EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2017)6748100

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 21 NOVEMBER 2017 - 22 NOVEMBER 2017

(Section *Phytopharmaceuticals - Residues*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/fea2d54f-21af-4a60-a5b8-26e1edf47ba1*

A.01 Exchange of views of the Committee as regards maximum residue levels for lambda-cyhalothrin (SANTE 2017/11228 Rev.0)(Art. 12).

The Commission presented the draft and communicated that an information note would be published in the pesticides database as agreed at the last meeting of the PAFF Committee, section Pesticides Residues, in September 2017. The Commission will share the legal text and the information note with Member States for comments.

Member States were invited to submit comments by 8 December 2017.

Post meeting Note: The legal text and Annex of the draft were circulated on Friday, 24 November and an exceptionally short deadline given for commenting (by 27 November 2017) in order to launch procedures for internal consultation of the Commission services and WTO/SPS notification.

A.02 Exchange of views of the Committee as regards maximum residue levels for penoxsulam, triflumizole and triflumuron ((SANTE 2017/10633)(Art. 12).

The Commission announced the three substances which will be included in the next Art. 12 draft. The work on this draft will start after the meeting and will be soon circulated to Member States for comments.

A.03 Exchange of views of the Committee as regards maximum residue levels for bromadiolone, etofenprox, imazalil, paclobutrazol, and penconazole (SANTE/10304/2017) (Art. 12).

Concerning bromadiolone, the Commission clarified that as for warfarin, the substance was restricted to the use as rodenticide and not intended for direct application on edible crops. Its MRLs will therefore be set at the default limit of quantification (LOQ).

Concerning imazalil, the Commission informed the Committee that it will do its best to coordinate the Art. 12 review with a pending Art. 6 application. The provisional schedules for the evaluations by the Rapporteur Member State and the European Food Safety Authority (EFSA) suggest that this might be feasible, but only if the Art. 6 procedure would not be delayed. In case of such delay the Art. 12 review would go ahead as health issues need to be addressed with priority. EFSA recommended a new residue definition including the metabolite FK-772 for animal commodities. One

Member State asked for the consequences of such a change, given the absence of a commercially available analytical standard. The Commission explained that a footnote would accompany the change of the residue definition referring to the lack of the standard and that it was a legal requirement for the manufacturer to make this standard available. A procedure was previously agreed in the Committee on how to handle situations where analytical standards are not commercially available.

For the other substances, the Commission invited the Committee to reflect on the adequate LOQ for animal commodities, as very low levels can be achieved by the latest available analytical methods according to the EU reference laboratories (EU RLs), while these methods may not be always routinely applied by national laboratories and no health concern would necessitate to ensure levels below 0.01 mg/kg.

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

The Commission introduced a draft for a Regulation setting chlorate maximum residue levels on the basis of monitoring data, as foreseen in the action plan for reducing the dietary exposure to chlorate in food and drinking water. This draft had already been presented to the Committee in 2015. It is based on a comprehensive data collection coordinated by EFSA in 2014. The MRLs are set at higher percentiles of the occurrence data (e.g. 90th or 95th percentiles depending on the amount of data making these percentiles statisticaly robust) for each food category assuming that extremes potentially resulting from bad practices would not be considered with this way of processing the data. Other percentiles are considered when not enough data are available, and a cut-off at a highest level of 0.7 mg/kg was used. In response to Member States requests, the Commission clarified that the additional data provided by Member States after the initial discussions on this proposal in 2015 would be considered for future amendments, and that the 2015 proposal was just a starting point for taking up the discussion again. However, no new exercise of global data collection will be initiated. Member States were therefore invited to check if the data they have submitted are well reported in the dedicated folder on CIRCABC.

One Member State asked why the action plan was mentioning a 95th percentile, while the draft was considering mainly 90th percentiles. The Commission indicated that the value given in the action plan was just an example for a higher percentile and that case-by-case decisions would be needed. A Member State asked to consider not only monitoring data but also best practices in disinfection, as such best practices are not always reflected in the monitoring data. The Commission acknowledged the need to consider best practices to reach lower chlorate residue values, but also indicated that it used a mechanism to exclude the highest residue levels in the collected data. A Member State asked to consider the particular case of high water consuming commodities (lettuce, cucumber), for which the chlorate level of irrigation water could also have a strong impact of chlorate residue level. Another Member State asked for the introduction of a revision clause in the Regulation, in order to ensure that the MRLs would be revised in the future.

The Commission indicated that stakeholders would be consulted via the feed-back mechanism, which foresees the publication of the draft after the Commission interservice consultation and a call for comments during 4 weeks. The Commission also clarified that in accordance with the action plan, the MRL of 0.01 mg/kg for

foods intended for infant and young children would remain unchanged, that the introduction of a chlorate maximum level for drinking water would be considered in the context of the revision of the Directive on drinking water, and that the actions related to the recommendation of using mineral water as drinking water and for the reconstitution of foods for infants and young children would no longer be pursued.

A.05 Art. 12 of Regulation (EC) No 396/2005 procedures.

1. Priorities under Art. 12 and work programme

   The Commission presented an updated table on substances prioritised under the Art. 12 MRL review process to the Committee. EFSA indicated that the reasoned opinion on quizalofop-P is now adopted.

2. Procedures for substances for which the Art. 12 review follows the renewal procedure

   The general principles of the procedure to be followed were already agreed in the June 2017 PAFF Committee - section pesticides residues (point A.07.04). Further comments had been received from Member States and the procedure was fine-tuned and agreed. On request of the Member States a document summarising the procedure will be uploaded on CIRCA BC under this agenda point after the meeting.

   While the ideal moment to start the MRL review under Art. 12 under Regulation (EC) No 396/2005 is one year after the finalisation of the renewal procedure, some flexibility is needed to give Member States sufficient time to renew their product authorisations in some cases. The cases where such flexibility could be provided were clearly defined, but flexibility should not be applied in cases where a possible health risk cannot be excluded. Procedures for identification of substances for which a priority review would be necessary and the procedures to carry out such a review were also agreed, involving both experts in the Member States dealing with pesticides residues and Pesticides Legislation and – if a thorough risk assessment is needed - also EFSA. The procedures will therefore also be presented in the forthcoming PAFF Committee - Pesticides Legislation and shared with the Post Approval Issues (PAI) expert group for their information.

   EFSA will share some further reflections with the Commission and the Member States on the approach for screening substances in view of their prioritisation in cases where both the residue definition for risk assessment and the toxicological reference values change.

3. Correction of Evaluating Member States' responsibilities for Art. 12 reviews
   The point was added to the agenda by the chair.

   The Commission was made aware of a mistake that had occurred in the public pesticides database as regards the responsible Rapporteur Member States established under Regulation (EC) 2016/183 amending Reg. 686/2012 on the AIR 4 work programme. While the error was in the meantime corrected, the wong attribution still appeared in the EFSA progress table for the Art. 12 review which was based on the database. The Commission requested EFSA to correct also the progress table and to re-allocate the two substances triazoxide and terbutylazine for which the data call-in was already launched just a few days ago to the correct

Member States (Germany and Spain, respectively) pending their agreement. Furthermore the Commission informed that another Regulation re-allocating dossiers to different Member States containing AIR 4 and AIR 5 substances is currently under preparation and will be discussed in the forthcoming PAFF Committee – section Pesticides Legislation for a possible vote in December. These substances should also be re-allocated to the new RMS in the EFSA progress table but highlighting their tentative nature since the vote on the re-allocation has not yet taken place.

Spain infomed the Committee that it agrees to the re-allocation for terbutylazine. Germany indicated that it will get back to the Commission on this for triazoxide after the meeting. (Post-meeting Note: agreement was received from Germany after the meeting).

As a general procedural point the Commission clarified that it should be always the Raporteur Member State responsible under Regulation (EC) No 1107/2009 that would also be responsible for the MRL review under Art. 12 of Regulation (EC) No 396/2005. If there was an "old" and a "new" rapporteur (established under the old Directive 91/4141 and under Reg. 1107/2009, respectively), the "new" Rapporteur should carry out the Art. 12 review. The Commission stated that it expects the Member States to ensure good communication and knowledge sharing in this case.

It was agreed that the draft updates of the EFSA progress table would be shared with the Member States for a final check in view of their workload.

A.06 Specific substances – update of state of play:

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

   EFSA published since the last meeting a conclusion on a New Active Substancer: Beauveria bassiana IMI389521

2. Substances that could form aniline during processing

   The Commission updated the table listing active substances that may be a potential source of aniline formation. For carbetamide, the renewal process will not be launched before 2021. All MRLs were already lowered in the framework of the Art. 12 review except for lettuce and scarole. The Commission proposed to wait for the outcomes of the renewal process before taking action.

3. Substances falling under the cut-off criteria: linuron and iprodione

   The Commission announced its intention to table in a near future regulatory proposals concerning the MRLs for these active substances, whose approvals have not been renewed. The reasons for the non-renewals include but are not limited to the non-compliance with certain exclusion criteria laid down in Regulation (EC) No 1107/2009 and other human health concerns are identified for both active substances. As a consequence, by application of Article 17 of Regulation (EC) No 396/2005, the proposed Regulations will lower the MRLs of these active substances to the LOQ, taking into account the maximum grace periods that Member States can grant.

4. Acetamiprid

At the PAFF Committee - section Pesticides Legislation held on 5-6 October 2017, Member States agreed to submit the mandate to EFSA to review the existing MRLs for acetamiprid prior to the renewal decision of the active substance. A draft measure renewing the approval of acetamiprid is scheduled for a vote on 12-13 December 2017 at the PAFF Committee - section Pesticides Legislation.

The mandate was sent on 16 October 2017 requesting EFSA to provide an assessment within 6 months. Member States were already contacted by EFSA to identify those fall-back Good Agricultural Practices (GAPs) that would lead to a safe scenario.

A.07 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. Five Art. 12 reasoned opinions, has recently been adopted, several substances are currently in the commenting period with Member States, including the reasoned opinion for copper. The glyphosate Art. 12 reasoned opinon is expected to be adopted by end of December 2017 together with the Art. 43 reasoned opinion on glyphosate/animal health, but both might be published only in early 2018. Seven Art. 10 reasoned opinions were adopted, 43 are in progress and 45 questions are under the clock-stop procedure. Member States were invited to withdraw applications for which there is no longer any interest and where the stop-clock procedure is ongoing for a long time. An Art. 43 mandate was sent by the Commssion on acetamiprid which will be delivered by EFSA by 16 April 2018. Furthermore the Comssion has sent the mandate on the scientific report for preparation of the 2018 Codex Committee on Pesticides Residues (CCPR).

Agreement of Member States on the EFSA PRIMO model rev. 3

EFSA thanked the Member States for their comments on revision 3 of the Primo model and outlined the main changes that were made taking into account the Member States' comments. The Member States agreed on the Primo model rev. 3.

It will now be put on the EFSA webpage together with a guidance document. It was agreed to apply the Primo model rev. 3 to new applications as from 1 February 2018 (date of receipt of the application in the Member State) and for Art. 12 reviews (date of launch of data call-in by EFSA).

For the future EFSA is already working on a major revision 4 which will take some time as it will contain the more comprehensive food consumption database, but signalled that in the meantime minor revisions should be done more frequently. The Commission and the Member States welcomed this proposal.

One Member State raised issues with mixing of bulk commodities and the use of the supervised trial median residue (STMR) versus the highest residue (HR) and requested clarification why different percentiles for the consumption data were used. EFSA clarified that revision 3 fully addressed the first point as it is now in line with the International Estimated Short Term Intake (IESTI) equation for the different cases

and that different percentiles are needed to account for the fact that sometimes the number of data points is insufficient to calculate with the P97.5.

Another Member State reminded that the link to Primo model rev. 2 must be updated in the Working Instructions for pesticide residues under the Standard Operating Procedure (SOP) for the Rapid Alert Sysetem for Food and Feeed (RASFF). The Commission committed to take care of that.

Project on dithiocarbamates

Once the renewal exercise under Regualtion (EC) No 1107/2009 for the substances belonging to the the group of dithiocarbamates is finalised (last conclusions expected by end 2018), the Art. 12 review of MRLs should be launched (by end of 2019). The assessment wil be challenging as the common analyte CS2 is also formed naturally, e.g. by brassica vegetables but also other plants. On request of the Commission, EFSA and the EU RLs therefore worked out some guidelines for the data collection to estimate natural background levels of dithiocarbamates. The Commission thanked EFSA and the EU RLs for this extensive work. Based on a comprehensive table with background data from the EU RLs EFSA worked out guidance on numbers of samples to be taken on relevant crops that would be needed for the Art. 12 review. The Commission asked the Member States to consider these guidelines as much as possible in their national monitoring programmes for 2018 and to collect the necessary data on organic samples. It was clarified that also samples from certified bodies (e.g. bodies involved in organic farming) could contribute to the data pool as long as the origin of the data was clearly described.

A.08 Honey guidance – State of play.

The Commission thanked all members of the working group for their valuable contributions which lead to the final draft. This final draft had been shared with all Member States via CIRCABC.

The Commission highlighted some aspects of the technical guidelines and gave an overview of the decision making scheme.

Member States were invited to provide comments in a table format which is made available on CIRCABC. The Commission intends to include these technical guidelines for note taking on the agenda of the next PAFF Committee, Section Pesticides Residues.

Member States were invited to comment by 8 January 2018.

A.09 Screening exercise on temporary MRLs in Regulation (EC) No. 396/2005 that will expire in 2017-2018.

For oxadixyl, temporary MRLs had been set for lettuces and other salad plants, celeries and parsley at a value of 0,05 mg/kg, pending the submission of further monitoring data by 19 January 2018.

Belgium forwarded to the Commission the results of the official controls conducted by the national authority in 2015-2017 as well as data provided by trade associations. In parallel, the Commission requested EFSA to extract monitoring data from its database for 2014-2016.

For diphenylamine, temporary MRLs had been set for apples and pears at a value of 0.1 mg/kg, pending the submission of further monitoring data by 22 January 2018. European stakeholders forwarded a study showing a reduction of cross-contamination and elimination of diphenylamine in storage rooms when using good practices. A South African association submitted recent monitoring data showing that there are still some findings of diphenylamine on untreated products. In parallel, the Commission requested EFSA to extract monitoring data from its database for 2014-2016.

All documents received were uploaded on CIRCABC. Member States were invited to examine the data and share their views on the appropriateness to further extend the validity of the temporary MRLs by 31 December 2017.

A.10 EFSA Guidance Document on the Residue Definition for Risk Assessment.

The Commission outlined the positions received from several Member States. Only one Member State had no objections and was in favour of the implementation schedule. Moreover, it proposed to anticipate the applicability of specific parts of the guidance document, which would lead to benefits such as reducing animal testing. The Commission reiterated that neither Member States nor EFSA should make use of the Guidance Document before it becomes applicable.

Other Member States raised concerns on the complexity of the guidance document and the need for training. Furthermore, the involvement of toxicological experts is needed to address those situations that would require expert judgement when using the new tools. It was also acknowledged that the overall workload would increase at Rapporteur Member State level.

One Member State was concerned about the impact that the future residue definitions, which would include an increased number of metabolites, would have on the implementation of Codex maximum residue limits (CXLs) into EU legislation. A further two Member States questioned the benefits resulting from the revision of the residue definition. These Member States believe a trial phase should be carried out to assess the additional workload and the actual consequences in relation to the application of the guidance document.

The Commission took note of the concerns expressed by Member States. It had already contacted international organisations with a view of starting discussions on the topic at international level to ensure that a consistent approach is taken. Moreover, it also agreed that the possible consequences of the guidance document should be assessed.

It suggested that EFSA would finalise the three case studies that are already reported in the guidance document in terms of estimating the consequences that the new residue definition for risk assessment would have on the decision making process. It would also be beneficial to understand how the residue definition for monitoring would be affected in order to evaluate the effects on the implementation of CXLs.

The European Crop Protection Association (ECPA) had informed the Commission that they are also willing to develop some case studies. Member States agreed to this.

A.11 Monitoring:

- Draft Monitoring Regulation 2019, 2020, 2021 (SANTE/11141/2017 rev. 0)

The Commission presented the draft of the Monitoring Regulation concerning the EU coordinated multiannual programme for the years 2019, 2020 and 2021 as amended according to comments received from Member States. It was noted that the main body of the text remained unchanged, as changes concerned only the Annexes. Changes involving footnotes, number of samples for processed cereal-based baby food and headers of columns were specified. Furthermore, the range of plant commodities in which glyphosate should be analysed was extended and glyphosate and fipronil were added in Annex I concerning products of animal origin. One Member State questioned this addition since glyphosate was hardly ever found in animal products. It considered that this would be a waste of resources of testing laboratories. Another Member State remarked that it would only make sense to test for high-water content animal products, such as liver, kidney and muscle, while currently 4 out of 6 products of animal origin in the multi-annual control plan are fats.

The Commission justified the inclusion with the need for a complete overview in all food products and referred to the recommendations EFSA made in its 2015 annual report that were also taken up by the European Parliament in a recent Resolution. The Commission added that from a technical point of view, the EU RL confirmed that it is feasible to analyse glyphosate and is willing to provide support. The Commission proposed to invite a colleague from the EU RL to the next meeting to answer more detailed questions on the analytical methods.

The Commission mentioned that in view of the upcoming departure of the United Kingdom from the EU, and in the absence of clarity on potential transition periods, it had consulted EFSA on the potential need for re-distribution of samples per country per commodity to ensure globally sufficient and robust sample numbers. The Commission presented an initial draft sampling distribution proposal which will be uploaded on CIRCABC after the meeting. The further proceeding still needs to be defined, also in view of progress with the ongoing negotiations.

Concerning the distribution of samples, one Member State noted that while it would not be against the new distribution, it considers that the overall number of samples would still be sufficient, even with a potential decrease due to Brexit. It also noted that in the past the number of samples had been increased.

The Commission invited Member States to submit comments by 15 December 2017.

- Working document on pesticides to be considered for inclusion in national control programmes for Note Taking (SANCO/12745/2013 rev. 9)

The Commission presented revision 9 of the Working Document making reference to the addition of gamma-cyhalothrin in Annex II concerning the substances for which support is required from the EU RLs and to the addition of Annex X concerning the project on phytogenic dithiocarbamates that was presented by EFSA. Glyphosate was added to the working document. The Commission, in line with the comments made under agenda item A.10, expects the Member States to extend their national sampling plans to include the analysis of glyphosate in the widest possible range of commodities.

The Commission mentioned that it had received comments from the EU RLs for a better structure of the Working Document, as its current form is not very user-

friendly. As the Member States are its main users, the Commission invited them to submit their comment concerning its form, but mentioned that any change would take place in next year's version of the document and could be discussed in an expert group to be held in 2018.

One of the Member States remarked that the carbon column for the detection of lambda/gamma-cyhalothrin was available, but expensive for the purpose. It welcomed a presentation of the working document in table form as it would facilitate reading.
The Member States took note of the working document.

A.12 Analytical QC document for Note Taking (SANTE/11813/2017 rev.0).

The EURL for Fruits and Vegetables presented the main changes made compared to the old version of the technical guidelines. The document got a new number, but the changes were actually minor. The Commission thanked the EURLs for their valuable work.

Concerning the method performance acceptability criteria for validation, a Member State requested clarification concerning the recovery factor of 140%. The EU RL remarked that recoveries above 100% are quite common and they could reach 140%.
Another Member State made an editorial remark.

The Member States took note of the technical guidelines on AQC procedures. They will apply as from 1 January 2018.

A.13 Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods (SANTE/2017/10632 Rev.3) for Note Taking.

The Commission presented revision 3 of the document and the few amendments introduced in its section 7 on application. It confirmed the application date to be 22 November 2019, two years of the date of Note Taking.

One Member State required to specify an exception for minor uses, adding a reference that "on a case by case basis the data might not be required". The Commission considered it impossible to specify all possible cases in such guidelines.

Another Member State commented on the actual wording of the paragraph on the requirements for Art. 6 requests. The Commission did not see this as substantial and no change was made.

The Member States took note of revision 3 of the Guideline.

A.14 CCPR 2018 preparations:

1. e-Forum of the eWG on Classifications of food and feed

The Commission recalled that, as from 2017, the Codex electronic Working Groups will use the new tool of e-Forums, in order to avoid emails and to facilitate the sharing of information between members. In particular for the eWG on Classification of Food and Feed, the comments received in the first round have been very few. The Commision recalled the basic rules and functioning of the e-Forum.

The Commission informed Member States that it will not coordinate their replies at this stage, but only after finalisation of the document by the eWG. The deadline for uploading comments into the e-Forum is 30 November 2017.

2. E WG on the Codex priority list

The Commission informed the Committee that documents were uploaded on the Codex platform and proposed a prioritisation for the periodic review of active substances. The European priorities being well taken into account in the proposed scheduled, the Commission does not envisage any comment at that stage but indicated that Member States were free to provide their own comments via the Codex platform.

3. e WG on IESTI equation.

The Commission informed the Committee that the following documents were uploaded on the Codex platform:

- history, background and use of the IESTI equation;
- advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade; and
- additional information on bulking and blending

Member States were invited to provide comments directly to the Codex platform by 1 December 2017. Member State were also informed that a new discussion paper providing recommendations for consideration at CCPR50 would be available during the first two weeks of December 2017 and that they could provide their comments until end of January 2018.

4. Antimicrobial resistance

The Commission coordinates the EU comments on the revision of the Code of Practice to minimise and contain antimicrobial resistance and the draft Guidelines for the integrated monitoring and surveillance of foodborne antimicrobial resistance. In line with the One Health approach, the scope of these code of practice and guidelines now include the use of antimicrobial agents in crops.

In order to prepare these comments, Member States were also asked to provide the answers given to the questionnaire on antimicrobial use in plant production systems referred to in Codex document CX/PR 17/49/03 Add.1 discussed at CCPR49.

The Commission thanked Member States which had made some statistics on the main reasons for the EU reservations in the 2017 CCPR. The Commission stated that while it is important that the EU maintains the principles of its solid and strict regulatory framework, good coordination at international level (Codex Alimentarius, OECD) is needed. The discussion now ongoing at international level on the IESTI equation is a good example how things should work, another example is the agreement on the proportionality principle reached in CCPR in 2013. Further discussion is ongoing on involvement at international level on the residue definition for risk assessment (see point A.10).

A.15 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

No issue was raised under this point.

A.16 Designation of Member States for maximum residue levels (MRL) applications.

No issue was raised under this point.

A.17 Info on substances falling under the hazard based criteria in Regulation (EC) 1107/2009 and follow up on MRL side.

The Commission acknowledged the positions of Member States regarding the procedural aspect for the maintenance and the setting of import tolerances (ITs) for active substances falling under these criteria.

While different positions had been expressed on the possibility to maintain existing ITs and to set new ones, it appears clearly that Member States do not want to take the responsibility for rejecting at their level any requests for new ITs for such active substances.

The Commission informed Member States that the issue was still under discussion among the Commission services and that their views would be taken into account in order to establish a Commission position on the subject.

A.18 State of play of evaluation of Reg. (EC) No. 396/2005 and Reg. (EC) No. 1107/2009.

A set of surveys and a public consultation had been launched with the aim to collect views and data from all relevant parties. The following deadlines apply:

1. Survey of EU Member State Competent authorities – 31 December 2017
2. Online surveys of EU stakeholders – 31 December 2017
3. SME survey – 15 January 2018
4. Open public consultation – 12 February 2018

The Commission informed that in addition to the surveys, interviews will be carried out and focus groups will be set up on the following topics:

1. Risk assessment;
2. Risk management and decision making;
3. PPP Authorisation; and
4. MRL setting.

The Commission has created a specific mailbox to address all queries in relation to the evaluation process: SANTE-PESTICIDES-EVALUATION@ec.europa.eu.

A.19 Feedback from Post Approval Issues (PAI) group.

No issue was raised under this point.

A.20 Procedures for routine MRL setting under Regulation (EC) No 396/2005: Planned revision of SANTE/2015/10595.

The Commission intends to revise the Technical Guidelines on the MRL setting procedure in order to address issues that are not yet included. For instance, a paragraph should be added outlining those cases where an extrapolation may be carried out by simply applying the relevant EU technical guidelines instead of having to draft an evaluation report or a reasoned opinion.

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

A.21 Possible update on the guidance document for MRL setting (SANTE/2015/10595).

This point corresponds with agenda item A.20.

A.22 AOB

- Initial information concerning Brexit

  The Commission informed that a Notice to business operators regarding the placing of the market and residue of pesticides as well as a Q&A document had been published on the Commission's website: https://ec.europa.eu/food/plant/pesticides_en.

- Request by a Member State on the correct forum for Art. 15(5) of Regulation 669/2009 discussions

  As a follow up to the question raised by a Member State at the last meeting, the Commission informed about the appropriate working groups for Member States to discuss issues on TRACES, issues falling under Art. 15(5) of Regulation 669/2009, on safeguard measures and on technical issues related to pesticides residues. The Commission will keep the Member States informed about all relevant developments, however, the discussion in the PAFF Committee – pesticides residues should remain focussed on technical spects that are not already dealt with by the other groups, in particular such issues for which specific expertise is needed. General discussions on the need for further controls should remain under the working group for Art. 15(5) of Regulation 669/2009.

- Prosulfocarb/Olives – request for a temporary MRL on the basis of Art. 16

  The point was added to the agenda on request of a Member State who informed about an issue on prosulfocarb in olives for oil production for which it sought advice from the Committee on the further proceeding.

  Prosulfocarb had been found in olives as a consequence of cross-contamination from lawful uses on cereals and possible spray drift. Restrictions on use and other measures were implemented in 2017, but not yet effective to resolve the problem. The Member State therefore proposed to set a temporary MRL in accordance with Article 16 of Regulation (EC) No 396/2005 for a period of 2 years and had already drafted an evaluation report.

  The Commission reminded that in such cases it would be appropriate to inform directly the Commission before starting work on an evaluation report to clarify procedures right at the onset. It considered that cases are very different and procedures must be defined case-by-case, e.g. the question whether it is appropriate to go for a temporary MRL at all, which legal basis should be used for the work requested from EFSA, whether data from other Member States would be needed, to define an Evaluating Member State if Art. 43 of Regulation (EC) No 396/2005 would be used, etc.

  Several other Member States reported similar cases that they had in their territories, related to this and other volatile substances used on cereals. Such issues arose also often on organic crops. They referred to a whole range of risk management measures available to prevent such problems and that in their views were not yet exploited in this particular case. Setting a temporary MRL would not be an appropriate measure as it would not resolve the cause of the problem.

  The Commission agreed that first of all good practices should be promoted and all possible measures taken to tackle the problem at source. It invited all Member States to come forwared with details of the measures that were taken in their

territories in similar cases by 15 December 2017 to inform a further discussion on the way forward at the next PAFF Committee – section pesticides residues.

- Revision of GD SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1

  In the May 2017 PAFF Committee – section pesticides legislation, one Member State voluntarily took the lead to revise the above guidance documents, which are outdated.
  The Member State in charge presented two preliminary drafts and requested comments from Member States, EFSA, EU RLs and the Commission by 22 December 2017. A comments reporting template and a dedicated contact point had been also provided by the Member State and uploaded on CIRCABC.

- Propargite

  The point was added to the agenda by the chair on request of a Member State who reported on findings of propargite in imported products at levels above the existing MRLs. No toxicological reference values had been set in the past. In view of the genotoxic potential of the substance, the Member State derived a very conservative Acute Reference Dose by using the TTC approach.

  The Committee was informed of the EFSA expert meeting on mammalian toxicology that was held on 19 October 2017. The meeting was established when evaluating two import tolerance requests on citrus fruit and tea. EFSA will propose toxicological reference values in the framework of the Art. 10 reasoned opinion on propargite.

- Mercury
  The point was added to the agenda by the chair on request of a Member State who reported on findings of mercury compounds in seaweeds and asked the Commission to clarify the framework in which the issue should be addressed.

  The Commission informed about the discussions which are taking place in the contaminant sector. A recommendation to address occurencies of heavy metals in seaweeds is currently under preparation. However, it clarified that the product algae is listed in Annex I to Regulation (EC) No 396/2005. Therefore, if there is a need to amend the existing MRL, this should be carried out in the framework of pesticides residues.

- Cumulative risk assessment

  The point was added to the agenda by the chair upon the request from a Member State who informed about an ongoing national project to investigate cumulative risks. This was triggered by findings of multiple residues in e.g. strawberries. The Member State asked the Commission for its view on the way ahead.

  The Commission invited the respective Member State to share further details of the approach. This could give useful input into the work that the Commission and EFSA are currently jointly carrying out to develop a methodology on cumulative risk assessment. The Commission clarified that the development is progressing well but that a lot of work still remains to be done. Such a methodology would only be implemented at EU level once it would be at a more mature stage and the consequences of its implementation would be clearer. A discussion at international level would also be desirable.

One Member State supported the view of the Commission and stressed the importance of good communication. Another Member State reported about similar assessments in its territory which showed that no consumer health risks had been identified. This was also confirmed by a third Member State which referred to the reassuring preliminary calculations made by EFSA in the 2012 monitoring report.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products (SANTE/11743/2017) (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):

- abamectin for the use on bananas;
- acibenzolar-S-methyl for the use on kiwi fruits;
- fluopyram for the use on purslanes;
- fluxapyroxad for the use on various crops;
- tefluthrin for the use on carrots.

An MRL application had been submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005 (import tolerance) for fluxapyroxad used in Brazil on citrus fruits. Residue trials had been carried out on oranges, limes and lemons. EFSA concluded that the submitted data were not sufficient to set a new MRL for the entire group of citrus fruits. However, in accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for grapefruit at the value of the existing MRL for oranges. The existing MRLs for citrus fruits should therefore be kept at the current values except for grapefruit for which the MRL should be increased to 0,3 mg/kg.

The approval of maleic hydrazide had recently been renewed under Regulation (EC) No 1107/2009. In that framework, a MRL application had been submitted in support of the representative uses on potatoes, carrots, onions, garlic and shallots. Following those uses, residues occur in animal products for which MRLs need to be set.

Beer and mustard seeds powder had recently been approved as basic substances under Regulation (EC) No 1107/2009. It was proposed to included them in Annex IV to Regulation (EC) No 396/2005. At the meeting, EFSA highlighted that mustard seeds powder might contribute to the findings of CS2. This should be considered when assessing dithiocarbamates.

As regards fluxapyroxad in herbal infusions from roots, EFSA performed an extrapolation from carrots and transposed the MRL of 0.3 mg/kg. A Member State requested to apply a processing factor of 8 to reflect the drying process. A higher MRL is thus derived at the value of 2 mg/kg. This approach was agreed by the Committee.

The application for the use of acibenzolar-S-methyl on kiwi fruits is addressed by SANTE/11295/2017, since that proposal already includes the substance.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products (SANTE/11295/2017).

The Commission explained that the proposed draft Regulation was a trade facilitating measure transposing Codex MRLs (CXLs), for which the EU had not reserved its position in the Codex Committee for Pesticides Residues (CCPR), into EU legislation. Since MRLs are raised, no SPS/WTO consultation is necessary.

Deltamethrin was recently added to the draft as the CXL for rapeseed should be implemented in this framework.

As regards metrafenone, a Member State highlighted that the EU did not make a reservation to CCPR in relation to the CXL for peaches. In view of this, although different extrapolation rules apply at EU and international level, the MRL for apricots should be set at the same level as for peaches in the Annexes of Regulation (EC) No 396/2005.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos, chlorpyrifos-methyl and triclopyr in or on certain products (SANTE/10304/2017).

The Commission introduced the last drafting changes made to the draft Regulation on the basis of the comments received from Member States and EFSA and reported the SPS comments received from Australia, India and the United States of America.

Monitoring data from EFSA, Member States and stakeholders had shown a cross-contamination of untreated pulses, oilseeds and cereals by commodities treated with chlorpyrifos-methyl during storage in silos. A temporary MRL of 0.05 mg/kg for 4 years was therefore proposed for the commodities for which a lower MRL was initially foreseen in the groups of pulses, oilseed and cereals with a footnote indicating a review and the need for additional data within four years.

A request for similar temporary MRL had been made to cover possible cross contaminations of untreated herbal infusions, fresh herbs and edible flowers by commodities treated with chlorpyrifos. The monitoring data provided by a stakeholder were compared with monitoring data from EFSA, which did not confirm the levels observed by the stakeholder for herbal infusions. Concerning fresh herbs and edible flowers, the high levels observed seem to correspond to unreported uses rather than cross contamination. It was therefore decided to leave the MRLs for these commodities at the levels initially foreseen in the draft Regulation.

Vote taken: Favourable opinion.