EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 11 JUNE 2015 - 12 JUNE 2015

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/e7754235-504d-4dce-8b12-72361c4937c4k*

A.01 Working document on the summing up of limits of quantifications (LOQs) in case of complex residue definitions. Doc. SANCO/12574/2014 Rev. 3 (For note taking).

The Commission introduced the revision 3 of the working document.

Following discussions at the Committee meeting in February 2015, where Member States expressed strong concerns with the approach of summing up limits of quantification (LOQs), two alternative options were proposed that both avoid the summing up of LOQs of individual components for reporting the LOQ value of the analysis result in case of complex residue definitions. Twenty Member States were in favour of option 1, which was the basis for the revision 3 of the working document.

The Commission proposed to apply the working document only from 01 January 2016 onwards.

EFSA raised strong concerns on the proposed approach. It pointed to the need for adding Standard Sample Description (SSD) codes for all possible metabolites to the SSD database, for an inventory of residue definitions and for a distinction between simple and complex residue definitions, which would be difficult given current resources at EFSA. The Commission considered that a strict definition of simple and complex residue definitions would not be needed and that it would suffice to foresee all necessary codes in the SSD format to give the Member States some guidance. A Member State suggested conducting a survey to list all components that would need to be encoded to allow Member States reporting on all components that are measured separately, which is currently a legal obligation. EFSA proposed that Member States submit a sum LOQ in the field of “ResLOQ”, as a value of sensitivity analysis. However, such a proposal was rejected by the Member States in an earlier version of the document.

A Member State indicated that it is in favour of first assessing the full impact of the proposal before taking note. Another Member State highlighted that changes to the SSD format could create additional work for Member States.

A Member State pointed out that this discussion had been initiated because currently there is no harmonised approach. It proposed to discuss first whether the proposed solution is suitable in principle, and then to verify how much time is necessary to implement it.

The Commission stressed that it had already spent a lot of time and resources on this discussion hoping to find a satisfactory solution. The Commission made it clear that if no agreement was reached, current problems that are due to the lack of a harmonised approach would persist. The Commission considers abandoning this discussion since a compromise solution between the approach that EFSA favours and the one the majority of Member States favours could not be found. Resources in the Commission do not allow putting further effort into this discussion.

Given that several Member States were in favour of continuing the discussion, the Commission agreed to explore with EFSA, including EFSA IT-experts, whether solutions could be found for implementing the approach described in Rev. 3 of the working document. In case these discussions result quickly in a realistic implementation plan, the discussions in the Committee could be re-opened, otherwise they will be abandoned in autumn.

Note taking postponed.

A.02 Update of the Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005. Doc. SANCO/11188/2013 (For note taking).

Note taking postponed to the next meeting to allow the Commission time to analyse comments received and modify the proposal as appropriate.

A.03 Commission working document on drafting proposals to amend pesticides Maximum Residue Levels (MRLs) following Article 12 of Regulation (EC) No 396/2005. Doc. SANCO/11485/2012 Rev. 6 (For note taking).

The Commission introduced the latest revision of the working document and outlined the modifications compared to the previous version.

The Committee took note of Rev. 7.

A.04 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 of Regulation (EC) No 396/2005). Doc. SANCO/11739/2013.

The Commission will circulate a new revision once it is available.

A.05 Exchange of views of the Committee as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (Article 12 of Regulation (EC) No 396/2005). Doc. SANCO/11481/2014 Rev. 1.

The Commission will circulate a new revision once it is available.

A.06 Exchange of views of the Committee as regards maximum residue levels for boscalid, captan, clothianidin, thiametoxam, folpet and tolclofos-methyl in or on certain products (Article 12 of Regulation (EC) No 396/2005). Doc. SANTE/10530/2015 Rev. 0.

The Commission introduced the draft and presented its contents. It referred for further details to explanations available in writing.

The Commission invited Member States to send comments by 10 July 2015.

A.07 Exchange of views of the Committee as regards maximum residue levels for diethofencarb, mesotrione, metosulam, pirimiphos-methyl, propiconazole and spiroxamine in or on certain products (Article 12 of Regulation (EC) No 396/2005). Doc. SANTE/10274/2015 Rev. 0.

The Commission introduced the draft and presented its contents.

A Member State suggested a different wording of the recital on pirimiphos-methyl, as chronic consumer concerns are due to the sum of the different uses. It also pointed out a mistake in the document number of the Excel file. It will submit further comments in writing.

A good agricultural practice (GAP) authorised in Austria was reported for sea weed for which no data were available in the Article 12 review. However, it concerns a GAP for China weed, a plant for energy production. This GAP is not relevant for the maximum residue level (MRL) setting for seaweed and therefore Austria agreed that this MRL was reduced to the LOQ.

The Commission invited Member States to send comments by 10 July 2015.

A.08 Exchange of views of the Committee as regards maximum residue levels for AMTT, diquat, dodine, glufosinate and tritosulfuron in or on certain products (Article 12 of Regulation (EC) No 396/2005). Doc. SANTE/10376/2015 Rev. 0.

The Commission outlined the state of play of the proposal.

Specific comments were sent by the applicant on glufosinate. In particular, as regards soya bean, EFSA recently revised the reasoned opinion to take the relevant Codex MRL (CXL) into account. As regards the uses on grapes, bananas and top fruits, the applications were not submitted within the timeline required by the Article 12 procedure. As regards the use on potatoes, the Commission asked Hungary to submit data on the variability factor by 26 June 2015.

Moreover, the Committee was informed that at the Codex Committee on Pesticide Residues (CCPR), a comparison was made between the toxicological reference values derived by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and those set at European Union (EU) level. Sweden, as rapporteur Member State (RMS), confirmed that the same dataset was used by JMPR and EFSA, although they came to different conclusions.

A.09 Exchange of views of the Committee as regards maximum residue levels for oxadixyl and spinetoram in or on certain products. Doc. SANTE/10543/2015 Rev. 0.

Member States were invited to share their monitoring data on occurrences of oxadixyl in specific crops by 30 March 2015. Meanwhile, EFSA published a technical report on the monitoring results on residues of oxadixyl in food products. It was concluded that no residues occur in leeks and root and tuber vegetables. In contrast, in lettuce and salad plants, parsley and celeries residues are still found at levels below 0.05 mg/kg.

A Member State asked that a deadline be set for the next review of those temporary MRLs. The Commission agreed to specify a date in the relevant footnotes consistent with other similar cases.

Spinetoram was added to the proposal in order to better transpose the CXL, which was adopted in 2009 for mammalian meat. As spinetoram is fat soluble, a higher MRL should have been set for mammalian fat.

The proposal was notified in accordance with the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), with a deadline for commenting set on 27 July 2015.

A.10 Safeguard measures relating to pesticides residues:

1. General information
   Discussion postponed

2. Information on voted safeguard measure Nigeria/dried beans

The Commission informed the Member States' residues experts present in this section of the Committee about the recent vote in the section Animal Health and Animal Welfare (should have been the section Controls and Import Conditions) on a safeguard measure suspending imports of dried beans from Nigeria.

Post-meeting note: The measure was meanwhile published in the Official Journal as Commission Implementing Regulation (EU) 2015/943.

3. Information on planned safeguard measures

The Commission reported on internal discussions on planned safeguard measures due to findings of pesticide residues. The Committee will be kept informed of any follow up to these discussions.

A.11 Procedures for routine MRL setting under Regulation (EC) No 396/2005 procedures:

1. Update from the European Food Safety Authority (EFSA) and **possible agreement of MSs** on the procedural documents presented at the 2014 Pesticides Steering Committee

The Member States agreed to the procedures with the amendments discussed in the meeting. EFSA will make available a version taking into account the agreed amendments by 31 July 2015. The procedures will be applicable as from 01 October 2015.

EFSA referred to the comments received from Member States, which were taken into account for the latest version available on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). The main changes are in the evaluation report in section 4 on MRL setting for animal products, and an improved excel calculator for the animal dietary burden.

EFSA highlighted that the approach under the old and new data requirements is divergent. Since there are differences in the number of animal species and in animal diets, this would lead to different MRL proposals based on which guidelines are used.

The Commission explained that currently it is a transitional phase between old and new data requirements. The main difference lies in the trigger values for animal commodities. The guidance should be consistent with the legal requirements. If necessary, different templates, e.g. for the evaluation report, need to be used.

A Member State mentioned that the data underlying Organisation for Economic Co-operation and Development (OECD) guideline 73 are from Europe and better than the data used for the EU guidelines that were drafted 20 or more years ago. The Commission agreed but stated that OECD guideline 73 should also be included in the Commission Communications accompanying the data requirements, as long as it does not contradict current legislation. It was clarified that feeding studies were inherently covered by the Commission Communications, through reference to the OECD

overview document. Later on, OECD moved feeding studies out of the overview document and into guideline 73.

All Member States present agreed that the trigger values are to be used according to the prevailing data requirements, noting that the transitional period ends on 31 December 2015. The Commission will look into a possible update/repeal of the old EU guidelines.

On the proportionality principle, it was clarified that the EU agreed to its use at the CCPR 2013. In September 2013, the Standing Committee agreed that it can be used also in the EU, under the same conditions as defined at Codex level (Appendix VIII of the Report of CCPR 2013), including the scaling range and the possibility to request (or not) part of the data generated at GAP. More experience should be collected with the application of the approach. It was noted that at OECD level, discussions are ongoing on a slightly narrower scaling range due to the statistics applied. In the EFSA procedures, reference to the conclusions of CCPR 2013 will be made.

A Member State commented that the format of tables in the documents is not compatible with other tables for the same data. It is likely that data would be submitted in the format in which it was evaluated for the first time. Several Member States supported this comment. The Commission will discuss details for the possible alignments of formats with EFSA.

2. Update from SANTE on procedures:

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

A revised version of the document is in preparation for discussion at the Committee meeting on 21/22 September 2015.

- Procedure as regards submission of MRL application form

Member States were reminded to submit MRL applications and Evaluation Reports to both EFSA and the Commission by using the relevant mailboxes:

EFSA: APDESK.applications@efsa.europa.eu

COM: SANTE-MRLs-applications@ec.europa.eu

- MRL setting for NAS evaluated under Reg. (EU) No. 1107/2009

The Commission outlined the procedures. MRLs for new active substances will only be presented for vote in the section Pesticide Residues of the Committee after the active substance has been approved in the section plant protection products (PPP) Legislation. MRLs will not normally be presented for vote in the section PPP Legislation.

MRLs cannot be voted before the approval of the active substance due to the possible introduction of restrictions, and confirmation of the relevant toxicological endpoints as well as the residue definitions by the Member States only at the time of approval. Furthermore, the Commission considers it important that the relevant experts on pesticides residues remain responsible for voting MRL proposals.

The Commission will make sure that the vote on MRLs can be taken at the next possible Committee meeting of the section Pesticide Residues after approval by

already starting preparatory work on the MRL proposal before approval of the active substance.

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

1. Priorities under Art. 12

The Commission referred to the updated excel sheet with priorities. For certain substances, in order to remain under the interim procedure, the Member State evaluation needs to be submitted in the first half of 2015. The RMSs for several substances informed on the planned submissions (imidacloprid, prochloraz, imazalil).

2. Other issues

2.1 Follow up on Art. 12 confirmatory data

The Commission referred to the discussions at the Committee meeting in February 2015 and the summary document on CIRCABC. It highlighted new elements for data submitted within the procedure for renewal of the approval of an active substance, and the follow-up for cases where data is not submitted within the deadline.

EFSA will check internally whether the overview table on Article 12 data gaps on the EFSA Document Management System can be amended also by Member States, or whether Member States should report the submission of relevant data to EFSA who will then update the table.

Post-meeting note: for the time being, the latter approach is preferred by EFSA.

In some cases the EU Reference Laboratories (EURLs) identified that analytical standards were not commercially available and an 'A' footnote was added to the residue definition, stating that the EURLs identified the reference standard for a specific substance as commercially not available and that when re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard one year after publication. The Commission will systematically follow up on these footnotes. In case the applicant has made an application for a new MRL under Article 6 of Regulation (EC) No 396/2005 after the date given in the footnote, it will receive a letter, reminding of the fact that the standard has not been made available yet. The applicant will be given 3 months for making the standard commercially available, during which the respective legislative proposal will be put on hold. If the standard is not made available by that time, the application for the new MRL will be rejected.

At the end of each calendar year, the Commission will provide an overview on the substances with an expired 'A' footnote and make this information available to authorisation holders informing that an additional 3 months period is given for making the standard commercially available. For substances for which the standard is not made available by that time, the MRLs will be reduced to the LOQ.

2.2 Changes of residue definition for risk assessment under Art. 12

The Commission reported that internal discussions are ongoing and will present details once those discussions have progressed sufficiently.

2.3 Participation of MS in Art. 12 review

EFSA referred to its document on CIRCABC and urged Member States to check documents and submit information in time to avoid problems in later stages of process.

A Member State highlighted certain practical problems, e.g. for commodities such as honey where no GAP exists, and the notification of less critical GAPs to EFSA in case the critical GAP in the table is not supported by any Member State. The Commission asked Member States to send information regarding such examples so that it can discuss the issue in more detail with EFSA.

A.13 Specific substances:

1. Copper compounds

The Commission has not yet received feedback from the animal feed experts, which is important before providing comments on the Evaluation Report prepared by France.

2. Mercury

The Commission referred to its analysis of occurrence data from the EFSA data warehouse. This document was already discussed in the Expert group on environmental and industrial contaminants under the Committee's section on Toxicological Safety of the Food Chain. In that group, the proposed approach was generally accepted, though discussions are still at a preliminary stage.

A Member State re-iterated its doubts already raised in previous meetings whether an implementing regulation could supersede Article 18(1)(b) of Regulation (EC) No 396/2005.

The Commission analysed the comments in detail and referred to the outcome of its discussions with the Commission's Legal Service and at previous meetings of the Committee.

3. Chlorpyriphos

EFSA reviewed the consumer risk assessment for chlorpyrifos following the lowering of the toxicological reference values for this substance.
The Commission introduced a draft proposal and presented its contents.

The Commission emphasised that EFSA's mandate for this review has a narrower scope than a full Article 12 review of all existing MRLs, since it focused on the

assessment of MRLs of concern. It referred to the discussion on priorities and emphasised that the review of chlorpyriphos under Art. 12 remains in the priority list (interim procedure).

The Commission invited Member States to send comments by 10 July 2015.

4. Bromuconazole

An application was submitted to modify the MRLs for wheat and rye. EFSA concluded that the submitted information does not require the change of the existing MRLs. As no amendments are being proposed for the substance, it is not appropriate to include the application in a routine MRL proposal. The evaluating Member State should inform the applicant of the decision taken by the Standing Committee.

5. Cyprodinil

An application was submitted to modify the MRL for celery. EFSA concluded that the submitted trials do not support the change of the existing MRL. As no amendments are being proposed for the substance, it is not appropriate to include the application in a routine MRL proposal. The evaluating Member State should inform the applicant of the decision taken by the Standing Committee.

A.14 News from the European Food Safety Authority (EFSA):

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

EFSA referred to the updated table on CIRCABC. Five substances remain under the old procedure. The interim procedure has been initiated for about 20 substances.

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

EFSA referred to the discussion on new templates and procedures under agenda item A.11.01.

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

EFSA reported that currently there are no mandates pending. Work on atrazine and chlorpyrifos is completed.

4. Presentation of the 2012 and 2013 Annual monitoring Reports

The 2012 European Union Report on pesticide residues in food was published in December 2014. The 2013 Report was finalised in February 2015 and published in March 2015, in compliance with legal deadlines. EFSA presented the results of both reports. Both the coordinated EU programme and the national programmes show that overall the situation of pesticide residues in food did not give reason for concern. EFSA used the 2012 monitoring data to test their suitability for future cumulative risk assessments. The results indicated that the presence of multiple pesticide residues on

individual samples is not likely to pose significant additional health concerns that would not be detected with the risk assessment performed for individual pesticides.

Furthermore EFSA made recommendations for improving the efficiency and quality of the controls and for revising certain legal limits or residue definitions.

EFSA asked Member States to pay attention to using the lowest hierarchical level of food classification possible (specific commodities rather than groups). In particular where no group MRL exists, there are otherwise problems to express results in terms of MRL exceedances.

The Commission thanked EFSA for its work.

A Member State appreciated the expression of residues in terms of acute reference dose (ARfD) exceedances and the cumulative exposure assessment, which puts risks related to samples showing multiple pesticides residues in perspective.

Two Member States expressed concerns on the very conservative approach used for dealing with non-detects in the chronic exposure assessment. EFSA stressed that it is a screening exercise and this is clearly described in report. Only when the conservative approach identifies potential problems, refinements are done.

A Member state explained the approach taken by its national laboratories on reporting results between the limit of detection and the LOQ as 'detected, not quantified'. For future cumulative risk assessment it would be good to also include this possibility in the SSD format. EFSA indicated that this option is not yet added to the SSD Guidance for the 2014 monitoring results.

Furthermore the Member State expected that open questions on dithiocarbamates can be addressed in the framework of the Article 12 review. EFSA indicated that it welcomes any data from Member States or the EURLs on background residues of carbon disulphide in various commodities.

A.15 Monitoring exercise 2017-2019 and Monitoring Working document:

1. Small monitoring WG – proposed date for meeting

For the monitoring exercise 2017-2019, an expert group meeting is planned on Friday, 23 October 2015. Member States are asked to nominate experts for participation to the Commission by 15 July 2015.

2. Monitoring Working Document: new substances to be added

During the expert group meeting for the monitoring exercise 2017-2019, also the working document on pesticides to be considered for inclusion in the national control programmes will be discussed. As described in Rev. 5 of this document, Member States, EFSA, the EURLs and the Commission can propose substances to be included in the working document by filling out the form in Annex VI. Proposals for inclusion of new substances should be sent to the Commission by 30 June 2015.

A.16 State of play - approach for acute exposure assessment (IESTI equation (International estimated short-term intake)).

Further to the impact assessment of the discussed changes to the International estimated short-term intake (IESTI) equation carried out by a Member State and discussed at the last meeting of the Committee, another Member State presented its impact assessment, which is available on CIRCABC. It focused on the impact on the level of protection by using the MRL instead of the Highest Residue in the IESTI equation with the simultaneous replacement of the variability factors of 5 and 7 with the variability factor of 3, using the Article 12 review of the existing MRLs for lambda-cyhalothrin as an example. By applying the revised IESTI equation, the level of protection increased or remained unchanged for commodities with a variability factor of 1, while for commodities with variability factors of 5 or 7, examples were identified for both increased and decreased levels of protection. In contrast to earlier datasets, where less than 1% of the market survey samples corresponded to a variability factor of 7, the percentage of samples with variability factor 7 in the 2015 monitoring program of the presenting Member State corresponds to 68%.

EFSA provided information on the stakeholder meeting and scientific workshop that will take place on 07 and 08/09 September, respectively, i.e. before the 2015 JMPR meeting in Geneva. Risk managers (Commission and Member States) should provide input during the stakeholder meeting. The Commission will coordinate with Member States once further details are available.

The Commission invited Member States to send comments by 10 July 2015.

A.17 Codex Committee for Pesticides Residues (CCPR):

- Substances where reservations could be lifted for Codex Alimentarius Commission (CAC) meeting

The Commission presented cases of proposed Codex MRLs for which it had asked EFSA and the RMS to provide their input whether the EU reservation at the 2015 CCPR meeting should be maintained at the 2015 Codex Alimentarius Commission meeting. The Member States agreed to the proposed way forward. This information will be provided as input to the Council Working Party for the preparation of the EU position at the 2015 Codex Alimentarius Commission meeting.

- Opinion of MSs on Global Zoning Project

Germany summarised the ongoing discussions on the Global Zoning Project, which is also on the agenda of the OECD Residue Chemistry Expert group meeting on 07/08 July 2015. It raised the question how far and under which conditions the EU and its Member States are ready to accept residue trials from other regions for EU MRL setting, pointing out that uncertainties may increase or decrease.

EFSA highlighted the impact on discussions on the revision of the IESTI equation, since higher MRLs (that are likely with the larger variability in a global dataset) may lead to a larger number of consumer concerns identified.
The Commission invited Member States to send comments by 22 June 2015 to Germany and the Commission.

- Tentative dates of Council Working Party meetings 2016

The following dates are currently under discussion with the Council Secretariat: 15 March and 11 April 2016.

- Submission of harmonised monitoring data from EFSA on behalf of MSs to JMPR

The 2015 CCPR meeting recommended using the Global Environment Monitoring System (GEMS)/Food database to collect monitoring data for extraneous MRL setting at Codex level. The Commission reported that discussions with EFSA are ongoing to see if EFSA can submit such data on behalf of the Member States. The Commission asked Member States if they can agree to the proposed approach and to bring any concerns to its attention in writing by 30 June 2015. If no comments are received, the Commission assumes agreement to this approach.

- Approach for prioritisation of substances for inclusion in priority list

The Commission referred to the proposal from Australia at the 2015 CCPR to review, in the electronic Working Group on Priorities, the ratio of new vs. old compound evaluations with a possible stronger focus on periodic reviews. Currently, too few periodic reviews are scheduled to ensure that compounds are regularly re-assessed, i.e. every 15 years. The Commission presented a short analysis of the numbers of periodic reviews carried out in recent years vs. what is needed to achieve reasonable re-assessment periods, and discussed possible solutions in terms of JMPR's evaluation capacity and adjustment of the above mentioned ratio. It pointed out that the discussions will likely begin soon after the summer and possibly before the next Committee meeting.

Several Member States agreed with the analysis and supported the proposed way forward. It was suggested to consider a ratio that is suitable to gather support from other Codex members, and a tiered approach to selecting compounds for periodic review based on toxicity or review history.

In order to appropriately react to ad-hoc requests during CCPR meetings for decisions to prioritise within the list of compounds proposed by the EU, the Commission considered that it would be helpful to have criteria agreed in advance, and asked the Member States for feedback. Several Member States made suggestions in the subsequent discussion. The Commission invited Member States to send comments and plans to have a proposal ready for the next Committee meeting.

- Work organisation for preparation of the work in eWG for cucurbits and cereals

The Commission suggested that preparatory work could be done before the electronic Working Group is established, in particular on data collection. It asked Member States to check which data is available to contribute to the questions to be addressed by the electronic Working Group.

A.18 Screening exercise on t-MRLs in Regulation (EC) No. 396/2005 that will be expiring in 2015/2016 .

The Commission outlined the contents of the temporary MRL table. The Committee was informed of the upcoming measures. The table is available on CIRCABC.

On diphenylamine in apples and pears, the Commission had requested EFSA to provide the most recent monitoring results. Currently, only data for 2012 and 2013 are available, i.e. when the old MRLs were still applicable. To decide whether MRLs can be lowered further, it is necessary to obtain data from samples taken when the current MRL (0.1 mg/kg) was applicable. The Commission plans to propose an extension of the current temporary MRL and re-assess the situation at a later stage on the basis of those additional data.

The Commission invited Member States to send comments by 10 July 2015.

A.19 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

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

A Member State considered that it would be good to strengthen the coordination between the sections PPP Legislation and Pesticide Residues of the Committee. The assumption that microorganisms will be included in Annex IV is not necessarily correct for all cases. To ensure consistency the Commission will regularly inform experts at the section Pesticide Residues about new active substances currently under discussion in the section PPP Legislation.

2. Exchange of views of the Committee as regards inclusion into Annex IV to Regulation (EC) No 396/2005 of 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 COS-OGA, Cerevisane, Calcium hydroxide, *Pythium oligandrum* M, *Verticillium albo-atrum* strain WCS850 and *Bacillus amyloliquefaciens* ssp. plantarum D747 in or on certain products. (SANTE/10753/2015)

The Commission introduced the draft, presented its contents, and invited Member States to send comments by 10 July 2015.

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

EFSA accepted the mandate on this subject and allocated it to the Panel on Biological Hazards. This mandate will result in a scientific opinion adopted by that panel and endorsed by the Panel on Plant Protection Products and their Residues.

A.20 Update on foods intended for infants and young children.

The Commission reported that delegated acts on foods intended for infants and young children were prepared and other services of the Commission consulted. Currently the World Trade Organisation (WTO) consultation phase is ongoing, followed by scrutiny by Council and Parliament. The delegated acts are likely to be adopted by early November 2015. They do not contain changes to existing provisions. A comprehensive mandate will be sent to EFSA soon. A possible introduction of the reference to Regulation (EC) No 396/2005 into the legislation on food intended for infants and young children will be addressed in a comprehensive review later on, taking into account the EFSA conclusions.

A.21 Cumulative risk assessment:

1. State of play

An update was given on the current activities on cumulative risk assessment (CRA) by the Commission and EFSA. A communication action from the Commission and EFSA is planned for September 2015.

2. Commission working document on risk management aspects related to the assessment of cumulative exposure (SANTE-2015-10216 rev.5). (For agreement on chapters 3.1.2, 3.4, 3.5.1.3, 3.5.1.4, 3.5.1.5, 3.5.2.2, 3.5.2.3, 3.5.3.2, 3.7, 3.8).

The Commission presented a summary on the above mentioned chapters of the current version of the working document. Member States agreed on their content. These risk managers' points of view can now be taken into account by EFSA and the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) for the further developments of the method. The Commission clarified that 'agreement' of Member States should be understood as 'agreement to mandate EFSA and RIVM to implement the proposed approach'. If future developments showed that the agreed points need to be amended, they can be changed in future versions of the working document.

A Member State commented that it should be specified that chapter 3.1.2.3 refers to chronic risk.

In response to a Member State’s question, the Commission clarified that the percentile values mentioned in the slides are only examples, as a decision has been taken neither on a general approach, nor on specific values.

A Member State asked to clearly define 'random sampling' and 'targeted sampling'. Clarifications could be added to the EFSA SSD Guidance.

A Member State enquired about the minimum amount of consumption data that need to be available in order to be able to draw a reliable conclusion. The Commission will enquire with RIVM and EFSA.

A Member State commented on the reference that is made in the document to Regulation (EC) No 1107/2009. If the scope of the working document covers also that Regulation, CRA should not be restricted to consumers but also include operators, workers and bystanders. The Commission considered it necessary that the reference remain in the document, even if CRA is not yet applied to all areas of risk assessment.

A Member State informed the Committee on a project for testing the ACROPOLIS tool. The Commission welcomed this project and is looking forward to its results.

A.22 Notifications under Article 18(4) to Regulation (EC) No 396/2005.

A Member State informed the Committee about an emergency use for cyantraniliprole on cherries. No export to other Member States is planned for the time being. In the near future, a new EU-MRL will become applicable after which export to other Member States is possible.

Post meeting note: The MRL of 6 mg/kg for cherries came into force on 24 June 2015 by Regulation (EU) No 845/2015.

A.23 Designation of Member States for maximum residue levels (MRL) applications.

Point not discussed.

A.24 Information on ongoing work on endocrine disruptors and substances falling under the other cut-off criteria.

The Commission presented the latest developments. The public consultation closed on 16 January 2015. Responses received were published on a dedicated website. Round-tables with stakeholders were held, as well as a public conference on 01 June 2015. Minutes of these events are also available on the dedicated website. The impact assessment will be based on two sets of studies.

A Member State enquired about the impact of the application of cut-off criteria on MRLs. The Commission replied that it cannot provide details at this point in time as internal discussions are still ongoing, but that it is well aware of issues raised by Third Countries. It referred to presentations given at the above mentioned events and available on the dedicated website.

A Member State reported on discussion in its national parliament where it was claimed that the delay in setting of criteria on endocrine disruptors is connected to the Transatlantic Trade and Investment Partnership (TTIP) negotiations. The Commission clarified that there is no link between TTIP and the impact assessment on endocrine disruptors.

A.25 Planned evaluations of Regulation (EC) No. 396/2005 and Reg. (EC) No. 1107/2009 – State of play

The Commission is obliged to draw up a roadmap for the planned evaluation and to consult stakeholders on it. This will have some impact on the timelines. The work on the roadmap is currently ongoing. The Commission will include points raised by Member States and stakeholders in the recent past on areas for improvement of both Regulations into the process.

A.26 State of play on chlorate.

On 03 June 2015, the EFSA Panel on Contaminants in the Food Chain adopted a scientific opinion on the risks for public health related to the presence of chlorate in food. The publication date is envisaged for 24 June 2015. EFSA presented the content of the opinion, which the Commission will now analyse. Possible risk management measures may be discussed during the Committee meeting in September 2015, taking into account both toxicological aspects and microbiological safety.

A Member State requested further clarifications on the establishment of the ARfD. More specifically, it enquired on the margin between the No Observed Effect Level and the Lowest Observed Effect Level. EFSA provided explanations on why it was decided not to use an additional safety factor for establishing the ARfD.

A.27 Update on the state of play of MRL setting for biocides.

The Commission presented the state of play of MRL setting for biocides. According to Article 19 of Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) an MRL application by a biocide authorisation holder is only necessary where appropriate. The BPR does not prescribe any specific procedure for setting MRLs but contains references to other legal acts. While no biocidal MRL has been established so far, procedures become necessary, as active substances are becoming approved under the BPR, and MRLs should be set, where appropriate, between approval and authorisation of biocidal products. It is the task of the competent authority to decide if there is a need to establish a biocide MRL.

Several Member States expressed their appreciation that work is now moving forward in this area. They commented on the application of a default MRL and the ALARA (as low as reasonably achievable) principle, on a trigger value based on a certain percentage of the acceptable daily intake, consumer risk due to bad practice, considerations of safety and practicability, the lack of experience with national MRLs and a long lead-in phase for harmonisation (as was the case for MRLs based on uses in plant protection), the importance of biocidal products for safety reasons (e.g. hygiene), the use of monitoring data for MRL setting, and the necessity for transitional measures in order not to endanger the necessary uses of biocidal products. Several Member States stressed that they do not consider residues consequent to the use of biocidal products as unintentional.

The Commission replied to the points raised and invited Member States to send comments by 10 July 2015. It stressed the importance of coordinating with Member States' experts in competent authorities for biocides. The next meeting of the expert group of biocide competent authorities will take place in September 2015.

A.28 AOB

1. Phosphonates-recent developments

The Commission summarised the history and recent developments on the dossier. It referred to the letters from stakeholders available on CIRCABC. For few crops, trials were initiated to collect data with a view to submit an import tolerance request. The majority of requests received concern an extension of the temporary MRLs set in Commission Regulation (EU) No 991/2014. The Commission outlined its concerns as regards such an extension.

The Commission invited Member States to send comments, even if preliminary, by 17 June 2015, to inform ongoing internal discussions.

2. Update on the state of play of the Official Control Regulation

The Commission reported that the proposal for the new Regulation on official controls is currently under discussion at Council level. As certain articles from Regulation (EC) No 396/2005 will be repealed by that Regulation, it needs to be ensured that the implementing powers necessary to replace the repealed provisions are included in the Regulation on official controls. Furthermore, sufficient time should be foreseen before the repeal becomes applicable, in order to allow the development of the corresponding implementing provisions.

3. ECPA survey on timelines of MRL setting

The Commission referred to the documents from the European Crop Protection Association (ECPA), which are available on CIRCABC. A discussion was not possible since they were received only shortly before the meeting.

4. Status of Norway under Regulation (EC) No 396/2005

The Commission will consult internally and respond by e-mail.

5. CZ on extrapolations from rape seed to sunflower for tebuconazole

The Czech Republic clarified bilaterally with EFSA that extrapolation is possible only at early growth stages but not at late growth stages.

6. FR on progress of work on extrapolation document

The Commission informed the Member States that work on the extrapolation document will resume after the return of the responsible colleague.

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 bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products (Article 10)

The Commission introduced the draft and presented its contents.

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

- bifenazate for the use on blueberries, cranberries, gooseberries and azaroles;
- boscalid for the use on beans and peas (with pods);
- cyazofamid for the use on aubergines;
- cyromazine for the use on "lettuces and salad plants", "spinaches and similar leaves" and "herbs and edible flowers";
- dazomet for the use on fruits of code number 0100000, carrots, radishes, fruiting vegetables (except sweet corn), leafy brassica, "lettuces and salad plants" and "spinaches and similar leaves";
- fluazifop-P for the use on celeriac, Jerusalem artichokes, peas (without pods), globe artichokes, dry beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusion (dried roots) and spices (roots or rhizome);
- mepanipyrim for the use on strawberries, tomatoes, aubergines and cucumbers;
- metrafenone for the use on hops;
- picloram for the use on borage;
- propamocarb for the use on garlic, onions and shallots;
- pyridaben for the use on cucurbits (edible peel);
- pyriofenone for the use on table grapes;
- tebuconazole for the use on cucumbers and courgettes;
- tebufenpyrad for the use on citrus fruits, plums, strawberries, tomatoes, peppers, aubergines, gherkins, melons and watermelons.

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

- thiram for the use on avocados.

EFSA concluded that for the use of cyromazine on scarole and the use of tebufenpyrad on peppers, a risk to the consumer cannot be excluded. For dithiocarbamates, a new MRL for avocados needs to be set at the level of 7 mg/kg to adequately address the use of thiram on that crop.

As regards the use of cyromazine on lamb's lettuce and fresh herbs, the use of dazomet on fruits and the use of tebufenpyrad on plums, gherkins, melons and watermelons, the submitted data support lower MRLs than the existing ones. However, since it needs to be verified whether these lower MRLs adequately reflect

the critical GAP in the EU and given that the existing MRLs are safe to the consumer, it is appropriate not to lower the existing MRLs in the framework of the current regulation, but to use the information derived from the submitted data when reviewing all existing MRLs for those substances.

For sulfoxaflor, EFSA published a conclusion on the peer review of the pesticide risk assessment of the active substance. In that framework, it recommended to set MRLs covering both the representative uses according to GAPs in the Union and import tolerance requests from several Third Countries. The Commission consulted the EURLs on the appropriate limits of determination.

As regards the use of propamocarb on leek, several Member States raised concerns regarding a possible exceedance of the ARfD where the crop is consumed raw. The Commission removed reference to that specific application from the proposal to allow time for further discussions.

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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products (Article 12) (SANCO/12560/2014 Rev. 1)

The Commission introduced the draft, presented its contents, and responded to written comments from Member States. It referred to the comment to the SPS notification received from Australia on the MRL for haloxyfop-P on rapeseed. That comment was taken into account in rev. 2.

Vote taken: Favourable opinion.

B.03 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 capric acid, Paraffin oil/(CAS 64742-46-7), Paraffin oil/(CAS 72623-86-0), Paraffin oil/(CAS 8042-47-5), Paraffin oil/(CAS 97862-82-3), lime sulphur and urea in or on certain products

The Commission introduced the draft and presented its contents.

Vote taken: Favourable opinion.