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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
12 - 13 DECEMBER 2017

CIRCABC Link: *https://circabc.europa.eu/w/browse/dc726a32-02ef-4a22-8050-d228c60601a3*

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Committee was informed that the summary reports from all previous meetings except the one for October have been finalised and published.

A.02 New active substances:

1. New admissible dossiers to be noted:
   a. Limestone
      Note taking was postponed as one Member State reported that they had not received the dossier from the rapporteur Member State.
   b. (3E)-3-decen-2-one
      (3E)-3-decen-2-one is a plant growth regulator, the rapporteur Member State is the Netherlands and the applicant is AMVAC Netherlands. Admissibility was reported to the Commission on 29 August 2017.
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
   No discussion.
3. Commission Draft Review Report and Regulation concerning the (non-) approval of:
   a. Flutianil
      The 11th adaptation to technical progress (ATP) under Regulation (EC) No 1272/2008 is currently being discussed with Member States. That draft also contains flutianil. With a view on this process, a draft concerning the approval of the active substance is currently under preparation.
   b. Reynoutria sachalinensis extract
      The Commission informed about the receipt of a letter on 16th of October from the applicant announcing the withdrawal of their application. A draft for the non-approval of this new active substance based on the withdrawal of the application was prepared and is currently under interservice consultation.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
   The Commission informed Member States about the fifth renewal programme (AIR 5), which concerns substances expiring between 1 January 2022 and 31 December 2024. In order to manage the workload for Member States, some substances in the AIR 5 programme may have to have their expiry of approval extended. The Commission therefore intends to prioritise substances that are expected to meet the hazard based cut-off criteria or that are listed or approved as Candidates for Substitution. The intention is also to group together substances with similar properties to have them assessed in parallel. A draft Commission Decision outlining the AIR 5 programme will be discussed during the next Standing Committee in January. The draft Commission Decision will also be published for public feedback during four weeks following the adoption of the legal act allocating RMS and co-RMS to AIR 5 substances.

2. Exchange of view on EFSA conclusions:
   a. Etoxazole
      Postponed until the January 2018 meeting.
   b. Methoxyfenozide
      No discussion.
   c. Zoxamide
      The Commission informed the Committee about two main concerns expressed in the EFSA conclusion. Member States were invited to send in their views by 10 January 2018.

3. Draft Review/Renewal Reports and Regulations for discussion:
   a. Propineb
      The inter-service consultation on the draft for non-renewal of propineb has been finalised but the vote had to be postponed due to an ongoing TBT notification.
      Member States were invited to send any further comment by 10 January 2018.
   b. Pseudomonas chlororaphis strain MA342
      The Commission seeks not to renew the approval of Pseudomonas chlororaphis MA342 based on concerns identified by EFSA in the consumer risk assessment area. The Member States were updated as regards the information provided by the applicant for Pseudomonas chlororaphis MA342, the position of EFSA and comments provided by the Member States authorities. Member States were invited to submit their final positions.
   c. Oxasulfuron
      The Commission seeks not to renew the approval of oxasulfuron based on concerns related to a number of data gaps and non-finalised areas of risk assessment. The Member States were updated as regards the position of the applicant for oxasulfuron and comments provided by the Member States authorities. Member States were invited to submit their comments.
   d. Thiram
      Member States were informed that since the October meeting a number of additional comments and views had been received from Member States – all correspondence had been made available to Member States via CIRCABC prior to the meeting.
      Furthermore, the Commission informed Member States about a meeting that had been held on 7 December with the Thiram Task Force (TTF) in which the

TTF made a presentation about their ongoing work to address the birds and mammals risk identified in the EU review. The Commission made it clear in the meeting with the TFF and to the Member States during the Committee that new data could not be taken into account during the decision making process but agreed to carefully consider the presentation and points that were discussed during the meeting. Additionally the Commission recalled that the issue related to birds and mammals has been well known for some time and also that mitigation measures cannot simply overrule the failing risk assessment.

Moreover, the Commission still considered that there was no acceptable risk demonstrated for the use of thiram as seed treatment and that despite the work presented by the TFF there were still uncertainties regarding the risk to birds and mammals.

It was highlighted that the applicant could submit a new application for approval that could include all of their new data.

It was recalled that for the use of thiram as seed treatment there are still some other issues that remain open aside from the issue of risk to birds and mammals.

Member States were informed that the draft for non-renewal had been slightly updated to add a provision to prohibit use of treated seeds.

Member States were asked for their views in the meeting and subsequently invited to submit further comments in writing ahead of the January meeting of the Standing Committee.

e. Diquat

The Commission informed Member States of a letter sent by EFSA to the applicant. In that letter EFSA acknowledges that the Commission might consider the need to re-assess the non-dietary exposure to diquat. The Commission will reflect on this internally. Member States were invited to send in their views on the technical specification and the equivalence to this specification of the ecotoxicology and toxicology batches by 10 January 2018.

f. Mecoprop-P

The Commission informed Member States of the comments received on the EFSA conclusion. They will be carefully considered when drafting the renewal report.

g. Carfentrazone-ethyl

Postponed.

h. Propyzamide

Postponed.

i. Silthiofam

Postponed.

j. Pymetrozine (short update only)

No update and no discussion

k. Isoxaflutole (short update only)

No update and no discussion

l. Clonostachys rosea J1446

The Commission informed the Committee about the draft for renewal of approval as a low-risk substance. Member States were asked to provide their comments to the Commission by 10 January 2018.

m. Forchlorfenuron

The Commission seeks to renew the approval of forchlorfenuron. The comments provided by the Member States authorities were made available. Member States were invited to submit their final comments.

n. Mepanipyrim

The Commission informed Member States about further investigations and discussions with the RMS whether or not finally a safe use could be identified.

o. Tribenuron

The Commission presented the draft documents prepared in view of the non-renewal of approval of tribenuron based on concerns identified in the residue and consumer risk area. Member States were informed on the comments and additional information submitted by the applicants, the position of the EFSA and the RMS. Member States were invited to provide their comments.

p. Pethoxamide

The Commission informed Member States of the comments received on the EFSA conclusion. They will be carefully considered when drafting the renewal report.

q. Flurtamone

The Commission informed Member States about the comments that had been received since the October meeting. The draft for non-renewal of approval was currently unchanged. Member States were invited to provide further comments.

r. Propiconazole

The Commission announced that due to the issues identified in the EFSA conclusion a draft concerning the non-renewal of approval had been made and Member States were invited to provide comments and views on this draft. The applicant would also be invited to submit comments on the draft Renewal Report in line with the requirements of the legislation.

Member States were informed that since the October meeting two Member States had submitted comments on the EFSA Conclusion. Both supported non-renewal of approval.

A.04 Confirmatory Data:

1. Bifenthrin

   The Commission informed that it had received comments from India through the TBT procedure. The Commission drafted a reply to India. The draft Regulation to amend the conditions of approval will be ready to be discussed and possibly voted upon at the next Standing Committee planned for January 2018.

2. Cyflumetofen (follow-up discussion only)

   The Commission informed Member States of the comments received on the different options to come to a decision on the confirmatory data on cyflumetofen. Those Member States which have not commented yet were invited to identify their preferred option.

3. Malathion

   Member States were informed that the interservice consultation had been concluded. The draft Regulation to amend the conditions of approval will be notified to WTO for TBT procedure.

4. Dithianon
   Some data were missing from the submission to address the request for confirmatory data and therefore some uncertainties about the exposure and the toxicological relevance of certain metabolites persist. As they cannot be ignored the exposure of humans to these metabolites has to be excluded in order to ensure consumer safety.
   The applicant, the Rapporteur Member State (RMS) and some other Member States claimed that these gaps occurred because EFSA has used a new guidance document which is not yet adopted. EFSA confirmed that his was not the case.
   The Commission also clarified that no new data can be presented at this point in time and that a decision must be taken on the basis of the information available; it is not possible to use Article 12 of Regulation (EC) No 396/2005 procedure under these circumstances, as that procedure is foreseen to re-evaluate residue levels that are already in place, and not to evaluate new data that should have been evaluated during the approval procedure.
   The proposed restriction of use to non-edible crops is therefore maintained.

5. Tri-allate
   Postponed.

6. Terbuthylazine
   Member States were updated on comments and views received since the previous meeting. Of the comments received, the majority expressed concerns about the groundwater profile and the non-finalised consumer assessment for several (non-relevant) metabolites. The Commission noted that the groundwater profile was complex and asked other Member States to consider the assessment and the possible options: to either enable the issue to be considered at Member State level, taking into account the types of uses authorised and the available monitoring data or to take more severe regulatory action.

7. Iprovalicarb (to be noted)
   Postponed.

8. Metazachlor
   Postponed.

9. Pyrethrins
   No discussion

10. Picloram (to be noted)
    Discussion postponed to the next meeting

11. Chlorsulfuron
    Postponed.

12. Triazine amine (common metabolite)
    Member States were informed that the Commission had received requests from the concerned applicants for iodosulfuron and prosulfuron to extend the deadline to provide their submissions of additional information, taking into account the need to finalise a data sharing agreement between the different companies involved.
    The Commission reacted to the applicants to inform them that they should ensure they meet the existing deadlines for providing confirmatory information as set in the approvals of the substances. However, it was mentioned that since the

companies were working to provide a weight of evidence assessment using all the existing data (no new studies) by the end of the year, the evaluating Member States may take this into account in their evaluations, if appropriate.
It was mentioned that the possibility for the Rapporteur Member States to collaborate during their evaluations is not precluded.
Once each assessment is available it will also be considered how to best coordinate the peer review to ensure that a single harmonised view on the metabolite is available for decision making.

13. *Pseudomonas* sp. Strain DSMZ 13134 (draft review report)
    Member States are requested to comment on the revised draft review report by 10 January 2018 at the latest.

14. Pyroxsulam (draft review report)
    Member States are requested to comment on the revised draft review report by 10 January 2018 at the latest.

15. Chlorantraniliprole (draft review report)
    Member States are requested to comment on the revised draft review report by 10 January 2018 at the latest.

16. Halauxifen-methyl (draft review report)
    Member States are requested to comment on the revised draft review report by 10 January 2018 at the latest.

17. Thiencarbazone-methyl (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

18. Kieselgur (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

19. Mandipropamid (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

20. Bupimirate (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

21. Azimsulfuron (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

22. Tau-fluvalinate (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

23. Disodium phosponate (draft review report)
    Member States are requested to comment on the revised draft review report by 22 January 2018 at the latest.

24. AOB
    No AOB.

A.05 Article 21 Reviews (no news).

No discussion.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:
   No new dossiers

2. Exchange of view on EFSA conclusions
   No new EFSA conclusions to be discussed.

3. Draft Review/Renewal Reports and Regulations for discussion:
   a. Fenazaquin
      The Commission presented the draft documents prepared in view of the amendment to the conditions of approval of fenazaquin. Member States were updated as regards the information submitted by the applicant for fenazaquin and comments provided by Member States' authorities. Member States were invited to submit their positions.

A.07 Basic substances:

1. Pilot projects: state of play
   The Commission reported about a meeting of the expert group held on 11 October 2017. A new version of the Guidance for applications under Article 23 has been discussed with the group and the Commission is currently collating comments to finalise it. In addition, some Member States argued on the interpretation of Article 23 for possible "basic plant protection products" and asked the Commission to further deepen legitimacy of current implementation.

2. New dossiers received (only for information)
   Member States were made aware of the submission of the two dossiers referred to hereunder; no further discussion.
   a. Extract from rhododendron
   b. Chitosan ascorbate

3. Exchange of views on EFSA Technical Reports
   No discussion.

4. Draft Review Reports for discussion:
   a. *Saponaria officinalis* root extract
      The Commission informed the Committee that since the last meeting the Commission is now seeking a non-approval due to substances of concern present in *Saponaria officinalis* root extract as reported in the EFSA technical report and public literature. Member States were asked to send in their comments on the draft by 10 January 2018.

A.08 Exchange of views on Guidance Documents:

1. Guidance document on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO/6895/2009 Rev. 2, for discussion)
   No discussion. The document may be noted in January 2018.

2. Proposed Mandate to revise the Guidance Document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011, rev. 2)
   Topic discussed under agenda point A.27.

3. Technical guidance on the Evaluation Efficiency of Residue Analytical Methods (SANTE/10632/2017, for information)
   The Commission informed that the technical guideline was noted in the last SC PAFF, section pesticides residues on 21-22 November 2017. It will be applicable as from 22 November 2019.

4. Guidance document on the establishment of the residue definition for dietary risk assessment (SANTE/11644/2017, possible follow-up discussion)
   The Commission informed about the most recent discussions in the SC PAFF pesticides residues on 21-22 November 2017. Since Member States raised many concerns as to the complexity of the document and the potential additional animal testing, the need for training as regards the new tools such as Quantitative structure–activity relationship (QSAR) methods and the potential negative impact on the acceptance of Codex MRLs (CXLs), the Commission believes that the consequences of the document first need to be clear before it can be implemented. Therefore it suggested that EFSA should finalise work on the three case studies already reported in its guidance document. The European Crop Protection Association (ECPA) had offered assistance in generating further mock up dossiers, which was welcomed by Commission and Member States. The Commission also will investigate options for taking up this issue at international level, i.e. in OECD or in the Joint FAO/WHO Meeting on Pesticides Residues (JMPR). First contacts were already made in this respect.

5. Commission Communications on the data requirements for active substance and plant protection product dossiers (for discussion)
   The Commission informed the Committee of the update of the list of guidance documents and test guidelines which are validated at international level. This update was performed to take into account the scientific progress achieved since the adoption of the Commission Communications on data requirements in 2013. This "database" will be used to update the Communications. Member States and EFSA were asked to provide their feedback.

6. Revision of Guidance document on zonal evaluation and mutual recognition withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 Rev. 11, for discussion).
   The Commission informed the Committee about the revision of this guidance document, which now includes a chapter specific to the authorisation of low-risk plant protection products. The Commission pointed out that this revision is based on the previous revision (revision 10) which the Committee has not yet taken note of. Member States were invited to send in comments on the draft revision by 22 January 2018.
   One Member State asked the Commission whether the proposed approach in the case of mutual recognition of regular products as low-risk products would fit within the concept of mutual recognition. The Commission explained that the current draft is considered in line with the rest of the guidance document with respect to mutual recognition and the evaluation of national specific requirements.

7. Revision of Template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 Rev. 1, for discussion)
   The Commission informed that the template was updated to allow applicants to indicate their intention to apply for authorisation as a low-risk plant protection product. The opportunity was taken to remove references to renewal of authorisations, because the template is not used for such applications. Member States were invited to send in comments on the draft revision by 22 January 2018.

A.09 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

One notification was submitted by Spain for a product for which there was a discrepancy between the specification as authorised and the specification as placed on the market.

The Commission asked other Member States to verify whether the product is also placed on the market in their territory.

The Committee took note of the notification submitted by Spain.

A.10 Notifications under Article 36(3) of Regulation (EC) No 1107/2009.

1. New notifications (to be noted)
   Four notifications have been provided, two by the United Kingdom (Ratron ST, Poncho Expert), one from The Netherlands (ZYPAR) and one from the Czech Republic.
   The notification for ZYPAR was rejected, as obligatory mutual recognition does not apply. Note taking of the notification from Czech Republic was postponed because the Commission asked for further clarifications.
   The Committee took note of two notifications submitted by the United Kingdom.
2. Differences in application of article 36(3) amongst Member States
   Discussion postponed.

A.11 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

- Metalaxyl-M (Belgium)
- Fludioxonil (Belgium)
- Metalaxyl-M (Belgium)
- Pyrethrins (Croatia)
- Zinc phosphide (Croatia)
- Abamectin (aka avermectin) (Croatia)
- Thiamethoxam (Denmark)
- Beta-Cyfluthrin (Denmark)
- Clothianidin (Denmark)
- Asulam (Denmark)
- Chlorpropham (Finland)
- Metalaxyl-M (France)
- Cyantraniliprole (France)
- Copper hydroxide (Germany)
- Hexythiazox (Germany)
- Pelargonic acid (CAS 112-05-0) (Germany)
- lambda-Cyhalothrin (Germany)
- Abamectin (Greece)

- Iprodione (Greece)
- Cyclanilide (Greece)
- Ethephon (Greece)
- Beta-Cyfluthrin (Hungary)
- Clothianidin (Hungary)
- Fludioxonil (Hungary)
- Metalaxyl-M (Hungary)
- Thiamethoxam (Hungary)
- 1,3-Dichloropropene (Malta)
- Spiromesifen (Portugal)
- 1,3-Dichloropropene (Portugal)
- Propiconazole (Portugal)
- Boscalid (Slovakia)
- Pyraclostrobin (Slovakia)
- Cyantraniliprole (Slovakia)
- Cyprodinil (Slovakia)
- Fludioxonil (Slovakia)
- Spinosad (Slovakia)
- Azadirachtin (Margosa extract) (Slovakia)
- Flonicamid (Slovakia)
- Emamectin (Slovakia)
- Thiram (Slovakia)
- Spirodiclofen (Slovakia)
- Mancozeb (Slovakia)
- Bupirimate (Slovakia)
- Methoxyfenozide (Slovakia)
- Captan (Slovakia)
- Acequinocyl (Slovakia)
- Bifenazate (Slovakia)
- Ampelomyces quisqualis strain AQ10 (Slovakia)
- Bacillus thuringiensis subsp. Tenebrionis strain NB 176 (TM 14 1) (Slovakia)
- Zinc phosphide (Slovakia)
- Diflubenzuron (Spain)
- Bentazone (Spain)
- 1,3-Dichloropropene (Spain)
- Chloropicrin (Spain)
- Copper hydroxide (Spain)
- Copper oxide (Spain)
- Azoxystrobin (Spain)
- Fluopyram (Spain)
- Trifloxystrobin (Spain)
- Diquat (Spain)
- lambda-Cyhalothrin (Spain)
- Deltamethrin (Spain)
- Hydrolysed proteins (Spain)
- Abamectin (Spain)
- Tebuconazole (Spain)
- Gibberellic acid (Spain)
- Hexythiazox (Spain)
- (Z,E)-9,12-Tetradecadien-1-yl acetate (Spain)

- Thiram (Spain)
- Dichlorvos (Spain)
- Picoxystrobin (Spain)
- Tebuconazole (Spain)
- Mepiquat (Spain)
- Spirotetramat (Spain)
- Spirodiclofen (Spain)
- Thidiazuron (Spain)
- Ethephon (Spain)
- Fosetyl (Spain)
- Spirotetramat (Spain)
- Spinosad (Spain)
- Phosmet (Spain)
- lambda-Cyhalothrin (Spain)
- Spinetoram (Spain)
- Gibberellic acid (Spain)
- Chlorantraniliprole (Spain)
- Spinetoram (Spain)
- Pyrimethanil (Spain)
- Cyantraniliprole (Spain)
- Spinosad (Sweden)
- Metazachlor (Sweden)
- Quinmerac (Sweden)
- Ethametsulfuron (Sweden)
- Flonicamid (IKI-220) (Sweden)
- Halauxifen-methyl (Sweden)
- Picloram (Sweden)
- Prochloraz (Sweden)
- Glyphosate (Sweden)
- Copper oxychloride (United Kingdom)
- Spirotetramat (United Kingdom)
- Copper oxychloride (United Kingdom)
- Cyantraniliprole (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Malta, Portugal, Slovakia, Spain, Sweden and the United Kingdom.

The Commission recalled that under the provisions of Article 53, Member States concerned shall immediately inform the Commission and the other Member States of the measures taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

In addition, the Commission pointed out that even if a Maximum Residue Level (MRL) set under Regulation (EC) No 396/2005 cannot be met and a national MRL is set, a consumer risk assessment needs to be carried out and forwarded to the Commission, the European Food Safety Authority and Member States.

Member States were reminded that they shall put in place the necessary risk mitigation measures to ensure acceptable uses for human and animal health and the environment.

Furthermore, the Commission pointed out that for minor uses Member States should make use, whenever possible, of the provisions laid down in Article 51 of Regulation (EC) No 1107/2009. Member States should also take into account efficacious alternatives which are available among bio-pesticides and bio-control agents to promote low input techniques as required by Directive 2009/128/EC.

The Commission requested Member States to assure entering all information requested into the Plant Protection Application Management System, as this information is necessary to judge whether any such authorisation was granted according to the provisions of Article 53 of Regulation (EC) No 1107/2009.

In case of doubt, the Commission, in line with the provisions of Article 53(2), will consider asking EFSA to evaluate whether the preconditions for granting an authorisation according to Article 53 are fulfilled.

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

A new policy on independence will be implemented in the future. This will also concern experts attending peer review meetings. Apart from a cooling period for staff working with industry before, it is also intended to exclude experts involved in risk management in the future.

The EFSA action plan has been finalised and published as technical report. EFSA is interested to explore with Member States an increased engagement in the assessment of products.

The first parallel peer reviews EFSA/ECHA are foreseen to start in February/March 2018. The process shall be based on a single document based on combined templates (CADDYxml/IUCLID).

The Article 21 review of clothianidin, imidacloprid and thiamethoxam will, after some delays, be finalised around mid February. As this process has provided more clarity on a number of elements of the EFSA bee guidance document, EFSA suggest to start a discussion with experts from Member States as soon as the conclusions are adopted.

EFSA is amending the list of endpoints in the area of residues. A final draft will be submitted to the Commission, Member States and EFSA for finalisation and note taking in the Standing Committee.

EFSA briefly informed about the outcome of the PPR plenary meeting in November and the progress with the guidance document on endocrine disruption.

A.13 News from the Directorate General for Health and Food Safety (SANTE) Directorate F, Health and Food Audits and Analysis (former FVO).

An overview was presented about the audit series on plant protection product authorisations in 2016/17. Seven Member States were audited and audit reports have been published on the SANTE website *http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=108* in July.

Overall, it can be concluded that the zonal system laid down in the Regulation is not working effectively. Member States do not avail of the opportunities to use the work done by other Member States and they have not taken measures to compensate for this lack of work sharing. Delays reduce the range of pest management tools. Delays in

decisions on re-authorisation of PPPs authorised before Uniform Principles mean that products remain in the market.

Another overview was given on the audit series on marketing and use controls. 11 Member States have been audited in 2015/16. The overview report has been released in June 2017
http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=109.

As a follow-up action to the recommendations, the Commission has established two expert groups on enforcement and on formulation analysis.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)
   The Commission explained that work remained ongoing on the next release of PPPAMS and that an update would be provided once this was completed.

2. Post Approvals Issues group (PAI)
   a. Terms of Reference of the Working Group on Post Approval Issues from the Standing Committee on Animals, Plants, Food and Feed: section Pesticide Legislation (SANTE/11102/2017 follow-up discussion)
      The Commission presented the finalised version taking into account all the comments received. The ToRs will be adopted formally in January.
   b. Update on the November meeting
      Member States were reminded that they should report new developments on confirmatory data on active substances for which they are Rapporteur Member States. Such information should be provided to Germany (BVL) as secretariat of the PAI group.

3. Sustainable plant protection experts group Dutch proposal
   The Commission informed that the expert group met for the last time on 30 November 2017 to discuss the draft progress report on the implementation plan on low-risk products and IPM. The meeting included a stakeholder session.

4. Working group on Biopesticides
   The Commission informed on the meetings of the biopesticides WG of 17-18 October and 21 November where topics such as secondary metabolites, antimicrobial resistance and clearance were discussed.

5. Working group on Seed Treatments (short update)
   The Commission informed the Committee that the development of the Guidance Document on Authorisations of plant Protection Products for Seed Treatments is on hold due to pending input from experts of the WG on seed treatment.

6. Working Group on Co-formulants
   The Commission presented the outcome of the discussion amongst the experts of the Working group:
   More detailed criteria should be set to identify unacceptable co-formulants. Since co-formulants are as active substances parts of plant protection products, the approval criteria set for active substances should be retained.
   Since co-formulants are substances or mixtures not only used in the area of plant protection products, they fall under the scope of horizontal legislation on chemicals. To avoid redundancy the identification of unacceptable co-formulants should take advantage of the data and assessments performed in accordance with

other regulations. A specific procedure is however necessary for co-formulants only used in plant protection products.
Member States were asked to comment by the 31 January 2018 on two draft regulations, one laying down the criteria and the procedure to identify unacceptable co-formulants and the other populating Annex III with a first batch of substances meeting the proposed criteria.

7. Working Group on Low-risk criteria
The expert group last met on 15 November. The experts discussed further steps in the implementation of the amended low risk criteria, including the draft guidance document, which was presented to the Standing Committee for commenting in October. The experts also discussed the draft non-binding list of active substances complying with the low risk criteria and some issues related to semio-chemicals.

A.15 OECD (no news).

No discussion.

A.16 Court cases:

1. Case C325/16 – preliminary ruling from the Spanish Tribunal Supremo – re-registration deadlines
The Commission reported on the audience held in Luxembourg on the preliminary question whether Member States could postpone the timelines set in a Directive for the review of authorisations of plant protection products under the Directive. The opinion of the advocate-general will be available in February 2018. The ruling of the Court will follow.

2. Case T-719/17- annulment of Commission Implementing Regulation (EU) No 2017/11496 concerning the non-renewal of the approval of the active substance flupyrsulfuron-methyl.
The Commission gave a short introduction into this case.

A.17 Endocrine Disruptors – state of play.

The Commission informed that the public consultation[1] on the draft guidance to identify endocrine disruptors (ED), developed by EFSA and ECHA with support of the Joint Research Centre of the European Commission (JRC), is open until 31 January 2018. The final guidance will be applicable to both biocides and pesticides, provided that the criteria that will in the end be adopted for pesticides will not substantially differ from those adopted for biocides.
The Commission will organise a workshop on 1-2 February 2018 to test the applicability of the draft guidance on the basis of case studies using active substances currently under assessment in the context of the pesticides and biocides Regulations. Member States were invited to notify by 20 December 2017 on which active substance(s) they will submit case studies (a letter had been sent on 4 December, also uploaded on CIRCABC). The full case studies shall be submitted to the agencies and the Commission by 29 January 2018. Member States were invited to consider in particular substances currently under assessment and to cover human health and the environment. Two experts per Member State (one for biocides, one for pesticides)

[1] https://echa.europa.eu/-/give-comments-on-the-draft-guidance-for-identifying-endocrine-disruptors

plus the speakers presenting selected case studies will be reimbursed. Stakeholders will also be invited.

The Commission will soon make available in CIRCABC for the Member States Competent Authorities for pesticides and biocides about 600 Excel files (one file per substance) containing the data and evaluations used in the screening[2] for the impact assessment that had been prepared to accompany the Commission's drafts for the criteria to identify endocrine disruptors. The data contained in these Excel files may contain confidential information and therefore shall not be distributed publicly. The data can be useful as a basis for evaluating endocrine disrupting properties of individual substances and for preparing case studies in view of the workshop mentioned above. However, the Commission strongly emphasised that the data and conclusions contained in these Excel files were only estimates performed for the aim of an impact assessment. Therefore, these data and conclusions do not constitute evaluations of substances to be carried out under the respective chemical legislations and shall in no way prejudge future decisions on substances to be taken pursuant to the respective chemical legislations.

A.18 Minor Uses.

A priority for the Coordination Facility will be ensuring longer term financial sustainability, beyond the first three years, by encouraging financial commitments from all Member States. Currently, the funding of the Coordination Facility has been guaranteed by France, Germany and the Netherlands for the first three years until April 2018. Several other Member States have already indicated their willingness to contribute to the funding of the Coordination Facility.

A mid-/long-term planning (5-10 years) and a strategy how other Member States can contribute, has been prepared. A letter from the European Commission on the long-term funding of the Coordination Facility has been circulated to Permanent Representations of the Member States. The issue of the long-term funding of the Coordination Facility was also discussed in the AGRI-FISH Council meeting on 9 October 2017. Member States have been approached by the Coordination Facility with a request for a voluntary assessed contribution.

In preparation of the Global Minor Use Priority Setting Workshop the EU Minor Uses Coordination Facility (MUCF) has submitted a priority list of minor uses needs on behalf of the EU (www.eumuda.eu Menu: GMUS Survey). The table of minor uses needs as prepared by the C-IPM and the list of priorities for the Global Minor Use Priority Setting Workshop will now be merged so that finally the EUMUDA-database will contain one single table of EU minor uses needs.

The second Stakeholder Advisory Forum of the Coordination Facility will be held on Tuesday 6 February 2018, in Brussels.

[2] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf

A.19 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009:
   a. Plant strenghteners (request by Lithuania)
      A company provided several label claims which are linked to "plant hygiene". These claims include "strengthening plant immunity", or "prevention of diseases". All these claims seem to fall under the definition of Article 2(1) of Regulation (EC) No 1107/2009 and the products are therefore to be considered plant protection products.
      Member States are invited to comment on this suggestion from the Commission.
   b. Fertinema (request by Belgium)
      The product consists of plant oils and some chemicals. Several claims are made for the product, including the promotion of growth of beneficial bacteria in soil and the formation of a physical barrier. These claims are not considered to fall under the scope of Article 2(1) of the Regulation. However, there is another claim that the products also make the roots less attractive for nematodes. Such repellent effect would fall within the scope of that article and therefore, the product is considered a plant protection product.
      Member States are invited to comment on this suggestion from the Commission.
   c. A Polyvinyl alcohol-based product to reduce pod shattering on rapeseed crops (request by Belgium)
      The product is a solution of polyvinyl alcohol in water. It reduces the physical strain on the pod seam thanks to its sticking and filming properties on rape crops. In this way, the product allows rape crop to grow to its full maturity, reducing the problems of pod shattering and improving pod filling. As the mode of action seems to be completely physical, with no physiological interaction with the plant, the product seems to be outside the scope of Article 2(1) and is not considered to be a plant protection product.
      Member States are invited to comment on this suggestion from the Commission.

A.20 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications
   An updated Excel table was shared with the Member States on CIRCABC.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances
   Internal discussions are ongoing. The Committee will be updated as soon as there is progress.

3. Follow-up of the merging of CLH and xAR templates (discussion only)
   The Commission informed about the editorial changes and the publication of the joint template on DG SANTE's website.

A.21 Glyphosate – State of the Dossier.

Member States were informed that the renewal of glyphosate and the Communication responding to the European Citizens/ Initiative had been adopted by the College on 12th December and that publication would shortly follow.

Post-meeting note: both documents have been published:
Renewal act:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1513679672002&uri=CELEX:32017R2324
Communication:
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_eci_final.pdf

The Commission explained that a rapporteur Member State and co-rapporteur Member State will need to be designated in the coming months ahead of the next possible renewal of approval (an application must be submitted 3 years before the expiry date i.e. on or before 15 December 2019).

A.22 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

Firstly, the Commission gave an update on issues discussed in the most recent SC PAFF, section Pesticides Residues. A draft was voted on the review of Maximum Residue Levels (MRLs) under Article 12 of Regulation (EC) No 396/2005 for the substances chlorpyriphos, chlorpyriphos-methyl and triclopyr. Some MRLs were lowered by this measure. As regards chlorpyriphos, MRLs of concern had already been lowered in a previous Regulation (Regulation (EU) No 2016/60 which became applicable in August 2016).

Secondly, a procedure had also been agreed in the Committee's section on residues on the best moment to start the Art. 12 review in those cases where the renewal exercise precedes the Art. 12 review and where as a consequence Member States would need to make changes to existing authorisations. The Commission clarified that the procedural document it provided in advance of the meeting only referred to this specific situation, that it was not intended to become a formal guidance document and that its purpose was mainly to give some guidance to EFSA for their Article 12 planning.

In summary, the residues Committee agreed that some flexibility was needed to deviate from the legal deadline to carry out the Article 12 review one year after approval or non-approval in some cases. These cases were clearly defined in the document and maximum delays given for different situations. However, it was also agreed that no flexibility should apply in cases of possible consumer health concerns.

The Commission highlighted that the reason to present the procedure in this Committee was that action from the experts on legislation side would be needed in those particular cases, e.g. cases where the lowering of toxicological reference values during the renewal exercise could lead to consumer health concerns. The action required is presented in point 5 of the document: after having taken note of the review report (and therefore after having formally agreed on the toxicological reference values) an exposure assessment should be carried out by the Rapporteur Member State who prepared the renewal assessment report (RAR) using either as a worst case all existing MRLs and entering them in the EFSA PRIMO model or more refined data

from trials where those would be available. If this worst case exposure assessment showed a potential risk, the residues experts should be proactively and swiftly informed so that in the next following Standing Committee, section pesticides residues, a decision on prioritisation of the Article 12 review could be taken. If those calculations were already done at an earlier stage in the procedure (e.g. by the RMS in the RAR and later reported in the EFSA Conclusion), they could of course be used provided that the toxicological reference values proposed by EFSA would be accepted by risk managers. The Commission emphasised that also in this case proactive communication from the RMS after finalisation of the decision making procedure (Note Taking of the Review Report) would be essential to ensure proper follow up at the right moment by the Residues Section of the Committee. Member States were invited to provide comments by 31 December 2017.

A.23 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

The Commission informed Member States that all the surveys of the REFIT evaluation are currently open. Stakeholders, Member States, SMEs and citizens are invited to submit their responses. Member States inquired if it is possible to extend the deadline for submitting the competent authority survey and the Commission agreed to extend the deadline until 19 January 2018.

The Commission also informed Member States of the upcoming focus groups in which Member States are expected to participate. The four focus groups are planned in January, February and March. The dates will be confirmed and invitations sent by the Contractor. Member States are invited to indicate to the Commission if they are willing to participate in one of the focus groups.

A.24 Mandate for a Working Group (WG) to set up a procedure to assess new variants of approved active substances (to be noted).

No discussion – postponed to January 2018.

A.25 Initial information concerning Brexit.

No new information specifically concerning plant protection products.

A.26 EU Pollinators Initiative (DG ENV).

The Commission presented the state of play on the development of an EU Pollinators Initiative. Reduction of risks of pesticides will be one the main actions for tackling the threats to pollinators. The Commission would like to hear the views of national experts how the risk assessment could be further strengthened and will disseminate a short expert survey to the Committee in this regard. The Commission plans a consultation workshop in March in order to gather additional views and evidence from a broad range of experts on pesticides and pollinators. The Committee will be kept up to date in this regard. The Commission will also launch a public consultation in January 2018 to which members are also welcome to contribute as well as invited to further disseminate within their networks [edit: launched on 11 January https://ec.europa.eu/info/consultations/public-consultation-eu-initiative-pollinators_en.

A.27 Possible update of the "guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) N° 1107/2009" (draft DE/FR).

Germany briefly introduced its planning for an update of the guidance document. Together with France, Germany will take the lead in the process.

A.28 Scientific publications and information submitted by stakeholders.

The Commission presented to the Committee a draft notice concerning a list of potentially low-risk substances. The Commission explained the purpose and limitations of such a non-legally binding list and the screening approach that was used to produce it. Member States were invited to send in their comments on the draft Commission Notice by 22 January 2018.

A.29 Date of next meeting.

The date of the next meeting was confirmed as 25-26 January 2018.

A.30 Confirmatory data pending and renewal ongoing – Clofentezine and Difeconazole (RMS ES).

Discussion postponed to the next meeting in January 2018.

A.31 Data requirement on peer reviewed literature (Art 8.5).

The Commission reminded Member States in their role as Rapporteur Member States, about the requirement to submit peer reviewed literature in application dossiers (Article 8.5 of Regulation (EC) No 1107/2009). For some active substance dossiers, a data gap on this point was identified in the corresponding EFSA Conclusion.

Even where no relevant peer review literature is available for particular active substances, a search of peer reviewed literature needs to be documented in the application dossiers in order to fulfil the data requirement. This documentation should be done according to the corresponding Guidance Document (GD) of EFSA, which is listed in the Commission Communication published in 2013 in the framework of Regulation (EU) No 283/2013. This GD also provides information on how to review the peer reviewed literature.

A.32 Draft Commission Notice concerning a list of potentially low-risk substances (presentation).

The Commission presented a draft Notice concerning a list of potentially low-risk substances to the Committee. The Commission explained the purpose and limitations of such a legally non-binding list and the screening approach that was used to produce it. Member States were invited to send in their comments on the draft Commission Notice by 22 January 2018.

B.01 Exchange of views and possible opinion of the Committee on draft Commission Implementing Regulation renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10502/2017 Rev 3).

Reasons for abstention/negative opinion:

- National ban on neonicotinoid active substances
- Approval should be restricted to foliar spraying during non-flowering non-growth phases

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance laminarin, as a low risk substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft review Report SANTE/11558/2017/Rev.2).

Reasons for abstention/negative opinion:

- Calculation of impurities should be included.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances.

Reasons for abstention/negative opinion:

- Re-allocation of substances currently attributed to the United Kingdom.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing approval of active substance bentazone in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12012/2015 Rev 6).

The Commission outlined the draft, its content and informed the Member States that the inter-service consultation was not yet finalised. Consequently the vote was postponed.

Vote Postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen (Draft Review Report: SANTE/10028/2017 Rev. 1.4).

Reasons for abstention/negative opinion:

- Not in favour of the initial approval decision in the past.
- Unacceptable risk to birds.
- Risk to groundwater.
- Penflufen should be classified according to Regulation (EC) No 1272/2008

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of honey from rhododendron as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/10450/2017– rev. 0).

The Commission outlined the draft, its content and informed the Member States that the inter-service consultation was not yet finalised. Consequently the vote was postponed.

Vote Postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance Talc E553B in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11639/2017).

Vote Postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (Draft Addendum to the Review Report SANCO/10590/2013 Rev. 5).

A vote was envisaged for this draft but was finally postponed for several reasons; including diverging views between Member States and the request from many of them to await the EFSA reports on the evaluation of the data collected in an open call for the review of the 2013 measures (Regulation (EU) No 485/2013). During a commenting round 11 Member States indicated their support, 11 Member States did not have a position and 6 Member States expressed comments against the current drafts. The Commission envisages resubmitting the measures to the Standing Committee for a vote in early 2018.

Romania made the following declaration:

"Following the proposals launched by the European Commission in the last SCOPAFF meeting of 12-13 December 2017, regarding further restrictions applied to the remaining uses of the products containing the neonicotinoid active substances Imidacloprid, Clothianidin and Thiametoxam, we would hereby like to present our opinion.

We are worried that these proposals have the potential to restrict the access to essential plant protection products for Romanian farmers and thereby limit pest management options, accelerate resistance development in pest insects and negatively impact the sustainability and competitivity of our farmers.

The proposed restrictions would lead to a significant decrease of the available control solutions, while the remaining products would manage to tackle only partially some of the existing challenges. Neonicotinoid-based products would be replaced by other chemical alternatives (other insecticides) that can pose a high risk for pollinators and have a high environmental impact that would ultimately lead to an increase in the number of treatments and the total quantity of products applied. We argue again that neonicotinoids are safe if there are used as recommended in the label.

To improve the way in which Neonicotinoid-based products are used so that they do not affect the health of users, consumers and the environment, the National Phytosanitary Authority has developed the "CODE OF GOOD PRACTICES FOR THE SAFE USE OF PLANT PROTECTION PRODUCTS ". In addition to this National Phytosanitary Authority has signed two protocols with Association of Bee Breeders of Romania and Federation of Apiculture Associations in Romania-ROMAPIS.

At the Ministry of Agriculture and Rural Development this year was also received from the Farmer Association of Agricultural Producers of Romania requests for emergency authorizations in accordance with Article 53 of Regulation (EC) No 1107/2009 for the use of plant protection products containing clothianidin, imidacloprid and thiamethoxam for the treatment of corn and sunflower seeds in spring of 2018.

In conclusion, given the arguments presented above, Romania does not support the proposals of the European Commission to restrict any different use of the active substances clothianidin, imidacloprid and thiamethoxam, to allow farmers to continue to use seed treatment solutions for crops such as sugar beet, autumn cereals and potatoes. There are few alternatives on the market replacing neonicotinoids, and farmers are not prepared for the withdrawal of these products."

Vote Postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (Draft Addendum to the Review Report SANCO/10589/2013 Rev. 5).

A vote was envisaged for this draft but was finally postponed for several reasons; including diverging views between Member States and the request from many of them to await the EFSA reports on the evaluation of the data collected in an open call for the review of the 2013 measures (Regulation (EU) No 485/2013). The Commission envisages resubmitting the measures to the Standing Committee for a vote in early 2018.

Romania made the same declaration as under Agenda Point B.08.

Vote Postponed

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (Draft Addendum to the Review Report SANCO/10591/2013 rev 5).

A vote was envisaged for this draft but was finally postponed for several reasons; including diverging views between Member States and the request from many of them to await the EFSA reports on the evaluation of the data collected in an open call for the review of the 2013 measures (Regulation (EU) No 485/2013). The Commission envisages resubmitting the measures to the Standing Committee for a vote in early 2018.

Romania made the same declaration as under Agenda Point B.08.

Vote Postponed

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, clothianidin, copper compounds, dimoxystrobin, mancozeb, mecoprop-p, metiram, oxamyl, pethoxamid, propiconazole, propineb, propyzamide, pyraclostrobin and zoxamide.

Reasons for abstention/negative opinion:

- List contains substances that are not expected to meet the approval criteria.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances FEN 560 (also called fenugreek or fenugreek seed powder) and sulfuryl fluoride.

Reasons for abstention/negative opinion:

- Approval period for potential low risk substances should be extended by a longer, for normal substances by a shorter time period.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

Reasons for abstention/negative opinion:

- One Member State voted against, because they could at this point not support the draft amendment and proposed to postpone the vote until January 2018 instead.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

The Commission explained that the revised draft Regulation is identical to the text voted in July, except for the deletion of the last paragraph with the provision on the growth regulators and the corresponding Recital. The revised draft Regulation thus followed exactly the request of the European Parliament (EP), which had objected on legal grounds to the draft Regulation voted in July by the Committee.

One Member State indicated it had no position so far and expressed concerns about the deletion of the growth regulators provision because the active substances concerned by that provision are important from the perspective of a more sustainable use of pesticides. Another Member State also expressed dissatisfaction about the deletion of the growth regulators provision and therefore could not support the draft Regulation.

One Member State recalled that it had already had misgivings about the earlier removal of the amendment to the derogation possibilities (changes to point 3.6.5 and 3.8.2. of Annex II to Regulation (EU) No 1107/2009) that had been part of the Commission's first draft in June 2016. Furthermore, it criticised that the Commission only followed the views of the European Parliament but was not considering in an equal manner the views of the Member States and the Council. In its view, the growth regulator provision was an important provision which merely reflected the current arrangement of the plant protection product legislation which accepts and recognises the intended endocrine mode of action of growth regulators. The European Parliament had agreed in 2009 and 2013 to the plant protection product legislation and thus this Member State did not believe that the Parliament's position had been based on an in-depth analysis. The Member State further announced that it would abstain in a vote on the draft Regulation.

Another Member State agreed with the previous one speaking and stressed that the provision on growth regulators was important, but wondered if it could be considered in a separate legal document. It stressed that the adoption of the criteria should be done quickly and indicated it would support the draft presented.

The Commission reminded the Member States of its commitment made in July 2017 to table the 2nd text with the amendment to the derogation possibilities (changes to points 3.6.5 and 3.8.2 of Annex II to Regulation (EU) No 1107/2009) once the criteria will be adopted. The Commission also explained that, in case of no opinion of the Committee, according to the Comitology procedures, the Commission would prepare a draft Council Regulation and submit it to the Council and inform the European Parliament. The Council may then try to amend this draft Regulation within 2 months, and, if a qualified majority would support such a modified version, the European Parliament can object in the 2 subsequent months.

A Member State expressed its support for the draft Regulation, but indicated that the Commission should have asked the Court of Justice to annul the European Parliament objection, also to avoid setting a precedent, because the Commission had not exceeded the mandate given by Article 78 of Regulation (EC) No 1107/2009.

Another Member State indicated it cannot support the draft Regulation as both, the growth regulator provision and the amendment to the derogation possibilities were absent. It wondered whether the Commission had conducted an impact assessment

concerning the growth regulators. The Commission indicated that the impact assessment performed in the context of this work only focused on the EATS modalities and that the growth regulators had therefore not been specifically considered. However, about 15 active substances are listed as insect growth regulators under Regulation (EC) No 1185/2009 concerning statistics of pesticides. As regards plant growth regulators the number is significantly higher, but not all substances listed are plant hormones. The Commission indicated also that the potential impact cannot only be measured in terms of number of active substances, because other agronomical factors need to be considered like for instance the need of alternative modes of action of the active substance to avoid resistance.

One Member State indicated that it did not support the draft Regulation. In its view, consistency is needed between the criteria for biocides and pesticides, and the European Parliament did not object to the criteria for biocides, although these contained the growth regulators provision. This was supported by another Member State, which indicated that it would be illogic if the same active substance will be identified as ED for pesticides and not for biocides. The Commission explained that the regulatory consequences for growth regulators in the biocides Regulation as regards their use by general public are the same for substances with endocrine disrupting properties on target organisms and non-target organisms, whereas a clear distinction as regards target and non-target organisms exists in the pesticides Regulation.

One Member State indicated that it does not support the text because the burden of proof needed to fulfil the criteria is too high. This was echoed by a second Member State.

One Member State suggested amending the proposed text. It had considered several possible alternatives and suggested it's preferred draft, which is to amend the provisions under paragraph (2) sub (2)b of point 3.8.2 as follows: "*the relevance of the study design for the assessment of the adverse effects and its relevance at the (sub)population level, for the taxonomic groups mentioned in (2) (a), and for the assessment of the endocrine mode of action"*. This Member State asked the Commission if it would consider this or any other amendment. The Commission explained that the proposed modification was incoherent as the list of taxonomic groups to which it refers is an open list and thus the amendment has no effect.
One Member State did not support the draft Regulation as it insisted on the need for an amendment to the derogation possibilities in point 3.6.5 and 3.8.2 of Annex II to Regulation 1107/2009.

Another Member State supported the draft Regulation and stressed that a quick decision is needed on this topic.

Reasons for abstention/negative opinion: see detailed reasoning above.

The Commission welcomed this outcome and indicated that the draft Regulation would now be sent to the Council and the European Parliament for scrutiny according to the regulatory procedure with scrutiny. They will have three months to examine it before final adoption by the Commission. The Regulation will enter into force 20 days after its publication in the Official Journal and be applicable six months after this.

Vote taken: Favourable opinion.