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 06 DECEMBER 2016 - 07 DECEMBER 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/0f8269da-8e2a-4bc3-a2ef-54a65dfe57c4*

A.01 Summary Report of previous meetings.

The Committee was informed that the report was published on 6 December.

A.02 New active substances:

1. New admissible dossiers to be noted:

No new dossiers.

2. Exchange of view on new European Food Safety Authority (EFSA) conclusions (no specific conclusion identified)

No discussion required.

3. Commission draft Review Report and Regulation concerning the (non-) approval of:

i. Beta-cypermethrin

A brief summary of the current state of play was given. The Commission informed Member States that it was reflecting on how to proceed and had been in contact with the applicant to discuss the concerns and issues identified.

ii. Pseudozyma flocculosa ATTC 64874

The Commission brought to the attention of delegates the comments of the applicant which had been recently uploaded on CIRCABC. Member States were invited to comment by 13 January 2017.

iii. Bacillus amyloliquefaciens FZB24

Comments were received from several Member States and the applicant which resulted in minor changes to the Review Report. Member States were asked to provide their final comments by 23rd December 2016.

iv. Cyclaniliprole

No comments were received from Member States on the draft proposal.

v. Beauveria bassiana strain 147

Comments were received from one Member State. The Commission will contact the applicant on the purity specification. Member States were asked to provide their final comments by 23rd December 2016.

vi. Beauveria bassiana NPP111B005

Comments were received from one Member State. The Commission will contact the applicant on the purity specification. Member States were asked to provide their final comments by 23rd December 2016.

vii. Orthosulfamuron

A consultation according to the TBT (technical barriers to trade) agreement was launched recently. The substance will be scheduled again on the agenda after the procedure is finished.

viii. Flutianil

The Commission informed the Committee that the decision-making process is put on hold until the classification of the substance according to Regulation (EC) No 1272/2008 is adopted.

Following two points added to original agenda:

ix. Mild Pepino Mosaic Virus isolate VC1

The Commission seeks the approval of this substance as a low-risk substance and presented the draft review report. Member States were asked to provide their comments as soon as possible, by 23rd December at the latest.

x. Mild Pepino Mosaic Virus isolate VX1

The Commission seeks the approval of this substance as a low-risk substance and presented the draft review report. Member States were asked to provide their comments as soon as possible, by 23rd December at the latest.

A.03 Renewal of approval:

1. AIR III (Annex I Renewal Projects): State of play

Member States were informed that the Implementing Regulation concerning extensions of approval regarding the AIR III programme, as voted in October, was published on 17 November 2016 in the Official Journal L312. The Implementing Regulation regarding fipronil and maneb also voted on in October, was published on 21 November 2016 in the Official Journal L314.

2. AIR IV: State of play

Since October, 11 substances had the application deadline for renewal. 10 out of 11 applications have received an application for renewal. A draft regulation will be prepared and presented in January or February.

3. Exchange of view on the following EFSA conclusions:

i. 2,4-DB

The Commission presented the EFSA Conclusion and several comments received from the notifier, many of them relating to the evaluation phase. The notifier is of the opinion that there is incoherency between the reference toxicological endpoints in the current Conclusion and the one on 2,4-D is examined, and the notifier points out that the situation might occur again for other substances still under evaluation. In any case, it would seem that that alleged incoherency has no dramatic effects on the outcome of the debates but might induce additional measures to protect operators and workers.

Other points raised by EFSA relate to the consumer risk assessment, the risk to mammals, macro-organisms (other than earthworms) and aquatic organisms. Given the amount of data provided, Member States were given the necessary time. The Commission will try to propose a draft review report by the next meeting for further debate. Member States were asked to provide their comments by 13 January 2017.

ii. Silthiofam

Comments from applicant on the EFSA conclusions have been uploaded.

iii. Propyzamide

A draft review report has been uploaded on the basis of which the substance is proposed for renewal as candidate for substitution. Member States were asked to provide their comments by 13th January 2017.

iv. Carfentrazone-ethyl

The Commission presented the EFSA Conclusion and the comments hereupon by the notifier. Currently the substance is unclassified for human hazard but EFSA is proposing a classification as Carc 2 on the basis of a rat study at the highest doses. There is no application of the interim criteria for endocrine disruption nor indications for such effects.

Points raised by EFSA relate to consumer assessment due to unknown residues that might be present in surface water treated to become drinking water, metabolites in groundwater, the aquatic risk (algae and aquatic plants) and to non-target soil macro-organisms (with the exception of earthworms).

The Commission will further study the dossier but feels that some of the issues raised should be addressed via requests for confirmatory information. A draft Review Report will be proposed at the next meeting for further discussion. Member States were asked to provide their comments by 13th January 2017.

4. Draft Review Reports for discussion:

i. Flupyrsulfuron-methyl

Member States were informed about comments received from Member States and the applicant since the October meeting. One Member State indicated that a non-renewal was preferred due to the high risk of groundwater contamination by metabolites. The applicant had provided information to address the new issues identified in the updated Conclusion (from October 2016). The Commission explained that the ongoing processes to consider negligible exposure and Article 4.7 remained ongoing but that consideration was being given to the proposal going forward since there is uncertainty about groundwater contamination from some metabolites plus known possibility for exposure above 0.1 μg/L in all scenarios for other metabolites.

ii. Pymetrozine

Member Sates were reminded about the last discussion that took place on this file. They were also informed that a draft EFSA statement concerning negligible exposure has been circulated for comments and would be finalised before Christmas.

The Commission asked Member State to consider the Statement and provide their views and comments on whether they consider negligible exposure has been demonstrated, taking into account the draft Guidance Document on negligible exposure.

iii. Fenamidone

No specific discussion.

iv. Isoxaflutole

Member States were informed that the assessments of negligible exposure and Article 4.7 were now ongoing and that the item would be taken off the agenda until further ouputs were available for discussion.

v. Imazamox

Member States were reminded that the key issue precluding renewal of approval was the lack of ability to conclude on the genotoxic potential of the metabolite. The proposal for non-renewal remains but may be re-considered given the views

expressed by Member States on the issue. Member States were asked to provide their comments by 13th January 2017.

vi. Maleic hydrazide

Comments were received from the applicant, several Member States and other stakeholders in relation to the Commission proposal for non-renewal The Commission explained that the comments are carefully considered and asked Member States to raise any possible further comments by 13th January 2017.

vii. Picoxystrobin

A summary of the comments received since the October meeting was provided by the Commission. The Committee was also informed about exchanges between the Directorate General for Health and Food Safety (DG SANTE) and the applicant. All information had been made available to Member States before the meeting.

The Commission reiterated that the proposal for non-renewal of approval remained unchanged due to the number and type of concerns identified in the EFSA Conclusion.

Member States were asked to provide any final comments or their positions in writing by 13th January 2017.

viii. Flazasulfuron

The Commission seeks to renew the approval of this active substance. A short summary of the issues identified in the EFSA Conclusion was given to Member States. Member States were asked to provide their comments by 13th January.

ix. Coniothyrium minitans strain CON/M/91-08

The Commission seeks to renew the approval of this active substance. A short summary of the issues identified in the EFSA Conclusion was given to Member States. Member States were asked to provide their comments by 13th January.

x. Mesosulfuron-methyl

The Commission seeks to renew the approval of this active substance. A short summary of the issues identified in EFSA's conclusion was given to Member States. Member States were asked to provide their comments on the renewal report by 13 January 2017.

xi. Mesotrione

A draft review report was uploaded on CIRCABC. The Commission proposes to renew the approval of this active substance. A short summary of the issues identified in EFSA's conclusion was given to Member States. Given that EFSA does not conclude on persistency in water, the Commission asked Member States to provide their opinions in view of a possible identification of the substance as candidate for

substitution. Comments from applicant have also been uploaded. Member States were asked to provide their comments on the renewal report by 13 January 2017.

xii. Pendimethalin

A draft review report was uploaded on CIRCABC on the basis of which the substance is proposed for renewal as candidate for substitution. A short summary of the issues identified in EFSA's conclusion was given to Member States. The Commission also brought attention to the comments received by the applicant. A Member State presented comments with respect to the bioaccumulative properties of the substance. Member States were asked to provide their views on the renewal report by 13 January 2017.

Following point added to original agenda:

xiii. Prosulfuron

Member States were made aware of new information that had been submitted by the applicant to the Rapporteur Member State (RMS) France, to address the groundwater issues identified in the EFSA Conclusion. The Commission explained that whilst this data could not be considered for the decision on renewal, the RMS could evaluate it once a decision on renewal has been taken; assuming that the approval of prosulfuron is renewed with a restriction, the new information could form the basis for an application to amend the conditions of approval.

Member States were asked once again for their positions on the proposal to renew approval with restriction

A.04 Confirmatory Data:

1. Bifenthrin

The Commission explained that two problems remain after the assessment of the requested confirmatory information: the risk to non target arthropods in field and the possible shortcomings of the monitoring study on bioaccumulation/biomagnification. A formal mandate to EFSA is theoretically possible but it is unlikely this would modify the current outcome. In any case, a decision must be taken and one option would be to set a restriction by regulation of the currently admitted application rates, so as to reduce to acceptable levels the exposure of the said non-target arthropods. The question as regards the representativeness of the monitoring study to realistic conditions is another issue that needs careful reflexion. The matter will be on the agenda again of the next meeting.

2. Thiamethoxam

Member States were requested to provide their views on the next steps for this substance given the unsufficient submission of confirmatory data by 15 December 2016.

Two Member States requested additional information to be uploaded on CIRCABC.

One Member State indicated support for a restriction to permanent greenhouses.

One Member State wondered how a restriction to permanent greenhouses would influence the evaluation of representative uses.

3. Clothianidin

Discussion postponed.

4. Imidacloprid

Discussion postponed.

5. Oxyfluorfen

A very short update was given to inform Member States that a TBT notification was ongoing and that a vote was foreseen for the January 2017 meeting.

6. Tetraconazole

Point not discussed

7. Fluquinconazole

Point not discussed

8. Metazachlor

Point not discussed

9. Buprofezin

Member States were informed about a number of comments received from Member States and the applicant following the proposal to restrict the approval to non-edible crops only. There were a range of views but the majority supported the action proposed to ensure consumer safety. The Commission did indicate that the issue regarding possible exposure to genotoxic carcinogens was complex and sensitive but that in the future, tools available to consider such exposure should not automatically be disregarded (reference was made to the Margin of Exposure methodology) and that each case should be considered carefully.

Member States were informed that a TBT notification was ongoing and that a vote was foreseen for the January 2017 meeting.

10. Malathion

Point not discussed

11. Tri-allate

Point not discussed

12. Diclofop (to be noted)

While the matter seems unproblematic as such, Member States did not have sufficient time to discuss this internally. Therefore the debate and note-taking is shifted to the next meeting.

13. Cyflumetofen

Point not discussed

14. Napropamide

Point not discussed in detail. The Commission however points out the surprise expressed by EFSA as regards the limited nature of the data submitted by the applicant.

15. Fluroxypyr

Point not discussed but revised documents and comments were made available before the meeting for Member States to consult.

16. Tall oil pitch

Point not discussed

17. Tall oil crude

Point not discussed

18. 8-hydroxyquinoline (to be noted)

The Commission reminded the Committee that the draft revised review report was discussed in 2015 in order to finalise the process for confirmatory data. At that time no comments were received but the document was not formally noted. However due to the late upload of the document, the Committee was not able to take note of the review report.

19. Methyl nonyl ketone (lack of data submission)

The Commission explained that all the internal steps have been taken to withdraw, for formal reasons, the approval of this substance. As the TBT procedure is still ongoing, a vote could only take place in the March 2017 meeting at the earliest.

20. TDM (Triazole Derivative Metabolites)

This dossier is very complex and needs further reflection in the Commission. A mandate to EFSA is however likely.

21. AOB

None

A.05 Article 21 Reviews:

• *Diflubenzuron* (Draft Review Report and draft Implementing Regulation for discussion)

The Commission presented a draft act prepared in line with the discussions on the draft Review Report at the preceding meeting of the Committee and invited Member States to submit comments by 13 January 2017. The Commission also referred to correspondence with the applicant available on CIRCABC and explained its view.

• *Thiametoxam*, other uses than seed treatments and granules (Revised Review Report to be noted)

The final documents were recently uploaded on CIRCABC. In order to give Member States the time to analyse them the discussion is postponed.

• *Clothianidin*, other uses than seed treatments and granules (Revised Review Report to be noted)

The final documents were recently uploaded on CIRCABC. In order to give Member States the time to analyse them the discussion is postponed.

• *Imidacloprid*, other uses than seed treatments and granules (Revised Review Report to be noted)

The final documents were recently uploaded on CIRCABC. In order to give Member States the time to analyse them the discussion is postponed.

A.06 Amendment of the conditions of approval:

1. Fenazaquin

There was no news to discuss.

2. 8-Hydroxyquinoline

The Commission informed the Committee that after additional checks, it was confirmed that the studies used for the classification of 8-hydroxyquinoline were all available at the time of the original assessment. Therefore it is proposed not to lift the

existing restrictions and to reclassify this active substance as a substance which products should undergo a comparative assessment at national level.

Following sub-point added to original agenda:

3. Penflufen

The Commission informed the Committee that EFSA conclusions on the request to amend the conditions of approval of penflufen were available. The request sought an amendment on the restrictions on crops but not on the restrictions on the frequency of use. Member States were asked to provide comments on the way forward.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission asked Member States to nominate by 13 January 2017 a delegate for the expert group on basic substances which will be re-organised in the first quarter of 2017, to continue to develop the working document on applications.

2. New dossiers received

i. Beer

The Commission informed Member States of the new dossier received. Dossier was uploaded on 17 November.

ii. *Saponaria officinalis*

The Commission informed Member States of the new dossier received. Dossier was uploaded on 29 November.

iii. Vinegar (extension of use)

The Commission informed Member States of a new application for extension of use. The applicant was requested to complete the dossier.

3. Exchange of view on EFSA Technical Reports

i. Talc :

The Commission informed on new information submitted by the applicant to address concerns expressed in the EFSA technical report issued in July 2016. In particular, Member States were asked to comment on the operator exposure assessment which applies as reference value the OEL of 2 mg/m3 in the absence of EU harmonised reference value and taking into account the respirable fraction being a part of total inhalable dust. Member States were asked to provide their views by 13 January 2017.

4. Draft Review Reports for discussion

i. Clayed charcoal

The Commission informed on two comments received on the first proposal. One Member State preliminary indicating support for approval as a basic substance and another Member State questioning if the use falls within the scope of Regulation (EC) No 1107/2009. For the latter comment the Commission referred to point A20 in the minutes of the Standing Committee of 10-11 December 2015.

ii. Urtica spp.

The Commission seeks approval of this substance as a basic substance and presented the draft review report. The Commission proposes to mention in the conditions of use that general hygienic practices must be adhered to when preparing the fermented extract in order to prevent contamination with pathogenic microorganisms. Member States were asked to send in their comments by 23 December.

iii. Hydrogen peroxide

The Commission seeks approval of this substance as a basic substance and presented the draft Review Report. The Commission proposes to limit the approval to ready-made solutions with a concentration lower than 5% hydrogen peroxide since such solutions have no classification and proved safe for biocidal use as hand disinfectant. Member States were asked to send in their comments by 23 December.

A.08 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (Doc. SANTE/10832/2015) (to be noted)

The Commission presented a revised cover note which clarifies where the EFSA piece of guidance already in place should be used. It also sets a draft procedure to derive acceptable acute operator exposure level (AAOEL). The document will be noted in January 2017.

2. Draft Guidance Document on Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414), (Doc. SANCO/3030/1999 Rev. 5) (for discussion only).

Discussion postponed.

3. Draft template for the data matching check (Doc SANTE/11449/2016) (to be noted)

The Commission presented the document revised according to the comments received from Member States.

The Committee took note of the revised template with an implementation date of 1st March 2017. Upon request of a Member State, it was decided that the Commission should also publish the template as a user-friendly spreadsheet.

Following sub-point added to original agenda:

4. Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (for discussion - changes of specification)

Point not discussed.

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

29 notifications have been received from Hungary, Lithuania and Sweden, concerning amendments of authorisations of products containing the active substance glyphosate.

The Committee took note of the notifications submitted by Hungary, Lithuania and Sweden.

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

Two notifications have been received. One of them is linked to questions about efficacy of the product and therefore outside the scope of Article 36(3). For the second notification, the Member State of origin is asked to provide a position.

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

Ethylene (Belgium)
Dimethoate (Belgium)
Chloropicrin (Belgium)
Cyazofamid (Belgium)
Fosetyl (Belgium)
Azadirachtin (Croatia)
Chlorpropham (Croatia)
1,3-Dichloropropene (Cyprus)
Zinc phosphide (Czech Republic)
Fenpyroximate (Czech Republic)
Spirotetramat (Czech Republic)
Spinosad (Denmark)
Propyzamide (Denmark)
Deltamethrin (Finland)
Lambda-cyhalothrin (Finland)
Lambda-Cyhalothrin (Germany)
Lime sulphur (calcium polysulphid) (Germany)
Acetamiprid (Germany)
Metobromuron (Germany)

Trifloxysulfuron (Greece)
Tricyclazole (Greece)
Pyrimethanil (Greece)
Iprodione (Greece)
Carboxin, Thiram (Greece)
Acibenzolar-S-methyl (benzothiadiazole) (Greece)
Boscalid (formerly nicobifen) (Greece)
Spirotetramat (Greece)
Chloropicrin (Hungary)
Chlorophacinone (Hungary)
Hexazinone (Hungary)
Beta-Cyfluthrin, Clothianidin (Hungary)
Fludioxonil, Metalaxyl-M, Thiamethoxam (Hungary)
Boscalid (formerly nicobifen), Pyraclostrobin (Ireland)
Benfluralin (Italy)
Laminarin (Italy)
Abamectin (Netherlands)
Sodium hypochlorite (the Netherlands)
Hydrolysed proteins (Portugal)
Zinc phosphide (Slovakia)
Azadirachtin (Slovakia)
(E,Z)-3,8-Tetradecadien-1-yl acetate, (E,Z,Z)-3,8,11-Tetradecatrien-1-yl acetate (Spain)
Giberellic acid (Spain)
Ethephon (Spain)
S-Abscisic acid (Spain)
Molinate (Spain)
Thiram (Spain)
Dichlorvos,(Spain)
Fluxapyroxad (Spain)
Tricyclazole (Spain)
Thidiazuron (Spain)
Spirotetromat (Sweden)
Thiacloprid (Sweden)
Thiophanate-methyl (Sweden)
Chlorantraniliprole (United Kingdom)
Cyantraniliprole (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Portugal, Slovakia, Spain, Sweden and 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.

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

- Endocrine Disruption (ED):
    - Outline paper under drafting, will be shared and discussed with Member States in next Pesticide Steering Network (PSN).
    - Call for nominations of ED expert advisory group was sent on 02/12/2016, nominations to be sent by 21/12/2016
    - Joint ECHA/EFSA Guidance Document (GD) (only covering hazard assessment) to be drafted by April-June 2017, followed by public consultation

- Next Pesticide Steering Network: will take place on 14-15/02/2017. Draft topics for discussion: ED outline paper, paper on improving efficiency peer review, update on classification (alignment of procedures and common template), update on list of endpoints database

- Update on Guidance Document development:
    - Residue definition GD: will be presented by EFSA in the January Standing Committee on Plants, Animals, Food and Feed (PAFF)
    - Dermal absorption GD: public and PSN consultation on draft GD foreseen to be launched by end December 2016. Deadline for finalisation GD: 31/05/2017

- Classification
    - Update on combined Draft Assessment Report/Harmonised Classification and Labelling (DAR/CLH) template: EFSA and ECHA are finalising the template on the basis of the comments received recently. Template will then be submitted to PAFF for note taking.
    - On going discussions between ECHA and EFSA on alignment of procedures, pre-RAC (Committee for Risk Assessment) discussions between EFSA and ECHA have been established.

- Update on flutianil and isoproturon apparent divergency cases. EFSA published on its website alongside the conclusions a paper clarifying the classification status:

  - flutianil:

    http://onlinelibrary.wiley.com/store/10.2903/j.efsa.2014.3805/asset/supinfo/efs23805-sup-0001-RAC_conclusions.pdf?v=1&s=5b91046081a014bde23c6aa2d8ddb631af83a40e

  - isoproturon:

    http://onlinelibrary.wiley.com/store/10.2903/j.efsa.2015.4206/asset/supinfo/efs24206-sup-0001-SupInfo.pdf?v=1&s=195900a12127229425c2de0f02c5eba3a02e1d18

After looking at the evidence available to RAC and the scientific explanations indicated in the RAC opinion, EFSA considers that the differences regarding the proposal in the EFSA Conclusion are justified by the additional evidence considered by RAC; consequently, EFSA refers to the RAC proposal for future assessments.

- EFSA requested Member States to follow legal provisions regarding applications and summary dossiers to be submitted to EFSA for publication, including sanitisation check. EFSA APDESK Unit is experiencing many problems with delays from different Member States. Furthermore, frequent requests for public access to documents are received for these documents.

- Article 4(7) and negligible exposure update:

  - On going assessments: flumioxazin, flupyrsulfuron-methyl, pymetrozine, isoxaflutole

  - Experience first application using herbicide protocol:

    - Huge amount of data received (up to 800 rows to be compared for some uses)
    - Protocol leaves flexibility for Member States so some apply it very strictly, whereas others take a broader approach
    - The applicant submitted all its authorised uses, without making a selection of which uses are considered essential
    - No clear drop down lists for e.g. weed spectrum have been foreseen in protocol templates, making selection and comparison of data very difficult
    - EFSA will launch a call for Members States experts in plant health to assist with the evaluation of these applications. Ad hoc teleconference will be organised when needed.

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

1. Follow up workshop Formulation laboratories

See agenda point A.13.03

2. Sustainable Use Directive (Directive 2009/128/EC)

Directorate F is now responsible for the Sustainable Use of Pesticides Dossier. Seven fact finding missions are planned to Member States in 2017. One single report on sustainable use covering the evolution of national action plans, the results of a survey to all Member States and the missions to 7 Member States, is planned in mid 2017.

3. Article 68 Enforcement Working group

Directorate F presented the work of the two recently established Working Groups, dealing with Plant Protection Products (PPP) formulation analysis and PPP enforcement. The WG on formulation analysis has undertaken to draw up guidance documents. It is planned to develop two guidance documents in 2017, focusing on defining the equipment/facilities required to conduct formulation analysis and the evaluation of analytical results. The Working Group on PPP enforcement has developed a template on reporting controls conducted under Article 68 of Regulation (EC) No 1107/2009. It is planned that Member States will use this template to report the results of controls for 2016 and future years. Completing this template will not require additional work from Member States and will greatly facilitate analysis of the results of controls to identify trends over time, emerging risks etc.

In addition, Directorate F outlined the results of recent audits on the authorisation of PPP. They found that there are significant delays in authorising PPPs and granting parallel trade permits in the majority of Member States. The root causes include the failure to use the mutual recognition system fully and the increasing complexity of evaluations. In particular, national requirements were identified as a barrier to mutual recognition. The audits to the United Kingdom and in particular Luxemburg, demonstrated that some Member States can comply with the deadlines of the Regulation.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

This point was not discussed. A post meeting action was set for Member States to provide details of any uses where they could not allocate European and Mediterranean Plant Protection Organisation (EPPO) codes.

2. Post Approvals Issues group (PAI)

The Commission informed the Committee that the PAI group met on the 29th and 30th November. The group discussed about the way forward on implementing the gained experience in the guidance document on renewal of product authorisations. An exchange amongst the experts took place regarding the remit of the work of PAI.

3. Sustainable plant protection experts group Dutch proposal

The Commission briefed on the recent meeting of 10 November 2016. The mandate was revised and will be uploaded on CIRCABC. The group will follow up implementation of the plan and for the matter concerning Integrated Pest Management (IPM) related to SUD will keep coordination with the experts group now chaired by colleagues of F3. A workshop will be held on 4 and 5 April with Member States to deepen the ideas identified for future amendment of Regulation (EC) No 1107/2009. It will focus also on identifying why current provisions are not working and examine the pros and cons of the identified ideas for change. Member States not participating in the expert group are also invited. Please send details on nominated experts by 13 January 2017.

4. DRAW Setac-Workshops

Postponed.

A.15 OECD

No news.

A.16 Bees:

1. Review of Neonicotinoids – state of play and next steps

All issues concerning this agenda point were already discussed under other points of the agenda.

2. Review of Fipronil – state of play and next steps

The approval of fipronil will expire on 30 September 2017 and the applicant no longer supports the active substance with further data submissions.

In order to save resources, the Commission decided not to insist on EFSA continuing the ongoing review any longer, as this review is not expected to have any regulatory effect.

The Commission thanked the RMS Austria for their support in the review process.

3. Commission Communication amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees

The Commission informed that it still intends to update this Communication but will include the update regarding test guidelines on bees in the general update of this

Communication. The Commission intends to have a first draft of this general update available for the meeting of the Standing Committee in January 2017.

4. Amendment 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.

Comments was received from one Member State. Based on that comment an updated version of the draft proposal was prepared. Member States were asked to send in their comments on this revised proposal by 13 January 2017.

5. Draft Commission Notice concerning time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees).

Changes to the revised draft Commission notice were explained. Member States were asked to send in their comments on this revised proposal by 13 January 2017.

6. AOB

Nothing to report.

A.17 Court cases:

- Case T-746/15 - Biofa AG v European Commission - Order of the General Court of 9/11/2016 – Action for the annulement of Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate dismissed.
- Cases C-442/14 and C-673/13

The Commission provided a summary of the 2 rulings dated 23/11/2016.

In particular as the ruling in case C-442/14 concerns the studies submitted in support of an application for authorisation, the Commission suggested to organise a meeting to discuss the consequences of this ruling in relation to the studies submitted to Member States, the Commission and EFSA in the frame of approval of substances and authorisation of products. Some Member States indicated that the status of the detailed composition of substances and products was also a very important issue. Other Member States indicated that it was important that Member States apply the ruling in the same way. Member States were requested to indicate if they had an interest in participating in a meeting by 13 January 2017. EFSA expressed its interest in participating in the discussion.

A.18 Endocrine disruptors.

Following the meeting of the Standing Committee on 18 November 2016 and the recent comments received from some Member States, the Commission provided

detailed explanations on the reasons to propose an amendment to the already foreseen derogation on negligible exposure under Regulation (EC) No 1107/2009.

It was anticipated that the Member States will soon receive the invitation to a dedicated Standing Committee meeting to discuss the draft proposal before Christmas, which will be held back to back to a meeting regarding the criteria proposed under Regulation (EU) No 528/2012.

One Member State asked whether, with the amendment to the derogation, cases could be expected where the MRLs would be set at levels higher than the default value. Another Member State asked whether import tolerances could be set at values higher than the default value. One Member State thanked for the clarifications and mentioned that they would not support the amendment to the derogation because of the uncertainties linked to the definition of negligible risk. For this reason, this Member State asked to include a review clause in the proposal.

One Member State asked clarification on the content of the guidance which is being developed by EFSA and ECHA. One Member State asked whether an updated draft proposal will be submitted before the next meeting in December. Another Member State asked whether the legal arguments on the mandate to amend the derogation could be made available in writing.

A.19 Update concerning Minor Uses.

Proposal for long term funding of the EUMUCF (EU Minor uses Coordination Facility)

The funding of the Coordination Facility has been guaranteed by the European Commission, France, Germany and the Netherlands for the first three years (from April 2015 until April 2018). A priority for the Coordination Facility will be ensuring longer term financial sustainability by encouraging financial commitments from all Member States. Preferably commitment for contributions should be provided for a longer period.

The preferred option is voluntary assessed contributions from all EU Member States according to their population. Contributions by industry, and third parties, shall be dedicated for specific minor use projects. This will avoid any conflict of interest in the running of the Coordination Facility.

It must be emphasized that with the indicated contributions the continuity of the Coordination Facility can be guaranteed, but that Member States are invited for further voluntary contribution.

Stakeholder Advisory Forum/Annual Meeting 25 January 2017

The first Stakeholder Advisory Forum will take place at the Square Meeting Centre in Brussels on 25 January 2017. It will be the annual meeting of stakeholders at which the work of the Coordination Facility and wider aspects of the Minor Uses Programme will be reported. This will also be an opportunity to discuss the long term

funding strategy of the EU Minor Uses Programme. A detailed programme will be available in due course.

Global Minor Use Summit 1-4 October 2017, Montreal, Canada

The GMUS-3 will put greater emphasis on policy considerations that can help specialty crop growers around the world to obtain access to safe and modern tools to produce their crops, and to promote trade among nations.

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009

Postponed.

2. Questions and answers

Not discussed.

A.21 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications.

An updated status of harmonised classifications was made available via CIRCABC.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States

Pursuant to Article 36(2) of Regulation (EC) No 1272/2008 (CLP Regulation), active substances should normally be subject to harmonised classification. The Commission is planning to draft an amendment to Implementing Regulation (EU) No 844/2012 requiring that rapporteur Member States submit a harmonised classification proposal to ECHA in the frame of the renewal procedure. This provision would concern substances which do not have a harmonised classification today but could also concern the substances which benefit from a harmonised classification under CLP, as this would allow the possibility to update the existing harmonised classification. The amendment would include transitional provisions. The Commission plans to present a draft at the meeting of January 2017 or March 2017.

Some Member States asked which end-points would be covered and whether the text would cover only the end points linked to cut off criteria. They underlined that the choice of end points would have an important impact on the workload. EFSA noted that in the choice of end-points, one could consider end-points which could help the decision-making for low-risk substances.

A.22 Glyphosate:

- State of the dossier:

EFSA and the Commission updated the Committee on the ongoing assessments. The Commission thanked Member States who had provided information on the implementation of the restriction on the use of POE-tallowamine as a co-formulant in glyphosate-based plant protection products. Following a request from the Danish Parliament, the Commission asked Member State to send information on the implementation of the provisions on the use in specific areas referred to in Article 12(a) of Directive 2009/128/EC and on the compliance of pre-harvest uses with good agricultural practices by 13 January 2017.

A.23 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

The Commission prepared a table containing information on draft measures recently voted at the Pesticide Residues section of the Committee that may have an impact on authorisations. The table is available on CIRCABC.

A.24 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany).

The Commission reiterates that following the most recent version of the uniform principles for decision-making, there is no difference anymore between organic and anorganic active substances, when it comes to relevant metabolites in groundwater. At the same time, it is also recalled that the scope of the uniform principles was not intentionally changed.

A.25 Proposal on amendment of criteria for the approval of low risk active substances (SANTE/12376/2015).

The Commission briefly introduced the new version of the proposal which has been subject to intense discussion through the Commission interservice consultation. Some elements of the initial draft were removed to be put in a Guidance Document instead. The feedback mechanism on the proposal has been recently closed; 11 comments were received. Most Member States welcome the proposal and several ask for detail on interpretation of multiple resistance in micro-organisms. Two Member States commented with respect to classification for aquatic environment asking for amendment on the acute and chronic toxicity category 2. One Member State referred to the need to correct the issue of potential multiple resistance in baculovirus. The same Member State underlined the importance of finalising in parallel the guidance document for the application of criteria and where to keep the considerations deriving from risk assessment.

The Commission asked all Member States to comment by 13 January 2016 in order to finalise the proposal for vote as soon as possible.

A.26 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 gave a brief update on the REFIT evaluation for the two pieces of legislation.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the 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 Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/12012/2015 Rev. 5).

The European Parliament voted a resolution against the proposal to renew the approval of bentazone on 23 November 2016. This resolution was presented to the Member States.

Vote postponed

B.02 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 sulfuryl fluoride (Draft Review Report SANCO/10567/2010 Rev. 1).

The Commission presented the draft revised Review Report and the draft regulation restricting the conditions of approval of sulfuryl fluoride, as needed after the evaluation of the confirmatory data.

No comments were raised.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance thiabendazole 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 doc. SANTE/10315/2015 Rev. 2).

The draft Regulation and Renewal Report were presented for vote by the Commission.

One Member State voted against as there are data gaps in the section on residues regarding the representativeness of the batches used in the tox and ecotox studies. One Member State abstained as they requested to postpone the vote due to the late availability of the Review Report.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance linuron, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANTE/10944/2016 Rev. 1)

The draft Regulation and Renewal Report were presented for vote by the Commission.

One Member State commented on whether the grace periods allowed for in the withdrawal were too long and should be shortened, given the concerns identified. The Commission took note of this comment.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 686/2012 as regards the co-rapporteur Member State for the active substance metaldehyde.

The Commission presented a draft Regulation changing the co-rapporteur for metaldehyde to Austria for vote.

No comments were raised.

Vote taken: Favourable opinion.

B.06 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 several active substances listed in Part B in Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).

The draft Regulation on extending the approval periods for the AIR IV renewal program was presented for vote. One Member State abstained as some of the substances in the package might be subject to non-approval once the risk assessment is finalised.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation modifying the conditions of approval of

the active substance abamectin 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 Addendum to the Review Report doc. SANTE/11617/2016)

The Commission presented the draft addendum to the review report and the draft Regulation to extend the use of abamectin as nematicide. No comment was raised. The voting was postponed because the inter-service consultation was not finalised.

Vote postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance oxathiapiprolin, 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 doc. SANTE/11169/2016 Rev. 1)

The draft document was presented for vote. Two Member States voted against for different reasons: one for risk of metabolite leaching into groundwater and one disagreed with addressing technical specification via request for confirmatory information.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance iodosulfuron-methyl-sodium (approved as iodosulfuron) 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 doc. SANTE/11167/2016 Rev. 2)

The draft document was presented for vote and was unanimously supported.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Satureja montana* L. essential oil 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/11411/2016 Rev. 0)

The draft Regulation was presented for vote. One Member State voted against, because it felt the substance was widely available as a foodstuff. One Member State abstained because it has the position that foodstuffs shall be considered as a basic substance.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Origanum vulgare* L. essential oil 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/11413/2016 Rev. 0)

The draft Regulation was presented for vote. One Member State voted against, because it felt the substance was widely available as a foodstuff. One Member State abstained because it has the position that foodstuffs shall be considered as a basic substance.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation confirming the conditions of approval of the active substance acrinathrin, as set out in Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11357/2011 Rev. 6)

As the interservice consultation was not yet finalised, the vote was postponed. There seems however, a wide consensus on the nature of the proposal. One Member State already informed that it may not be in a position to support the draft as a matter of principle.

Vote postponed

M.01 New Scientific publications and information submitted by stakeholders.

Documents submitted by the European Crop Protection Association, Pesticide Action Network, Greenpeace and the European beekeeping association ahead of the meeting were made available through CIRCABC.

M.02 AOB

1. Antibiotics used in plant protection

The Commission reminded Member States to submit their annual report about use of antibiotics for purpose of plant protection, where such uses have been authorised.

2. Draft Guidance Document on residues definition (Denmark)

Denmark asks whether there is a date foreseen for the note taking of the new EFSA guidance document on the residue definition. The Commission intends to first enter a discussion with experts from Member States. As a first step, EFSA will introduce the document with a presentation during the next meeting of the Standing Committee.

3. Workshop concerning data requirements inhalation toxicity (Denmark)

Denmark offers hosting a workshop concerning data requirements inhalation toxicity. Member States were asked to comment on the proposal.

4. Acetamiprid (Germany)

Germany reminded of the note taking of the toxicologiocal reference values for acetamiprid, which also will have some implications for MRLs.

M.03 Date of next meeting.

The date of the next regular meeting is 23/24 January 2017. An extraordinary meeting concerning endocrine disruptors might be organised beforehand.