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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Residues*

26-27 February 2018

SUMMARY REPORT

CIRCABC Link: ***https://circabc.europa.eu/w/browse/e9883338-bbb3-4a48-98c2-8da81ee5fd3c***

A.01 Exchange of views of the Committee as regards maximum residue levels for penoxsulam, triflumizole and triflumuron ((SANTE 2017/10633)(Art. 12).

The Commission presented few changes introduced in revision 1: the legal text was amended following the consultation of other Commission services, some footnotes for triflumuron have been completed and a different residue definition (RD) for animal products was proposed, following a suggestion of the EU Reference Laboratories (EURLs).

On this last point one Member State asked for more clarification. The representative of the EURLs explained that when no information or data are available, the simplest RD should be used, in most cases the parent compound only.

In addition, the Commission presented two amendments which will be used from now on in all Article 12 (of Regulation (EC) No 396/2005) drafts, regarding the wording of the transitional measures in Article 2 and the introduction of a specific footnote for the product ginger (spice). One Member State asked about the reason why the phrase *'or imported into the EU'* was introduced into Article 2. The Commission explained that this clarification was needed given that questions on interpretation of the current text had been received from third countries.

Member States were invited to submit comments by 10 March 2018.

A.02 Exchange of views of the Committee as regards maximum residue levels for bromadiolone, etofenprox, imazalil, paclobutrazol, and penconazole (SANTE/11715/2017) (Art. 12).

The Commission introduced the last modifications made to the draft on the basis of the comments received from the European Food Safety Authority (EFSA) and Member States. Concerning imazalil, a Member States signalled an incorrectly reported highest residue (HR) level of a banana trial. With the correct (higher) value, the acute Reference Dose (ARfD) is exceeded and the proposed maximum residue level (MRL) of 5 mg/kg for banana cannot be maintained. The MRL for imazalil in banana will consequently be revised to the lower Codex maximum residue limit (CXL) value of 2 mg/kg, which is the value currently in force. Corrigenda will be published for the evaluation report and for the EFSA reasoned opinion.

Regarding the coordination of this MRL review with a parallel Article 6 (of Regulation (EC) No 396/2005) application concerning partially the same commodities, the Committee was informed that the Article 6 application is still on hold because of lacking data. The rapporteur Member State (RMS) acknowledged the receipt of additional data by the applicant and will amend its evaluation report consequently. The RMS will then send its amended report to EFSA in order to allow for further assessment of this additional information. Some Member States were of the view that the Article 12 review should not be delayed for a too long time. The Committee accepted that the Commission would continue its efforts of coordination between the timelines of both procedures until the next SC PAFF meeting on 13 and 14 June 2018 as a maximum acceptable delay. If then it becomes clear that the Art. 6 assessment cannot be integrated, the Art. 12 draft would be finalised and its vote scheduled for September 2018.

A.03 Exchange of views of the Committee as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridabene (SANTE/10154/2018) (Art. 12).

The Commission presented an overview of the five substances that will be included in a next Article 12 review and referred to the explanatory note and the Limits of quantification (LOQ) table already uploaded on CIRCABC.

One Member State highlighted that the applicant for carboxin had sent a letter complaining about data that had not been taken into account while revising MRLs, but the Member State pointed out that the data had been submitted after the deadline. One Member State questioned how the MRL of pyridaben for the citrus group had been extrapolated, as it explained that based on the EFSA Reasoned Opinion the data collected for mandarins and oranges were not comparable. EFSA replied that the proportionality principle was used and that it would further investigate the issue. The EURLs updated on new studies carried out for the method of analysis for fenbutatin oxide.

Member States were invited to submit comments by 20 March 2018.

A.04 Exchange of views of the Committee as regards maximum residue levels for chlorate (SANTE/10684/2015).

The Commission announced the adoption of a draft Regulation for the revision of the Directive on drinking water, which includes now a maximum level of chlorate set at 0.25 mg/l, a level 3 times lower than the current guideline level by the World Health Organization (WHO) of 0.7 mg/l.

The Commission introduced the last modification made to the draft Regulation and invited Member States to reflect on the role of processing factors as referred to in Article 20 of Regulation (EC) No 396/2005 to address chlorate levels in processed foods, given that chlorate concentration could increase during food processing. Those Member States who took the floor were all of the view that processing factors according to Art. 20 of Regulation (EC) No 396/2005 would only apply in cases where changes of levels would arise from concentration, dilution or the degradation of pesticides already present in the raw commodities (e.g. through operations such as drying). In their view it would be not appropriate to apply processing factors to account for changes of pesticides levels resulting from the introduction of substances

during the processing step itself (e.g. formation of chlorate from chlorinated water through washing/blanching operations).

One Member State re-iterated its position to base the MRL on the 95th percentile instead of the 90th percentile, another Member State questioned the approach to base a draft for chlorate MRLs on monitoring data altogether. Some Member States asked for the revision of the proposed MRLs on the basis of more recent monitoring data.

The Commission stated that the overall approach had been agreed with Member States back in 2014 and confirmed by the heads of agencies meeting in 2017. It emphasised that the only alternative would be to maintain the existing legislation with the default value of 0.01 mg/kg for all crops. It also stated that it would be ready to make adjustments to specific proposed levels if new data would support this. Stakeholders will be consulted via the feed-back mechanism, which foresees the publication of the draft Regulation after the Commission inter-service consultation and a call for comments during 4 weeks.

The Commission will revise the proposed MRLs on the basis of the additional monitoring data received.

A.05 Exchange of views of the Committee as regards maximum residue levels for lambda-cyhalothrin (SANTE/11228/2017).

This draft had already been discussed in several previous meetings of the Standing Committee for Plants, Animals, Food and Feed (SC PAFF) - section Pesticides Residues. The Commission therefore focussed on the question whether certain CXLs, considered by EFSA as safe, should be taken over despite the fact that they were not fully supported by data.

As some Member States expressed already in the meeting their preference for keeping these CXLs in the draft, the Commission proposed to include them in revision 2 and invited other Member States to express comments in writing by 2 March 2018.
The Commission also announced that the draft is scheduled for vote at the next SC PAFF meeting of the legislation section, on 22 March 2018.

A.06 Exchange of views of the Committee as regards maximum residue levels for linuron (SANTE/10145/2017).

The Commission introduced a draft Regulation setting the MRLs for linuron to the LOQ, following the non-renewal of the approval of this active substance. The draft takes into account the grace period that Member States can grant for the use and sell-off of plant protection products containing that substance, which ends on 3 June 2018.

The discussion focussed on transition measures. Some Member States asked to check whether maintaining certain MRLs for an extended period of time could lead to a risk for consumers, and as the case may be, to withdraw such MRLs from the scope of transition measures. The Commission announced its intention to carefully study in which cases transition measures should be provided when the MRLs of a given active substances are lowered to the LOQ and will discuss a general approach with EFSA and the Member States at the next Committee meeting.

A.07 Exchange of views of the Committee as regards maximum residue levels for iprodione (SANTE/11836/2017).

The Commission introduced a draft Regulation setting the MRLs for iprodione to the LOQ, following the non-renewal of the approval of this active substance. The draft takes into account the grace period that Member States can grant for the use and sell-off of plant protection products containing that substance, which ends on 8 June 2018.

Like for linuron (see point A.06), the discussion focussed on the transition measures and the conditions to grant such transition measures. For iprodione, EFSA will check whether the new toxicological reference values set during the peer review of that substance lead to a risk for consumers. Commodities for which a risk would be identified would then be excluded from the transition measures.

Member States were invited to submit comments by 20 March 2018, however the commenting period will likely be extended given that the EFSA assessment needs to be available first.

A.08 Exchange of views of the Committee as regards maximum residue levels for diphenylamine and oxadixyl (SANTE/10070/2018).

For diphenylamine provisional MRLs had been set by Regulation (EU) No 772/2013 for apples and pears until 2 September 2015, to address an unavoidable cross-contamination that affected untreated apples and pears and which was due to the presence of residues of diphenylamine in storage facilities. Regulation (EU) 2016/67 extended the validity of these MRLs until 22 January 2018 to provide the necessary time for business operators to completely remove the residues of diphenylamine in storage facilities.

For oxadixyl provisional MRLs had been set by Regulation (EU) No 592/2012 for parsley, celeries and the group of lettuces and salad plants until 31 December 2014, to address an unavoidable cross-contamination that affected untreated crops and which was due to the presence of residues of oxadixyl in soil. Regulation (EU) 2016/46 extended the validity of these MRLs until 19 January 2018 in view of the persistence of the active substance in soil.

For the two substances, EFSA and food business operators submitted recent monitoring data showing that residues no longer occur at levels above the relevant LOQ. The Commission proposed to lower the provisional MRLs to the LOQ and to transfer the substances into Annex V to Regulation (EC) No 396/2005 in view of the fact that the active substances are not approved under Regulation (EC) No 1107/2009. Member States were invited to submit comments by 10 March 2018.

A.09 Future work on maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim.

The Commission informed the Committee that a draft measure is under preparation to lower to the LOQ the existing MRLs for a set of substances that are no longer approved under Regulation (EC) No 1107/2009 or whose approval was restricted, in accordance with Article 17 of Regulation (EC) No 396/2005.

The Commission asked Member States to identify MRLs that should be maintained, in the absence of health concerns, to meet the needs of international trade. It also asked Member States to indicate their position on possible transitional measures.

Member States were invited to submit comments by 20 March 2018.

A.10 Glyphosate Art. 12 and animal health mandate.

EFSA informed the Committee on the state of play regarding the MRL review and the scientific report on animal health.

Trimesium is a counter ion of glyphosate in certain product formulations, which is considered to be relevant in view of its toxicological profile. Specific MRLs were set in the annexes to Regulation (EC) No 396/2005. Since trimesium was not supported in the context of the renewal of approval of glyphosate and it is no longer used in plant protection products authorised in Member States, the MRLs for trimesium could be set to the LOQ in parallel with the review of MRLs for glyphosate.

Stakeholders informed the Commission and the EU Reference Laboratory for single residue methods (EURL SRM) about findings of trimesium in tea and herbal infusions that are unlikely to be linked to plant protection. Preliminary information indicates that trimesium is possibly formed during the drying processes in these commodities.

A.11 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 to the Committee.

2. Procedures for substances for which the Art. 12 review follows the renewal procedure
   The Commission informed the Committee about comments received from the Post-Approval Issues (PAI) group. While welcoming the suggestions, it expressed its view that a revision of the document describing the procedure is currently not necessary.

3. Experience with the new process under Article 12
   The Commission referred to a letter from an applicant regarding its experience with the new process for MRL reviews, and asked Member States and EFSA to share their experience as well.
   Issues raised concerned timelines that are too tight for substances with a large number of uses, and on the necessity to include not only information on uses authorised in EU Member States but also on import tolerances, where such information is available. Member States also required clarification on the reporting of uses authorised through mutual recognition and suggested improvements to the tools used for collection of Good Agricultural Practices (GAPs). EFSA has already taken up some of these issues and informed about further improvements to be discussed in the course of March 2018.
   Member States were invited to submit comments to EFSA by 10 March 2018.

A.12 Annex 1 to Regulation (EC) No 396/2005 - radish leaves.

The Commission presented the details of the issue, which had been subject to many interventions and comments both from Member States and stakeholders since the beginning of January 2018 and is related to the application of Commission Regulation (EU) 2018/62 amending Annex 1 to Regulation (EC) No 396/2005 since 1 January 2018.

The commodity 'radish leaves' had been introduced in the updated Annex I and was linked to the main product 'kales'. However the 'small radishes' (product already present in Annex I) are frequently sold together with the leaves. This means that small radishes should comply with two different MRLs, one for tubers and one for kales (MRL applicable to radish leaves). However, stakeholders submitted data indicating that the MRLs for kales might not be appropriately reflecting the residues in radish leaves.

The Commission reacted swiftly to the concerns and proposed a further amendment to Annex I to Reg. (EC) No 396/2005 introducing a 4-year transitional period until 2022 before MRLs of kales will apply to radish leaves. This will allow conducting specific trials on radish leaves with a view to clarifying the required MRL and the most appropriate position of the commodity within Annex I.

The amendment is scheduled for vote at the SC PAFF meeting - section legislation - on 22 March 2018 and undergoes the regulatory procedure with scrutiny. Since under this procedure the adoption of the measure is not expected before summer/early autumn 2018, exceptionally a retroactive application of 1 April 2018 is proposed to avoid problems with the spring harvest of radishes. On request of a Member States the Commission clarified that an earlier date was not possible given that the vote only takes place in March 2018.

The Member State who had not yet expressed any position were invited to send comments (if any) before 2 March 2018.

The Member State who originally asked for the introduction of radish leaves into Annex 1 clarified that in the original request the possible consequences on the small radishes had not been considered and thanked the Commission for the fast reaction. It offered to conduct some trials on the radish leaves, in order to produce the missing data. Also another Member State confirmed that it would carry out trials on radishes.

The Commission advised the Member States that in view of the upcoming vote on the transitional measure, enforcement action on radish leaves should be proportionate.

A.13 Specific substances – update of state of play:

1. New active substances currently under discussion in the Legislation section of the Committee
   The Commission updated the Committee that since the last meeting the following three new active substances are under discussion in the SC PAFF – section legislation: Metschnikowia fructicola NRRL Y-27328, Fenpicoxamid (XDE-777) and Pasteuria nishizawae strain Pn1.

2. Prosulfocarb/olives
   The Commission followed up on this request of a Member State at the November 2017 meeting to set a temporary MRL for prosulfocarb/olives in a situation of cross-contamination. Several Member States commented that they felt that setting a temporary MRL would not be appropriate in this situation as other tools for managing cross-contamination would be available. Such tools were presented by several delegations in their comments. The Commission agreed and advised the Member State not to proceed with its evaluation of the application. It proposed that an exchange of views of Member States in similar situations on options and risk mitigation measures is extremely useful and that it will facilitate such future exchanges.

A.14 News from the European Food Safety Authority:

Overview on the state of play of mandates under Art. 10, Art. 12 and Art. 43 of Regulation (EC) No 396/2005

EFSA gave an update on the state of play on the progress of the reviews under Art. 10, Art. 12 and Art. 43 of Regulation (EC) No 396/2005. 15 Art. 12 reasoned opinions are currently still ongoing under the interim procedure, 20 active substances under the new procedure. The glyphosate Art. 12 reasoned opinion was revised with some additional information and is expected to be adopted in March 2018 together with the Art. 43 reasoned opinion on glyphosate/animal health. The copper Art. 12 reasoned opinion is also expected to be adopted in March 2018.

19 new questions for Art. 10 were assessed since the last meetings, 37 are ongoing and 45 are in the stop-clock procedure. The Art. 43 review for acetamiprid is planned to be adopted by 16 April 2018. Acute concerns were identified for a number of commodities, for some of them fall-back GAPs (Good Agricultural Practice) had been provided by Member States. EFSA also informed that the mandate on fipronil for which a deadline for end of January 2018 was set, would require more data analyses requested by Member States and would therefore be delayed (finalisation expected mid March 2018).

Furthermore EFSA informed about the ongoing establishment of a List of endpoints (LoEP) for peer review and MRL assessments which is part of the template for Assessment Reports and is planned to be noted in the March PAFF Committee-section legislation. It also informed about the new features of a revised GAP template for which training to users will also be provided.

EFSA Art. 12 work programme for 2018

EFSA and the Commission presented the workplan for MRL reviews until September 2018, on which Member States had been consulted in December 2017. Two Member States requested an amendment to better match the available resources. The Committee agreed to the workplan as presented with the additional amendment.

EFSA opinion on foods for infants and young children

The opinion of the EFSA PPR Panel on foods for infants and young children is expected to be adopted by the PPR Panel in May 2018.

EFSA PRIMO model rev. 3

At the November 2017 meeting of the Committee it was decided to apply the new version of the PRIMO model (rev. 3) as from 1 February 2018 to new applications (date of receipt of the application in the Member State) and for Art. 12 reviews (date of launch of data call-in by EFSA). Ongoing applications would be finalised with revision 2 of the PRIMO model, as well as the EFSA scientific report for preparation of the Codex Committee for Pesticides Residues (CCPR) and the EFSA annual monitoring report 2016 which were done with revision 2 and are already at an advanced stage.

Furthermore the Member States should use revision 3 for other ad-hoc risk assessments, e.g. in the context of the Rapid Alert System for Food and Feed (RASFF).

The Commission had received letters from industry with concerns about that date of application for the rev. 3 of the PRIMO model, in particular because some of the applications already under preparation or in the process of submission would need to be modified at short notice. The Commission stated that it considered it important to introduce the new model which is more accurately reflecting consumption habits as soon as possible. It would however be prepared to discuss the introduction of a short transition phase until end of June 2018 with the Member States, during which the use of both models would be possible.

Member States indicated that they would not be in favour of such a solution which creates uncertainty and inconsistencies during the transition phase as to which conclusions to draw if both models would give different results. It was mentioned that in the past new versions were also always introduced without transition period and this had not given rise to major problems.

It was therefore decided to stick to the implementation plan decided at the November PAFF Committee.

EFSA informed that small editorial changes will be made in a minor revision 3.1 without affecting the overall assessment. The representative of the EURL for single residue methods (EURL SRM) remarked that in a future revision also the residue definition for risk assessment should be reported. EFSA replied that when Article 12 review is performed, conversion factors are derived which will be included in the future database on endpoints rather than in the PRIMO model.

A.15 Project on data collection dithiocarbamates.

The Commission presented the project and highlighted that this was part of Annex X of the Working Document on pesticides' monitoring that had been taken note of by Member States during the November SC PAFF. The Commission requested that the sampling of organic products for analysis of dithiocarbamates should be included in the national programmes of Member States for 2018. It was specified that the EURL SRM would manage the project and that for this purpose an online web-based application had been created by the EURL.

The EURL SRM gave a presentation on the use of the online application. Several Member States raised questions. One Member State noted that reporting of the results would duplicate their work as they already report results from their annual programmes to EFSA. The EURL replied that the idea was that official labs would collect samples and report the results directly. On this point another Member State mentioned that its laboratories have no responsibility for sampling, that the online system would require extra manual work and that it would require changes to the already established sampling programme for 2018. The EURL pointed out that the online system is user-friendly and requires a very limited amount of information. The Commission suggested that access would be given to competent authorities and official laboratories in the Member States, so that organisational issues could be arranged in each Member State according to its specific needs.

Concerning the samples to be taken, a Member State proposed that samples could be retrieved from certification bodies of organic products or from organic products' associations. The EURL and the Commission welcomed the proposal.

EFSA added that samples from the EU multi-annual control plan (MACP) and the national programmes are already collected by EFSA and that it would not be necessary to report them twice as this would create extra workload.

The Commission suggested that it would discuss the details with EFSA and the EURL and subsequently send an e-mail to Member States with organisational details and the time planning for the next steps.

A.16 Honey - technical guidelines.

The Commission thanked Member States for having submitted detailed comments. Also the European Crop Protection Association (ECPA) had submitted comments, all of which are available on CIRCABC. The Commission will circulate a revised version soon which would take into account the comments received and plans to take note of the document in the June PAFF Committee.

A.17 State of play on cumulative risk assessment.

The Commission underlined its intention to move forward with the methodology on Cumulative Risk Assessment (CRA) and announced that a meeting of the Working Group on CRA is scheduled to take place on 15 June 2018 in Brussels.

Member States were invited to nominate experts (only one reimbursed per Member State) by 4 May 2018.

Member States welcomed the proposal to move ahead.

One Member State asked for the agenda of the meeting in order to be able to appoint the appropriate expert. The Commission agreed to send out the draft agenda by the end of March 2018.

A.18 Work organisation for next monitoring exercise 2020, 2021, 2022.

The Commission announced that a meeting of the Working Group on pesticide monitoring is scheduled to take place on 12 October 2018, while informing that the agenda would be similar to the one of the meetings held during previous years.
Member States were invited to nominate experts (only one reimbursed per Member State) by 7 September 2018.

A.19 Screening exercise on temporary MRLs in Regulation (EC) No. 396/2005 that will expire in 2017-2018.

The Commission gave an update on the state of play.
For flupyradifurone and difluoroacetic acid, provisional MRLs had been set by Regulation (EU) 2016/486 in view of the change of the residue definition, which had been proposed by EFSA at a late stage in the approval process. The applicant was therefore not in a position to submit the missing information within the usual timeframe. Those MRLs will be reviewed taking into account information submitted by 6 April 2018.

A.20 EFSA Guidance Document on the Residue Definition for Risk Assessment.

At the November meeting of the SC PAFF the Member States who had taken the floor strongly objected to the endorsement of the EFSA guidance document on the residue definition for risk assessment without assessing its impacts first, even though a delayed application date of 18 months was proposed. The Commission had therefore decided not to take note of the guidance document.

On request of EFSA the point was put on the agenda again with a view to come to a final decision on the way forward. Both the Commission and EFSA made proposals on how to proceed and two options for a possible way forward were submitted to the Member States for a final decision on the approach.

While there was agreement between the Commission and the EFSA proposals on the need to pursue the topic also at international level, the main difference was that the Commission proposes to first assess the impact of the guidance document by carrying out fictitious case studies, whereas EFSA would be in favour of an official note taking of the guidance document followed by an implementation strategy on real cases.

EFSA re-iterated that it was ready to provide further training on its proposed guidance (some training was already provided in the past). Contrary to what was claimed by industry, EFSA believed that applying the guidance document would limit animal testing (e.g. carfentrazone). EFSA proposed to already decide on the possible implementation date. It stressed that the guidance document should be endorsed in its entirety and not only some sections of it.

The four Member States who took the floor, all re-confirmed their previous position that the impact of the guidance document should first be assessed before formal endorsement and opted for the Commission's proposal.

All Member States were invited to communicate their position by 10 March 2018.

As there was previous agreement on the need to act at international level in order to avoid that discrepancies in approach would hamper the EU acceptance of CXLs, the Commission already contacted international organisations to start discussions on the way forward.

The existing "Guidance Document on the definition of residue" of the Organisation of Economic Co-operation and Development (OECD) will soon be under review. The OECD residue Chemistry Expert Group had set up a writing group for this purpose. EFSA believed that the current EFSA Guidance Document follows the OECD principles and could be the basis for updating the OECD guidance document to ensure international alignment. As it is important that also FAO/WHO are on board for these discussions, a first meeting was held on 23 February 2018 between Commission, EFSA and a representative of the secretariat of the WHO/FAO Joint Meeting on Pesticides Residues (JMPR) with a view to discussing the next steps ahead.

A.21 CCPR 2018 preparations (International issues).

1. e-Forum of the eWG on Classifications of food and feed
   On the Codex website six circular letters and five documents related to the revision of the Codex Classification of Food and Feed have been uploaded. One document is not yet available and the Commission is investigating with the Codex secretariat.

One Member State, the co-chair of the eWG which prepared the Codex documents, gave a short update.
The Commission will prepare draft coordinated positions for the different issues by 9 March 2018 on which MS will be invited to submit comments by 15 March 2018.

2. eWG Priorities (incl. collection of national authorisations)
The Commission presented the Codex Circular Letter proposing priorities and schedules for the evaluation of active substances by the JMPR, as well as draft EU comments, which will be coordinated in March 2018 by Council Working Parties in advance of the meeting of the 2018 Codex Committee on Pesticides Residues (CCPR). Concerning periodic reviews, EU priorities are globally well reflected in the Codex document on proposed priorities. Comments by Member States will be included in the draft EU comments.
Regarding national registration of pesticides, Member States were asked to contribute directly by uploading the requested information on the Codex website. The draft answers to the questionnaire in the corresponding Codex Circular Letter were discussed and adjusted following Member States comments. They will be further discussed with Member States during the Council Working Parties.

3. e WG on IESTI equation
The Netherlands as the chair of the electronic working group presented the state of play.

4. OECD guidance document on rotational crops
A new version of the OECD guidance on rotational crops trials, dated 23 February 2018, addressing the concerns of EFSA and some Member States was circulated. The Commission considers that in this updated version all concerns have been addressed and invited Member States to submit last comments (if any) by 9 March 2018 in view of giving a final reply to OECD by the deadline 12 March 2018.

A.22 Revision of GD SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1 – state of play.

Member States who had volunteered to coordinate the updating of the two analytical guidance document informed that a more detailed update on the contents could be given at the next SC PAFF meeting in June and informed that all comments collected had been consolidated and made available on CIRCA BC.

A.23 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

No issues were raised under this item.

A.24 Designation of Member States for maximum residue levels (MRL) applications.

No issues were raised under this item.

A.25 Info on substances falling under the cut – off criteria in Regulation (EC) No 1107/2009 and follow up on MRL side.

The Commission informed the Committee that following its exchanges with Member States, it had reconsidered its approach on how to handle import tolerance (IT) requests for active substances falling under the cut-off criteria of Regulation (EC) No 1107/2009.

The Commission indicated that it had a more flexible approach in mind but that there was however not yet any official position on that matter as internal discussions were still ongoing. EFSA requested to be involved in the discussions at an early stage and the Commission confirmed that EFSA would be consulted in a next step.

A.26 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 5th Inter-service Steering Group (ISG) was held on 14 February 2018 to agree on the interim report. Due to a delayed launch of the surveys, the study by an external contractor to gather information was behind the expected schedule by about one month.

The following deadlines were agreed upon:

- Submission of the draft final report on 30 April 2018;
- Submission of the final report on 29 June 2018.

The 2nd workshop is scheduled on 16 May 2018. At that occasion, Member States, stakeholders, including non-governmental organisations (NGOs), EFSA and various services of the Commission will attend. The Commission clarified that all Member States will be invited, but only one expert may attend due to the large number of participants.
The 6th ISG meeting is scheduled for 23 May 2018 to agree on the draft final report taking into account the outcomes of the workshop.

A focus group on pesticides residues is scheduled for 28 March 2018 in which EFSA, some Member States and Commission representatives will take part.

A.27 Feedback from Post Approval Issues (PAI) group.

No issues were raised under this item.

A.28 Update on the technical guidelines for MRL setting (SANTE/2015/10595).

The Commission had prepared a first revision to the Technical Guidelines on the MRL setting procedure in order to address issues that are not yet included.

A paragraph should be added outlining those cases where an extrapolation may be carried out by simply applying the relevant EU technical guidelines without the need for an EFSA Reasoned Opinion. A 'light' version of an Evaluation Report should be drafted by the Evaluating Member State in such cases, reporting basic elements such as the MRL application, the GAP table, the animal dietary burden calculator (where relevant) and the PRIMO model.

The section on MRL applications in line with Article 18(4) of Regulation (EC) No 396/2005 should be further developed to reflect the experience recently gained. It was acknowledged that applications made in the context of Article 18(4) (setting temporary MRLs in exceptional circumstances, e.g. to reflect emergency uses) may not always be fully in line with the data requirements in view of the emergency circumstances. Moreover, the appropriate validity of the temporary MRLs should be outlined.

Where applicants requested the lowering or deletion (setting to LOQ) of an MRL under the Article 6 procedure, this should be justified by the applicant and/or the Evaluating Member State (EMS) in view of a better allocation of resources. In many previous cases such lowering was considered more appropriate in the context of the Art. 12 review. Justification is also needed for cases where LOQs are requested to be set at levels below the default value of 0.01 mg/kg.

A section should be added to address conflicts between Article 10 and 12 requirements. At the SC PAFF meeting in June 2017, it was agreed that Article 10 applications need to comply with the data requirements that exist on the day of submission. This means that new requirements set under Article 12 would trigger the stop-the-clock procedure only if the Article 12 Regulation already entered into force at the time of submission of the Article 10 application to the EMS.

Member States were invited to submit comments by 10 March 2018 on additional issues that should be considered in the updated version.

A.29 Extrapolation guidelines.

The Commission presented its reflections on the future updating of the Extrapolation Guidance document. The text part (chapters 2-5) will need to be updated taking into consideration the 'new' data requirements laid down in Regulation (EC) No 283/2013 and the two OECD Guidances on crop field trials and rotational crops.

On request of a Member State, the Commission clarified that in case of a possible discrepancy between the OECD Guidance and Regulation (EC) No 283/2013, the Regulation as legally binding act is applicable.

A Member State requested to consider whether extrapolation from crops listed in Part B of Annex I could be made to main crops of Part A. The question came up in relation to the issue on radish leaves (point A.12) where trials would be done on radish leaves, but extrapolation to kale could be considered. EFSA mentioned other similar cases in which trials were available on a crop in Part B of Annex I. One Member States proposed setting more broad extrapolations possibilities, like between all greenhouse vegetables or between outdoor crops.

The Commission invited the Member State to reflect on this possibility, which will be contrary to the approach followed until now, and submit comments by 20 March 2018.

A.30 AOB

- Info on Bacillus thuringiensis (BT)

  Following some criticism on the EFSA 2016 opinion of the BIOHAZ Panel on *Bacillus thurinigiensis (BT)* EFSA reacted with a statement defending the EFSA opinion. The statement was shared with the Member States.

- Processing factors in cold pressed lemon oil

  The point was added to the agenda by the chair on request of Spain.

  New studies have been submitted by a national association of producers of cold pressed lemon oil which demonstrate the safe application of certain processing factors for 11 substances. Spain, who had received the studies, suggested that those processing factors should be taken into consideration also by other national authorities. The Commission invited the other Member States to take those studies into account if considered appropriate.

- New AGM reimbursement system

  The Commission informed about the Commission's new electronic system for the organisation of meetings, the AGM system ("A new Gateway for EU Meetings"). The system will be gradually implemented during 2018 and will allow that invitations and reimbursement are managed in a paperless way. The basis of the system is that Member States will have to establish a contact point which will be responsible for the dissemination of information.

  Further links and training material for Member States have been communicated via CIRCABC.

- Information from EURLs on analysis of aniline

  The EURL SRM gave a presentation on recent developments regarding the methods of analysis of aniline. The main difficulties of the analysis, such as the bonding of aniline with certain oxidative derivatives formed during milling of samples were discussed, but also ways to overcome those issues, such as addition of ascorbic and citric acids during sample preparation.

  The Commission invited the Member States to review the current studies from the EURLs that have been uploaded on CIRCA BC.

- Feedback from WG under Regulation (EC) No 669/2009

  The Commission informed on ongoing discussions on a draft that consolidates existing safeguard measures linked to pesticide residues, including the possible lifting of some measures and adding of others.
  Discussions should be focussed in the section on controls and import conditions of the Committee and in the pertinent working group. Member States are encouraged to coordinate internally.

  Member States were invited to submit comments by 10 March 2018 in view of the next meeting of the Working Group on Commission Regulation (EC) No 669/2009 on 19 March 2018.

- LOQ for diquat in hops

  The point was added to the agenda by the chair on request of Germany.

  Germany requested to re-consider the existing LOQ for diquat in hops which is currently at a level of 0.01* mg/kg and difficult to achieve by routine analytical methods. It was confirmed by the representative of the EU RL SRM that both the substance diquat and the matrix hops are difficult to analyse. A level of 0.05* mg/kg would be more appropriate and would also be in line with the LOQs currently established for tea and herbal infousions which are similarly difficult matrices given that there was no risk to consumers. Germany informed that the applicant had filed an application for an MRL on hops of 0.1 mg/kg in parallel which is currently in the evaluation process. The Commission drew the attention of the Committee to the fact that the substance was currently being under discussion in the PAFF Committee section Legislation with regard to a renewal/non-renewal decision. The decision could have an impact on MRLs.

  The Commission asked the Member States for their views on a possible adaptation of the LOQ to 0.05* mg/kg by 10 March 2018.

- Chlorpyriphos – findings in products from third countries

  The Commission drew the Member States' attention to the fact that there was a high number of RASFF notifications in 2016 and 2017 on chlorpyriphos, in particular for chorpyriphos in peppers (about 50 notifications between January 2016 and November 2017) as a result of increased checks under Regulation (EC) No 669/2009 (border rejections). Chlorpyriphos was also frequently notified for lemons and vine leaves. Since the country of origin was often Turkey, the Commission raised the issue in a meeting with a Turkish delegation in early January 2018. As a follow up to this meeting a document was provided by Turkey giving an overview on the measures taken. The Commission recommended to be vigilant on this situation and to keep it in mind for further dicussions in the Working group on Article 15(5) of Regulation (EC) No 882/2004.

- Question on trigger values for processing studies for acute risk assessment of bulked commodities

  The point was added to the agenda by the chair on request of the United Kingdom.

  The United Kingdom raised a question on the trigger values for requesting processing data in the light of the new version of the PRIMO model (rev. 3). In the new version the Supervised Trials Median Residue (STMR) value is used instead of previously the Highest Residue (HR) in case of bulked commodities for acute risk assessment. While so far for bulked commodities the trigger values of 0.01 mg/kg for nature of residues studies and 0.1 mg/kg for the magnitude of residues studies applied to the Highest Residue (HR), the question would be whether the trigger values should now be applicable to the STMR.

  Member States were invited to submit comments by 20 March 2018.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products (SANTE/12049/2017 Rev. 1) (Art. 10).

The Commission introduced the draft and presented its content.

The following MRL applications had been submitted under Article 6(1) of Regulation (EC) No 396/2005 (EU uses):

- cymoxanil for the use on beans without pods;
- deltamethrin for the use on kale;
- difenoconazole for the use on "other flowering brassica", Brussels sprouts, escaroles, rocket, "spinaches and similar leaves", witloof and rhubarb;
- fluopicolide for the use on chards;
- folpet for the use on apples and pears;
- fosetyl for the use on pome fruits, peaches and potatoes;
- mandestrobin for the use on apricots, cherries, peaches and plums;
- metazachlor for the use on Chinese cabbage;
- propamocarb for the use on chards;
- pyrimethanil for the use on cucurbits with edible peel;
- sulfoxaflor for the use on grape leaves and globe artichokes;
- trifloxystrobin for the use on "other small fruits and berries", "lettuces and salad plants", purslanes, beans without pods, peas and pulses.

The following MRL applications had been submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005 (import tolerance requests):

- disodium phosphonate used in the United States on tree nuts (except coconuts);
- flubendiamide used in the United States on apricots, peaches, plums, soyabeans;
- propargite used in Brazil on oranges and India on tea.

On 11 July 2015, the Codex Alimentarius Commission adopted Codex maximum residue limits (CXLs) for fenamidone. CXLs for which the Union did not present a reservation to the Codex Committee on Pesticides Residues should be included in Regulation (EC) No 396/2005 as MRLs.

In accordance with Article 53 of Regulation (EC) No 1107/2009, the United Kingdom granted emergency authorisations for cyantraniliprole on blackberries, raspberries and leeks. Greece granted emergency authorisations for mepiquat on cotton. In accordance with Article 18(4) of Regulation (EC) No 396/2005, the Member States concerned submitted applications with a view to setting temporary MRLs for the affected crops. Those MRLs are valid until 30 June 2021.

As regards deltamethrin, EFSA concluded that the risk assessment is affected by non-standard uncertainties. However, considering the low contribution of kale to the overall dietary exposure, it is appropriate to set the MRL at 0.15 mg/kg.

As regards trifloxystrobin, the applicant submitted the missing information on analytical methods for products of animal origin and made the reference standard for CGA321113 commercially available.

As regards the use of flubendiamide on soybeans, the current MRL is set at 0,25 mg/kg in the exporting country. Considering that the highest residue measured in supervised field trials is slightly above that value, it is appropriate to set the MRL at a rounded value of 0.3 mg/kg.

As regards propargite, a Member State pointed out that it is current practice to accept new toxicological endpoints only after note taking by the SC PAFF section legislation. The Commission explained that a document will be presented at the next PAFF Committee section Legislation for a possible note taking. However, the Member State abstained when voting on the draft measure.

Vote taken: Favourable opinion.

B.02 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 2019, 2020 and 2021 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. (SANTE/11141/2017 Rev.1).

The Commission introduced the latest changes that took place after the comments received from Member States and during the consultation of other Commission services. Analysis for glyphosate is now required for all commodities of plant and animal orign covered by the coordinated programme 2019, 2020 and 2021. The Commission stressed again the importance to analyse as many samples as possible on the widest possible range of products. Commodities not covered by the coordinated programme should be taken up in national programmes.

The Commission mentioned that EFSA's Annual Reports on Pesticides of 2014 and 2015 stated that only for some foods the number of samples is sufficient and recommended that Member Sates should increase the number of analyses of glyphosate and related residues in general and particularly in products for which the use of glyphosate is approved and where measurable residues are expected. In particular, the number of samples of soybeans, maize, oilseeds (rapeseed, linseed, mustard seed, sunflower seed, etc.) and pulses (dry lentils and peas[1] should be increased. Analysis of processed cereal based foods for infants and young children as well as other baby foods should be continued.

Concerning the method of analysis of glyphosate on products of animal origin, the Commission mentioned that development of the method and an interlaboratory validation exercise on animal commodities are included in the annual working programme for the EURL SRM for 2018. The EURL SRM gave an overview of the state of play.

One Member State reacted stating that it understands the political considerations, but questions the relevance of analysing glyphosate in fat. The Commission referred to the EFSA Reasoned Opinion of 2009 for the "Modification of the residue definition of glyphosate in genetically modified maize grain and soybeans, and in products of

1 Dry beans are already part of the coordinated programme

animal origin", stating that glyphosate was indeed found in milk and fat of lactating goats and in fat of hens, while its metabolite N-acetyl-glyphosate was also found in fat. The Commission added that in view of the upcoming EFSA's Reasoned Opinion on glyphosate where the residue definition of glyphosate will be expanded to include its metabolites (including N-acetyl-glyphosate) it would make sense to analyse fat, too. Two more Member States expressed their concerns of including glyphosate for analysis on products of animal origin and two Member States confirmed that they would not analyse glyphosate in milk in 2019 as they have no method available.

One Member State questioned the use of processing factors for frozen products. The Commission explained that some frozen products undergo blanching, mainly to reduce microbial counts, and then they are frozen. This may lead to changes of residue levels in some cases. If no processing factor is required or available, a default factor of 1 can be used.

Another Member State requested an explanation on the "examination procedure" and the Commission gave a short overview on the comitology rules.

Vote taken: Favourable opinion.