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 30 NOVEMBER 2015 - 01 DECEMBER 2015

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/6b0c828e-2cf0-4d9d-bea9-c700fc0e4807*

A.01 Update of the "Extrapolation Guidance Document". (For Note Taking)

The Commission presented the modifications introduced into the Extrapolation guidance document (SANCO/7525/VI/95) in its latest revision (Revision 10.1).

One Member State emphasised that it could not support the document as some of its comments had not been taken into account. Some other comments were received on the tables of the document, in particular on the cases on zero residues situations which had been added to Table 2.

The Commission representative replied that all the Member States' comments had been taken into account as much as possible, but that the purpose of the current update of the guidance document had not been to completely re-draft it as was agreed at the onset of the exercise. Where Member States' comments were conflicting with each other the Commission made a choice.

France asked for a new revision of the document after the next Codex Committee on Pesticides Residues (CCPR) meeting. The Commission replied that a general revision was foreseen in the medium term, once the OECD crop field trials guidance and the ongoing work on the food and feed classification in Codex Alimentarius was finalised. The Commission emphasised however, that it would not commit on a specific date for such revision of the document.

The Committee took note of the Revision 10.1 of the Extrapolation guidance document, with the above mentioned amendment to Table 2.

A.02 Update of the Guidance Document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed. (For Note Taking)

A representative of the European Union Reference Laboratories (EU RLs) presented the main changes to the document compared to the previous version (SANCO/ 12571/2013).

EFSA made a proposal to add additional references to the document. This will be taken into account in the next revision of the document planned for 2017.

The Committee took note of the guidance document.

A.03 Working Document on the summing up of Limits of Quantifications (LOQs) in case of complex residue definitions. (For Note Taking)

The Commission presented the modifications introduced in Rev. 5.

Some Member States commented that in the limits of quantification (LOQs) were not always summed up for setting Maximum Residues Levels (MRLs) at the LOQ for complex residue definitions. As a result of the sensitivity check, that is described in the document, for certain components LOQs would need to be obtained that are lower than 0.01 mg/kg. The Commission explained that for MRLs that are set for authorised uses, Maximum Residue Levels (MRLs) at the LOQ have always been set by summing up the LOQs of the components of the residue definition. For MRLs at the LOQ for which no use is authorised, there could be cases where it might be appropriate to increase the LOQ-MRL. Member States can report such cases to the Commission and a proposal will be drafted to increase the LOQ-MRLs in such cases.

The Committee took note of the working document. Cyprus indicated it cannot support the document because it considers that due to the sensitivity check, additional method validation effort should be made.

A.04 Working Document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin. (For Note Taking)

The Commission outlined the main changes brought in revision 6(3) of the document.

A Member State indicated that the document should be made available to all the laboratories and competent authorities to ensure that the document will actually be implemented. The Commission will publish the document on its website and will present it at a European conference on pesticides residues. Furthermore the EU RLs intend to list the substances mentioned in the working document on their website together with a link to the available methods. Apart from this, the Commission underlined the importance of the dissemination of the document by the representatives of the Standing Committee for Plants, Animals, Food and Feed section Pesticides Residues (PAFF Residues) within their relevant national competent authorities and official control laboratories.

The Committee took note of the working document.

A.05 Exchange of views of the Committee as regards maximum residue levels for 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim in or on certain products (Article 12).

The Commission explained that comments from the applicant were received on the Article 12 reasoned opinion of fluazifop-P, requesting to keep some existing MRLs or to set them at another level, based on data that were submitted under the renewal procedure of the active substance or to data that are being generated or planned to be generated. The European Food Safety Authority confirmed that the reasoned opinion adequately reflects the current situation (existing Good Agricultural Practices (GAPs)) which is the purpose of the Article 12 exercise. Changes of GAP a posteriori are not possible within the Article 12 process. For such cases a new application under Article 6 of Regulation (EC) No. 396/2005 must be made.

A Member State sent written comments that it had a GAP in place for oil pumpkin that requires keeping the existing MRL of 10 mg/kg for pumpkin seed. It indicated that this GAP was reported to the Rapporteur Member State (RMS). EFSA clarified that it did not consider this GAP because the GAP was not reported and the comment not made at the time of the completeness check under the interim procedure. In such cases GAPs cannot be taken into account for the Article 12 proposal. If the Member State considers this GAP important, it can make an application under Article 6 for this MRL.

A Member State commented that for one of the substances product registrations are under evaluation. The Rapporteur Member State indicated that many of the proposed MRLs already take into account new uses that were applied for.

A Member Sate enquired for the origin of LOQs proposed for 1-naphthylacetamide and 1-naphthylacetic acid. The Commission clarified that these LOQs were a result of the summing of the LOQs of the 2 components of the residue definition.

Member States were asked to send comments by 15 December 2015.

A.06 Exchange of views of the Committee as regards maximum residue levels for carfentrazone-ethyl, ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone in or on certain products (Article 12).

The Commission presented Rev. 1 of the proposal. It reminded that changes and amendments introduced were listed and highlighted in the Explanatory note, circulated along with the proposal.

A discussion took place on the residue definition for ethofumesate. EFSA proposes not to report the parent compound, whereas both the Evaluating Member State and the EU RLs believe the parent should be included.

According to EFSA, the parent compound is likely not to be found in the crop and that therefore it might be misleading for control purposes. The EU RLs would prefer

including the metabolite in a multi residue method, thus avoiding to do a single residue analysis, which involves an additional hydrolysis steps.

The Commission committed to circulate an amended proposal for the residue definition of Ethofumesate after the meeting.

Member States were asked to send comments by 10 December 2015.

A.07 Exchange of views of the Committee as regards maximum residue levels for acrinathrin, bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph, metalaxyl, triflusulfuron in or on certain products (Article 12).

The point was not discussed as a draft document was not yet available.

A.08 Exchange of views of the Committee as regards maximum residue levels for AMTT, diquat, dodine, glufosinate and tritosulfuron in or on certain products (Article 12).

The Commission outlined the contents of the relevant reasoned opinions and informed the Committee on specific risk management decisions to be taken. In particular, there is a need to agree upon the residue definitions and the relevant limits of determinations before the proposal is notified to Third countries via the Sanitary and Phytosanitary (SPS) procedure.

Member States were asked to send comments by 7 December 2015.

A.09 Exchange of views of the Committee as regard a coordinated multiannual control programme of the Union for 2017, 2018 and 2019 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

The Commission presented the proposal, explained its content and gave an overview of the written comments received on Rev. 1 and 2

A Member State commented that the changes in Rev. 2 result in an increase of analyses by single residue methods and pointed to the impact on resources. The Commission explained that the changes in the document were a result of recent EURL comments and that Member States could further comment on the specific commodities. The Member States requested that such EURL comments should in future, be made at an earlier stage. The Commission agreed.

A Member State commented on the footnote for husked rice grain, indicating that if sufficient samples are not available, polished rice can also be analysed. As in some Member States husked rice is hardly consumed, this would lead to sampling that is not representative for the countries' consumption. In Rev. 3 the wording will be changed to 'if appropriate polished rice can also be analysed'.

A Member State indicated that it would be in favour of adding honey to the programme as the findings in honey are relevant for the exposure of children to pesticides residues. The Commission explained that many of the pesticide residues that are found in honey are due to veterinary uses which could cause a misinterpretation of the monitoring data. The matter will be further discussed within Directorate General for Health and Food Safety (DG SANTE).

Member States were asked to send comments by 24 December 2015.

A.10 Exchange of views of the Committee on a working document on maximum residue levels for chlorate in or on certain products (Article 16).

The Commission outlined the contents of the working document and gave an overview of comments received from Member States and stakeholders.

Several Member States raised concerns on specific MRLs, indicating that they would be too low and that a future reduced use of chlorine disinfectants in food production could cause microbiological health risks. The Commission pointed to the fact that the levels of chlorate residues are to a great extent also related to the use of good practices, like a regular refreshing rate of the water used in food production, which would not jeopardise a good hygiene of food products. Some Member States considered a specific MRL too high, referring to possible chronic health risks that could be caused by the exposure to chlorate residues.

For several commodities additional information would be needed to better understand the situation. The Commission explained that before any proposal would be presented for vote, a stakeholder consultation would be organised, allowing stakeholders to comment on specific MRLs. However such comments should be supported by sufficient monitoring data and details on how the product was treated.

As the major contributor to the exposure to chlorate is drinking water, several Member States requested setting limits for chlorate in drinking water. A representative from Directorate General for the Environment (DG ENV), dealing with Directive 98/83/EC on the quality of water intended for human consumption, clarified that this Directive currently doesn't cover chlorate. In general the principle is applied that any contamination due to disinfectants needs to be kept as low as possible without compromising disinfection. In order to set limits for a new parameter for drinking water, the co-decision procedure needs to be followed, making short term changes difficult. However the upcoming 5-yearly review of the drinking water parameters would be a good occasion to start the discussion on limits for chlorate in drinking water. Furthermore the Commission is planning a cooperation project with WHO for revising the parameters for drinking water, including a discussion on chlorate.

In view of comments received by several Member States, the Commission stressed that the responsibility for MRLs for chlorate remains within the remit of Regulation (EC) No 396/2005 and under the primary responsibility of the Plants, Animals, Food and Feed (PAFF) Committee - section Pesticides Residues. However, the multi-sectorial nature of the subject demands coordination and consultation of other sections

of the PAFF Committee, e.g. the sections on Biological Safety and Toxicological Safety of the food chain.

Following a comment from a Member State, the Commission clarified that for the underlying statistics from which the MRLs were derived, upper bound values had been used to represent a worst case scenario.

Member States were asked to send comments by 24 December 2015.

A.11 News from the European Food Safety Authority:

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

By the end of 2015 the MRL reviews for 214 active substances (204 reasoned opinions) will have been finalised. The state of play for some specific priority substances was given.

A new revision of the Profile will be available at the beginning of 2016 taking into account the new livestock dietary burden calculations.

A statement will be made as regards carvone in which Annex IV inclusion will be proposed.

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

Since 1 January 2015, 45 reasoned opinions (containing 175 MRLs) were published; in addition 5 conclusions including MRL applications (61 MRLs).

EFSA informed that 34 applications were currently on clock-stop which, as agreed with the Commission, is used more frequently when data gaps are identified. The most frequent reasons for clock-stopping were outlined by EFSA and Member States were requested to pay more attention on the missing data and inconsistencies which might occur in the GAPs.

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

The assessment of lambda-cyhalothrin is currently underway.

A Member State requested clarification on the state of play on the new revision of the Primo model. EFSA confirmed that work on the revision is on going but that due to lack of resources the work had progressed more slowly than foreseen.

A.12 Procedures for routine Maximum Residue Levels (MRL) setting under Regulation (EC) No 396/2005 procedures:

1. Planned revision of SANCO/01981/2008 - State of play

The Commission prepared the cover page and the table of contents of the guidance document on routine MRL setting and requested Member States to comment on the structure and planned contents of the guidance document by 24 December 2015.

2. EFSA Procedures: available on SANTE webpage.

The relevant documents were uploaded on DG SANTE's website on pesticides:

http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm

3. Other Issues

The Commission outlined the current procedure as regards the implementation of MRLs for new actives falling entirely under Regulation (EC) No 1107/2009.

The EURLs are being systematically consulted once the relevant EFSA conclusions are published. The intention is to involve them at an earlier stage of the process (i.e. draft assessment report (DAR)).

As regards data gaps, the Commission stressed that the Article 6 procedure of Regulation (EC) No. 396/2005 is fully applicable. In view of such, EFSA should not recommend setting provisional MRLs. Whenever data is missing, EFSA should make use of the stop-the-clock tool. In case of non-representative uses, which are not fully supported by data, EFSA will deliver a negative opinion. A new application form needs to be submitted by the applicant who will be informed of the data gaps at an early stage. EFSA will deliver a separate reasoned opinion addressing those uses.

This will enable the Commission to adequately prepare an MRL proposal, directly after the approval of new active substances. EFSA will thus be able to close the relevant question numbers without delay. In addition, the applicants may decide to narrow their request to specific products rather than the whole package.

For flupyradifurone, provisional MRLs were exceptionally set in view of the change of the residue definition, which was proposed at a late stage in the process. The applicant was therefore not in position to submit the missing information within the usual timeframe. Those MRLs will be reviewed within two years.

The Commission is currently investigating on how to deal with missing analytical methods and/or analytical standards for new active substances. While this is considered as a minor data gap in the context of approving the active substance, it hampers enforcement of MRLs by the competent authorities once authorisations for Plant Protection Products (PPPs) are given.

A.13 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Article 12

The Commission informed about the updated list of priorities under Article 12 of Regulation (EC) No 396/2005. It requested comments by 15 December 2015 on

whether buprofezin should be prioritised within the future process in view of its metabolite aniline, which is a genotoxic carcinogen formed during high temperature processing.

A Member State commented that it would be better to wait for the finalisation of the review report under Regulation (EC) No 1107/2009 as there are technical issues to be further investigated such as the use of the margin of exposure concept.

2. Discussion on the length of deferred application dates and transitional periods

The Commission clarified that the discussion was limited to the length of the deferral of application dates, as the current approach to transitional measures for products legally produced under the previous MRL, was not questioned.

The current approach for the deferral of application dates in Commission draft acts to lower MRLs will be maintained, based on feedback from Member States indicating broad support for this approach. One Member State advocated to shorten the deferral period on a case by case basis.

The Commission agreed with Member States that the period between a proposal for revised toxicological reference values by EFSA and the note-taking of such values in the Standing Committee should be reduced. The Commission acknowledged that it has a role to play, in particular to coordinate between different sections of the Committee, and asked Member States to ensure such coordination also among different experts and representatives from the same Member State.

3. Communication with Third Countries

In order to enhance transparency, the Commission is preparing an Information Note addressed to third countries' authorities, to outline the Article 12 procedure, as well as informing them on the substances that will undergo the process in the near future. EFSA had recently amended on its webpage the list of substances which will be examined in the interim and future process.

The draft of the Information Note will be circulated to the Member States and then formally notified to third countries, via the SPS notification system.

4. Other issues:

a) Cases where a GAP was identified but no/not sufficient residue data submitted
b) outcome of follow-up discussions on the last meeting with EFSA
c) Change of residue definitions for risk assessment (UK enquiry)

a) The Commission confirmed that for substances evaluated under the interim and future process for Article 12 reviews, it will take a strict approach and not accept late submission of information from Member States, in line with the clear procedures in place early in the process. For the few remaining substances under the current process, decisions will be taken case by case. Late submission of information from

Third Countries will always be dealt with on a case by case, since in contrast to Member States they are only informed through the SPS notification.

b) The Commission outlined the proposed procedures for evaluation of data submitted in response to footnotes on missing information. A summary of key elements by EFSA is available on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). The Commission plans to present a working document at the next meeting of the Committee.

The Commission reminded the Member States to inform EFSA when such data is received, in order to update the overview table maintained by EFSA.

c) Discussion postponed.

A.14 Specific substances:

1. Fosetyl/phosphonates

The Summary Report of the Committee meeting in which the vote took place on a draft act providing for the extension of temporary MRLs for fosetyl in certain tree nuts, was recently published.

The Commission reminded Member States to inform their respective enforcement authorities about the outcome of the vote (i.e. effectively prolonging the temporary maximum residue levels of 75 mg/kg for almonds, cashew nuts, hazelnuts/cobnuts, macadamias, pistachios and walnuts beyond 31 December 2015 until 1 March 2019), and the application date set out in the draft of 1 January 2016.

Member States were informed of the letters uploaded on CIRCABC. The Commission confirmed that it has no plans to propose extensions for commodities other than the above mentioned tree nuts, which is also in line with the position of a significant number of Member States supporting the above mentioned extension for certain tree nuts.

2. Mercury

The Commission gave an update on the state of play of the discussions in the Expert Working Group on industrial and environmental contaminants. The discussion is mainly focused on the proposed levels for predatory and non-predatory fish for which in future, four instead of currently two maximum levels are proposed. Furthermore, a number of specific maximum levels for other commodities are proposed. Two Member States commented on the need to maintain default MRLs for mercury for commodities for which no specific maximum levels apply. The Commission referred back to previous meetings where it had been agreed that maximum levels will be set under the contaminant's legislation only and according to the principles used under this legislation. Levels will therefore only be set where such levels are relevant (no default MRLs for all commodities). The Commission clarified that discussions with the Commission's Legal Service had taken place to ensure that such an approach would be legally sound. It was also clarified that if a health risk was identified with

levels in commodities for which no maximum levels had been established, enforcement action can always be taken under Article 14 of the General Food Law (Regulation (EC) No 178/2002). It was also clarified that the residue definition is total mercury and that there was no specific discussion on foods for infants and young children. If need be, maximum levels for foods for infants and young children could be set under contaminants legislation.

3. Acetamiprid

The Commission re-opened the discussion on acetamiprid for which EFSA in a conclusion of the PPR Panel of 2013 had proposed a lowered Acute Reference Data (ARfD) and Acceptable Daily Intake (ADI) based on neurotoxicological effects. The starting point for the discussion was an MRL application for acetamiprid in leafy brassica for which EFSA did not recommend MRLs based on the lowered values due to exposure concerns. A Member State requested to formally take note of the lowered endpoints in order to be able to review the existing MRLs and the authorisations. The Commission outlined that detailed discussions on the toxicological reference values had taken place previously in several meetings of the PAFF Committee section Plant Protection Products Legislation, where it was decided not to endorse the lowered toxicological reference values. The Commission acknowledged that the case illustrates that there is room for improvement in the communication and coordination between the PAFF Committees Legislation and Residues sections and proposed an approach for better coordination in the future. The Commission agreed with Member States that it may be necessary to endorse relevant toxicological endpoints that are relevant for MRL setting and exposure calculations early in the procedure, i.e. after publication of the EFSA conclusion (before the review report has been formally noted). While the ultimate responsibility for endorsing relevant endpoints (including toxicological reference values) remains with the section PAFF Plant Protection Products Legislation, prior discussion in the PAFF Pesticides Residues will be needed in such cases. It also highlighted that in order to ensure smooth cooperation, communication between national experts attending both sections is essential (cf. point A. 13.2.).

On the specific case of acetamiprid, Member States were invited to share their views on the need to endorse the lowered toxicological reference values with the Commission by 8 January 2016 taking into account all the relevant information on the matter. If the experts of the residues and legislation Committee would agree to endorsing the lowered values, those could be noted in the Legislation Committee in January 2016.

4. Acetochlor

An import tolerance request was made for acetochlor in soya beans and cotton seeds. In the relevant reasoned opinion, EFSA concluded that the submitted data was not sufficient to set new MRLs. The applicant claims that there are on-going studies addressing the concerns raised by EFSA. Furthermore, it asked for advice on how to proceed. The Commission believes it would be appropriate for the applicant to make a new request under Article 6(2) and (4) of Regulation (EC) No 396/2005, once the complete dataset is available.

5. Cyazofamid

Cyazofamid was found to be totally degraded to form the metabolite CCIM, under pasteurisation, boiling and sterilisation conditions. Since the available toxicological data were not considered sufficient to address the toxicological properties of CCIM, additional information is therefore requested to conclude whether the toxicological reference values set for cyazofamid also apply to CCIM.

In the relevant reasoned opinion, EFSA does not recommend the setting on MRLs. The Commission believes the existing MRLs should be reviewed in the light of the new information.

6. Fluopyram

Temporary MRLs were set for rotational crops until 19 October 2015. The applicant submitted data supporting the establishment of permanent MRLs in a wide range of crops. The request was assessed by the relevant evaluating Member States. The Commission requested EFSA to publish a reasoned opinion on the matter. A proposal will be prepared in line with EFSA's recommendations.

7. Mepiquat

A discussion took place on the approach for setting an MRL for mepiquat in mushrooms, where residues arise as a result of cross contamination from the cereals straw used as growing medium.

In the opinion EFSA gave several risk management options. The Commission proposed to set an MRL of 0.07 mg/kg mepiquat (as mepiquatchloride) in mushrooms, corresponding to the 97.5th (and 95th) percentile of the available occurrence data. Two Member States highlighted that since there is no health risk an MRL of 0.2 mg/kg (rounded up from the highest value found in the monitoring data (0.18 mg/kg)) would be more appropriate and less trade restrictive. The Commission emphasised that it considers this as cross-contamination for which the ALARA principle should apply and supports the applicants intention to put a use restriction on the label. A higher percentile should be used to set a temporary MRL which ensures that the highest values are cut off, but the vast majority of samples comply (only 10 out of 545 samples would not comply with the levels proposed). Another Member State requested to check which approach was followed in other cases of cross contamination. EFSA informed that another similar case, an Article 12 review of chlormequat, was currently in the pipeline, where cross-contamination of mushrooms with cereal straw treated with chlormequat was an issue. The Commission will consider the information on other cases of cross contamination but thinks that there is no "one fits all" solution for all cases. Case by case decisions will be needed taking into account the specificities of circumstances.

Member States were invited to comment by 31 December 2015 on the approach and the proposed level.

8. Metobromuron

The Commssion informed that a clock stop was applicable since 15 January 2015. EFSA proposes to extend the clock-stop period in order to receive confirmatory data, which would enable setting a residue definition for leafy vegetables.

9. New active substances (NAS) currently under discussion in the Legislation Committee

The Commission informed about the NAS currently under discussion in the PAFF Committee, section legislation since September 2015:

Reynoutria sacchalinensis extract
Pseudozyma flocculosa
Beauveria bassiana strain NPP111B005
Beauveria bassiana strain 147
Isofetamid

The Commission informed about the following changes which were noted in the corresponding EFSA conclusions regarding the Annex I Renewal Project (AIR II) renewal procedure:

Esfenvalerate: toxicological reference values

Iprovalicarb: toxicological reference values and residue definition

Lambda-cyhalothrin: toxicological reference values (already noted during a previous PAFF Committee, section legislation)

Picolinafen: residue definition

Thiabendazole: toxicological reference values

Thifensulfuron-methyl: toxicological reference values and residue definition

Triasulfuron: toxicological reference values and residue definition

A.15 State of play - approach for acute exposure assessment (IESTI equation (International estimated short-term intake)).

EFSA presented the outcome of the IESTI workshop in Geneva held in September 2015.

EFSA and a Member State stressed the need to define a common position ahead of the 2016 CCPR meeting, as the topic is also covered in the 2015 Joint/FAO/WHO meeting on Pesticides Residues (JMPR) Report, and the EU should take a clear position.

Member States were asked to submit comments to the Commission by the end of January 2016.

A.16 Codex Committee for Pesticides Residues (CCPR):

EFSA presented its preliminary findings on data received by the US Environmental Protection Agency (US EPA) on comparability of data from different geographical zones. This follows from discussions at a side event of the 2015 CCPR meeting and some bilateral discussions between the Commission, EFSA and the EPA. The Commission and Member States considered these findings as interesting and worthwhile to be further explored in the long term and at international level. It is however clear that there are still many practical and legal questions associated with the findings. Given the many priority issues that are currently on the Commission's agenda and the fact that the other project pursued at international level – the change of the IESTI equation - will require input and resources, the Commission considers the Global Zoning Project a project rather for the future, but not for the short or medium term. A Member State shared its doubts that a global GAP would be achievable given the agricultural and climatic diversity in the world. It considers that further work is needed.

- Approach for prioritisation of substances for inclusion in priority list

The Commission informed that it sent comments on 19 November 2015 to the chair of the electronic working group and thanked all Member States for their contributions. It invited Member States to reflect on two open issues prior to the discussions in the Council Working Party in spring 2016: a) whether the sub-criteria for selecting substances for inclusion into the priority list (as presented at the September PAFF meeting) should be included in the EU comments and b) under which circumstances a concern form should be submitted to the Codex secretariat.

The Commission's current proposal is not to include the sub criteria at this stage yet, but to use them internally to gain some experience first. As regards the concern forms, the Commission had received clarification that concern forms should only be provided when Codex Maximum Residue Limits (CXls) are recommended by JMPR but not yet adopted by CCPR. The JMPR would then re-assess its decision in the year following its original assessment based on the same data package. For cases where a changed overall situation and new data should be considered, inclusion into the priority list would be more appropriate. The Commission also clarified that concern forms should be sent by the EU and not by single Member States.

A Member State highlighted that there is a concern as regards the timeline to submit such form in view of the steps involved in the process.

Member States were asked to comment by 15 December 2015 on the two open questions.

- State of play on ongoing work in the eWG on food and feed classification

The Commission informed that replies have been sent on 18 November 2015 to the chair of the Codex electronic working group on food and feed classification and thanked all Member States for their contributions.

The Commission highlighted that further discussion would be needed before coming to an an agreed EU position at the Council Working Party meeting in spring 2016.

A.17 Screening exercise on t-MRLs in Regulation (EC) No 396/2005 that will be expiring in 2015/2016.

The Commission uploaded a revised table on CIRCABC.

A.18 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

The Commission presented an updated excel table of the substances proposed for inclusion in Annex IV to Regulation (EC) No 396/2005 available on CIRCABC.

2. Exchange of views as regards inclusion into Annex IV of *Streptomyces* K61 (formerly *S. griseoviridis*), *Candida oleophila* strain O, FEN 560, Methyl decanoate (CAS 110-42-9) and Methyl octanoate (CAS 111-11-5) (SANTE/12297/2015)

The Commission presented the content of proposal SANTE/12297/2015.

Member States were asked to submit comments to the Commission by 8 January 2016.

3. Follow-up on discussion of possible inclusion of Bacillus thuringiensis species: update on the state of play.

The Working Group handling the mandate on Bacillus thuringiensis will contact IBMA and the Member States with specific questions by mid January 2016.

A.19 Update on foods intended for infants and young children.

The Commission informed that there were no new developments as regards the pesticides issues. The delegated acts for foods for infants and young children will likely be the subject of discussion in the European Parliament in December 2015.

A.20 Cumulative risk assessment (CRA): second physical meeting CRA working group.

9 Member States and Norway already confirmed their participation in the working group on cumulative risk assessment on 22 January 2016. In case other Member States still would like to participate, they can inform the Commission by 7 December 2015.

A.21 Notifications under Article 18(4) to Regulation (EC) No 396/2005.

No notifications were received.

A.22 Designation of Member States for maximum residue levels (MRL) applications.

There were no issues under this point.

A.23 Information on ongoing work on endocrine disruptors and substances falling under the other cut-off criteria.

The Commission updated on the state of play of the impact assessment on endocrine disruptors, which is currently being carried out. By the end of this month, the list of chemicals to be screened will be uploaded on the DG SANTE website together with the rationale. The screening of all substances is expected to be finalised by end of April 2016 and the impact assessment completed by end of 2016. The criteria for endocrine disruptors are then expected to be established by 2017. Once the screening is finalized, its results will be published together with the methodology.

A.24 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

On 20 November 2015, DG SANTE chaired the first meeting of the Inter-service Steering Group (ISG) to discuss the roadmap and reach an agreement with the relevant services of the Commission. Once the roadmap is approved by DG SANTE hierarchy, it will be made publicly available to receive feedback.

A.25 Update on the state of play of MRL setting for biocides.

The Commission made a presentation outlining the main issues to be discussed on the proposed approach for setting MRLs for bicocides. The Commission emphasised that the proposed approach to set MRLs for biocides under contaminants legislation and based on monitoring data, is considered an interim approach for substances that are biocides only and that dual use substances (substances that are pesticides and biocides at the same time) are already covered by Regulation (EC) No 396/2005.

Several Member States stated that a clear explanation should be provided in the text of the working document clarifying the temporary nature of the interim approach and outlining the nature and time schedules for future permanent measures. Several Member States considered an amended Regulation (EC) No 396/2005 the most appropriate legislation to cover all types of biocidal substances (single use and dual use).

Several Member States were against the proposal to set MRLs based on monitoring data. The submission of such data should not be the duty of competent authorities that have limited resources, but the duty of the applicant. The applicant would also need to provide the information on the residue definition, the analytical methods and the reference standards. Furthermore, a Member State stated that MRLs should be set between substance approval and authorisation and that before authorisation, monitoring data would not be available.

Member States also highlighted the need for guidelines to evaluate exposure.

The Commission emphasised that it was looking for a pragmatic approach with which some experience should be first gained. In view of this experience further measures can be taken, but the exact type and deadlines cannot be given at this stage. Data should not be asked for all substances, but for the ones identified as being of greatest concern. Moreover, biocides companies are often SMEs and cannot afford to submit data unless necessary.

Member States are asked to submit comments by 15 January 2016. It is planned to take a final decision on the approach in March 2016.

A.26 Criteria for underperformance of laboratories.

The representative of the EU RLs presented a proposal for criteria for underperformance of National Reference Laboratories (NRLs) and official laboratories based on scope and z-score. These criteria will be taken up in the EU RL protocol for EU proficiency tests on pesticides residues in food and feed and will apply from 1 January 2016 onwards.

A.27 Guidance document on the extraction efficiency of residue analytical methods.

The Commission explained that the content of the document proposed by the Federal Institute for Risk Assessment (BfR) would be relevant for the data requirements for pre and post-registration analytical methods. It could be considered to publish a separate guidance document on extraction efficiency on the Commission's website and to include references to this document in the concerned guidance documents on data requirements. Once BfR has received all contributions from Member States, it will prepare a new version and present the changes to the PAFF Committee - section Pesticides Residues.

This document was also discussed during the Working Group Post Approvals Issues (PAI) for the Implementation of Regulation (EC) No 1107/2009 of 24 November 2015. A Member State indicated that this group should only discuss authorisation matters and that parallel discussions should be avoided on topics that fall under the scope of the PAFF Committee on Pesticides Residues.

A.28 AOB

Several points were added to te agenda by the chair.

• **Thiabendazole (SH)**

New toxicological reference values are planned to be noted by the Committee's section on PPP Legislation on 10/11 December 2015.

Once these reference values are noted, a mandate will be sent to the EFSA to review the consumer risk assessment for this substance.

• **Glyphosate: Issues related to residues**: new reference values and endpoints (residue definition) to be noted in December Legislation Committee

The Commission referred to a document on CIRCABC. The note taking of the new toxicological reference values is planned for the Committee's section on PPP Legislation on 10/11 December 2015.

The Commission sought Member States' opinion regarding a revision of the residue definition for enforcement. It currently covers the parent compound only.
EFSA proposed in the Conclusion on the peer review of glyphosate to include N-Acetyl-glyphosate in the residue definition for enforcement for crops for which glyphosate-tolerant GM varieties are on the market, and for animal commodities. Alternatively, a common residue definition for all commodities could be proposed in line with the approach taken for glufosinate.

The Commission clarified that the aim of a discussion on the residue definition at this stage is to facilitate EFSA's work on the ongoing Article 12 review. Any revision to the residue definition would only take effect after entry into force of an MRL Regulation following the Article 12 review.

Following a comment from a Member State, the Commission explained why N-Acetyl-glyphosate is investigated and not other metabolites.

A Member State commented that the inclusion of additional metabolites in the residue definition may lead to more difficulties in reporting the LOQs.

Another Member State stressed that setting the MRL is not a suitable way to enforce good practices of GM cultivations.

EFSA explained that the use of a suitable marker substance is essential. Glyphosate is not a good marker for certain GM crops (based on the GAT gene), hence the proposal to include N-Acetyl-glyphosate in the residue definition for the relevant commodities. Alternatively, it could be considered to have two separate residue definitions, one comprising glyphosate only for conventional crops and GM crops for which glyphosate is a suitable marker, and another comprising N-Acetyl-glyphosate for GAT-GM crops.

The Commission invited Member States to liaise with their representatives in the Committee's section on PPP Legislation.

Member States were asked to provide comments by 31 December 2015.

• Chlorpropham

The Commission informed about a letter received from Freshfel on sampling data on the exceedances regarding chlorpropham detected on fresh produce and some other products. The letter from Freshfel was made available on CIRCABC. In August 2014 many MRLs for chlorpropham were lowered to the new LOQ (from 0.05* mg/kg to 0.01*mg/kg). This leads to exceedances of these MRLs due to cross-contamination.

One Member State indicated prior to the meeting that no problems with enforcement had been encountered, but highlighting that care should be given when setting MRLs at very low LOQs.

Another Member State mentioned its concerns as regards exceedances of chlorpropham on cereals.

A third Member State mentioned observations made during transport and storage of potatoes. High temperatures will enhance volatilisation. This problem is considered measurable.

The Commission asked Member States to provide feedback on enforcement of chlorpropham in their respective countries by 8 January 2016.

• Tolclophosmethyl

A Member State expressed its concerns about the MRL for potatoes as voted in the last Standing Committee in September 2015. Particular concerns were raised about the procedure.

The Commission explained that the procedure was correct and fully in line with the Commission Working Document that was endorsed at the PAFF meeting in June 2015. MRL for potatoes was set at LOQ as potatoes are potentially feed and hence contribute to the animal burden and no data are available for animal commodities. The first version of the proposal on tolclophos-methyl, presented in June, was modified and aligned to the principles of this Working Document after the June meeting and the SPS notification included a MRL for potatoes set at LOQ. The change was explained in the PAFF meeting in September and no comments were made by Member States. The applicant submitted data in October 2015, only after the vote. The Commission confirmed that these data can only be taken into account through a new Article application. Efforts will however be made to evaluate this application in a timely manner. The Member State confirmed that such an application was already under preparation.

• Access to document requests for monitoring data

EFSA made a presentation on a simplified approach to be taken when EFSA receives requests for access to documents on monitoring data. EFSA proposes that Member States already flag information that should be kept confidential when submitting the results to EFSA. If such data are not flagged, EFSA would take this as agreement that data can be shared. Member States were asked to look at the details of the proposed procedure uploaded on CIRCABC and give feedback by 31 December 2015 whether they can agree on the proposed approach. In this case EFSA would provide more details of the procedures to be followed.

B.01 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 amitraz, coumafos, cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products (Article 10).

The Commission introduced the draft and presented its contents. The substances amitraz and coumaphos, originally included in the proposal, were taken out on request of the Commission's Legal service as some legal issues would first need to be clarified.

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

- cyazofamid for the use on spring onions, globe artichokes, leeks and hops;
- cycloxydim for the use on raspberries, currants, beetroots, celeriacs, horseradishes, Jerusalem artichokes, parsnips, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, cress, land cress, rucola, red mustards, leaves/sprouts Brassica, spinaches, purslanes, beet leaves, lentils, linseed, poppy seed, rapeseeds, herbal infusions from roots and dry horseradish;
- fenoxycarb for the use on peaches, table olives and olives for oil production;
- fluopicolide for the use on valerian;
- fluxapyroxad for the use on grapes and potatoes;
- kresoxim-methyl for the use on leeks;
- mepanipyrim for the use on blackberries, raspberries and peppers.
- metalaxyl-M for the use on gooseberries.
- pendimethalin for the use on lettuce.
- tefluthrin for the use on beetroots, celeriacs, radishes, swedes, turnips, garlic, onions, shallots, herbal infusions from roots, root and rhizome spices, sugar beet and chicory roots.

The Authority concluded in its reasoned opinions that, as regards the use of cyazofamid on globe artichokes and leeks, a risk to the consumer cannot be excluded. As regards the use of cycloxydim on cress, land cress, rucola, red mustards, leaves/sprouts Brassica, lentils, linseed, poppy seed, the submitted data were not sufficient to set new MRLs.

As regards cyazofamid, it was agreed that the concern highlighted by EFSA is also applicable to spring onions in view of the fact that the product may be cooked before consumption. As regards fluxapyroxad, it was agreed to set the MRL for potatoes at the level of 0.1 mg/kg, which was recommended in the relevant EFSA conclusions and addresses the issue of rotational crops. As regards metalaxyl-M, EFSA recalculated the appropriate value for gooseberries in line with the existing extrapolation rules, thus deriving an MRL at 0.4 mg/kg.

For flumetralin, flupyradifurone and mandestrobin, EFSA submitted conclusions on the peer review of the pesticide risk assessment of those active substances.

As regards flupyradifurone, several mistakes were reported in the relevant conclusions. EFSA informed the Committee on the correct values, which were then

reflected in the proposal under consideration. EFSA will publish a revised version of the conclusions.

A Member State flagged that where values were set for crops named as "others" under a specific category, some general rules should be discussed and applied to ensure consistency. The Commission agreed to check whether this issue is not already covered by the Working Document (WD) on drafting Article 12 proposal (Post meeting Note: the WD on drafting Article 12 proposals already contains such rules).

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 chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products (CXL proposal).

On 18 July 2014, Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for cyprodinil and flutolanil. On 11 July 2015, CAC adopted CXLs for aminocyclopyrachlor, benzovindiflupyr, buprofezin, chlorantraniliprole, clothianidin, cyflumetofen, dichlobenil, dimethomorph, dithiocarbamates, emamectin benzoate, fenamidone, fenpropathrin, fluensulfone, flufenoxuron, fluopyram, glufosinate-ammonium, imazamox, mesotrione, metrafenone, myclobutanil, phosmet, propamocarb, propiconazole, prothioconazole, pyraclostrobin, sedaxane, spirodiclofen, thiamethoxam, triadimefon, triadimenol and triforine.

In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council and in accordance with point (e) of Article 13 of that Regulation, the Commission implements Codex maximum residue limits (CXLs) into EU legislation in cases where the EU had no concerns and did not make a reservation at the Codex Committee on Pesticides residues (CCPR):

CXLs for chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen should therefore be included in Regulation (EC) No 396/2005 except where they relate to products which are not set out in Annex I to that Regulation or where they are set at a lower level than the current MRLs.

CXLs for clothianidin, mesotrione and thiamethoxam will be introduced in a future proposal because other MRL setting procedures are currently ongoing for these substances.

Sulfoxaflor: A Member State enquired why the substance for which in the first revision of the document Codex maximum residue levels were proposed to be implemented, was taken out of the proposal. The Commission representative explained that this was done following some internal discussions within DG SANTE,

but that the levels would be implemented at a later stage. Several Member States expressed their dissatisfaction with this decision and did not see any scientific or other reason not to put them forward for vote. They were concerned about negative consequences for ongoing authorisation procedures for PPPs in the EU.

Vote taken: Favourable opinion.

B.03 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 atrazine in or on certain products.

All existing authorisations for plant protection products containing atrazine have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005, the MRLs set out for that active substance in Annexes II and III should be deleted.

The Commission requested EFSA to provide a scientific opinion on the temporary MRLs, which were set for cereals, following an import tolerance request made by Argentina. Based on residue trials submitted by the applicant in support of the use of atrazine on maize in accordance with Argentinian Good Agricultural Practices, EFSA concluded that the MRLs for atrazine in cereals should be lowered to a level of 0.05 mg/kg. Such level corresponds to the existing relevant limit of determination for atrazine in products of plant origin.

Vote taken: Favourable opinion.

B.04 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 as regards maximum residue levels for captan, propiconazole and spiroxamine in or on certain products (Article 12).

The Commission introduced the draft and presented its contents.

For captan, the residue definition for grapes is temporarily kept as captan only with a corresponding MRL of 0.02* mg/kg for wine grapes only following several comments made by wine producing countries during the SPS consultation procedure. The Commission confirmed the availability of the reference standard for THPI. Reference standards for 3-OH THPI and 5-OH THPI are commercially not available. A footnote is set to address this data gap.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for Cydia pomonella granulovirus (CpGV), calcium carbide, potassium iodide,

sodium hydrogen carbonate, rescalure and Beauveria bassiana strains ATCC 74040 and GHA in or on certain products.

The Commission introduced the draft and presented its contents. No specific comments were made by the Member States.

Vote taken: Favourable opinion.