EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 12 JUNE 2017 - 13 JUNE 2017

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/207c80f2-4cdb-403a-8d18-9553dc66dd68*

A.01 Exchange of views of the Committee as regards maximum residue levels (MRL) for penoxsulam, triflumizole and triflumuron. (Article 12)

The Commission informed that the European Food Safety Authority (EFSA) reasoned opinions for the MRL review of penoxsulam, triflumizole and triflumuron were recently published and that it will now start drafting the MRL Regulation.

A.02 Exchange of views of the Committee as regards maximum residue levels for 2-phenilphenol, bensulfuron-methyl, dimethachlor and lufenuron in and on certain products. (Article 12)

The Commission presented the proposal, which contains only a few MRL changes. The issue of the residue definition of 2-phenylphenol was already discussed in previous meetings. One Member State still noted that the inclusion of the conjugates in the residue definition could cause some problems. The vote of the proposal is planned for the September meeting of the Standing Committee for Plants, Animals, Food and Feed (SC PAFF).

Member States were asked to submit comments by 1 August 2017.

A.03 Exchange of views of the Committee as regards maximum residue levels for chlorpyriphos, chlorpyrifos-methyl and triclopyr. (Article 12)

The Commission explained that the three substances covered by this Article 12 proposal were grouped because they share a common metabolite, 3,5,6-TCP, for which EFSA proposes as an option to set MRLs. The Commission proposed to limit the residue definition to the parent compounds for the three substances and to consider MRLs only for these parent compounds. The only exemption would concern chlorpyrifos-methyl MRLs for cereals, for which the residue definition should include

desmethyl-chlorpyrifos-methyl given its significant presence in cereals treated with this substance.

The rapporteur Member State for chlorpyrifos-methyl informed the Committee that new information concerning the toxicity of this metabolite and processing factors would soon be available and invited the Commission to wait for this information to take a more informed decision. On a proposal of a Member State it was discussed whether in this case the proportionality principle could be exceptionally used for deriving MRLs for cereals. The Commission highlighted that the Codex Committee for Pesticides Residues (CCPR) had explicitly decided in 2013, with support of the EU delegation, not to apply the proportionality principle for post harvest uses. The PAFF Committee endorsed this approach in its meeting of the SC PAFF in September 2013. The approach is also in line with OECD guidance. Any change of policy would have to be carefully examined first, agreed by the PAFF Committee and also discussed and agreed at international level to avoid diverging risk assessment outcomes. An issue of cross-contamination of oil seeds during storage was raised. While the residue levels found in oilseeds would comply with the present level of determination (LOD) of 0.05* mg/kg, the proposed LOD of 0.01*mg/kg would lead to exceedances. Monitoring data will be used to further investigate this issue.

The Commission agreed on the need for further discussion on the proportionality principle in case of post harvest uses, but made it clear that this should not delay the discussion on the proposal. The Commission proposed to consider additional data on the toxicity of desmethyl-chlopyrifos-methyl, on processing factors and possibly on cross-contamination of oilseeds in case such data would become available before the next SC PAFF in September 2017.

A.04 Update on chlorate.

The Commission informed that a general multi-disciplinary action plan for reducing the dietary exposure to chlorate and for resolving the systemic non-compliance with the pesticides MRLs was presented on 23 May 2017 for endorsement to the meeting of heads of national food safety agencies (HoA) in Oslo. The HoA will provide their coordinated point of view on this action plan by September 2017. Once the general way forward will have been decided, discussions on specific measures for the different policy areas will be conducted in the relevant sections of the SC PAFF.

The main action points of proposed plan are:

- Recommendations on good food hygiene practices in order to reduce chlorate residues in food,
- Reducing chlorate residues in drinking water by e.g. setting an EU limit for chlorate in drinking water,
- Dietary recommendations at national level for children to reduce the exposure to chlorate and to limit its impact on the thyroid,
- The setting of MRLs for chlorate in regular food at more realistic levels and based on occurrence data.

Furthermore the Commission informed the Member States of a meeting it had with the Directorate General for Environment (DG ENV) on chlorate residues in drinking water and on the possibilities for including a limit for chlorate in the EU drinking water parameters.

A Member State questioned the appropriateness of the meeting of HoA for discussing this plan, as the participants are risk assessors and the decision-making power lies with the national ministries.

The Commission explained that a forum was chosen, which has an overview on all the concerned policy fields, in order the get an indication of the general way forward. The HoA will consult all the relevant parties at a national level. However, the decisions on the specific measures for the different policy fields will be taken by the risk managers in the relevant sections of the SC PAFF.

The action plan will be shared with Member States via the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). Furthermore a communication for the public will be made available on the Directorate General for Health and Food Safety (DG SANTE) website.

A Member State enquired whether a change of the definition of 'pesticide residue' is being considered. The Commission referred to the ongoing REFIT evaluation of the existing pesticides legal framework, in which this definition will also be evaluated. However, a possible change of the definition, if appropriate, would be a long term process. On the short term it is the intention to find a solution for the systemic non-compliance of chlorate residues in food with the pesticides MRLs.

A.05 Exchange of views of the Committee as regards maximum residue levels for mercury.

The proposed draft Regulation concerns the review of existing MRLs for mercury compounds in certain food commodities to reflect the current environmental occurrence. The MRLs are set on a temporary basis in accordance with Article 16(1) of Regulation (EC) No 396/2005.

Recent monitoring data show that residues occur in several food commodities at levels higher than the LOD. The 95th percentile of all the sample results was considered when proposing MRLs. The Commission clarified that some MRLs were implemented in Annex IIIA to Regulation (EC) No 396/2005 by means of a footnote as the sub-groups are very specific and residues occur at considerably higher levels than the MRL applicable for the main commodity.

The Commission recently received data from Tea and Herbal Infusions Europe (THIE) showing that a temporary MRL of 0.02 mg/kg would address the environmental occurrence of mercury in products listed under code 0600000 of Annex I to Regulation (EC) No 396/2005.

The draft measure has been notified via Sanitary and Phytosanitary Measures (SPS) to WTO to inform third countries. No replies were submitted within the deadline of 28 May 2017.

The Commission invited Member States to provide comments by 14 July 2017.

A.06 Outcome of the Standing Committee on Plants, Animals, Food and Feed (PAFF) meetings on dimethoate in April/May 2017.

The Commission informed the Member States on the outcome of the extra meeting of the SC PAFF of 7 April 2017 on the French request for EU wide emergency measures on dimethoate and of the SC PAFF of 18 May 2017 on the French emergency measure on dimethoate, which was notified on 3 May 2017 to the Commission.

The summary records of both meetings are published on the Directorate General for Health and Food Safety (DG SANTE) webpage.

A.07 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Article 12 and work programme

The Commission updated the table on substances prioritised under the Article 12 MRL review process and gave an overview to the Committee. The Committee agreed to the principle that whenever a substance of concern is discussed, this should trigger a discussion on priority setting for the Article 12 MRL review.

EFSA made a presentation on the amended work programme for 2017, which had been slightly modified on request of a Member State after the last meeting. Since also another Member State had comments, EFSA asked for comments on the amended work programme by 20 June 2017. A progress report on EFSA Article 12 activities, which will be updated on a quarterly basis, is now publicly available on thee EFSA website at:
http://www.efsa.europa.eu/en/science/pesticides

The Commission informed that it had updated the "Note to Non-EU countries" with the link to the EFSA webpage and circulated again through the WTO/SPS notification system. The Note is also available at the SANTE website (http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf) and informs non-EU countries on the ongoing Article 12 exercise and outlines which substances will be dealt with in the near future so that non-EU countries have the opportunity to submit additional data at an early stage.

2. Follow up on interpretation of the term "produced"

The Commission outlined the feedback received from the Member States. Overall, there is currently not enough support for a change in the wording of the paragraph dealing with transitional measures. The Commission however considered that the

discussion had been useful and is ready to take the issue up again if there would be a need to do so in future.

3. Confirmatory data under Article 12

At the SC PAFF Pesticides Residues section held in February 2017, discussions took place on how to handle Article 6 applications where data, which was already requested in the framework of MRL review, is still missing. Some Member States have sent written comments asking to grant some flexibility to a certain extent.

At the current meeting, the Commission re-iterated that Article 6 applications should be fully supported by data. It also invited Member States to refrain from assessing such applications where data is missing in line with the procedure outlined in Article 7 of Regulation (EC) No 396/2005. This would prevent EFSA from having to make excessive use of the "stop-the-clock" tool, which creates additional administrative burden.

In terms of flexibility, the Commission is of the view that the date of submission of the original application is the reference to be made when assessing the data requirements that should have been considered by the applicant. It should be not expected that the applicant foresees, for instance, a change in endpoints that would take place after the submission of the application. The Commission also clarified that the new requirements are only applicable as from the time of entry into force of the relevant piece of legislation, which sets them.

4. Procedures for substances for which the Article 12 review follows the renewal procedure

The Commission followed up on a discussion held in the February 2017 SC PAFF on the right moment to start the Article 12 review for a substance that just underwent the renewal procedure. This situation will now occur more often. While legally speaking Member States should renew, amend or withdraw authorisations 12 months after the renewal, some flexibility may be needed to ensure that all changes in Plant Protection Products (PPP) authorisations/Good Agricultural Practices (GAPs) are implemented at the time of data call-in by EFSA for the Article 12 review. The Commission agreed with the comment made by a Member State that the additional buffer should be different for different situations. It proposed a maximum additional delay of 12 months for standard cases where toxicological reference values or residue definitions were not changed in the renewal exercise. However, if the renewal exercise would result in a lowered toxicological reference values faster action would be required. In such case Member States should flag to the Committee potential problematic MRLs. The Committee could then decide to prioritise the Article 12 review. In cases where more data would need to be generated (e.g. change of residue definition, confirmatory data under 1107/2009, etc) a Member State proposed a maximum delay of 4 years. The Commission considers this too long and proposes to split procedures whereby the Article 12 would be done in a shorter timeframe (standard, max. 2 years) and be updated by an Article 43 review once the additional data would be available.

The Commission invited Member States to comment by 15 July 2017.

One Member State agreed with the procedure and remarked that especially those cases where the acute reference dose (ARfD) changes, this should be flagged and urgently followed up.

5. Update on footnotes for analytical standards, that expired in 2016

The Commission informed the Member States that for the footnotes on lacking availability of analytical standards, which expired in 2016, no further follow up was needed as all the standards, needed for the enforcement of the MRLs, are currently commercially available.

A.08 Specific substances – update of state of play:

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

No new active substances were under discussion in the last Legislation Committee.

2. Anthraquinone

In reply to the Commission's request for comments on the way ahead for anthaquinone in the SC PAFF in February 2017, further comments had been received from Member States. One Member State proposed to deal with anthaquinone as a contaminant.

The Commission emphasised once again that the substance cannot be treated as a contaminant, beacause of its former use as a pesticide. The legal framework is therefore clearly Regulation (EC) No 396/2005. Moreover, though some non-EU countries and stakeholder associations claim anthraquinone to be an environmental contaminant and its residues due to reasons other than the pesticide use, both these assumptions have not yet been confirmed.

The Commission informed the Committee that the European Chemicals Agency (ECHA) has recently reviewed the classification of the substance. Following an assessment made by Germany in January 2015, anthraquinone has been confirmed by ECHA as a substance 'Carc. 1B'. The amended ECHA classification has been adopted by Commission Regulation (EU) 2017/776, published in the Official Journal on 4 May 2017 (uploaded on CIRCABC).

One Member State supported to invoke Article 16 to set temporary MRLs for the substance, taking into consideration monitoring data and the exceptional situation.

The Commission replied that Article 16 applies to exceptional cases where presence of residues is unavoidable. No evidence has been provided that this is the case for anthraquinone. Therefore the Commission emphasised that Article 16 should not be misued for such cases. In view of its carcinogenic properties the Commission does not see any justification to modify the current MRLs.

Two Member States informed that in their view different enforcement action is taken by Member States for anthraquinone in imported products. They urged the Comission

to make sure that a harmonised approach is followed. The Commission will take this up with colleagues dealing with import controls.

3. Acetamiprid

In the framework of the renewal of the approval under Regulation (EC) No 1107/2009, EFSA published a conclusion on the peer review of acetamiprid establishing lower toxicological reference values.

Considering the acute reference dose (ARfD) value of 0.025 mg/kg body weight (bw) and the highest residue levels related to the uses evaluated under the Article 12 MRL review, a risk to consumers was identified for several food products.

The Commission prepared a draft mandate to EFSA, in accordance with Article 43 of Regulation (EC) No 396/2005, to provide a reasoned opinion on the existing MRLs for acetamiprid which might lead to consumer intake concerns. A Member States' consultation is foreseen to identify those fall-back GAPs that would lead to a safe scenario.

The mandate will be submitted to EFSA only once the new endpoints are formally endorsed by the SC PAFF - Legislation Section.

4. Thiabendazole

The Commission informed that after the vote in the February SC PAFF on a proposal amending thiabendazole MRLs, comments from stakeholders associations and third countries have been received.

Two crops are of specific concern for the exporting countries: mangoes and sweet potaoes. For both crops MRLs were lowered to the limit of determination (LOD). On request of some Member States EFSA explained how their risk assessment was carried out and which data had been available to them.

For sweet potatoes supporting data were not available. For mangoes, a health risk for consumers could not be ruled out. Further processing studies and studies on unit to unit variability need to be submitted and assessed before a decision on possible refinement of the risk assessment can be taken. In the light of the comments received and the explanations provided by EFSA, the Member States confirmed that the levels voted upon in February 2017 were appropriate. The Committee also noted the commitment made by the applicant to provide further studies by beginning of 2018.

One Members State noted that for mangoes, a processing (peeling) factor would not seem appropriate as mango varieties exist that are eaten with the peel. The Commission emphasised that once the supporting data would become available the assessment should be done with high priority.

5. Residue definition folpet/phtalimid

The Commission informed the Committee about comments received by a Member State and the view of the EU Reference Laboratory (EURL). The Commission shared also the analytical results of analysis in tea submitted by one Member State.

Currently the residue definition for folpet is ´sum of folpet and phthalimide, expressed as folpet equivalents´. There are indications that phtalimide might be measured which originates from other sources than folpet, however folpet is extensively metabolised in plants with phtalimide as the only relevant metabolite. Furthermore phtalimide is formed by degradation of folpet in the injector of the gas chromatograph during analysis.

One Member State indicated that they will share findings in rye flour with the Commission and Member States.

Three Member States stated that since there are several sources of phtalimide the residue definition should be re-considered.

One Member State indicated that phtalimide is formed when drying at 80°C. Other scenarios, such as drying at a certain temperature or background contamination should also be investigated.

Member States were asked to submit comments by 14 July 2017.

6. Substances that could form aniline during processing

The Commission prepared a table listing active substances that may be a potential source of aniline formation. The status of those substances under Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 is also reported.

Member States were invited to submit comments by 31 July 2017.

7. 2,4-D

The Commission informed Member States that a reasoned opinion was recently published on 2,4-D used on GM maize. On the basis of the residue trials, there is no need to modify the existing MRL, which is currently set at the default value of 0.05 mg/kg. However, the Commission stressed that the GM maize under consideration is also treated with quizalofop-P and residues might occur from that use. It is therefore important to consider both levels to ensure that the crop can be marketed in the Union.

A.09 Feedback from Codex Committee on Pesticides Residues (CCPR) 49 (2017).

The Commission informed the Member States on the outcome of CCPR 49 in April 2017. It thanked the Member States for their active participation and outlined the progress made on specific issues such as the revision of the classification for food and feed, the guidance on performance criteria for methods of analysis, the Codex schedule of priority lists, the proposed draft MRLs and related EU reservations as well as the discussion on the future work on the Internationally Estimated Short Term Dietary Intake (IESTI) equation.

Member States were invited to check the list of reservations on draft Codex Limits (CXLs) that were presented during the CCPR meeting for which they are currently consulted, as these reservation will have to be reiterated at the coming meeting of the Codex Alimentarius Commission in July 2017.

As a support to the work of Joint FAO/WHO Meeting on Pesticides Residues (JMPR) on the IESTI equation, EFSA will share the EU monitoring data with WHO on behalf of Member States. However, as there are some compatibility issues between the EFSA data warehouse and the Global Environment Monitoring System (GEMS) format and as EFSA doesn't have resources for aligning the EU data in the required format, it will submit the data in the EFSA format. EFSA intends to automatise in future the conversion of the EFSA data into the GEMS format.

A.10 *Bacillus thuringiensis (Bt)* - follow up of EFSA opinion

Feedback was received from 3 Member States of which one indicated support of immediate inclusion of the Bt strains in Annex IV of Regulation (EC) No 396/2005. The other two Member States were in favour of postponing the decision on inclusion in Annex IV of Regulation (EC) No 396/2005 until the renewal of approval procedure for the substances will have been finalised.

The Commission will await finalisation of the renewal procedure before continuing the discussion on inclusion of Bacillus thuringiensis strains in Annex IV of Regulation (EC) No 396/2005 and send a letter to all involved Rapporteur Member States to inform them about this and to request they take fully into account the EFSA opinion of the BIOCONTAM Panel.

The Commission gave a short update on the discussion on Bacillus thuringiensis in the working group biopesticides of 23 February 2017.

A.11 News from the European Food Safety Authority (EFSA):

EFSA gave a presentation on the progress under Article 10, Article 12 and an overview on ongoing Article 43 mandates.

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

A progress report on Article 12 is now on the EFSA webpage (see point A.07.01). EFSA informed the Committee on the experiences with the new Article 12 procedure using a recent example and requesting Member States to pay particular attention to unclear Good Agricultural Practices (GAPs). Before submitting them to EFSA clarification should be sought from the applicant. EFSA also proposed that Member States could do a pre-screening and only send a limited number of GAPs for the identification of the most critical GAP to facilitate the work of the evaluating Member State at that step of the procedure.

On copper compounds, EFSA proposed to wait for the outcome of the expert meeting (planned for autumn 2017) in the framework of the renewal of the active substance before finalising the Article 12 review in order to avoid contradictions. EFSA also highlighted that monitoring data will also be considered to reflect natural occurrences of the substance.

A Member State commented that it would appreciate if a draft opinion could already be shared by this summer. EFSA agreed to do this.

Furthermore EFSA informed that it is working on aligning the template for Member States' evaluation reports with the new Article 12 template and that the screenshot with the PRIMO model was put back in the template.

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

As regards the Article 10 procedure EFSA highlighted the high number of questions (31) currently in the clock-stop procedure. Member States were invited to check as some substances are on this list already for a long time.

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

On Article 43 mandates, EFSA mentioned the draft reasoned opinion on lambda and gamma-cyhalothrin (see point A 11.07).

4. Update on EFSA work on foods for infants and young children relevant for the pesticides area

The ongoing scientific opinion for foods for infants and young children is planned to be adopted by the EFSA PPR Panel by mid 2018.

5. EFSA Presentation of the EFSA Guidance on the Residue Definition for Risk Assessment

EFSA made a presentation on the Guidance Document outlining the contents.

Industry submitted a position paper to EFSA and the Commission raising concerns as regards the increased number of metabolites to be considered in the residue definition. They believe that that new studies are triggered and overall more testing will have to be carried out. Moreover, upskilling of the staff would be necessary to enable them to use the scientific tools proposed in the document.

EFSA clarified that no additional requirements are set within the Guidance Document than the ones which were agreed upon at international level. Moreover, it stressed that also the tools foreseen by the document are already in place and being used. In terms of training, EFSA is organising sessions for experts within Member States to raise awareness on the contents of the document and provide assistance in using the various tools.

On procedural aspects, the Commission stressed that the Guidance Document should not be implemented until it has been officially endorsed by the relevant SC

PAFF (Legislation section). In that framework, an appropriate timeline for implementation should be agreed upon.

The Commission invited Member States to provide co-ordinated comments, between experts attending the Legislation and the Residues section of the SC PAFF by 31 July 2017.

6. Presentation of EFSA 2015 Monitoring Report and follow up

The following 3 items were added to the agenda by the chair.

EFSA presented its recommendations made in its 2015 report on pesticides residues in food. One of these recommendations was for Member States to report not only whether residues were present below or above the limit of quantification (LOQ), but also to report residues identified at a level between the LOQ and the limit of detection (LOD). This information would be particularly useful for the ongoing work on cumulative risk assessment. A Member State commented that the values between LOQ and LOD are not valid, as it is not clear whether they are gathered with a uniform procedure by all Member States. EFSA clarified that it is not the intention to perform calculations on the residues between the LOD and the LOQ, but that it is rather a 'yes/no' answer that is needed. It is important to EFSA to know whether any residue was detected at a level between the LOD and the LOQ.

7. Draft RO on lambda- and gamma-cyhalothrin

EFSA gave a presentation on the draft reasons opinion of the "Focussed review of the existing maximum residue levels for lambda-cyhalothrin, in light of the unspecific residue definition and the existing good agricultural practices for the substance gamma-cyhalothrin". EFSA first identified 21 MRLs of concern and launched a Member States' consultation for only those MRLs to see whether fall-back GAPs were available. A restricted assessment has been performed and two lists of proposed MRLs have been proposed by EFSA. EFSA highlighted that validated analytical methods are needed to allow discrimination between lambda and gamma-cyhalothrin. The finalisation of the draft reasoned opinion is planned for 15 July 2017.

One Member State commented that it would be more appropriate to authorise the more active substance only.

The Commission invited Member States to send comments to EFSA using the specific template before 26 June 2017, with the Commission in copy and suggesting possible risk management decisions on the way forward.

8. Other activities

Work is ongoing also on the revision of the PRIMO model revision 3 for which Member States urged EFSA to speed up the work. Instead of making minor corrections to revision 2 as discussed in the February SC PAFF, revision 3 will be launched for Member States consultation by end of June 2017 with a commenting period of 6 weeks and a questionnaire on consumption data. PRIMO revision 3 is planned to be presented in the September SC PAFF meeting together with a guidance

document. EFSA highlighted the importance for Member States to check their consumption figures.

EFSA gave an overview on the ongoing activities on uncertainty assessment and informed about a workshop that will take place on 22-23 June 2017.

A.12 Honey guidance – State of play.

The Commission gave an update on the first working group meeting for this guidance document which took place on 10 March 2017 and thanked all participants for their valuable input.

Several points need to be re-discussed and the protocols for residue trials still need an in-depth discussion. Therefore a second meeting of the working group will be organised for which meeting invitation will be sent out soon.

One Member State questioned why the draft needs internal approval before being shared with experts. The Commission referred to the discussion under agenda point A.23. The Commission will circulate the new draft as soon as internal approval is received.

A.13 Screening exercise on t-MRLs (maximum residue levels) in Regulation (EC) No 396/2005 that will be expiring in 2017.

The Commission gave an update on the state of play.

A.14 Requests for new extrapolations.

The Commission received a request to introduce the extrapolation from apples to kakis in the Extrapolation Guidance Document. The supporting dossier was made available on CIRCABC and Member States were already invited to comment. Five Member States and EFSA have expressed support for this extrapolation.

The Commission explained that a comprehensive update of the Extrapolation Guidance document (last updated in September 2016) is not planned in the near future. However single new extrapolations could be, as in this case, evaluated and discussed case by case by the Committee and added to the document if agreed. The Committee agreed on this procedure.

The Commission invited the Committee also to decide whether to extend the new extrapolation from pears to kakis (given that extrapolation from apples to pears is always possible) and vice versa.

Two Member States supported the extrapolations also from pears to kakis. One Member State clarified that the extrapolation in the reverse direction, from kaki to apple/pears, is not appropriate. The Extrapolation Guidance Document will be updated introducing the extrapolation from apple and /or pears to kakis, but not vice versa, and published on the SANTE website as revision 10.3.

Another Member States noted that as a consequence of the on-going revision of the CODEX crops classification system, many more extrapolations would need to be introduced, in order to align the EU Extrapolation Guidance Document to the CODEX extrapolations. The Commission confirmed that this wil be done once the whole CODEX classification review will be finalised.

A.15 Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods (SANTE/10632/2017 Rev. 0).

The Commission presented the documented and described the suggested approach for the application of the document.

Member States were asked to submit comments by 21 August 2017.

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

No issues were raised under this item.

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

No issues were raised under this item.

A.18 Information on ongoing work on endocrine disruptors.

The Commission gave an update on the progress of the decision making on the criteria to identify endocrine disruptors under Regulation (EC) No 1107/2009. The last SC PAFF Legislation took place on 30 May 2017. All information (reports of the meetings and versions of the draft criteria) is available on the SANTE website https://ec.europa.eu/health/endocrine_disruptors/next_steps_en

A.19 Information on substances falling under the hazard based criteria in Regulation (EC) No 1107/2009 and follow up on MRL side, example linuron.

The Commission recalled the two main possible approaches regarding the maintenance of current import tolerances (ITs) and the setting of new ITs for active substances falling under the hazard based criteria (cut-off criteria) of Regulation (EC) No 1107/2009: (a) current MRLs could be maintained in order to preserve the current ITs and IT requests handled on the basis of the usual risk assessment procedures required by Regulation (EC) No 396/2005, or (b) MRLs could be lowered to the limit of determination (LOD) and new IT requests refused. The Commission informed the Committee that its Legal Service provided advice, which favoured the lowering to the LOD and the refusal of new ITs (approach (b)) only when this lowering of LODs is the consequence of an EU legal act, such as a Commission implementing Regulation non renewing the approval of an active substance and setting out the substance's

hazard classification as a reason for the non renewal. The Legal Service advised that in this case the rejection should be made by the rapporteur Member State upon receipt of the IT request. In other cases, when the active substance is falling under the cut-off criteria but no EU legal act is available, the Legal Service advises to follow the standard risk assessment procedure. This is the case, for example, for active substances whose approval period has elapsed but no non-renewal procedure has been initiated (no dossier submitted).

Member States' comments were diverse. Some Member States voiced concerns regarding their responsibility in rejecting IT requests without risk assessment, pointing that such rejections could be legally challenged and were in favour to systematically prepare an evaluation report, go through an EFSA reasoned opinion and take a decision at EU level. It was also recognised that approach (b) would lead to more EU reservations on CXLs.

A.20 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

The Commission informed the Committee that the process to select the contractor who should perform the independent external study was finalised. The kick-off meeting with the contractor is scheduled for 3 July 2017.

A dedicated website has been created for the evaluation:
http://ec.europa.eu/food/plant/pesticides/refit_en.

In the framework of the evaluation a comprehensive consultation of all relevant stakeholders will be conducted. Member States will be consulted via an online survey, followed by in-depth interviews as well as focus groups.

The Commission informed about other consultations foreseen for the evaluation. An open public consultation being open for three months during autumn 2017 with the aim to collect the views from citizens and consumers, a survey targeting stakeholders, and a survey specifically targeting Small and Medium Enterprises.

A.21 Update on the state of play of MRL setting for biocides.

The Commission informed that the interim approach for the establishment of MRLs for residues of active substances contained in biocidal products was endorsed by the competent authorities for biocidal products in March 2017.

A.22 Feedback from Post Approval Issues (PAI) group.

No items were discussed under this agenda item.

A.23 AOB

The Commission representative informed the Committee on some procedural changes for the workflow of draft proposals. As some draft proposals fell in the transition

phase between old and new procedures, they could not be finalised for discussion. A Member State commented that it was very concerned about any systematic future delays as strict deadlines apply in the pesticides legislation.

The Commission representatives believed that for those proposals where the new workflow applies from the start, the delay may remain limited.

Cyproconazole on borage seeds – Article 10 application – extrapolation

The agenda item was added by the chair.

The Commission received an application to set a new MRL for cyproconazole in borage. It that framework, an extrapolation from rapeseed to borage is proposed by the applicant. Since the use on the main crop was recently reviewed by EFSA (2013) and since the two GAPs are comparable, the Commission believes it is not necessary for the Evaluating Member State to draft an evaluation report nor for EFSA to draft a Reasoned Opinion. This would save unnecessary efforts where it appears clear that there is no concern in relation to the consumption of the minor crop. Reference to the existing guidelines on extrapolation of MRLs needs to be made in the relevant recital of an Article 10 proposal.

The Commission clarified that these exemptions are made on a case-by-case basis and should be discussed at the Standing Committee to inform all relevant parties.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for Bacillus amyloliquefaciens strain FZB24, Bacillus amyloliquefaciens strain MBI 600, Beauveria bassiana strain NPP111B005, Beauveria bassiana strain 147, clayed charcoal, cyclaniliprole, dichlorprop, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and Urtica spp. in or on certain products.(Article . 10)

The Commission introduced the draft and presented its contents.

Several MRL applications were submitted under Article 6(1) of Regulation (EC) No 396/2005:

- dichlorprop-P for the use on citrus fruits;
- ethephon for the use on Japanese persimmons;
- etridiazole for the use on cucurbits with edible peel;
- flonicamid for the use on apricots, head cabbage, beans and peas (with pods) and sugar beet roots;
- fluazifop-P for the use on carrots and courgettes;
- metaldehyde for the use on leeks;
- penconazole for the use on grapes;

- spinetoram for the use on cherries, cane fruit, "other small fruits and berries", "lettuces and salad plants", "spinaches and similar leaves", "herbs and edible flowers", leeks and herbal infusions from leaves and herbs;
- tau-fluvalinate for the use on citrus fruits.

As regards spinetoram, EFSA identified a risk in relation to the use on scarole. The existing MRL should therefore be kept.

As regards flonicamid, EFSA recommended increasing the existing MRLs for several products of animal origin in order to accommodate for the intended uses of that active substance on sugar beet.

As regards etridiazole, EFSA could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Four Member States raised concerns as they believe that further data should be submitted by the applicant to address this issue.

The Commission clarified that the SC PAFF - Legislation section noted at its meeting on 29 May 2015 that the substance concerned does not produce relevant metabolites of significant toxicity or at levels leading to an exposure higher than negligible. It is therefore appropriate to set the MRL for cucurbits with edible peel in Regulation (EC) No 396/2005 at the level of 0.4 mg/kg, which reflects the GAP.

The Commission initially proposed to include four microorganisms in Annex IV to Regulation (EC) No 396/2005. However, Beauveria bassiana strain NPP111B005 and Beauveria bassiana strain 147 were withdrawn from the draft measure as the two substances have been approved on the basis of uses on non-edible crops. Further discussion is needed on the appropriateness to include these substances in Annex IV to Regulation (EC) No 396/2005. One Member State raised concerns as regards the two Bacillus amyloliquefaciens strains.

Also cyantraniliprole was withdrawn from the measure as there is currently not enough information provided in the residue section of the conclusion on the peer review of the active substance.

The draft measure provides for the inclusion of three basic substances in Annex IV to Regulation (EC) No 396/2005 (i.e. clayed charcoal, hydrogen peroxide and Urtica spp.).

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No…/…amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenpropidin and pymetrozine.

With this proposal it was intended to lower certain MRLs because of the lacking commercial availability of analytical standards and the expiration of the deadline for commercialising them. The Commission informed the Member States that in the

meanwhile the applicant for fenpropidin and pymetrozine signed a contract with a chemical distributor in order to commercialise the missing analytical standards. As this eliminates the need for lowering MRLs for fenpropidin and pymetrozine, it was decided not to vote on this proposal.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No…/…amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council.

The Commission explained that due to the changed internal procedures the proposal was not finalised for vote at this meeting. The proposal will be re-scheduled for vote at the SC PAFF in September 2017. Minor corrections can still be integrated but not major changes.

The Commission explained that since the application date of the revised Annex 1 must be set to 1 January 2018 and since the measure falls under the regulatory procedure with 3 months scrutiny, a very tight timetable needs to be respected. After this meeting the translations will be prepared and the proposal voted in the SC PAFF in September 2017. A likely publication date in January would not preclude the application of the amended Annex 1 by 1 January 2018 as foreseen.

One Member State asked the Commission to keep the national authorities updated on any development as they need to amend their national database to reflect the new list of commodities.

The Commission presented the main amendments proposed in the Revision 0 uploaded on CIRCABC. The position of ginger and galangal in Annex 1 was discussed as there could be a risk to list the crops twice in the Annex, once as a fresh commodity and once as a spice. The Commission proposed to follow the same approach taken for horseradish and to list both as spices only. A Member State suggested to deal with ginger in the same way as for horseradish, adding a footnote, but to the fresh commodity. EFSA proposed that the footnote could refer also to the processing factor to be applied from fresh root to spices.

Some Member States did not agree to this proposal, as the issue of the processing factor should be dealt in Annex VI and not in Annex I. Other examples of unclear situations exist in the Annex I (e.g. peppermints) and they have never been dealt with in Annex I.

The Commission will prepare a revised version taking into account the comments received after the deadline given to the Member States of 26 June 2017 and then proceed with the translations.

A Member State raised an issue on citrus pulp and the application of the footnote 1 to this specific commodity. The Commission clarified that the issue of applying footnote 1 was extensively discussed in the November and February SC PAFF and that it had

been concluded that Member States' authorities are responsible for taking the ultimate decision on a case-by-case basis and in view of all the evidence available.

Vote postponed