulation (EC) No 396/2005, transition measures can only be granted when they are without prejudice to the obligation to ensure a high level of consumer protection. Following Member States' comments after the discussion at the meeting of the SC PAFF Phytopharmaceuticals – Section Residues on 18/19 September 2018, the notion of suspected genotoxicity versus inconclusive genotoxicty was discussed in this context. It was proposed to consider that the gentoxicity of a compound is suspected when positive or equivocal results are obtained in in-vitro test and to distinguish this notion from the notion of inconclusive genotoxicity, which reflects the absence of data allowing to conclude on the gentotoxicity. A Member State requested some explanation of the term "equivocal" and EFSA explained that results are considered equivocal when both positive and negative results are obtained. Certain Member States supported the position that no transition period should be provided when the genotoxicity of the parent compound or of one of its metabolite is suspected, while other Member States supported a case-by-case approach. Further discussions will be needed to clarify this aspect and its impact on the granting of transition periods.
Member States were invited to provide their comments by 31 December 2018.

A.08 Project on data collection dithiocarbamates.

The Commission provided information on the project's current state-of-play in terms of the number of samples currently included in the "Pestipedia" database held by the EURL SRM for this purpose. The Commission informed Member States of the receipt of analytical results for dithiocarbamates in 176 samples of organically grown raw materials for herbal and fruit infusions from the association Tea and Herbal Infusions Europe (THIE).

One Member State informed that it would shortly report on 40 organic samples, while another Member State reminded that it would also report on results from certification bodies. From the side of EFSA, the 2017 monitoring results are being validated and will soon be extracted and fed into the database.

A.09 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2019-2020.

The Commission gave an update on the state of play. The Rapporteur Memer State (RMS) for flupyradifurone is currently assessing the extensive data package that was submitted as Article 12 confirmatory data in relation to the occurrences of difluoroacetic acid in rotational crops. All other footnotes on confirmatory data under Article 12 expire only as of 2020.

A.10 International Matters:

1. **Organisation for Economic Development and Cooperation (OECD) Guidance document on the residue definition)**

The Commission informed of the meeting that will be held on 3-7 December 2018 in the World Health Organisation (WHO) premises with the OECD Residue Chemistry Expert Group and members from the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The aim of the meeting is to identify those parts of the existing 2009 OECD Guidance document on the "Definition of Pesticide Residue", which need to be updated and to reach some preliminary agreements on the key issues. Moreover, the expert group will consider to what extent veterinary medicinal products can be covered by the OECD guidance document.

In the EU, EFSA had prepared a Guidance document on the residue definition for risk assessment, which was not yet taken note of by the Member States. The European Crop Protection Association (ECPA) had proposed an alternative approach and recently prepared two case studies to compare the outcomes when using the different approaches proposed by ECPA and EFSA. The results of these comparative case studies were summarised and shared with the Member States and the Member States were invited to comment by 31 December 2018.

2. **Codex Alimentarius/JMPR issues**

The Commission informed Member States that it had received draft concern forms for buprofezin, diflubenzuron, iprodione and picoxystrobin. The concern forms will be sent to the chair of the Codex Working Group on Priorities and to the Codex secretariat.

Several Member States informed the Committee about ongoing work in the various electronic Working Groups of the Codex Committee on Pesticide Residues (CCPR).

A.11 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

No notifications had been received.

A.12 Designation of Member States for maximum residue levels (MRL) applications.

The applicant asked another Member State than the earlier RMS if it could assess an import tolerance request for pyridaben in several commodities, in view of the fact that the latter has recently carried out the Article 12 review, thus having gained the relevant experience. The two Member States agreed and the Committee took note of this agreement.

A.13 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The Commission gave an update on the state of play.

The study supporting the REFIT Evaluation was finalised and published on 18 October 2018: http://publications.europa.eu/s/i9z4.The Commission is now preparing a Staff Working Document, based on this supporting study, but also considering other pieces of information. A review by the Regulatory Scrutiny Board is scheduled on 23 January 2019 to assess the draft document.

A.14 Update on the technical guidelines for MRL setting for Note taking (SANTE/10595/2015).

The Commission informed that the chapter on import tolerances relating to substances falling under the cut-off criteria had been taken out of the document as it requires further internal discussion within the Commission in the light of the comments received by Member States in the SC PAFF Phytopharmaceuticals –Section Residues at the meeting on 18/19 September 2018.

The Commission went through the comments sent by Member States and EFSA and explained how they had been addressed in the final version. Subjects discussed were the division of responsibilities between Member States experts attending the Legislation and the Residues Sections of the PAFF Committee Phytopharmaceuticals, the procedures for Member States to submit dossiers to EFSA and the procedures in case of withdrawal of MRL applications.

One Member State raised a reservation as the guidelines make a cross-reference to the wording now systematically used in Article 12 transitional measures as regards imported products to which that Member State does not agree as it considers this wording discriminatory vis-à-vis non EU countries.

The Committee took note of the revised version of the guidance document noting the reservation made by one Member State.

A.15 Feedback from Member States on the question on the number of trials for seed treatment raised at the last meeting.

Following a question raised by a Member State at the last meeting of the SC PAFF Phytopharmaceuticals - Section Residues, two Member States had taken the initiative to develop a discussion paper on the number of trials needed in case of seed treatments and on extrapolation of MRLs in such cases. The current extrapolation guidance document SANCO 7525/VI/95 rev. 10.3. was considered not to be

sufficiently clear on this point. The discussion paper was presented. A Member State pointed out that consistency needs to be ensured as regards the number of zones and trials needed in case of seed treatments with the relevant existing legislation (Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 283/2013).

The Commission thanked the two Member States who prepared the discussion paper and invited the other Member States to comment directly to both of them by 15 January 2019. The item will be put on the agenda again in a forthcoming meeting.

A.16 Other Information points.

A.16.1 Meeting dates 2019

The Commission informed about the tentative dates for the 2019 meetings of the SC PAFF Phytopharmaceuticals – Section Residues and the planned dates for the Council Working parties (CWPs) for preparation of CCPR 2019 but emphasised that all dates are still subject to confirmation.

Meetings dates of the SC PAFF Phytopharmaceuticals - Section Residues:
21/22 February 2019
13/14 June 2019
26/27 September 2019
25/26 November 2019

Meetings for preparation of the 2019 CCPR:
11 March 2019: 1st CWP meeting
25 March 2019: 2nd CWP meeting
08-12 April 2019: CCPR meeting in China

A.16.2 Motion for resolution on a draft measure amending MRLs for acetamiprid in and on certain products

The Commission informed that the European Parliament's Committee on the Environment, Public Health and Food Safety (COMENVI), during the scrutiny period, intended to object to the draft Regulation setting maximum residue levels for acetamiprid which had been voted in the 18/19 September meeting of the SC PAFF Phytopharmaceuticals – Section Residues. A draft motion for resolution received a favourable opinion on 27 November 2018 in this Committee. It will likely be on the agenda of the December 2018 Plenary meeting of the European Parliament.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation 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 clothianidin, cycloxydim, epoxiconazole, flonicamid, haloxyfop, mandestrobin, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products (Art. 10)(SANTE/11195/2018).

The Commission introduced the draft measure and presented its content.

The following MRL applications had been submitted under Article 6 of Regulation (EC) No 396/2005:
- clothianidin for the use on potatoes (import tolerance);
- cycloxydim for the use on strawberries;
- epoxiconazole for the use on beetroots;
- flonicamid for the use on several crops;
- haloxyfop-P for the use on linseeds (import tolerance);
- mandestrobin for the use on strawberries and grapes (import tolerance);
- mepiquat for the use on cotton seeds;
- prohexadione for the use on oilseeds.

As regards mepiquat, EFSA recommended amending the MRLs for certain products of animal origin following the use of the substance on cotton seeds. The Commission clarified that the draft measure reflects the increase of MRLs only as the products for which a lower MRL was proposed do not pose a risk to consumers.

The draft measure proposes the inclusion of the substance Metschnikowia fructicola strain NRRL Y-27328 in Annex IV to Regulation (EC) No 396/2005 following its approval under Regulation (EC) No 1107/2009. The reason for such inclusion is outlined in the relevant Review Report (SANTE/10472/2018 Rev. 2).

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation 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 azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products (CXLs)(SANTE/11196/2018).

The Commission introduced the draft measure taking over into EU legislation such Codex MRLs (CXLs) that were adopted on 6 July 2018 by the Codex Alimentarius Commission. Only CXLs for which the EU had not reserved its position in the CCPR will be taken over in Regulation (EC) No 396/2005. The Commission clarified that the implementation of the CXLs for fenpyrazamine and penconazole will be postponed pending the publication of the Regulation reviewing the MRLs under Article 12 in order to avoid contradictory application dates.

Member States had sent comments identifying some errors in the draft measure. These errors were corrected in the revised version. During the meeting it was clarified that the CXL for mammalian meat also applies to "wild terrestrial vertebrate animals" as "wild boar" is clearly listed under this commodity group in the Codex classification system. Moreover, it was clarified that coconuts are covered by the group of tree nuts in the Codex classification.

At the meeting, one Member State asked to amend the MRL for difenoconazole in peppers to reflect the CXL that was adopted for chili peppers. EFSA confirmed in its scientific report that the use is safe for consumers. As regards fenpyroximate, EFSA asked to reintroduce the footnote concerning the lack of analytical methods. These changes were reflected in the final version of the draft measure.

Two Member States pointed out that the new CXL for chlormequat on wheat may have an impact on the current MRL for mushrooms due to cultivation practices with straw. This aspect should be kept in mind when reviewing the temporary MRLs for chlormequat in mushrooms in future.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee as regards maximum residue levels for bispyribac, denathonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop and tebufenozide (Art. 12) (SANTE/10482/2018).

The Commission presented for each substance an overview of the comments that had been received and how they were addressed. For denathonium benzoate the name of the substance was changed to denatonium benzoate in line with the name appearing under its CAS number (3734-33-6), but also in Appendix I of SANCO/2607/08-rev.1 (Review Report on the active substance denathonium benzoate). For the quizalofop esters, the Commission presented the changes to MRLs following comments from the Member States. As regards footnotes on confirmatory data, the Commission clarified that the intention is to only require confirmatory data for data gaps relating to the critical GAPs, i.e. those GAPs from which the MRLs are derived.

One Member State asked why denatonium benzoate would not be transferred to Annex V of Regulation (EC) 396/2005. The Commission clarified that the substance was approved and although currently all MRLs are set at the level of the LOQ, MRLs might be set in future following new applications.

Member States were invited to provide their comments by 13 December 2018.

C.02 Exchange of views of the Committee as regards maximum residue levels for 2,5-dichlorobenzoic acid methylester, mandipropamid, prochloraz and profoxydim in or on certain products (Art. 12) (SANTE/10935/2018).

Comments from Member States relating to the three active substances covered by the draft Regulation had been received and were presented by the Commission.

For 2,5-dichlorobenzoic acid methylester it was agreed to set the residue definition as "sum of 2,5-dichlorobenzoic acid and its ester expressed as 2,5-dichlorobenzoic acid methylester".

As regards mandipropamid it was proposed to extrapolate the MRL for leafy vegetables to the herbs of the category 0256000, but not to witloof, as initially suggested in the EFSA Reasoned Opinion. The Committee was also informed of recently published Article 10 Reasoned Opinions covering witloof (among a range of other crops) and cocoa beans, the latter being an import tolerance request. The outcome of these evaluations will be taken into consideration in the present review.

Concerning prochloraz the Commission received diverging comments regarding the residue definition and proposed to set a residue definition including the metabolites BTS 44595 and BTS 44596, following the EFSA conclusion on the peer review of that substance. Regarding the possibility to maintain the CXLs set for tropical fruits, EFSA signalled that a different residue definition had been set at Codex level and that this would result in a slight overestimation of the levels. The Commission noted the global support to maintain these CXLs since no health concerns were identified.

EFSA informed that in line with the agreement reached in the PAFF meetings of November 2017 and February 2018 the PRIMo model revision 2 had been used for the exposure assessment.

C.03 Exchange of views of the Committee as regards maximum residue levels for chlorate (SANTE/10684/2015).

The Commission explained that, as a general rule, the MRLs were derived from the latest available monitoring data collected between 2014 and 2017, using the 95th percentile. Data from the period 2011-2017 were used when the number of samples was insufficient for a robust estimation. Some flexibility towards higher levels was applied where this was justified on the basis of the low contribution to exposure of some commodities and in view of the wide range of levels found.

Furthermore, it was explained that the collected monitoring data used for establishing the MRLs already took into account the chlorate levels in food resulting from certain processing steps, e.g. during washing and blanching prior to freezing. Samples treated in this way as well as fourth range products (washed, cut, and packed fruits and vegetables) were part of the collected samples. Therefore no further correction factors were proposed for these products. It was once more clarified that processing factors according to Article 20 of Regulation (EC) No 396/2005 had been considered inappropriate by the Committee in previous discussions on this point (see point A.04 of the meeting of the SC PAFF Phytopharmaceuticals - Section Residues of 26/27 February 2018).

The Commission also explained that the geographical diversity of the collected samples ensured that the different situations in Member States regarding the possible chlorination of drinking water is well covered.

Some Member States continued to point to the need to fulfil hygiene requirements that could lead to chlorate residues when chlorinated solutions were used in food processing, and that these uses would be in line with the national legislation. The Commission recalled that the chlorate action plan was aimed at tackling a health issue identified by EFSA and that action both at national and European levels was needed to reduce the chlorate residues in drinking water and foods. Revision of any specific national legislation on the use of chlorinated products as processing aids should therefore be considered by Member States in order to bring chlorate levels down.

Some Member States also pointed to the discrepancy between the maximum levels of chlorate currently discussed for drinking water and the stricter levels foreseen for dairy products, while drinking water remains the main contributor to human exposure to chlorate.

The Commission recalled that the proposed levels were solely based on monitoring data, and that stakeholders will have the opportunity to provide their views or any additional data within the context of the feedback mechanism that is foreseen for this proposal. Adaptations and adjustments of some MRLs can still be considered. A Member State emphasised that the outcome of the feedback mechanism should be evaluated properly and that sufficient time should be dedicated to the evaluation and discussion with Member Sates of the comments received.

C.04 Exchange of views of the Committee as regards maximum residue levels for imazalil SANTE/11207/2018).

Following the adoption of the updated EFSA review of the existing MRLs for imazalil under Article 12 of Regulation (EC) No 396/2005, the Commission presented a draft Regulation modifying the existing imazalil MRLs. Due to the genotoxicity concern of the metabolite R014821, which is expected following post-harvest treatments, the corresponding MRLs are proposed to be set to the Limit of Quantification (LOQ).

Some Member States pointed to the difficulties that producers will face if the imazalil MRLs set for post-harvest treatments are lowered to the LOQ, as few alternative solutions exist. They questioned the proportionality of the draft measure and proposed to keep the CXLs corresponding to these post-harvest uses, or to maintain current MRLs for 2 years. This delay would allow for additional trials to be conducted and, possibly, genotoxicity concern to be ruled out.

The Commission recalled that this was not appropriate since health risks had been identified with the existing imazalil MRLs. For the same reason it is also not possible to grant transition measures, as Article 49(2) limits such transitional arrangement to the cases where no health risk is identified.

Member States were invited to provide their comments by 10 January 2019.

C.05 Exchange of views of the Committee as regards maximum residue levels for glyphosate and trimethyl-sulfonium cation (Art. 12) (SANTE/10520/2018).

The Commission informed the Committee that a revision of the EFSA Reasoned Opinion on the MRL review for glyphosate had become necessary, after the RMS confirmed that some studies had not been considered in the review in its present form, although they had been available and should have been taken into account. For this reason, no draft Regulation was presented to the Committee. The RMS informed the Committee that it expects a revised Evaluation Report to be available in January 2019. The Commission indicated that discussions in the Standing Committee will resume once a revised Reasoned Opinion is available.

C.06 Exchange of views concerning 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 (Art. 12) (SANTE/2018/11197).

The Commission referred to Revision 2 of the draft Regulation SANTE/2018/11197, which was agreed in the meeting of the Working Group of Experts on Monitoring of Pesticide Residues held on 12 October 2018 and gave an overview of the changes. In terms of the substances in the monitoring programme, the Commission noted that 2 substances were proposed to be removed (EPN, Parathion), while 4 substances were proposed to be added (cyflufenamid, fenpyrazamine, proquinazid and tricyclazole (for rice only)). Bovine liver was proposed to be included in the programme, replacing sheep fat in the table of commodities of animal origin to be analysed in 2020. To ensure that official control laboratories can analyse these matrices the EURL for Single Residue Methods (EURL-SRM) and the EURL for pesticides on commodities of animal origin (EURL-AO) will conduct an EU Proficiency Test on bovine liver in early 2019.

One Member State commented that flonicamid should be analysed on the entire range of crops in view of the fact that a range of new MRLs had recently been set. Another Member State proposed to reinstate the footnote in paragraph 5 of Annex II on the minimum number of samples to be analysed with a single residue method (SRMs) and a multi residue method (MRM). The Commission clarified that currently the Regulation sets out the minimum number of samples to be analysed per commodity per country without referring to the number of samples per analytical method, thus providing more flexibility to Member States. Two Member States reported that in practice they split samples to be able to analyse the same sample with a MRM and a SRM. The advantage of this procedure would be the overview on multiple residues in the same sample.

Member States were invited to provide their comments by 13 December 2018.

C.07 Exchange of views of the Committee as regards maximum residue levels for cyflufenamid, fenbuconazole, fluquinconazole, and tembotrione in or on certain products (Art. 12) (SANTE/2018/11337).

The Commission presented an overview of the 4 substances that will be included in a next Article 12 review and referred to the Explanatory Note and the LOQs table already uploaded on CIRCABC.

Member States were invited to provide their comments by 10 January 2019.

C.08 Exchange of views of the Committee as regards maximum residue levels for myclobutanil, napropamide and sintofen in or on certain products (Art. 12 (SANTE/2018/11371).

There was no discussion on this agenda item.

M.01 Outcome of SPS/WTO meeting November 2018.

In response to the request of a Member State, the Commission reported from the WTO-SPS Committee meeting on 1/2 November 2018, where the EU had been criticised by many other WTO members on several matters related to the MRL Regulations, including the draft Regulation lowering MRLs for buprofezin and several other substances, on which the SC PAFF Phytopharmaceuticals – Section Residues had given a favourable opinion at its meeting on 20/21 September 2018. The Commission also explained the general environment and procedural context of the discussions in the SPS Committee. A Member State asked to receive more regularly feedback on the proceedings of the SPS Committee.

M.02 Fosetyl – conclusions of the peer review.

In response to the request of a Member State, the Commission reported the state of play. It clarified that the toxicological reference values for fosetyl, and if appropriate also for phosphonic acid, need to be formally agreed by the SC PAFF Phytopharmaceuticals --Section Legislation, before a review of the MRLs can be considered. Given the joint residue definition comprising both fosetyl and phosphonic acid, and the interplay of procedures under Regulations (EC) Nos 1107/2009 and 396/2005, the Commission asked Member States to ensure exchange of information and coordination of positions between representatives in the sections Legislation and Residues of the Committee.

One Member State expressed agreement with the approach taken by the Commission. Another Member State indicated that they agreed with the bridging of toxicity data from fosetyl to phosphonic acid as described in the EFSA Conclusion on fosetyl. EFSA reminded the Committee that the MRL review under Article 12 of Regulation (EC) No 396/2005 is planned as a joint review for the three substances fosetyl, potassium phosphonates, and disodium phosphonate.

M.03 CXL for lamda-cyhalothrin.

A stakeholder had informed the Commission that the CXL adopted in 2009 by the Codex Alimentarius Commission for sunflower seeds and soya beans were fully supported by data. These CXLs should be reported in Annex II to Regulation (EC) No 396/2005.

The Commission proposed to address this issue in the framework of an MRL measure to be voted at the SC PAFF Phytopharmaceuticals – Section Residues in February 2019.

M.04 New batch of substances to be lowered to LOQ after non-renewal, withdrawal of renewal application, etc.

The Commission informed that it will prepare a draft measure containing a set of substances that are no longer approved in the EU and for which all periods of grace have expired. The measure will be presented at the meeting of the SC PAFF Phytopharmaceuticals -- Section Residues in February 2019.

M.05 Metobromuron.

In the past, one Member State had made an application to set the MRL for metobromuron in lamb lettuce. However, the assessment had been put on hold by EFSA pending the assessment of confirmatory information requested under Regulation (EC) No 1107/2009. The assessment of the confirmatory information has now been pending for two years. The respective Member State reported that it would urgently need to grant authorisations also for other crops. The RMS for this substance clarified that it will finalise the assessment of the confirmatory information as soon as possible. The workload in relation to such assessment was acknowledged by the Committee.