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 21 SEPTEMBER 2015 - 22 SEPTEMBER 2015

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/67338e2a-dabb-4e2c-bb7c-773b59aff79d*

A.01 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).

The document was noted by the Committee with a minor editorial change.

A.02 Updating on the state of play of the revision of the "Extrapolation Guidance Document" (doc. SANCO/7525/VI/95 Rev. 10).

The Commission recalled the state of the play of this dossier. Three rounds of consultations were completed with Member States and European Food Safety Authority (EFSA), and a fourth group of comments will be analysed and integrated in the Commission proposal.

The Commission aims to circulate a new proposal before the end of October 2015, in order to be able to take note of the revised extrapolation guidance at the Committee meeting on 30 November/01 December 2015.

A.03 Working document on the summing up of limits of quantifications (LOQs) in case of complex residue definitions: state of play (doc. SANCO/12574/2014).

During the Committee meeting of 11/12 June 2015, Rev. 3 of the working document on the summing up of limits of quantification (LOQs) in case of complex residue definitions was discussed. Although the approach proposed in this document was the preferred option for the majority of the Member States, EFSA raised strong concerns against the approach because of the timelines and problems for practical implementation. After further bilateral discussions with EFSA, an implementation plan for the approach was agreed with EFSA and was presented by the Commission at the meeting. A revised version of the working document will be presented at the Committee meeting on 30 November/01 December 2015 that will be in line with the

approach described in Rev. 3 and the timelines agreed with EFSA. The document will apply from the 2017 data collection onwards. These results will be reported to EFSA in 2018. Further technical discussions will take place in the EFSA Networking group meeting on pesticides monitoring in spring 2016. Member States will be requested to provide information on the components of complex residue definitions that they analyse separately.

A.04 Exchange of views of the Committee as regards maximum residue levels for propiconazole and spiroxamine in or on certain products (Article 12) (doc. SANTE/11621/2015 Rev. 0).

After the Committee meeting of 11/12 June 2015, the Commission received Member States comments on document SANTE/10274/2015 Rev. 0, requiring lower maximum residue levels (MRLs) for propiconazole and spiroxamine on certain commodities. As these lower MRLs would need to be notified to World Trade Organisation (WTO), these substances were taken out of SANTE/10274/2015 and are now taken up in SANTE/11621/2015. The proposal containing these two substances will be presented for vote during the Committee meeting on 30 November/01 December 2015.

The Commission introduced the draft, presented its contents, and responded to written comments from Member States. It referred to the comment on the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) notification received from the United States (US) on the MRL for propiconazole on peanuts.

The MRL proposal for spiroxamine on barley and oats was derived from an outdoor good agricultural practice (GAP) which, according to EFSA, would possibly no longer be supported following the re-registration procedure. Therefore the MRL proposals for oats and barley were reduced on the basis of a fall back GAP.

A Member State commented on the commercial availability of standards for a metabolite. The Commission explained that a footnote has been added to the residue definition, indicating that the standard should be made available within one year after publication of the Regulation.

The Commission invited Member States to send additional comments by 24 September 2015.

A.05 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) (doc. SANCO/11739/2013).

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 acrinathrin, bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph, metalaxyl, triflusulfuron in or on certain products (Article 12) (doc. SANCO/11418/2015 Rev. 0).

The Commission introduced the draft and presented its contents.

Following the publication in 2011 and 2014 of two separate EFSA Reasoned Opinions on Metalaxyl-M and Metalaxyl and a request by the Commission, EFSA published in April 2015 a "Combined review of the existing maximum residue levels (MRLs) for the active substances metalaxyl and metalaxyl-M", which will be the basis of the Commission proposal.

A.07 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) (doc. SANTE/10376/2015 Rev. 0).

The Commission prepared an excel table reporting the amendments to the existing MRLs for glufosinate. Following the discussions held at the Committee meeting on 11/12 June 2015 on the MRL for potatoes, Hungary submitted data on the appropriate variability factor to be applied. The Committee agreed to maintain the MRL at 0.3 mg/kg. Moreover, the Commission informed the participants of its intention to lower the MRLs for those commodities for which the GAP evaluated at European Union (EU) level is not supported by data.

The Commission intends to present the first draft proposal at the Committee meeting on 30 November/01 December 2015.

A.08 Exchange of views of the Committee as regards maximum residue levels for atrazine and potassium thiocyanate in or on certain products (doc. SANTE/11654/2015).

The Commission presented the proposal to lower the existing MRLs for atrazine and potassium thyocianate. The table reporting the proposed amendments was notified to WTO on 16 September 2015 (G/SPS/N/EU/144).

Comments on potassium thiocyanate had been received by the EU Reference Laboratories (EU RLs) highlighting the natural occurrence of the substance.

The Commission invited Member States to send comments by 15 October 2015.

A.09 News from the European Food Safety Authority:

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

EFSA reported that it considered the implementation of the interim process a success, resulting in more robust output. The further transition from the interim to the new process should be well prepared and may be the topic of a Pesticides Steering Network meeting in 2016. EFSA highlighted that following the decision to use the Organisation for Economic Cooperation and Development (OECD) livestock dietary burden calculator for MRL applications (Article 10), it should also be applied for

MRL reviews (Article 12). The Pesticide Residue Overview File (PROFile) will be amended accordingly.

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

EFSA informed the Committee about the overall progress as well as applications requiring particular attention.

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

EFSA reported on the ongoing update of the MRL review for lambda-cyhalothrin due to the recent changes in toxicological reference values.

A.10 Procedures for routine Maximum Residue Level (MRL) setting under Regulation (EC) No 396/2005 procedures:

1. EFSA procedures as discussed at June Pesticides Residues Committee meeting

Some further comments were received by Member States after the Committee meeting on 11/12 June 2015. The Commission clarified that the Committee agreed to these procedures in June and that therefore the discussion on the contents was closed. The procedures will become applicable as from 01 October 2015 and be placed on the EFSA Document Management System (DMS; accessible to Member States only). EFSA and the Commission will reflect further on possibilities to make documents publically accessible.

Member States highlighted problems due to differences in format between zonal registration reports and MRL evaluation reports. Member States have to use two different formats for the same data. EFSA agreed that harmonisation would be a better option but clarified that data in registration reports are not sufficient for use in MRL assessment. The Commission suggested an exchange of information between the Post Approvals Issues (PAI) Expert Group and EFSA on this point.

A Member State asked EFSA to check whether certain forage commodities are missing from the relevant table in the documents.

2. Update from Directorate General for Health and Food Safety (DG SANTE) on procedures:

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

The Commission intends to present a first draft of the guidance document at the Committee meeting on 30 November/01 December 2015.

A.11 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Article 12

The Commission referred to the updated Excel table with the Article 12 priorities that was uploaded on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC).

A discussion on the need to prioritise the Article 12 review of metam/dazomet took place prior to the meeting between the Rapporteur Member State Belgium, the Commission, EFSA and Spain who currently evaluates an Article 6 application for metam. A potentially shared metabolite N,N'-dimethylthiourea (DMTU) may need to be included in the residue definition for risk assessment, however it appears that there is currently no risk for consumers.

EFSA proposed to carry out an Article 12 review for both active substances under the interim procedure, also taking into account the existing Evaluation Reports from Belgium on metam and dazomet and the Evaluation Report from Spain on the ongoing Article 6 application. For dazomet, data on DMTU are currently not yet available and a confirmatory data requirement (footnote) might need to be set. Belgium agreed to this proposal.

The Commission also followed up on the outstanding Evaluation reports for the substances imidacloprid (Rapporteur Member State (RMS): Germany) and prochloraz (RMS: Ireland) in view of their assessment under the interim procedure. Germany confirmed that the Evaluation Report on imidacloprid had been submitted to EFSA very recently. On Prochloraz, EFSA confirmed that the RMS Ireland should finalise its evaluation report on the basis of the available data, and that additional data should be submitted during the completeness check. A Member State had requested quizalofop-esters to be prioritised. EFSA confirmed that the group of substances were already planned to be evaluated very soon under the Article 12 interim procedure. Another Member State inquired on the state of play of the Article 10 assessment of quizalofop/propaquizafop that was discussed by the Committee some time ago. EFSA confirmed that the assessment would be finalised within the coming weeks.

2. Other issues

As regards the procedures for follow-up on data submitted subsequent to an Article 12 review, the Commission referred to the outcome of the discussions of the Committee meeting on 12/13 February 2015. Although it may not be necessary to have an EFSA publication in each case, the procedure has to ensure that EFSA obtains all evaluation reports, so that the information can be taken into account in the evaluation of future MRL applications. EFSA and the Commission will discuss the details bilaterally and report back to the Committee.

A.12 Specific substances:

1. Chlorate

The Commission gave an update on the state of play regarding chlorate residues in regular food and in food for infants and young children. It referred to position papers and monitoring data that were received from stakeholder associations.

The Commission presented its proposed approach for deriving MRL proposals, however the work on this is still in an initial stage. At the request of a Member State, the Commission explained that the current EFSA opinion will be used as the basis for drafting the proposal and that for the time being no further assessments will be requested from EFSA.

The Commission stressed that a balance needs to be found between ensuring good hygiene of the food products and minimising possible health risks due to the presence of chlorate in food. A Member State considered that the use of chlorine disinfectants as processing aids should be reconsidered as it leads to residues relevant for human health. Several Member States agreed that an approach would be needed that would not increase microbiological risks, however a high level of protection for all age groups against the chemical risks is also required. All the different uses of chlorine disinfectants should be considered. Furthermore a Member State commented that the monitoring data described in the EFSA opinion reflect the current situation. Possible future decreases in chlorate residues might require adaptations to the MRLs.

A Member State expressed concerns regarding the chlorate residues present in drinking water. The Commission's Directorate General for Health and Food Safety (DG SANTE) ensured that the Directorate-General for the Environment (DG ENV) is aware of the EFSA opinion and is currently contributing to the ongoing work at international level for the review of the World Health Organisation (WHO) guideline levels for drinking water. The Commission invited Member States to send further comments by 15 October 2015.

2. Fosetyl/phosphonates

The Commission summarised the recent developments on the dossier. It referred to additional letters from stakeholders available on CIRCABC and responses received from several Member States following the discussion in the Committee meeting on 11/12 June 2015. The Commission outlined the arguments for and against an extension of certain temporary MRLs set in Commission Regulation (EU) No 991/2014.

Several Member States took the floor to present or further explain their position.

The Commission indicated that it would now consider the additional feedback from Member States and decide on the further course of action.

3. Copper compounds

The Commission presented the state of play. A document received from the feed experts was uploaded on CIRCABC and shared with RMS France in advance of the meeting.

France explained that there are few differences of opinion between feed experts and plant protection product (PPP) experts, but the approach is overall similar, and data can be considered comparable. Differences between the two committees rather stem from the general approach to risk assessment. Beef liver is the most critical

commodity. No exceedance of the acceptable daily intake (ADI) is identified when the PPP methodology is used but according to the feed methodology, the MRL proposed for beef liver may lead to an exceedance of the ADI.

However, France considers that an agreement can be reached and MRLs can be harmonised. It will finalise the Evaluation Report and will send it to EFSA, in order to issue the Reasoned Opinion on Copper compounds as planned under the interim process.

4. Mercury

A Commission representative responsible for legislation on contaminants explained the progress of the ongoing work of mercury in the Expert group on Environmental and Industrial contaminants and presented an updated working document with proposals for maximum levels of mercury for certain commodities. Member States were requested to provide comments on that document in view of further discussions with Member States in the next Expert group on Environmental and Industrial contaminants. Progress will be regularly presented to the Standing Committee on Plants, Animal , Food and Feed, section Pesticides Residues. On the specific question to which extent mercury would pass to the brewed beverage tea, the Commission will make further information available to the Member States.

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

The Commission informed about the new active substances for which the approval, under Regulation (EC) No 1107/2009, is currently under discussion in the Committee's section PPP Legislation.

New active substances currently under discussion are: flumetralin, flupyradifurone, rescalure, tricyclazole, benzovindiflupyr, Trichoderma atroviride SC1 and mandestrobin.

A.13 Monitoring exercise 2017-2019 and monitoring working document – small monitoring WG (Working Group).

The Commission recalled that the expert meeting on pesticide residues monitoring will take place on 23 October 2015 in Brussels.

A.14 State of play - approach for acute exposure assessment (IESTI equation (International estimated short-term intake)).

The Commission reported from a Stakeholder Meeting organised by EFSA, the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM), the Food and Agriculture Organisation of the United Nations (FAO) and WHO on 07 September 2015. It thanked the organisers for the successful event whose aim was to collect the views of stakeholders and inform the discussions during the subsequent Scientific Workshop on 08/09 September 2015.

EFSA reported from the Scientific Workshop. Participants reached an agreement on a proposal for a revised set of International estimated short-term intake (IESTI) equations. That proposal replaced the Highest Residue (HR) with the MRL, used a variability factor of 3, and no longer included the unit weight. The Scientific Workshop did not reach a conclusion on the Level of Protection. While this was considered to be a question to be addressed by risk managers, recommendations for risk managers were discussed. A draft report from the Scientific Workshop was submitted to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) for consideration in their September 2015 meeting. It is expected that JMPR will comment in the chapter on general considerations in the JMPR Report. A final report from the Scientific Workshop will be published by the end of the year. Further discussions are expected at the 2016 Codex Committee on Pesticide Residues (CCPR) meeting.

Member States commented that a pragmatic approach is needed to assess the impact of any changes to the IESTI equations on the Level of Protection. Such impact assessments should focus on crops with high consumption to identify critical cases with regard to acute reference dose (ARfD) exceedances. A Member State called for improved consumption data to be used in a relative comparison of the Level of Protection.

A.15 Codex Committee for Pesticides Residues (CCPR):

The Netherlands informed the Committee about a possible change of date for the first Council Working Party for the CCPR preparation to 14 March 2016. The second Council Working Party is likely to stay on 11 April 2016, as originally planned.

- Global Zoning Project – update from discussions at OECD

Germany reported back from the OECD meeting that took place in July 2015. The OECD guidance document on Crop Field Trials will be updated, however, no decision was yet taken. The OECD aims for a decision on a final document in 2016, meaning that a broad consultation would need to be launched in 2015.

The Crop Field Trial guidance document is being split into a section with recommendations and one with background to avoid a constant need to update the background text.

The Commission informed the Committee about exchanges with the US at technical level on the Global Zoning Project. The US Environmental Protection Agency (EPA) shared raw data with EFSA. EFSA intends to share its preliminary view on the data with the Committee in its meeting on 30 November/01 December 2015.

The Commission asked the views of Member States whether further work should be done on the Global Zoning Project, in view of limited resources and competing files, and asked for comments by 30 September 2015.

A Member State referred to the presentation of the Global Zoning Project at CCPR 2015 and stressed that before investing resources, the chances of the project to go ahead should be evaluated.

Another Member State weighed the potential benefits of the Global Zoning Project (larger datasets, lower statistical uncertainty) against the drawbacks (potential interest of industry to reduce field trials carried out in the own region). It considered a global Good Agricultural Practice not feasible given the need to combat different pests in different climatic conditions and other geographical factors.

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

The Commission did not receive any objections from the Member States on the proposal discussed at the last meeting that EFSA would forward the Member States' monitoring data to JMPR as a package. At CCPR 2015, the JMPR requested delegations to submit pesticides monitoring data in support of extraneous MRLs (EMRLs). Once EFSA has discussed specific technical questions with JMPR (e.g. details on the format of submission), the Commission will seek agreement from the Member States on these details, most likely in the Committee meeting on 30 November/01 December 2015.

- Approach for prioritisation of substances for inclusion in priority list

The Commission asked the Member States for their agreement to draft a coordinated EU position for the electronic Working Group on priorities for which the deadline for comments is 30 November 2015. This approach would ensure coordination between Commission and Member States already at an early stage and was already followed in 2014.

The Commission proposed that two main issues should be subject of the EU coordinated comments for the electronic Working Group (eWG):

- The question how to ensure a balance between new and old compound evaluations and to achieve compliance with the 15 year rule for old compound evaluations. The Commission referred to the comments made by the EU delegation at CCPR 2015 where it welcomed the proposal from the chair of the electronic Working Group to review the ratio of new and old compounds, with a possible stronger focus on periodic reviews and requested a thorough discussion on this point in CCPR 2016.

- The criteria used for prioritisation of specific substances within the schedule of periodic reviews.

As regards the balance of new compound evaluations and periodic reviews, the Commission referred to the discussion in the Committee meeting on 11/12 June 2015 and the subsequent written comments from Member States. Several Member States expressed their views on the balance within the existing evaluation capacity of JMPR

and on the need to expand that capacity further, to allow additional periodic reviews to be carried out. Identification of compounds no longer supported by a manufacturer and eventual withdrawal of the corresponding Codex Maximum Residue Limits (CXLs) might further contribute to reducing the number of substances for which a periodic review is overdue. The Commission invited Member States to send comments by 09 October 2015. It would then draft an EU position for submission to the electronic Working Group on the balance of new compound evaluations and periodic reviews, and measures to expand the capacity of JMPR.

On the criteria for prioritisation, the Commission had amended the list presented to the Member States at the Committee meeting on 11/12 June 2015 to include comments received from Member States. The criteria are intended to be used internally to decide about the ranking of specific substances that are candidates for inclusion into the priority list. Following a question from a Member State, the Commission clarified that it intends to send all compounds on which concerns exist to the electronic Working Group, however with a clear indication of our priorities for the likely case that the number of nominated compounds exceeds the capacity for reviewing them. The Commission invited the Member States to use the criteria and propose substances to be included in the priority list (with indication of relevance) by 09 October 2015.

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

The Commission recalled the discussions during CCPR 2015.

The Committee discussed the following issues: the proposal to merge wheat and barley; the position of the heterogenous group of pseudocereals (e.g. buckwheat, amaranthus, quinoa) and the possible addition of pseudocereals to one of the cereal crops; and the division of cucurbits into cucurbits with edible and inedible peel.

The Commission invited Member States to send comments by 15 October 2015.

A.16 Screening exercise on temporary Maximum Residue Levels (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. In particular, fluopyram is the next substance for which the deadline for submission of data is approaching (i.e. 19 October 2015). The table is available on CIRCABC.

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

1. State of play of Annex IV inclusions

Point not discussed.

2. Exchange of views as regards inclusion into Annex IV of Cydia pomonella granulovirus (CpGV), hydrolysed proteins, Straight Chain Lepidoptera pheromones, potassium iodide and sodium hydrogen carbonate (SANTE/11406/2015)

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. This table includes already a few rationales for the proposal SANTE/11406/2015 which will be sent out for commenting electronically by mid-October 2015.

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

The working group of the Panel on Biological Hazards met for the first time in July 2015 and will meet a second time on 29/30 September 2015 in Brussels. The Commission agreed to extend the deadline for this mandate to 30 June 2016.

A.18 Update on foods intended for infants and young children.

The Commission informed the Committee about the state of play and future work planning as regards the adoption of three delegated acts on 1) infant formula and follow-on formula, 2) processed ceral-based foods and baby foods, and 3) food for special medical purposes. For pesticides, the current approach is kept (provisions as they are will be transferred to delegated acts - they will also apply to food for special medical purposes intended for infants and young children), pending a thorough scientific evaluation of the approach by EFSA for which a mandate will be sent in the coming weeks.

The delegated acts are subject to a 2-months scrutiny period by the European Parliament and Council and, if no objection or request for extension of the period are received, publication and entry into force of the measures would take place around end 2015. The application date of the delegated acts is however deferred to 2018-2020.

A Member State requested that the residue definitions between Regulation (EC) No 396/2005 and the delegated acts on foods intended for infants and young children should be harmonised. Another Member State requested the clarification of the definition of "pesticide residues". The Commission clarified that it is aware of the issues and that they will be addressed only in a second step, once the evaluation of EFSA has been finalised.

A.19 Cumulative risk assessment.

1. Cumulative Assessment Groups for the effects on the nervous and thyroid systems: hazard characterisation

EFSA gave an update on the state of play of the EFSA and RIVM activities regarding cumulative risk assessment (CRA).

EFSA presented a document describing a proposed approach for the selection of index compounds and the calculation of relative potency factors. Member States are invited to comment on this document by 15 October 2015.

2. Second physical meeting CRA working group

The Commission announced that a second physical working group meeting on CRA will take place on 22 January 2016 in Brussels. Member States that are interested in participating are requested to send the names of the experts to the Commission by 16 November 2015.

3. Data sharing within electronic working group

The Commission gave an update on the sharing of data on the thyroid and neurotoxicity group with the members of the working group on CRA.

A.20 Notifications under Article 18(4) to Regulation (EC) No 396/2005.

Point not discussed.

A.21 Designation of Member States for maximum residue levels (MRL) applications.

Point not discussed.

A.22 Information on ongoing work on endocrine disruptors and substances falling under the other cut-off criteria.

The Commission informed about the state of play as regards the impact assessment on criteria to identify endocrine disruptors. A public conference took place on 01 June 2015 during which potential impacts on trade, agriculture, environment and health were discussed. The public consultation report was published on 24 July 2015. Further targeted events, meant to inform on specific parts of the impact assessment, may be organised at a later stage. The Commission drew attention to the dedicated website informing about the impact assessment .

Several Member States took the floor to highlight the considerable uncertainty for applicants and RMS, as it is difficult to predict whether a particular view would be accepted by other Member States and EFSA, to enquire on the methodology used for the screening of active substances in PPPs and biocidal products, and to stress the need for a systematic approach on endocrine disruptors, including for their residues.

A.23 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

The Commission is in the process of drawing up a roadmap together with an intervention logic for the planned evaluation, which will be made available to the public. It clarified that all relevant stakeholders will be consulted during the process. The evaluation will be carried out by an external contractor, who will gather data and

draft a preliminary evaluation report. A questionnaire will also be prepared. Specifically, the evaluation questions need to address at least the following aspects: relevance, effectiveness, efficiency, coherence and EU added value of the policy area.

DG SANTE is currently setting up an Inter-service Steering Group (ISG) to discuss the roadmap and reach an agreement of the relevant services of the Commission. In view of the steps laid down in the procedure, it is estimated that the contractor will carry out the evaluation as of spring/summer 2016. The final report to the European Parliament and the Council is expected to be ready by spring/summer 2017.

A.24 Update on the state of play of RASFF (Rapid Alert System for Food and Feed) Standard Operating Procedures and working instructions.

The Commission informed the Committee that the draft standard operating procedures (SOPs) are still in internal discussions in DG SANTE.

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

A Commission representative responsible for legislation on biocides gave a presentation on the state of play and outlined the proposed approach to deal with MRL setting for biocides, using the available legal framework of the contaminants legislation (Council Regulation (EEC) No 315/93 and Commission Regulation (EC) No 1881/2006) for biocides not covered by Regulation (EC) No 396/2005. This would however mean that the system of default levels would not apply.

While some Member States stated that they did not agree with the proposed approach, others supported the Commission's proposal as a pragmatic solution. The main issues raised by Member States were the absence of the system of default levels, the burden for providing data on biocides residues put on competent authorities instead of the applicants for biocidal products, as well as the proposed system of using the toxicological reference values in exposure assessment.

The Commission clarified that currently no legal basis exists to establish a system of default levels for "biocides only" substances. For this an amendment of Regulation (EC) No 396/2005 or the creation of another legal basis would be necessary, which takes time. The proposed approach could be a solution in the short and medium term until a long-term solution is established.

Several Member State stressed that even if considered an interim solution, data requirements would need to be developed. In the working document presented to the Committee, it should be highlighted more clearly that in the long term the Commission is looking for a solution that would better take into account these concerns.

The Commission pointed out that the uses of biocidal products are defined in a more generic way than plant protection products and that the same product could potentially be used for disinfection of very different types of equipment. It did not consider data generation for the different types of uses of biocidal products a workable solution. A

Member State did not agree and stated that the uses for biocidal products could well be clearly defined.

The Commission invited the Member States to provide further comments in light of the discussions by 10 October 2015, so that they could be considered in the next meeting of the Working Group on biocides.

A.26 AOB

- Update on Official Controls Regulation

The Commission provided an update on the state of play of the discussions at Council level regarding the provisions in the new official controls Regulation that would impact on Regulation (EC) No 396/2005. Currently it is unclear when the Presidency will receive the mandate to start negotiations between the Council and the European Parliament. However, the aim is to reach an agreement between the Council and the European Parliament by the end of 2015.

- Clarification status Norway under 396/2005

In reply to a question received at the Committee meeting on 11/12 June 2015, the Commission clarified that European Economic Area (EEA) countries (Norway, Iceland, Liechtenstein) can act as RMS and zonal RMS under Regulation (EC) No 1107/2009, as that Regulation has been integrated in the EEA agreement by the EEA Joint Committee Decision 2013/2014 of 30 September 2014 which became applicable on 1 June 2015. Regulation (EC) No 396/2005 is part of the EEA agreement already since 2007. The Commission clarified that in light of the applicability of the provisions of Regulations (EC) No 1107/2009 and 396/2005, its understanding is that Norway, Iceland and Liechtenstein could also act as Evaluating Member States for MRL applications under Regulation (EC) No 396/2005. However, it is worth noting that there are a number of important exceptions for substances that were still evaluated under Council Directive 91/414/EEC and have not yet undergone the renewal procedure under Regulation (EC) No 1107/2009.

- Classification of caraway (Carum carvii)

Finland requested to move caraway from the group “Spices from fruits” to the group “Spices from seeds” in Annex I to Regulation (EC) No 396/2005. The Commission took note of the request and will consider it for a future revision of Annex I. France proposed to look into possibilities to deal with the problem through introducing a new extrapolation rather than amending Annex I.

- Guidance document on the extraction efficiency of residue analytical methods (**point requested and presented by Germany**)

Germany referred to the document and accompanying e-mail available on CIRCABC. A working group of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) has developed a proposal for the assessment of the

extraction coefficient of analytical methods, and is interested in feedback from other Member States, EFSA and the Commission who are invited to provide comments by 20 November 2015 directly to BfR.

B.01 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 ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products (Article 10).

The Commission introduced the draft and presented its contents.

The chair clarified in the meeting that the substance propamocarb was erroneously omitted in the title of agenda point B.01.

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

- ametoctradin for the use on sage and basil;
- flonicamid for the use on peppers, Brussels sprouts, peas (without pods), cotton seeds, barley, oat and rye;
- fluazinam for the use on tomatoes;
- fluoxastrobin for the use on shallots;
- propamocarb for the use on leeks;
- prothioconazole for the use on shallots;
- thiacloprid for the use on Jerusalem artichokes.

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

- chlorothalonil for the use on cranberries.

As regards diphenylamine, monitoring data show that an unavoidable cross-contamination affecting untreated apples and pears still occurs. In order to provide the necessary time for business operators to completely remove the residues of diphenylamine in storage facilities, it is appropriate to maintain those temporary MRLs, which will be reviewed. The review will take into account the information available within two years from the publication of the Regulation.

As regards halauxifen-methyl, EFSA recommended to set MRLs in the conclusion on the peer review of the active substance.

As regards propamocarb, the Commission asked Member States to submit information on the consumption of raw leeks to better understand the real exposure. In view of the data received, it was agreed to apply the cooking factor of 0.88 derived for leafy crops to leeks. The proposed MRL of 20 mg/kg will not result in an exceedance of the acute reference dose and was considered sufficiently protective for consumers.

As regards trifloxystrobin, the CXL for olives for oil production was included in the proposal.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for oxadixyl and spinetoram in or on certain products.

The Commission introduced the draft and presented its contents.

Following a comment made by a Member State, the Committee agreed not to defer the application date of the proposal by six months, as monitoring data for oxadixyl show that the proposed MRLs are in line with the levels in products currently on the market. Transitional measures are nonetheless supported.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (Article 12).

The Commission introduced the draft and presented its contents.

As regards flutriafol, Spain introduced a request to maintain the current EU MRL in strawberry, pending the finalisation of an Article 6 application. Several Member States opined that temporarily maintaining the current MRL based on an ongoing Article 6 application deviates from the stricter line taken previously, and underlined responsibility of Member States to submit data, given that MRLs were taken over from national legislation during the harmonisation. Other Member States supported the Commission proposal. EFSA explained their approach taken consistently from the start of the Article 12 review programme, which is to include the current EU MRL in the risk assessment in cases where a GAP was notified but no supporting data are available, in order to give risk managers options.

As regards prothioconazole, Member States provided several comments on CXLs recently approved and the LOQ for milk, which should be set at 0.01* mg/kg, taking into account resources of enforcement laboratories.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, captan, clothianidin, thiametoxam, folpet and tolclofos-methyl in or on certain products (Article 12).

The Commission introduced the draft, presented its contents and responded to written comments received from Member States. It referred to the comment on the SPS notification received from India on the MRLs for thiametoxam on rice.

Following further comments received on the SPS consultation, captan was taken out from the proposal. The Commission invited Member States to send their observations on these comments by 15 October 2015.

Vote taken: Favourable opinion.

B.05 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 diethofencarb, mesotrione, metosulam and pirimiphos-methyl in or on certain products (Article 12).

The Commission introduced the draft, presented its contents, and responded to written comments from Member States. It referred to the comment on the SPS notification received from the US on the MRLs for mesotrione on cranberry and pirimiphos-methyl on corn.

A Member State questioned whether the deferral of the application date provided for in Article 2 of the proposal should be applicable in cases where a chronic health risk was identified. As for the specific case of pirimiphos-methyl monitoring data show that no chronic health risks have been identified, even with the conservative assumption of calculation with the LOQ for the non-detects, for this case it would not be appropriate to make an exemption. However, the Commission agreed to have a general discussion on the length of the transitional period needed after entry into force of a Regulation at the Committee meeting on 30 November/01 December 2015.

Vote taken: Favourable opinion.

B.06 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 chlorpyrifos in or on certain products.

The Commission introduced the draft and presented its contents. It referred to the comment on the SPS notification received from the US on the MRLs for chlorpyrifos on cherries, pear and spinach.

A Member State requested to await the publication of the EFSA Reasoned Opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 before

voting on the proposal. The Commission replied that due to concerns regarding the risk for consumers, it does not intend to postpone the vote on this proposal. It explained that chlorpyrifos remains on the priority list for MRL review according to Article 12 of Regulation (EC) No 396/2005.

Some Member States commented on the 6 months deferral of the application date, including crops where a consumer concern has been identified. The Commission agreed to have a general discussion on the length of the deferral period needed after entry into force of a Regulation at the Committee meeting on 30 November/01 December 2015.

Vote taken: Favourable opinion.

B.07 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 COS-OGA, cerevisane, calcium hydroxide, lecithins, Salix spp cortex, vinegar, fructose, Pepino mosaic virus strain CH2 isolate 1906, Verticillium albo-atrum strain WCS850 and Bacillus amyloliquefaciens ssp. plantarum D747 in or on certain products.

The Commission introduced the draft, presented its contents and responded to comments received from Member States. Four basic substances and one low risk substance were added to the initial proposal. One substance was withdrawn from the initial proposal to await the outcome of the assessment of confirmatory data under Regulation (EC) No 1107/2009 for that substance.

Vote taken: Favourable opinion.