EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)7555152

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 28 NOVEMBER 2016 - 29 NOVEMBER 2016

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/37dde3be-59ee-47d2-9338-88a29f999f02*

A.01 Exchange of views of the Committee as regards maximum residue levels for fluopyram, HCH isomers, profenos and nicotine.

The Commission presented the draft Regulation and informed the Committee about its notification to the World Trade Organisation (WTO) under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).

Concerning nicotine and profenofos, a Member State noted an inconsistency between the recitals and the Annex regarding the duration of the extension of the temporary maximum residue levels (MRLs). The Commission clarified that the intended duration of this extension was five years and will correct the recitals accordingly. It was also pointed out that the profenofos Codex maximum residue limit (CXL) for 'Teas (Tea and herb teas)' was set in 1997 and was not part of the 2008 JMPR periodic review, an issue that could be raised at the next Codex Committee on Pesticide Residues (CCPR) meeting.

Concerning hexachlorocyclohexane (HCH) isomers, two Member States were not in favour of setting limits of quantification (LOQs) lower than 0.01* mg/kg unless there is a real risk. The Commission explained that lower LOQs were proposed on the basis of recent monitoring results showing that lower levels were readily achievable for certain commodities by the majority of routine laboratories. The Commission also informed the Committee that the values notified to the WTO could still be adjusted to a higher value if necessary.

Member States were invited to submit comments by 3 January 2017.

A.02 Exchange of views of the Committee as regards maximum residues level for achrinathrin, metalaxyl and thiabendazole (Article 12).

The Commission presented the proposal. The specific issue of the metalaxyl MRL for cocoa beans and its impact on trade was discussed. The Commission invited the

Member States to comment on two possible options before notifying the proposal to WTO/SPS by 2 December 2016: either to leave the actual EU MRL of 0.1 mg/kg with a footnote indicating the data gaps or to implement the tentative MRL of 0.04 mg/kg proposed in the EFSA reasoned opinion.

Two Member States already expressed at the meeting their support for the first option. One of the two also noted that the same approach applies in the case of fenpyroximate (see Pt. B 04.00).

Post meeting note: taking into consideration the replies received, the Commission has notified to WTO/SPS a proposed MRL for metalxyl/cocoa beans of 0.1 mg/kg.

Member States were invited to submit comments to the overall proposal by 3 January 2017.

A.03 Exchange of views of the Committee as regards maximum residue levels for benthiavalicarb, fenpropidin and pymetrozine.

The Commission presented the draft Regulation lowering certain MRLs to the LOQ for the substances in the proposal due to the unavailability of analytical standards. For benthiavalicarb, the applicant informed that the required standards will become commercially available by 1 December 2016. As soon as this is the case, the substance can be removed from the proposal. For fenpropidin and pymetrozine the applicant informed that work is ongoing for making the required standards commercially available. A vote on the proposal is planned for 13 June 2017.

Member States were invited to submit comments by 31 December 2016.

A.04 Exchange of views of the Committee as regards a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 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 draft Regulation. Two Member States expressed reservations on late changes proposed by the European Reference Laboratories (EURLs) which were not discussed in the expert group on pesticides residues monitoring. It was proposed that the EURLs should circulate proposals for the EU coordinated multiannual control programme at least a month before the expert meeting, in order to enable a discussion in this meeting.
The Commission informed that those late suggestions would be removed from the proposal and be discussed in the 2017 expert group meeting again.

Member States were invited to submit comments by 16 December 2016.

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

The Commission presented draft Regulation and explained its contents.

A Member State informed that part of the missing data on this active substance were recently made available by the applicant and it asked an evaluation by EFSA of these new data. The Commission explained that new data should be assessed under the regular procedures for the approval of active substances and for MRL setting and pointed to the fact that the data package is still not complete. In the meanwhile the follow-up on the decision of the non-approval of tricyclazole should be continued by lowering the MRL for rice to the LOQ.

Several Member States indicated to be in favour of transitional measures for both Basmati and regular rice, produced before the application date and pointed to large stocks of legally produced rice, that could otherwise not be marketed anymore. Two Member States commented against such measures and referred to possible health risks for consumers.

The Commission explained that in any case, neither the deferred application date of 6 months, that could be granted as usual, nor any possible additional transitional measure should be used to grant new emergency authorisations for tricyclazole in 2017. The deferred application date is granted to allow food business operators to adapt to the new provisions and it should also be used as such e.g. to switch to alternatives.

Member States were invited to submit comments by 16 December 2016.

A.06 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 presented the document and explained its contents.

The Committee took note of document SANCO/12754/2013 Rev. 7(3).

A.07 Update on chlorate.

The Commission informed the Member States on its intention to organise a discussion on the problem of chlorate residues in food and drinking water at a more political level with Member States, not only restricted to pesticides experts in order to take into account the cross-sectorial nature of the issue. Furthermore the Commission referred to documents provided by seven industry associations, with an overview of the efforts they have undertaken to lower residues of chlorate in food and a summary of the obtained results. In these documents also possible further actions, alternatives and their drawbacks are discussed and suggestions are made for achievable levels for chlorate in food for different sectors.

A.08 EFSA presentation on the opinion on the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs.

Comments received from four Member States and EFSA were made available via the Communication and Information Resource Centre for Administrations, Business and Citizens (CIRCABC).

EFSA made a presentation on the opinion on the risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs.

One MS requested to upload a letter from an applicant on CIRCABC.

One Member State informed about ongoing analysis carried out on samples collected after the food poisoning incidents. In 10% of the samples analysed Bacillus thuringiensis was present. These are still preliminary findings. EFSA clarified that, as monitoring was not yet carried out, the data is quite limited.
On a question related to the appropriateness of Annex IV inclusion and the setting of a possible pre-harvest interval EFSA explained that only the questions mentioned in the terms of reference were addressed.

One MS inquired if EFSA will provide feedback on earlier written questions. EFSA confirmed this.

Member States were asked to send in further comments, especially their view on the next steps forward, by 3 January 2017.

A.09 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12

The Commission updated the table concerning Article 12 priorities and gave an overview to the Committee. One Member State suggested a priority review of the MRLs for iprodione following recent setting of an acute reference dose (ARfD) by EFSA in its peer review of the risk assessment of this active substance. The Commission took note of the request but estimated that it was premature to take action before a decision is taken concerning the renewal of authorisation of this active substance.

2. Other

2.1. Legal opinion on the term "produced"

The Commission updated the Committee on the recent legal interpretation for the term "produced" in the transitional measures of Art. 12 proposals and shared its first reflections on the way forward. The interpretation had been requested since several Member States and stakeholders had asked for clarification of the current provisions. A discussion took place on the need and options for a possible amendment of the current wording and the Commission presented some possible options for the way

ahead. The Member States were invited to submit their comments on the proposed options and on some detailed questions by 3 January 2017.

2.2. Art. 12 Evaluation of confirmatory data after non-approval of a substance

A Member State enquired on the need to evaluate confirmatory data submitted following an Article 12 review of the MRLs, when the approval of the substance is likely not to be renewed. The Commission outlined its view and highlighted several points in favour of a timely assessment. Member States should schedule the evaluation based on the type of confirmatory data submitted, and in the context of other pending applications.

A.10 Specific substances:

1. Quinclorac

The Commission informed the Committee that the 2016 JMPR did not discuss the concern form on quinclorac submitted by the EU. It presented the available options for the way forward.

Member States were invited to submit comments by 5 December 2016.

2. Mercury

The Commission informed that it was still waiting for the response from the Comission's Legal service on the proposed approach. Member States will be informed once new information is available.

3. Chlorantraniliprole

The United Kingdom (UK) granted a 120 day emergency authorisation for the use of chlorantraniliprole on hops under Article 53 of Regulation (EC) No 1107/2009. As this authorisation could potentially lead to an exceedance of the existing MRL, an application was submitted in accordance with Article 18(4) of Regulation (EC) No 396/2005 to set a temporary MRL at EU level. Currently, the authorisation includes restrictions that prevent the export of treated crops or commodities produced from the treated crops to other EU countries.

The assessment carried out by the United Kingdom established that the residues arising from the significantly overdosed trials from the USA, that lead to no consumer intake concerns, are highly unlikely to be exceeded by the UK GAP. Moreover, the UK would need to set the temporary MRL for a period of three years to prevent trade disruptions.

The Commission proposed to scale the residues down by a third and set a temporary MRL of 10 mg/kg as proposed in the EFSA reasoned opinion (i.e. option 3). EFSA clarified that the proportionality principle is not fully in line with the usual MRL setting procedure, but that in this case it might be appropriate in view of the emergency.

Several Member States expressed their support to the proposal brought forward by the Commission. The Commission asked Member States to submit their views on the matter by 3 January 2017.

4. Cyhalothrins (lambda-cyhalothrin, gamma- cyhalothrin and cyhalothrin)

The Commission informed MSs that because of the overlapping residue definitions it is necessary to further investigate the relationship between lambda- cyhalothrin, gamma-cyhalothrin and cyhalothrin. For this reason the substance lambda-cyhalothrin has been removed from the proposal SANTE 2016/11077.
A specific Article 43 mandate is being prepared to ask EFSA for a scientific opinion which would take into account the uses of lambda and gamma-cyhalothrin.

One Member State noted that also possible isomerisation of lambda and gamma cyhalothrin to cyhalothrin should be considered in the overall assessment. The Commission will investigate the issue with EURLs. Another Member State stated that irrespective to the isomerisation ratio, the most toxic isomer should be considered. A Member States reminded that in the similar case of fenvalerate relevant isomers had been considered.

Member States were invited to submit comments by 3 January 2017.

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

The following substances will soon be discussed in the Standing Committeee on Plants, Animals, Food and Feed (PAFF) - section Legislation:

- Mild Pepino mosaic virus isolate VC 1
- Mild Pepino mosaic virus isolate VX 1

A.11 Preparation Codex Committee on Pesticide Residues 49 (2017) (CCPR):

1.Priority of EU nominated substances and concern forms

The Commission informed Member States that the EU comments on the priorities for the JMPR periodic review would need to be sent by 30 November 2016 to the chair of the electronic Working Group (eWG). The Commission also acknowledged the receipt of most of the missing concerns forms for the prioritised active substances and called on the Rapporteur Member States of the missing ones to send them urgently. The following order of priorities was agreed:
1-dicloran, 2-amitraz, 3-phosalon, 4-imazalil, 5-dimethoate, 6-dithiocarbamates, 7-quintozene, 8-ethoxyquin, 9-prochloraz, 10-diazinon, 11-guazatine, 12-bromide (methyl bromide). It was also agreed to request the withdrawal of the Codex maximum residue limits (CXLs) of the following unsupported active substances: methidathion, bromopropylate, fenarimol and azinphosmethyl. Consequently, those substances should be deleted from the priority list for periodic review by the CCPR.

2. IESTI (Internationally estimated short term intake) equation

The Netherlands, who are the Chair of the eWG on the impact of the possible revision of the current IESTI equations, provided an update on the state of play and invited other Member States to contribute comments on the draft discussion paper.
Member States were invited to submit comments directly to the eWG by 20 December 2016.

3. Crop groupings

The CODEX eWG on crop grouping circulated an updated proposal which took into consideration previous comments. Due to the tight deadline it is not possible to coordinate an EU reply. Member States were invited to submit comments directly to the eWG by 31 December 2016.

4. Performance criteria analytical methods

The Commission presented the draft EU position on the Codex draft Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in food. In 2016 there was already a general agreement on the document, for the 2017 CCPR some additional comments will be made.
The EU coordinated reply will be sent by end of January 2017 to the Council.

5. Feedback from SPS working groups in Geneva

The Commission provided feedback from the WTO Workshop on Pesticide MRLs and the EU Information Session on Endocrine Disruptors on 24/25 October and 26 October 2016, respectively, which were held in the margins of the WTO-SPS Committee meeting on 27/28 October 2016 in Geneva.

A.12 Monitoring:

1. Annual Report 2014- conclusions on risk assessment

EFSA presented the outcome of the risk assessment performed with the 2014 monitoring data.

A discussion took place on the exposure assessment, and in particular:

- on the use of the upper bound approach chosen by EFSA as very conservative approach,
- on the possibilities to use levels between limit of determination (LOD) and limit of quantification (LOQ) for more realistic assessments also in view of cumulative risk assessment,
- on the reported exceedances of some acute reference doses which were in several cases due to recently lowered reference values and the way of communicating this fact,
- on the possibilities of refinement of assessments for omethoate and dimethoate for the 2015 report.

2. Feedback from Expert Group Meeting on Pesticides Residues Monitoring 2016

The Commission referred to the expert group meeting on pesticides residues monitoring that took place on 21 October 2016. In this meeting the 2018-2020 EU coordinated multiannual control programme and the working document on pesticides to be considered for inclusion in the national control programmes were discussed. The detailed contents of these documents were discussed under agenda items A.4 and A.6. The presentation and minutes of the meeting were shared with the Member States via CIRCABC.

A.13 News from the European Food Safety Authority (EFSA):

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

The review process was already concluded for 220 substances. 21 reviews are on-going.

On the question of a Member State whether the Excel table on confirmatory data could be shared with applicants EFSA replied that the Evaluating Member State (EMS) should be in contact with the applicant and then provide the information to EFSA in the right format.

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

Nine questions were closed since the PAFF Committee in September. Another six are expected to be finalised by the end of 2016.

74 questions are currently still in progress showing that there is an important backlog on the Art. 10 work. The high number of open questions was explained by structural changes in EFSA also affecting human resources. Moreover, higher priority was given to the peer review and urgent questions.

Regarding the stop-the-clock procedure, EFSA intends to be more flexible and to clarify minor questions directly with the EMS without formal clock-stop. A slimmed down template for Article 10 reasoned opinions in line with the Art. 12 template has been developed.

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

EFSA informed that the dimethoate opinion was published on the EFSA website.

One Member State raised the issue of acetamiprid, where a new acute reference dosis was proposed in the respective EFSA conclusion. The Commission informed that, as discussed in the PAFF Committee – section Residues of February 2016 (agenda item A.10.2.), the PAFF Committee - section Legislation would first need to take note of this new endpoint in the review report on the substance. The Commission will inform the Member States of the time planning.

4. AOB - PRIMO Rev. 3

The point was added to the agenda on request of a Member State. Several Member States underlined the importance of implementing the Primo model in its revision 3 as soon as possible and remarked that they were concerned with the delays. EFSA stated that this would need to be dicussed in the light of their overall priorities.

A.14 Amendments to Annex I to Regulation (EC) No 396/2005 (Commission Regulation (EU) No 752/2014) - state of play.

The Commission reminded that the final goal is to vote the amended text in the first half of 2017, so that the new legislation could enter into force on the 1st January 2018.

In view of this, the Commission proposed to follow a stepwise approach and close chapters successively. The Commission introduced an updated document in which chapters 1 to 4 are considered as 'closed', as agreements were already reached in previous PAFF meetings; chapters from 9 to 14 are indicated as 'open', as they will be discussed in future PAFF meetings; chapters from 5 to 8, on which discussions are already advanced, are indicated as 'to be closed'. On these chapters Member States were invited to submit comments by 3 January 2017.

The list of commodities proposed to be added into the Part B of the Annex I will be kept open for late additions, until the final vote will be taken on the entire set of amendments.

As regards the wording of the footnote (1) referring to category 12 of Annex I on "crops or part of crops exclusively used for animal feed production" specific proposals were made to clarify further the current text that will be taken into account by the Commission.

Several Member States reiterated the request to the Commission to complete the Annex I of Reg. 396/2005 and to establish the commodities falling under category 12. The Commission replied that, though being aware of this need, for the near future priority is given to other issues, e.g. those for which legal deadlines need to be respected.

A.15 Honey guidance.

Comments were received from one Member State. Based on these comments a revision 2 of the draft Guidance Document was prepared and made available via CIRCABC. While preparing this new draft, several technical discussion points were identified. It is therefore proposed to organise a technical expert meeting with experts from the Member States and EFSA on 10 March 2017.

One Member State confirmed the need for this Guidance Document given the recent findings in honey. This Member State however thinks that the current draft may not fit the current needs regarding the setting of MRLs in honey. For examples residues of substances are found while these substances were not used in the field.

The Commission informed that monitoring data on honey for the years 2013-2014-2015 were requested from EFSA. If available in time, this data will be discussed during the next meeting.

Member States were invited to send their nomination for the expert meeting by 15 December 2016.

A.16 Screening exercise on temporary maximum residue levels (t-MRLs) in Regulation (EC) No 396/2005 that will be expiring in 2016 and beginning of 2017.

The Commission gave an update on the state of play.

A.17 Inclusions in Annex IV of Regulation (EC) No 396/2005.

Currently no new proposals regarding inclusions in Annex IV are planned. Next inclusions in Annex IV will be included in the routine MRL proposals.

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

No new notifications were received.

A.19 Designation of Member States for maximum residue levels (MRL) applications.

France agreed to act as EMS for an import tolerance request on pyraclostrobin/oilseed in agreement with the RMS Germany.

A.20 Number of residue trials from non-EU countries.

Several Member States had sent written comments to the earlier enquiry of a Member State on the acceptable proportion of residue trial from non-EU countries. The majority of comments referred to the EU data requirements and the OECD Crop Field Trial Guidance and were generally in favour of accepting some trial from outside the EU, based on the conditions that the trial meets EU guidelines, matches the relevant Good Agricultural Practice, and was conducted under comparable cultivation practices and climatic conditions. Suggestions for acceptable proportions ranged from 40% to 50% of the number of required trials. The Commission pointed out that while the difference in percentage seems small, it may make a significant difference in particular for minor crops.

EFSA requested more guidance on the assessment of comparability, and on the relevant zone (NEU and SEU).

Member States were invited to submit comments by 3 January 2017.

A.21 Information on ongoing work on endocrine disruptors.

The Commission summarised the discussion that took place in the recent expert meeting and PAFF Committee on endocrine disruptors on 18 November 2016, as well as the main comments it had received on the draft criteria published in June 2016 in the context of the WTO/TBT and SPS notifications and from the public through the "feedback mechanism".

A new revision was drafted in November 2016 reflecting the comments and published on the following webpage: http://ec.europa.eu/health/endocrine_disruptors/next_steps/index_en.htm. Member States were invited to comment on the document by 30 November 2016.

A Member State asked feedback about the reactions of third countries at the recent SPS meeting in Geneva. The Commission confirmed that there was a high interest and that therefore the dedicated Information session (see point A.11.5.) had taken place on request of third countries. It also confirmed that in particular the impact on MRL setting was of concern to third countries.

A.22 Planned evaluations of Regulation (EC) No. 396/2005 and Regulation (EC) No. 1107/2009 – State of play.

The final version of the roadmap was published on the following website: http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_197_ealuation_plant_protection_products_en.pdf

The changes brought to the roadmap only relate to the timeline of the evaluation process. The Commission intends to launch the call for tenders in the first quarter of 2017. The overall evaluation process should be completed by November 2018.

A feedback period of four weeks is currently on-going for all interested parties to provide comments on the roadmap. Those inputs may be reflected in the Terms of Reference. Member States were also invited to provide feedback.

On 18 October 2016, the 2nd Inter-Service Steering Group was held to agree on the draft Terms of Reference. In that framework, it was clarified that the current evaluation is a retrospective (backward-looking) exercise, being an ex-post evaluation of criteria such as the effectiveness, efficiency, coherence, EU added value etc. Based on the outcomes, an ex-ante (prospective) assessment may need to be carried out in a form of an impact assessment.

A.23 Update on the state of play of MRL setting for biocides.

The Commission presented the outcome of the discussion in a recent meeting of the Member States' competent authorities in charge of biocidal products.
While the Member States felt that the document had much improved, Member States still requested clarification on the term "significant levels of residues" that was considered to be too generic by several delegations and on the need to solve the issue

on dual use substances in a more structured and comprehensive way. More guidance was requested to assess the relevance of residues.

The Commission noted these comments that were in line with comments made at the recent meeting of the competent authorities for biocidal products. It explained that some flexibility of the term "significant level of residues" was intentional and called on the Member States to show some flexibility in finding an agreement quickly now after the long and extensive discussions. It was emphasised that without a harmonised approach there would clearly be risks to pose problems for mutual recognition later on. As regards the issue of dual use substances, the Commission confirmed that this was subject to the forthcoming Refit evaluation of the pesticides legislation. It clarified that the proposed pragmatic interim approach presented here refers to substances that are biocides only. For substances currently or formerly used as pesticides regulation (EC) No 396/2005 applies.

Member States were invited to submit comments by 15 December 2016.

A.24 Guidance document extraction efficiency (Germany).

The German risk assessment body (BfR) presented a revised version of the document, taking into account comments received from Member States, the Commission, EFSA and the EURLs.

The content of this document is relevant for both the DG SANTE Guidance on data requirements for pre- and post-registration analytical methods, that are listed in respectively SANCO/3029/99 and SANCO/825/00. It is considered to publish the guidance on extraction efficiency as a DG SANTE Guidance document and to introduce a reference to this document in the DG SANTE Guidance on data requirements for pre- and post-registration analytical methods. Some Member States stressed that enough time should be provided before the document becomes applicable. Other Member States asked some technical questions regarding extraction efficiency.

Member States were invited to submit technical comments to the BfR and comments of general nature (e.g. application date) to the Commission by 31 January 2017.

A.25 Guidance document processing factors (Germany).

The BfR gave a presentation on its project for compiling a database of processing factors. The database is publically available under the following link: http://www.bfr.bund.de/en/search.html?search%5Bquery%5D=processing+factor.

The BfR intends to further update and complete the database in future.

EFSA suggested aligning the codes in the database with the ones provided in Annex I to Regulation (EC) No 396/2005. The BfR will check whether it can implement this suggestion.

Several Member States expressed their support on the project, carried out by Germany. However, they stressed that they would appreciate having Annex VI established providing for a harmonised approach at EU level.

The Commission informed that EFSA is working on a future project for compiling data on processing factors in the framework of cumulative risk assessment. The Commission indicated that a collaboration between BfR and EFSA would we very useful.

A.26 Question referred to the Committee by Post Annex 1 Group.

A question on chronic exposure assessment at product authorisation stage was referred to the Committee by the Post Approval Issues (PAI) group of Member States. Three options for dealing with chronic exposure assessment were presented.

The Commission had analysed the information on current practices from seven Member States. While the authorisation of products remains fully the responsibility of the Member States, it could be useful to agree on some main principles. The approaches of Member States vary in detail but there was a common understanding that evaluation should be as complete as possible, but not cause unnecessary work or even re-duplication of work already undertaken. On basis of the analysis of the existing practices, the Commission presented a possible pragmatic and stepwise approach extracting elements that it would consider "best practice" from the information received. The Commission proposed to put this approach on paper shortly after the meeting and invited Member states to comment on this document by 3 January 2017. On the basis of the outcome of this consultation the further proceeding can be determined.

A.27 AOB:

- Feed, Food and dual-purpose commodities (follow up on the issue of paraquat/soybean case)

The Commission presented a document outlining a pragmatic approach on how to deal with different types of feedingstuffs in the light of the exemption that was discussed under agenda item A.14. (footnote 1 in Annex 1). For the purpose of the document feedingstuffs were grouped into three main categories.
Some Member States presented their preliminary views on the proposal, but will also send comments in writing. The Member States were updated on the outcome of the case of the residues of paraquat in soya bean meal, discussed in the September PAFF meeting. It was clarified that in this specific case the substance was fat soluble and therefore it was very unlikely that residues would occur in the part of the soya bean cake which could end up in the food chain.
Member States were invited to submit comments by 3 January 2017.

- New EFSA reasoned opinion on dimethoate

The point was added to the agenda by the chair.

EFSA published its prioritised review of the existing MRLs for dimethoate and omethoate according to Art. 43 of Reg. (EC) No 396/2005 on 28 November 2016. EFSA proposed to change the combined residue definition of 'sum of omethoate and dimethoate' to two separate residue definitions ('dimethoate' and 'omethoate'). The Commission presented a proposal amending the existing MRLs for dimethoate and omethoate in line with the outcome of the EFSA assessment. A Member State opposed to the changing of the residue definition and the increase of certain MRLs as a consequence of this change.
Member States were invited to submit comments by 20 December 2016.

- Copper

The point was added to the agenda by the chair on request of a Member State.

One Member State asked for an update on the state of play of the Art. 12 review of copper. A stakeholder association complained that copper is found in beef liver at levels mich higher than the existing MRLs under Regulation (EC) No 396/2005, because of the use of copper as a feed additive.

The Commission confirmed that levels of copper resulting from its use as feed additive and its accumulation in liver were taken into account already at the stage of the Evaluation Report on which EFSA experts from the Panel on Animal Feed were consulted (see item A.12.3. of the PAFF Committee September 2015).The EMS confirmed that in the evaluation report these circumstances were considered and significantly higher MRLs were proposed.

EFSA confirmed that the Art. 12 reasoned pinion on copper compounds is expected to be available in February 2017.

- Draft proposal for a Commission Regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiametoxam in or on certain products (SANTE/11934/2016)

The point was added to the agenda by the chair.

Clothianidin and thiamethoxam were withdrawn from proposal SANTE/11442/2016 (under Pt. B 01.00). The relevant CXLs will be implemented in the framework of proposal SANTE/11934/2016, which is scheduled for a vote at an extra Standing Committee – section Residues on 7 December 2016:
https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_2016120607_ppr_agenda.pdf

Member States were asked to share their position with the relevant colleagues attending the Standing Committee of the PPP-Legislation section.

- Folpet

The point was added to the agenda by the chair.

The Commission uploaded on CIRCABC a position paper of a laboratory on the new residue definition for folpet.
One Member State indicated the finding of phtalimide as an artefact is not only an issue for organic farming and false positives are also possible in conventional farming as raised by their national laboratories. This Member State will send in a written contribution on this subject.

- Exceedance of MRL in tea from China

The point was added to the agenda by the chair on request of a Member State.

A Member State mentioned the frequent non-compliances of Chinese tea under Regulation 669/2009 and wondered whether further measures would be necessary. The Commission informed that internal discussions on this topic are currently ongoing within the Commission and that it would update the Member States on any developments.

- CCPR indicative planning

The point was added to the agenda by the chair on request of a Member State.

The Commission informed that the first Council Working Party meeting for the preparation of CCPR 2017 would take place on 29 March 2017. As regards the second meeting the dates are not yet confirmed. Proposed dates are 10 April or 12 April 2017.

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 acequinocyl, amitraz, coumaphos, diflufenican, fluazinam, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products (Article 10). (SANTE/11769/2016).

The Commission introduced the draft and presented its contents.

Fluazinam was included in Rev. 0 of the proposal to clarify the amendments that were recently brought by two pieces of legislation (i.e. Regulations (EU) 2016/1902 and 2016/1822) both dealing with that substance. The Commission consulted its legal service to ensure that there is no legal misinterpretation given the different application dates.

The legal service confirmed that Regulation (EU) 2016/1902 is currently applicable and provides for a fluazinam MRL value for blueberries in Annex III to Regulation (EC) No 396/2005. Moreover, given the wording of Articles 2 and 3 of Regulation (EU) 2016/1822 (already incorporating the change in the value made for blueberries), the Regulation will become applicable as of 7 May 2017 and move fluazinam from

Annex III to II. Thus, the desired goal will be achieved despite the mix up in the publication timing.

In view of the above, the substance fluazinam was withdrawn from the current proposal.

Several MRL applications were submitted under Article 6(1) of Regulation (EC) No 396/2005:
- acequinocyl for the use on gherkins;
- diflufenican for the use on olives for oil production;
- metribuzin for the use on olives for oil production;
- pyraclostrobin for the use on chards.

Amitraz, coumaphos, flumequine, permethrin and streptomycin are pharmacologically active substances in veterinary medicine. As regards products of animal origin, MRLs should be set in Regulation (EC) No 396/2005 at the same levels as provided for in Commission Regulation (EU) No 37/2010 because exposure from use in veterinary medicinal products is expected to be higher than from use in plant protection products.

As regards coumaphos, EFSA identified concerns in relation to the chronic risk assessment, which need to be addressed by means of a risk management decision. Taking into account that Regulation (EU) No 37/2010 sets an MRL for coumaphos only in honey and considering the low contribution of that product to the chronic consumer exposure, the Committee agreed to set the MRL for honey and other apiculture products in Regulation (EC) No 396/2005 at the same level noting a reservation from one Member State who abstained.

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 clothianidin, mesotrione, sulfoxaflor and thiamethoxam in or on certain products. (SANTE/11442/2016)

The Commission introduced the draft and presented its contents.

In revision 1 of draft proposal SANTE/11442/2016, CXLs were implemented for clothianidin, mesotrione, sulfoxaflor and thiamethoxam. The Commission proposed to apply the following changes:

i) sulfoxafor remains in proposal SANTE/11442/2016;
ii) mesotrione was transferred to the existing proposal SANTE/11707/2016 (under Agenda Point B 03.00);
iii) clothianidin and thiamethoxam were transferred to a new proposal SANTE/11934/2016 (see under Agenda Point A 27.04).

The Commission clarified that the substances were shifted to different proposals, whilst reporting the same MRL amendments as provided for by SANTE/11442/2016 in its previous revision.

As regards sulfoxaflor, the Commission clarified that the CXL for pome fruit is also applicable to kaki in view of the international commodity grouping. The same applies for chili peppers (dry) being covered by the group of fruiting vegetables (other than cucurbits).

Vote taken: favourable opinion.

B.03 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 acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. (SANTE/11707/2016)

The Commission introduced the draft and presented its contents. As stated under point B.02 the substance mesotrione was added to this proposal without any changes in content.

A Member State asked whether the CXL for tebuconazole on sunflower could be implemented at the level recommended by EFSA in the framework of the Scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR). The Commission clarified that the Codex Limit, adopted at 0.1 mg/kg, should not be implemented in view of the fact that the Union presented an official reservation at CCPR, because the OECD calculator suggested setting the MRL at a lower level (i.e. 0.06 mg/kg). That MRL should be set at EU level in the framework of an import tolerance request under Article 6(2) and (4) of Regulation (EC) No 396/2005. A new risk assessment does not need to be carried out, as EFSA already recommended a value that reflects the Good Agricultural Practice and is safe to consumers.

Vote taken: favourable opinion.

B.04 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 fenpyroximate, triadimenol and triadimefon in or on certain products (Article 12). (SANTE/10781/2016)

The Commission introduced the draft and presented its contents.

Comments were received from the United States and from Costa Rica during the commenting period of the SPS notification and were taken into account in the revised version of the document.

Some Member States suggested that the full scientific name of the fenpyroximate metabolite 'M3' should be reported instead of an abbreviation, in order to prevent legal misinterpretation. The Commission indicated that this name is included in the EFSA reasoned opinion, to which reference is made in the Regulation. The Commission will reflect on how such clarifications could be implemented in the proposals in future, however for the current proposal it was not possible anymore to make such an amendment.

A Member State re-iterated its position that is would be in favour of keeping the combined residue definition of 'triadimenol and triadimefon'. However, as EFSA considered it necessary to split up the residue definition to 'triadimenol' and 'triadimefon' separately, this option cannot be implemented, as no assessment is available for the combined residue definition.

Vote taken: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, daminozide and tolylfluanid in or on certain products. (SANTE/11397/2016)

The Commission introduced the draft and presented its contents. No comments were made on the draft proposal.

At previous standing Committee meetings, a Member State proposed to also increase the LOQs for captan and folpet, because the existing MRLs at the LOQ are set at levels that cannot be achieved by the current routine analytical methods. However, according to the EURLs, these LOQs can be achieved by acidifying the sample, which avoids degradation of the parent compound.

A Member State plans in January 2017 a seminar to discuss the analytical difficulties experienced by laboratories for the quantification of captan and folpet. As the analytical problems were confirmed by other Member States, the Commission will ask the EURLs to organise a ring trial, to circulate the method and to provide support and training where needed.

Vote taken: favourable opinion.

B.06 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 bitertanol, chlormequat and tebufenpyrad (Article 12). (SANTE/10827/2016)

The Commission presented the latest changes to the proposal. A Member State pointed to an incorrect reference to Annex III of Regulation (EC) No 396/2005 concerning the chlormequat temporary MRLs for pears and cultivated fungi. With the agreement of the Committee, the Commission deleted the related sentence from the draft Regulation.

Vote taken: favourable opinion.