EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 24 NOVEMBER 2014 - 25 NOVEMBER 2014

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/a6c9bbb3-ca04-4afe-9b49-4b483f9c4314*

President: Michael Flueh

A.01 Presentation of the new voting rules.

The Commission presented the new voting rules required by the Lisbon Treaty and applicable from 01 November 2014.

A.02 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). (SANCO/11739/2013)

The Commission referred to additional comments, received after the last meeting of the Committee, that are available on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). Further consideration is required before circulating a new revision of the draft.

A.03 Exchange of views of the Committee as regards maximum residue levels for captan, flonicamid, flutriafol, folpet, indolylacetic acid, indolylbutyric acid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (Article 12). (SANCO/11481/2014)

The Commission introduced the draft and presented its contents.

The Commission withdrew several substances from the proposal: as regards metalaxyl and metalaxyl-M, a recalculation of the recommended MRL values is necessary to achieve a consistent application of the Organisation for Economic Co-operation and Development (OECD) calculator. As regards captan and folpet, further internal consideration is required. As regards lambda-cyhalothrin, new data was presented by a Member State. Furthermore, lower toxicological threshold values have been established within the renewal procedure and need to be taken into account.

Those substances were replaced with 1-methylcyclopropene, indolylacetic acid, indolylbutyric acid and pethoxamid.

Indolylacetic acid and indolylbutyric acid are auxins and there are natural occurences. The Commission proposed to set maximum residue levels (MRLs) for these substances in Annex V to Regulation (EC) No 396/2005 at the appropriate limit of determination (LOD).

A Member State commented on the proposed MRL for prothioconazole in rye and will provide further details in writing.

The Commission invited Member States to send comments by 08 December 2014.

A.04 Exchange of views of the Committee as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products (Article 12). (SANCO/11973/2014)

The Commission introduced the draft and presented its contents.

It responded to Member States' comments on certain substances.

As regards oxadiargyl, a specific application date was set in Article 3 of the draft because the grace period following the expiry of the approval of the active substance under Regulation (EC) No 1107/2009 is still on-going.

As regards methoxyfenozide, the Codex maximum residue limit (CXL) in edible offal was maintained.

The Commission stated its intention to present the draft for the Committee's opinion at the next meeting.

A.05 Exchange of views of the Committee as regards maximum residue levels for amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (Article 12). (SANCO/11404/2014)

The Commission introduced the draft and presented its contents.

A Member State commented on the possibility to extrapolate for trifloxystrobin from currants to elderberries, and will provide further details in writing.

The Commission invited Member States to send comments by 08 December 2014.

A.06 Monitoring of pesticides residues:

- EU multiannual programme 2016-2018 (SANCO/12097/2014)

The Commission introduced the latest revision (i.e. Rev. 2) of the draft and presented its contents.

A Member State asked to specify as regards the products to be sampled for pig fat whether fat tissue or fat should be analysed. The Commission replied that there are several different ways in which laboratories analyse fat of animal origin. Too specific wording may interfere with the current work procedures in some laboratories. The Commission preferred to keep the wording neutral, while Member States can give more specific instructions to their inspectors.

Another Member State favoured the inclusion of both muscle and fat as separate commodities with a specification of which substances need to be analysed in each matrix. This was originally foreseen in Rev. 0 but because the current draft contains no substances for which relevant residues are expected in muscle, only the commodity fat was retained. The Commission agreed to consider the uptake of muscle in future multiannual control programmes once pesticides resulting in relevant residues in muscle would be included.

The Commission stated its intention to present the draft for the Committee's opinion at the next meeting.

It invited Member States to send comments by 08 December 2014.

- Note taking of working document SANCO/12745/2013 Rev. 3

The Commission introduced the latest revision of the working document (i.e. Rev. 5) and presented its contents.

It received comments on this revision from a Member State and from the EU Reference Laboratories (EU-RLs).

In response to Member States' questions, the Commission replied that indeed prochloraz should not be listed as a priority and that this change would be added.

The European Food Safety Authority (EFSA) clarified that it cannot perform a risk assessment based on residue results on meat only: results on both muscle and fat are needed. For fat soluble substances however, results on fat only are sufficient. Furthermore, EFSA stated that there is a need to obtain more monitoring data on fat to further improve the confidence in the risk assessment, as currently values for fat are frequently calculated back from results on meat.

The Committee took note of the working document with few changes as agreed during the meeting. The Commission will circulate the final version (Rev. 5) to Member States after the meeting.

A.07 Extrapolation Guidance Document updating.

- Presentation of the document SANCO/7525/VI/95 Rev. 10, for note taking.

A Member State enquired on supporting data for the proposal to introduce a new extrapolation for apricots.

The Commission informed the Committee that it was not possible to take note at this meeting because additional important comments were received late in the process. It stated its intention to present the draft for note-taking by the Committee at the next meeting.

It invited Member States to send comments by 08 December 2014 and plans to circulate a new revision in January 2015.

A.08 RASFF SOPS and working instructions for note taking.

The Commission informed Member States that the Rapid Alert System for Food and Feed (RASFF) Standard Operating Procedures (SOPs) underwent a final discussion in the PAFF (Plants, Animals, Food and Feed) Committee's section on Biological Safety of the Food Chain in November 2014. In contrast, the draft Working Instructions (WI) 2.2 (Guidelines for the calculation of consumer intake and evaluation of the risk for pesticide residues), to which the RASFF SOPs refer, should be discussed and agreed by the Committee's section on Pesticide Residues.

The Commission introduced a revised version of the draft WI 2.2 and referred to the comments it had received from Member States. In the subsequent discussion, Member States clarified some of the comments sent in writing and provided additional feedback.

The Commission decided to postpone the note taking and prepare an amended draft, taking into account the comments and clarifications received. It plans to circulate that draft in advance of the next meeting of the Committee, with a view to taking note at that meeting.

A.09 Article 10 procedures of Regulation (EC) No 396/2005:

1. Commission discussion paper on import tolerances

The Commission introduced a revised version of the discussion paper.

Several Member States supported the discussion paper in general. One Member State enquired if it can carry out an evaluation even without available documentation on the authorisation in a third country. The Commission clarified that this is possible but that the Evaluation Report should not be forwarded to EFSA until documentation on the authorisation was received.

It invited Member States to send comments by 05 January 2014.

2. Update from European Food Safety Authority (EFSA) on documents presented at the 2014 Pesticides Steering Committee.

EFSA referred to the documents presented at the Pesticides Steering Committee in June 2014 as regards the processing of MRL applications under Article 10. It highlighted certain new features of the procedures and related amendments to the documents. EFSA received feedback on those documents from Member States and expects to finalise the analysis of and reply to this feedback by end of January 2015.

The Commission explained that the item will be discussed at the meeting of the Committee in February 2015, for both Article 10 and 12 procedures, to seek agreement of Member States on procedures and documents.

3. Updated MRL application form (additional point to original agenda)

The Commission introduced a revised version of the MRL application form and plans to ask Member States to take note at the meeting of the Committee in February 2015.

It invited Member States to send comments by 05 January 2014.

A.10 Article 12 procedures of Regulation (EC) No 396/2005:

1. Priorities under Article 12 (e.g. pyrethrins, dithiocarbamates, chlorpyriphos, chlorpyriphosmethyl and triclopyr)

Member States, EFSA and the Commission exchanged views on the prioritisation of substances for review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005.

As regards pyrethrins, the review should only start after confirmatory data under Regulation (EC) No 1107/2009 is received. Once available, the substance could be prioritised within the future process.

As regards cypermethrins, a Member State commented that the EFSA Panel on Plant Protection Products and their Residues (PPR panel) should be involved. EFSA clarified that in the process for renewal of approval of the active substances (AIR III) it is not required to consult the panel. The Commission suggested keeping the substances in the future process and to evaluate them in a group after completion of the AIR III process. At that stage the panel could be involved if appropriate.

As regards deltamethrin, it was suggested that it should stay in the intermediate process.

As regards dithiocarbamates, it is likely that the toxicological reference values will be amended and they should hence stay in the future process for MRL review after completion of AIR III.

As regards chlorpyrifos, chlorpyriphos-methyl and triclopyr, the existing MRLs should be reviewed under the interim process, in spite of the upcoming evaluation of the active substances under AIR III. The Commission considers the review of these substances a priority. As the Evaluation Reports are already available, EFSA can start work soon.

As regards buprofezin, the Commission took the view that more information is needed before taking a decision.

EFSA highlighted issues with prochloraz, imidachloprid, imazalil and dithianon, whose MRLs are to be reviewed under the interim process but no data has been submitted so far. EFSA can review the MRLs with priority as soon as the Evaluation Reports are received.

2. Changes of residue definitions for risk assessment under Article 12

The Commission identified three main issues from the comments by Member States received after the last meeting of the Committee: an easily accessible overview of up-to-date endpoints, including the residue definition for risk assessment; the formal procedure to agree on an amendment of the residue definition for risk assessment; and an appropriate lead-in time. Further consideration is required before addressing the above points

3. Involvement of third countries in Article 12 procedures at early stage

The Commission referred to Member States' comments, received after the last meeting of the Committee, that are available on CIRCABC.

It clarified that data on new MRLs should not be submitted within the review of existing MRLs under Article 12 of Regulation (EC) No 396/2005, neither from authorisations in the EU nor as import tolerances. Such data should be submitted with an application in accordance with Article 6. Member States raised concerns on how to ensure that the data is really not new, and on MRLs that are based on an authorisation in the EU but where additional data was generated by a third country.

The Commission plans to share the work programme in the minutes of the Pesticide Steering Committee in June 2014 with third countries, to provide them with indicative information about the planned order of substances. For the submission of data, third countries should be directed to the Rapporteur Member State.

4. Feedback from MSs on experiences with the follow-up table on data gaps under Article 12 on EFSA Extranet

The Commission asked Member States to monitor the Article 12 follow-up table on the EFSA Extranet, as from mid-2015 onwards, the two-year deadlines for data submission will expire for the first acts adopted on the basis of MRL reviews under Article 12. It is the Member States' responsibility to follow up on submitted information, however which Member State (rapporteur or other) may differ based on the context in which data was submitted (separately or within an MRL application under Article 6). Moreover, the degree of EFSA's involvement in the assessment may vary according to the type of data submitted. These issues require further consideration and clarification. Member States are invited to provide further feedback on the follow-up table.

5. Data protection – follow up from last meeting

The Commission referred to discussions on the same topic at the meeting of the Post Approvals Issues (PAI) Expert Group meeting, a summary of which is available on CIRCABC. It considered that those discussions provided sufficient general orientation on the subject. The Commission will reply in writing to a Member State and the notifier on a concrete case.

A.11 Specific substances:

1. Dichloprop-P

The MRLs recommended in the Article 12 Reasoned Opinion are based on the current approval of the active substance and do not yet take into account a restriction of the approval which will become applicable before any modifications of the MRLs based on the Article 12 Reasoned Opinion. There are currently no further data available to derive new MRL values. No consumer risk was identified. In this particular case, the Commission will base its proposal on the Reasoned Opinion as published.

A Member State considered that in the absence of a consumer risk, it would not ask the authorisation holder for new data and would not take measures, until the authorisation is considered for renewal.

2. Quizalofop/propaquizafop

The topic was already discussed at the last meeting of the Committee. EFSA proposed to only maintain MRLs for quizalofop and to delete propaquizafop from the Annexes to Regulation (EC) No 396/2005 and to make that change within a proposal based on the upcoming Reasoned Opinion under Article 10. Feedback from Member States was mixed. The Commission agreed that the Article 12 review would be too far in the future and asked EFSA to present both options (maintaining or not maintaining separate MRLs for propaquizafop) in the upcoming Reasoned Opinion under Article 10.

3. Copper compounds

As regards the Article 12 review, in addition to plant protection product (PPP) uses, natural background levels and uses as feed additive have to be taken into account. France as Rapporteur Member State has prepared an abstract of the Evaluation Report for copper compounds that focuses specifically on products of animal origin. Member States' experts on feed additives will be consulted to provide feedback on this topic, and possibly provide additional information to be incorporated into the assessment.

As regards an application to set MRLs for copper compounds in wild game, the Commission provided a discussion paper, aiming to harmonise the approach. It considers that the procedure under Article 6 of Regulation (EC) No 396/2005 is not always the most appropriate and preferred to have general discussion in the Committee first. Ideally, data from as many countries as possible should be included when setting MRLs on the basis of monitoring data. The Commission proposed to discuss and agree on a general approach for such cases first. The Commission

indicated that it does not intend to present a proposal on the basis of the Article 10 Reasoned Opinion but rather in the context of the Article 12 review.

The Commission asked the Rapporteur Member State to take into account the full range of monitoring data on copper when preparing the Article 12 Evaluation Report. The data currently available in the EFSA database were uploaded on CIRCABC in advance of the meeting. The Commission highlighted the need to have as complete data as possible and requested the Member States to provide any further data, if available.

The Commission proposed to have a further discussion on the draft Evaluation Report in the next meeting and to also focus on the approach to establish MRLs based on the occurrence data. The approach for spices or extraneous MRLs proposed by Joint FAO/WHO Meeting on Pesticide Residues (JMPR) may not be the most suitable in cases where occurrence of residues results from environmental contamination rather than from pesticides use. Other working practices (e.g. the ones used in the contaminants area) should also be considered.

A Member State highlighted that as copper is an essential element, all samples will always contain some copper residues. Moreover, uses as feed additives were authorised without making consequential amendments to the MRLs.

Another Member State welcomed that the problem has been taken up and acknowledged that MRL setting on the basis of Article 16 requires asking other Member States for data. While more time is needed for further discussion, the Member State considered that an MRL could provisionally be set on the basis of the Article 10 Reasoned Opinion to deal with recurring enforcement issues, before the issue is re-examined in the framework of the Article 12 review.

The Commission invited Member States to send comments by 05 January 2014.

4. Mercury compounds

The Commission reported that background levels of mercury compounds higher than default level set in Regulation (EC) No 396/2005 are detected in several food commodities. Maximum levels for fish and dietary supplements have been fixed under the contaminants legislation. A comprehensive EFSA Reasoned Opinion on mercury, based on monitoring data, was published in 2012. The Commission provided a discussion paper and identified certain groups of food products where enforcement issues occur. It proposed to consider different options to address the issue, whose legal feasibility is still under investigation, including use of the contaminants legislation and of Article 16.

Several Member States indicated a tendency towards a solution through the contaminants legislation but also the need to analyse the options further.

The Commission invited Member States to send comments by 05 January 2014.

A.12 News from the European Food Safety Authority (EFSA):

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

EFSA reported that under the current process, 13 Reasoned Opinions need to be finalised by the end of 2014. For the interim process, the first consultation will be launched in December 2014. In 2015, review of MRLs for 50 substances is planned, i.e. 4-5 Reasoned Opinions per months, if resources permit.

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

EFSA reported that applications for MRL setting for 36 substances are in progress, 7 in finalisation, 2 on clock-stop, and 17 notified but pending submission of the Evaluation Report

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

EFSA reported on its current work under Article 43 mandates, for the preparation of the 2015 Codex Committee on Pesticides Residues (CCPR), and on atrazine in maize. For atrazine, submission of further data is required and expected for February 2015, with a planned finalisation of Reasoned Opinion by May 2015.

A.13 Codex Committee on Pesticides Residues (CCPR) 2015 – state of play of preparations.

The Commission referred to the Joint FAO/WHO meetings on Pesticide Residues (JMPR) Summary Report that was published and asked Member States to be prepared for a request for comments on a draft common position by end of February or beginning of March 2015, with a short deadline for response. It reported that a coordinated reply to the electronic working group on priorities was sent. It is the task of Member States to send information on existing authorisations. Occurrence data on lindane will be sent by EFSA. The Commission informed Member States that it had sent the coordinated position on priorities to the chair of the electronic working group, but that information on national registrations would need to be sent by each Member State by 30 November 2014, to the chair of the electronic working group.

A.14 Update of membership list for CIRCA BC.

The Commission asked for Member States participation in a survey of all CIRCABC members to ensure that the membership for each Member State is up-to-date. Forms can be returned in paper or by e-mail to the Commission.

A.15 Inclusions in Annex IV to Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

2. Exchange of views of the Committee as regards maximum residue levels for Streptomyces K61, Beauveria bassiana strains ATCC 74040 and GHA, Candida oleophila strain O, Metarhizium anisopliae strain BIPESCO 5/F52, Paecilomyces

fumosoroseus strain Fe9901 and Pseudomonas sp. strain DSMZ 13134 in or on certain products (SANCO/12426/2014)

3. Follow up on discussion of possible inclusion of Bacillus thuringiensis species in Annex IV to Regulation (EC) No 396/2005: next steps.

The Commission provided an update on the state of play and referred to the overview table. Work on Bacillus thuringiensis (Bt) is ongoing. The Commission plans to draft a mandate to EFSA on the subject and consult Member States before sending it.

A Member State asked the Commission if it should hold off applications for authorisations of PPPs containing Bt. The Commission replied that the Member State should ensure that the strain at hand is approved under Regulation (EC) No 1107/2009.

Another Member State referred to its general concerns (see also agenda item B.05) that the assessment for microorganisms and basic substances, where no criteria are yet defined under Article 23 of Regulation (EC) No 1107/2009, was not suitable for using it to decide on a possible inclusion in Annex IV to Regulation (EC) No 396/2005. The Commission acknowledged the concerns on Bt, which it will take into account when deciding on the mandate. Furthermore, the relevant guidance document on inclusion in Annex IV to Regulation (EC) No 396/2005 will be revised to include guidance on basic substances.

A.16 Footnotes for substances in Regulation (EC) No 669/2008 (Article 15(5)).

The Commission summarised the proposal discussed previously in this section of the Committee and in the working group on Article 15(5) of Regulation (EC) No 669/2008. It asked Member States to coordinate with their representatives in advance of the working group meeting on 12 January 2015. If agreement was reached in the working group, the proposal would be forwarded to the PAFF Committee - section Controls and Import Conditions in February 2015.

A Member State raised a concern on the attribution to single or multi-residue methods, which was not always straightforward, as it may change with the matrix and with the multi-residue method used by the lab in question, and hence diverging interpretations may arise. It requested that the issue be discussed in the Committee's section on Pesticide Residues, as the discussion appeared too technical for the section on Controls and Import Conditions.

Another Member State raised concerns on fees for analysis and on holding of products until results are obtained under Commission Regulation (EC) No 669/2009, which may lead to problems if a footnote in that act mentions substances other than those for which food products were included in the list for increased monitoring.

A.17 Update on foods intended for infants and young children.

The Commission reported that it is currently discussing the draft mandate with EFSA.

A.18 Cumulative risk assessment - State of play.

The Commission reported that currently discussions are ongoing with the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) on a grant agreement for follow-up on the ACROPOLIS project.

Member States' views on questions posed in the working document were received and uploaded in the CIRCABC folder of the working group. The most likely date for a physical meeting of the working group is 23 January 2015.

A.19 Notifications under Article 18(4) of Regulation (EC) No 396/2005.

Austria notified a national MRL for fosetyl in horseradish under Article 18(4) of Regulation (EC) No 396/2005, which it justified with residue levels exceeding the limit of determination set in the annexes to the Regulation, due to use of foliar fertilisers containing phosphonates. A Member State indicated its preference for an MRL that is harmonised EU-wide. Austria explained that it had received the data on horseradish too late for inclusion in the preparation of Commission Regulation (EU) No 991/2014, and referred to and ongoing application under Article 6.

A.20 Designation of Member States for maximum residue levels (MRL) applications.

There were no updates as regards this agenda item.

A.21 Outcome of the survey on the MRL database – language versions (results collected by the European Union Reference Laboratory).

The Commission reported on the outcome of the survey and referred to detailed results that are available on CIRCABC.

Based on the results, it proposed to keep the list of food products (Annex I) as well as the substance names, residue definitions and substance footnotes in the EU Pesticides database available in all languages. It proposed however to provide footnotes linked to individual MRLs only in English, to simplify the maintenance of the database.

Member States agreed with the Commission proposal.

A.22 Summing up limits of quanitification (LOQs) for substances with complex residue definitions.

The Commission referred to the discussions in the Committee meeting on 22/23 September 2014 and in the monitoring working group on 10 October 2014. A discussion paper was made available on CIRCABC, comprising two options: (1) to set the limit of quantification (LOQ) for the complex residue definition at the sum of the LOQs of all metabolites analysed separately; (2) to set the LOQ for the complex

residue definition at the highest LOQ of the individual metabolites analysed. The advantages and disadvantages of both approaches regarding both use and no-use situations were discussed. The Commission responded to Member States' comments on the discussion paper.

A Member State enquired whether the proposed approach allows reporting of a measured value for a single metabolite only if it exceeds the proposed maximum target LOQ that needs to be achieved by the labs. The Commission clarified that residues of individual metabolites can always be reported if they exceed the LOQ value that was validated for that substance in the lab. This LOQ value should be below the proposed maximum target LOQ.

During the discussions on possible enforcement solutions in a no-use situation under approach 2, another Member State raised the concern that the MRL does not allow to deduce on a use or no-use situation in the production of the commodity at hand.

The Commission invited Member States to send comments by 05 January 2014.

A.23 Interpretation of Regulation (EC) No 178/2002 with regard to pesticides residues.

A representative of the unit dealing with the General Food Law (Regulation (EC) No 178/2002) was present for this agenda point. The Commission clarified a question submitted by a Member State at the last meeting on the interpretation of Regulation (EC) No 178/2002. The Commission confirmed its initial interpretation that food that does not comply with an MRL but does not constitute a health risk and therefore is not "injurious to health" in the sense of Article 14(4) of Regulation (EC) No 178/2002, is not automatically considered "unfit for human consumption" in the sense of Article 14(5) of Regulation (EC) No 178/2002. Unfitness for consumption is linked to the notion of "unacceptability" as further explained in the existing Implementation Guidelines for Regulation (EC) No 178/2002 . A non-compliance without health risk should therefore not automatically trigger the procedures laid down in Article 19 of Regulation (EC) No 178/2002 in the interest of applying this Article in a proportionate way to unsafe foods only. The Commission considers that the Implementing Guideline therefore does not need to be amended.

A Member State opined that products that do not comply with Regulation (EC) No 396/2005 cannot be placed on the market, irrespective of whether they are considered safe or not. It highlighted its dissatisfaction with the current text and raised concerns as regards the food operator's obligation to report.

Several other Member States agreed with the Commission's interpretation that the guidance does not need to be amended. Article 19 of the General Food Law does not provide for obligatory reporting by food business operators of all non-compliances but only of food which may be injurious to human health.

As regards Article 14(8) of Regulation (EC) No 178/2002, and referring to the example of chlorpyrifos, the Commission outlined the procedures involved if Member States would impose national restrictions for placing on the market or withdrawal

from the market of food complying with the current EU MRL for chlorpyriphos, on the basis of an identified health risk using the new lowered acute reference dose established by EFSA. In such cases the notification procedures according to Directive 98/34/EEC laying down a procedure for the provision of information in the field of technical standards and regulations apply.

The Commission asked Member States to provide information on whether measures are being taken at national level in respect to MRLs for chlorpyrifos, after the recommended lowering of the acute reference dose (ARfD). Responses differed but at least in some Member States there were indications that private laboratories were already applying the new ARfD and/or industries were applying stricter conditions than public authorities. The Commission underlined its intention to maintain harmonised application of MRLs at EU level and not to encourage Member States to take their own measures. To support this, the Commisssion considers the review of chlorpyriphos MRLs a high priority. The alternative options for national action at Member State level were clarified for information only.

A.24 Data requirements on fish feeding/fish metabolism studies.

The Commission received Member States comments on the European Crop Protection Association (ECPA) discussion paper.

It clarified that the Commission working document on the nature of pesticide residues in fish was discussed in 2013 and it was concluded that it is not yet finalised and ready to be noted as a guidance document.

The Commission emphasised that for the time being there are no agreed test guidelines and that hence the pertinent data requirements can be waived. This was also clarified in general at the meeting of the Committee's section on Plant Protection Products - Legislation on 09/10 October 2014, and laid down in document SANCO/10181/2013 Rev 2.1. Such test guidelines must be published in the form of an update of the respective Commission Communications.

Given the higher priority of other pending tasks, the Commission does not currently foresee further work on the working document. However, it asked Member States to submit any new information when available, to collect it for possible resumption of the discussion in the future.

Member States did not agree with certain positions of ECPA as regards the necessity of fish metabolism studies in light of information derived from studies in other animal species, and as regards the necessity of fish feeding studies. The Commission informed that also the ECPA proposal to take up fish in the multi-annual control plan for monitoring was rejected by the expert working group, however, analytical work on fish is ongoing by the EU reference laboratory on food of animal origin.

A Member State referred to findings of organochlor substances, substances with uses in veterinary medicine, and pendimethalin (pointing clearly to a use as PPP). The focus should be on fat-soluble substances.

It further considered that in the absence of a guidance document, as long as a working document exists, applicants should take it into account, even though its application is not binding until the Commission communication published in part C of the Official Journal is amended.

The Commission re-iterated that in the absence of test guidelines published in form of an update of the respective Commission Communications, data requirements can be waived.

A.25 German project on processing factors.

Germany provided an update on the project. It referred to Member States' comments received and available on CIRCABC. The project paper was revised in light of the comments received, and a project report is targeted for autumn 2015. Germany clarified that it does not have the intention to provide a draft for the establishment of Annex VI to Regulation (EC) No 396/2005. The Commission confirmed that despite the useful project carried out by Germany, the establishment of Annex VI to Regulation (EC) No 396/2005 remains low priority.

A.26 AOB

The Commission informed the Member States that it appreciates all the useful contributions made by the Member States in advance of the meeting and that those that were provided timely were already addressed as much as possible. The Commission highlighted, however, that preparation has become increasingly difficult since some contributions were still arriving at the last moment. For future meetings, the Commission will not be able to assess and/or upload contributions arriving less than 2 working days before the meeting.

The Commission informed Member States that the next meeting of the Committee is provisionally planned for 12 and 13 February 2015 but not yet confirmed. It also announced further planned dates for 2015, stressing the preliminary status and referred to the periodically updated calendar of Committee meetings available on the website of the Directorate-General for Health and Consumers (SANCO).

The Commission informed Member States that the new Commissioner for Health and Food Safety has taken office since November 2014. It further informed the Committee on the ongoing reorganisation of the Commission’s Directorate-General for Health and Consumers into the DG for Health and Food Safety. The acronym will change from SANCO to SANTE. The unit responsible for this section of the Committee will be reorganised and renamed Pesticides and Biocides. The changes will take effect on 1 January 2015.

The Commission informed Member States of the currently ongoing public consultation in the context of an impact assessment on the criteria to identify endocrine disruptors. Regulations (EC) No 1107/2009 and (EU) No 528/2012 require the Commission to set scientific criteria for the identification of endocrine disruptors by end 2013. Until these scientific criteria are defined, protective interim criteria defined in the legislation are applicable. The Commission decided to carry out a

comprehensive impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors following standard rules for impact assessments in the context of policy making. This impact assessment is considered essential because: (1) so far there is no consensus regarding how to address endocrine disruptors scientifically and from a regulatory perspective; (2) impact of the criteria on health, environment, agriculture, industry, and trade are not fully understood and might be significant; (3) the definition of the criteria will also impact on other legislation, e.g. Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Cosmetics and the Water Framework Directive.

The roadmap of the impact assessment was published in June 2014. It outlines different options for setting the criteria, including the baseline where no change to the legislation is proposed. The public consultation is open from 26 September 2014 until 16 January 2015. The Commission asked Member States to distribute the link to the public consultation among interested parties. The questionnaire is divided in in two parts: (a) on personal data and confidentiality; (b) questions on the impact of different options. Given the complexity and the sensitivity of the issue, the Commission is particularly interested to gather data for the impact assessment. In addition, open questions allow for submission of comments, data or information. It is possible to provide references and upload files. All contributions will be published unless confidential treatment of certain information is clearly claimed. Responses will in any case be subject to the EU rules on access to documents.

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 acetamiprid, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products (Art. 10).

The Commission introduced the draft and presented its contents.

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

- acetamiprid for the use on bananas;
- ametoctradin for the use on hops;
- amisulbrom for the use on grapes;
- bupirimate for the use on apricots, peaches, strawberries, grapes, cane fruit, cucurbits, herbs and globe artichokes;
- clofentezine for the use on cherries, cucurbits with edible peel, tomatoes and aubergines;
- ethephon for the use on table grapes;
- fluopicolide for the use on Chinese cabbage;
- propamocarb for the use on spring onions and Chinese cabbage;
- pyraclostrobin for the use on swedes and turnips;
- tau-fluvalinate for the use on pome fruit, apricots and peaches.

An import tolerance application to modify MRLs was submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005:

- imazapic for the use on soya bean (Brazil).

As regards clofentezine, a Member State pointed out that the toxicology data identified by EFSA as missing in the context of the MRL application was already submitted as confirmatory data under Regulation (EC) No 1107/2009. It is prepared to evaluate the data but asked for clarification on how the confirmatory data and its evaluation can be fed into the MRL process.

As regards ethephon in table grapes, a Member State reiterated its concerns expressed at the last meeting of the Committee. Another Member State shared those concerns but pointed out that it is the result of the currently agreed procedure for MRL setting. Several Member States stated their preferred solution for the case at hand. The Commission noted that this is another case underlining the need for a revision of the IESTI equation (International estimated short-term intake) and proposed to set the MRL at 1.0 mg/kg, which corresponds to the unrounded value calculated with the OECD MRL calculator.

As regards imazapic, a Member State pointed out that the LOD values set in Commission Regulation (EU) No 270/2012 are not reflected in the draft. The Commission amended the proposal accordingly.

Sweden asked that the following statement expressing its views be included in the Summary Report of the meeting:

"An MRL for ethephon in grapes of 1,0 mg/kg constitutes almost 150% of the acute reference dose for Swedish and German children. There are a number of RASFF-notifications on ethephon in grapes from third countries, many of which are close to the MRL of the proposal. These notifications indicate that we will most likely have situations in the future where the residue level found is in compliance with the MRL of 1,0 mg/kg, but the grapes are at the same time unsafe to consumers due to exceedance of the acute reference dose. We find it problematic that this is a commodity that may be consumed in large amounts by children."

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 azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac in or on certain products (CXL implementing measure).

On 18 July 2014 the Codex Alimentarius Commission (CAC) adopted CXLs for azoxystrobin, bentazone, chlorantraniliprole, clothianidin, cyantraniliprole, cyproconazole, dicamba, difenoconazole, diquat, dithianon, fenbuconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, glyphosate, imazapic, imazapyr, indoxacarb, isoxaflutole, malathion, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat, sulfoxaflor, tolfenpyrad, triazophos, triflumizole and trinexapac.

In accordance with the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), MRLs should be adapted to international standards, except where there is a scientific justification to maintain a higher level of protection than provided by an international standard.

Accordingly, the Union presented a reservation to the CCPR on the CXLs proposed for the following pesticide/product combinations: bentazone (all products); chlorantraniliprole (eggs; peas; coffee beans; hops); clothianidin (all products); cyantraniliprole (leafy vegetables, except lettuce head; fruiting vegetables other than cucurbits); difenoconazole (brassica vegetables; melons; fruiting vegetables, other than cucurbits; mammalian edible offal; mammalian meat; eggs; milks; potatoes); diquat (dry peas; potatoes; soya bean); dithianon (all products); fenbuconazole (all products); fenpyroximate (mammalian meat, mammalian edible offal; stone fruits); fludioxonil (chilli peppers; cucurbits); glyphosate (all products); imazapic (products of animal origin); malathion (all products); penthiopyrad (products of animal origin); propiconazole (plums); spirotetramat (bush berries); sulfoxaflor (all products); tolfenpyrad (all products); triazophos (all products); triflumizole (all products) and trinexapac (mammalian edible offal).

CXLs for azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac should therefore be included in Regulation (EC) No 396/2005 as MRLs 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. Those CXLs are safe for consumers in the Union.

CXLs for flutolanil and cyprodinil will be introduced in a future proposal because other MRL setting procedures are currently ongoing for these substances.

As regards imazapic, a Member State pointed out that the LOD values set in Commission Regulation (EU) No 270/2012 are not reflected in the draft. The Commission amended the proposal accordingly.

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 2,4,5-T, barban, binapacryl, bromophos-ethyl, camphechlor (toxaphene), chlorbufam, chloroxuron, chlozolinate, DNOC, di-allate, dinoseb, dinoterb, dioxathion, ethylene oxide, fentin acetate, fentin hydroxide, flucycloxuron, flucythrinate, formothion, mecarbam, methacrifos, monolinuron, phenothrin, propham, pyrazophos, quinalphos, resmethrin, tecnazene and vinclozolin.

The purpose of the draft proposal is to set or amend MRLs for certain substances that are not or no longer approved for use in PPPs in the European Union.

The draft proposal was already discussed in the previous meetings of the Committee. The Commission outlined some minor amendments in the latest revision.

As regards dinoterb, a Member State raised concerns on background levels in excess of the proposed new MRLs. As regards resmethrin, a Member State raised concerns on problems with the method validation.

The Commission took note of concerns and will share them with the EU-RLs.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for guazatine in or on certain products (Art. 12).

The Commission introduced the draft and presented its contents.

It referred to a position paper of a stakeholder organisation and a request for an administrative review under Article 13 of Regulation (EC) No 396/2005 of the EFSA Reasoned Opinion on the modification of the existing MRL for guazatine in citrus fruits, published in August 2014.

In view of the ongoing administrative review, the Commission decided to postpone the formal opinion of the Committee on the draft.

Spain asked that the following statement expressing its views be included in the Summary Report of the meeting:

"Spain expressed its concern about postponing the proposal for the MRL reduction of the active substance guazatine considering that according to EFSA´s view the existing MRLs are not safe for the consumers. The available toxicological data are clearly insufficient to maintain authorizations for use in the EU and, therefore, they cannot

either ensure the safety for the consumer of treated fruits from third countries. For this reason the setting of MRLs for guazatine to LOQ should no longer be delayed."

Vote postponed

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 Trichoderma polysporum strain IMI 206039, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strains IMI 206040 and T11, Trichoderma harzianum strains T-22 and ITEM 908, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma asperellum (strain T34), Trichoderma atroviride strain I-1237, geraniol, thymol, ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate), folic acid and sucrose in or on certain products.

The Commission introduced the draft and presented its contents.

The purpose of the draft is to include certain substances in Annex IV to Regulation (EC) No 396/2005.

A Member State did not agree with the Commission's view that it can be excluded that these substances present a risk for consumers, based on the conclusions on the peer review of the active substances. The Commission explained that the considerations of risk managers in the Committee's section on PPP - Legislation were reflected in an amended recital.

Another Member State stressed the need for a prudent approach to MRL setting for the substances.

A third Member State pointed out that a finalisation of the risk assessment for human health is needed for the respective Trichoderma strains, as in its view the condition for inclusion into Annex IV, i.e. that it has no toxicity and does not produce/contain any enterotoxin, could not be confirmed for Trichoderma. The Member State opined that a proposal for inclusion in the list of approved active substances under Regulation (EC) No 1107/2009 is not sufficient to support a proposal for Annex IV inclusion.

Several Member States indicated that they see the need for further consultation with experts in their respective authorities and/or the representatives in the Committee's section on PPP - Legislation.

Hence, the Commission decided to postpone the formal opinion of the Committee on the draft.

Vote postponed