



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 09 OCTOBER 2014 - 10 OCTOBER 2014  
(Section Phytopharmaceuticals - Plant Protection Products - Legislation)**

*CIRCABC Link:* <https://circabc.europa.eu/w/browse/6d042fd6-4193-4d89-a3e1-4cbab5e9b468>

**A.01 Summary Report of previous meeting.**

The summary report has been uploaded on the EU Health and Food Safety website:

[http://ec.europa.eu/food/plant/standing\\_committees/sc\\_phytopharmaceuticals/index\\_en.htm](http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm)

**A.02 Stage 4 of the review programme under Directive 91/414 – “Green Track”:**

1. Giberellic acid (amended review report to be noted)

The Commission amended the document to include the correct values of the Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL).

The Committee took note of the amended review report.

**A.03 New active substances:**

1. New admissible dossiers

There are no updates as regards this agenda point.

2. EFSA conclusions

There are no updates as regards this agenda point.

#### **A.04 Renewal of approval:**

1. Draft Working Document Renewal Programme (Doc. SANCO 11284/2012 Rev.13) (For information)

A new revision was uploaded on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). Following a comment made by a Member State, the Commission clarified that for active substances for which no application was submitted no further action will be taken by the Commission. At the expiry date of approval, authorisations for Plant Protection Products (PPPs) should be withdrawn according to Regulation (EC) No 1107/2009 (Member States may apply the provisions of Article 46 on the grace period).

2. Applications for renewal of approval of active substances submitted under article 14 of Regulation (EU) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (SANCO/ 10148/2014 Rev. 3) (For information)

The Commission reminded that the decisions on admissibility should also be forwarded to the European Food Safety Authority (EFSA).

3. EFSA conclusions

*i) Amitrole*

The Commission outlined the main issues reported in the relevant EFSA conclusions. A Member State believes there is no safe use for operators and would therefore support a non-approval proposal.

*ii) Pyridate*

The Commission outlined the main issues reported in the relevant EFSA conclusions.

*iii) Flumioxazin*

The Commission outlined the main issues reported in the relevant EFSA conclusions. The draft Review Report will be made available via e-mail before 5 December 2014.

4. State of play Annex 1 Renewal Project 2nd phase (AIR 2)

The Commission is planning to prepare a proposal as regards the allocation of the Rapporteur Member State (RMS) and Co-RMS for active substances with an expiry date from 2019 onwards.

The next agenda point covers the first two active substances under the second list of substances scheduled for review and renewal (AIR2). The Commission clarified that AIR2 substances are only affected by provisions laid down in Regulation (EC) No 1107/2009 and that the old data requirements still apply.

Following a comment made by a Member State, the Commission confirmed that candidates for substitution will also be considered under this framework.

## 5. Draft Review Reports for discussion

### i) Lambda-cyhalothrin

The Commission prepared a draft Review Report which was uploaded on CIRCABC. The main issues were outlined during the current meeting.

Member States were asked to submit comments by the end of October 2014.

### ii) Acibenzolar-S-methyl

The Commission prepared a draft Review Report which was uploaded on CIRCABC. The main issues were outlined during the current meeting.

Member States were asked to submit comments by the end of October 2014.

## **A.05 Confirmatory data:**

### 1. Flurochloridone

The conclusions of the original risk assessment are not substantially modified by the evaluation of the submitted confirmatory data. Following input from the Commission, the notifier made a request at ISO level to amend the name of the active substance. However, due to the timelines foreseen for the purpose, such amendment will only be reflected at a later stage.

The draft review report will be put for note taking at the next Committee.

### 2. Metosulam

A Member State sent written comments expressing concerns regarding the possible leaching of a metabolite into groundwater and the genotoxic potential of a relevant impurity.

Member States were asked to submit comments by the end of October 2014.

### 3. Clethodim

The Commission questioned as to whether the soil degradation of a metabolite should be further investigated.

Member States were asked to submit comments by the end of October 2014.

### 4. Triclopyr

The Commission prepared a draft Review Report in view of restricting the approval to uses with a maximum of one application per year on pasture and amenity grassland at a maximum rate of 480 g/ha.

Some Member States reacted by stating that the current proposal would severely restrict the possibility for localised applications on other crops and ask the Commission to consider the restriction to rate of application.

5. Dimethoate (revised report to be noted)

On the basis of the information available, the Committee agrees that the risk to birds, mammals and non-target arthropods is acceptable and that the metabolites potentially present in representative crops are not relevant. Member States should however pay particular attention to the risk to birds, mammals and non-target arthropods when granting authorisations.

Five Member States believe that the risk to birds and mammals is not adequately addressed by the current proposal and expressed reservations on the note taking.

*The Committee took note of the revised review report.*

6. Sintofen (revised report to be noted)

The Committee agrees that, on the basis of the current outcome, the specification of the technical material, as commercially manufactured, is supported by analytical data (including relevance of impurities and equivalence with the material used in toxicity dossiers) and that the metabolites involved in the remaining confirmatory requests are not relevant.

*The Committee took note of the revised review report.*

7. Tall oil pitch

The Commission intends to prepare a withdrawal proposal as the data was not submitted within the deadline set in Regulation (EU) No 637/2012.

8. Tall oil crude

The RMS will assess the data submitted by the applicant.

9. Pyridaben

The Commission will prepare a draft review report for the next Standing Committee.

10. Paclobutrazol (revised report to be noted)

The point was deleted from the agenda.

11. Bensulfuron (revised report to be noted)

It seemed generally agreeable that the route and rate of degradation is duly clarified and that the risk to consumers from metabolites is covered by the assessment that preceded the approval of the substance. Nonetheless, one Member State requested further explanations which will be provided by the RMS.

*The note taking was postponed.*

12. Paclbutrazol (revised report to be noted)

The Committee agrees on the finalisation of the reference specification and considers that the analytical methods in soil and surface water for a certain metabolite are adequate.

*The Committee took note of the revised review report.*

13. Hexythiazox (revised report to be noted)

The Committee agrees that the toxicity of a certain metabolite is well addressed. Moreover, an unacceptable risk to bee brood is deemed to be unlikely.

*The Committee took note of the revised review report.*

14. Hymexazol (revised report to be noted)

The Commission prepared a revised review report outlining that the risk for granivorous birds and mammals has been addressed and that further data was submitted clarifying the nature of residues in root crops.

A Member State asked to postpone the note taking, since the document was only recently uploaded on CIRCABC.

*The note-taking was postponed.*

16. Pirimicarb (revised report to be noted)

The applicant submitted further studies to confirm the long term risk assessment for birds and for potential groundwater contamination.

The Committee agrees that, on the basis of the current outcome, the conclusions of the original risk assessment are not substantially modified by the evaluation of the submitted confirmatory data.

*The Committee took note of the revised review report.*

17. SCLPs (revised report to be noted)

The review report was modified to include two new blends of pheromones in Appendix III.

A Member State asked to postpone the note taking, since the document was only recently uploaded on CIRCABC.

*The note taking was postponed.*

18. 8-Hydroxyquinoline

There are no updates as regards this agenda point.

19. Etridiazole

There are no updates as regards this agenda point.

20. AOB

There are no updates as regards this agenda point.

**A.06 Amendment of the conditions of approval:**

- Fenazaquin

The active substance was approved by Directive 2011/39/EU. The approval provides for the active substance to be used as acaricide only on ornamentals in greenhouses. The notifier submitted an application to amend the current conditions of approval of the active substance fenazaquin in order to lift the restrictions in place. The RMS assessed the request and EFSA delivered its conclusions in 2013.

Considering the EFSA conclusions, the Commission believes it is not appropriate to modify the current conditions of approval. EFSA identified data gaps for the consumer risk assessment and potential risk to aquatic organisms in all the evaluated uses. A draft Regulation proposing to maintain the conditions for approval was prepared to provide clarification on the matter.

Some Member States object to the proposal as they believe the risk to aquatic organisms could be dealt with at Member State level and that the current restriction should be lifted.

Member States are asked to submit comments by the end of October 2014.

**A.07 Basic substances**

1. Pilot projects: state of play

The application made for talc was rejected mainly due to lack of information with respect to risk assessment on operator exposure.

2. New dossiers received

A new dossier was submitted for diammonium phosphate.

3. EFSA Technical Reports

The following Technical Reports were recently published:

- *Artemisia vulgaris L.*
- Vinegar
- Lecithins

#### 4. Draft Review Reports for discussion

- *Salix alba*

The Commission outlined the main issues identified by EFSA. The draft Review Report will be made available via e-mail in November 2014.

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

1. Guidance Document on the authorisation of plant protection products for seed treatment (SANCO/10553/2012 Rev. 1) (for information)

Following a request for clarification from a Member State, the Commission clarified the status of seeds improper for cultivation or dead seeds are used as a support for a plant protection product also called "dummy pills". These are to be considered PPP, as a granular formulation. In the case of "phytodrip", this can cover different technologies. Member States will need to assess on case by case whether a specific application would fall under the scope of seed treatment.

2. Draft Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation) (SANCO/2012/11251 Rev. 2.1) (for discussion only)

The new revision of the guidance document is still under preparation.

3. Draft Guidance Document on comparative assessment (SANCO/11507/2013 Rev. 11) (to be noted)

The draft guidance document was thoroughly discussed in the past meetings. The application date has been extended by two months.

A Member States expressed reservations in making reference to Article 29 of Regulation (EC) No 1107/2009. Two other Member States are of the same view, but can still support the current proposal.

*The Committee took note of the guidance document together with the reservations expressed by a Member State.*

4. Draft Guidance Document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 Rev. 2) (for discussion only)

The new revision of the guidance document is still under preparation.

5. Draft Guidance Document on the Assessment of Applications for which Article 34 of Regulation (EC) No 1107/2009 applies (SANCO/11371/2014) (for discussion only)

The new revision of the guidance document is still under preparation.

6. Draft Guidance Document on Decision Making under points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009 (SANCO/12093/2014) (for information)

The Commission prepared a first draft, which was uploaded on CIRCABC. The current version reflects the outcomes of the expert meetings and comments sent by Member States.

During the current meeting, some discussions were held upon specific issues. EFSA suggested that the Questions & Answers document on interpretation issues should also cover this topic.

7. Draft Focus Report "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" (SANCO/13144/2010, version 2, 16 May 2014) (to be noted)

The Commission outlined the main issues related to the guidance document. The implementation date applies to applications submitted as of 1 May 2015.

A Member State asked the Commission to only take note of the document once the EFSA guidance document on aged sorption is finalised. The Commission believes it is not appropriate to postpone the note taking as it will unduly delay the implementation of this report which is awaited by all involved parties.

*The Committee took note of the guidance document together with the reservations expressed by a Member State.*

8. Draft Guidance Document on renewal, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009 (SANCO/2010/13170 Rev. 9) (for discussion only)

The new revision of the guidance document is still under preparation.

9. Draft Guidance Document for the Assessment of the Equivalence of Technical Grade Active Ingredients for Identical Microbial Strains or Isolates approved under Regulation (EC) No 1107/2009 (SANCO/12823/2012 Rev. 2) (for discussion only)

A new revision was recently uploaded on CIRCABC.

Member States were asked to submit comments by 14 November 2014.

(Additional points to the agenda):



10. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (implementing document SANCO/12117/2014) (to be noted)

Some Member States asked to postpone the note taking of the guidance document because they need more time to study the matter.

Member States were asked to submit comments by the end of October 2014.

11. EFSA Guidance Document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (implementing document SANCO/12184/2014) (to be noted)

Some Member States asked to postpone the note taking of the guidance document because they need more time to study the matter.

Member States were asked to submit comments by the end of October 2014.

#### **A.09 Notifications under Article 53 of Regulation (EC) No 1107/2009:**

##### 1. Letter from Italy on mutual recognition

Italy sent a letter expressing concerns regarding the different approaches taken by Member States when implementing Article 53 of Regulation (EC) No 1107/2009. Italy urges the Commission to review Article 53 to make sure that there are no unbalances in terms of mutual recognition.

The Commission understands the concerns, but recalls that Member States are responsible for granting emergency notifications and for preventing any misuse of the legal provisions.

##### 2. Notifications under Article 53 (To be noted)

Ethephon (Belgium)  
Ethylene (Belgium)  
Potassium hydrogen carbonate (Germany)  
Pyrethrins (Germany)  
Spinosad (Germany)  
Zinc phosphide (Germany)  
Azadirachtin (Denmark)  
Captan (Denmark)  
Dazomet (Denmark)  
Pyrethrins (Denmark)  
(E,Z)-7,9-Dodecadien-1-yl acetate (Spain)  
1,3-dichloropropene (Spain)  
1,3-dichloropropene/Chloropicrin (Spain)

Abamectin (Spain)  
Buprofezin (Spain)  
Chlorpyrifos (Spain)  
Chlorpyrifos/Cypermethrin (Spain)  
Deltamethrin (Spain)  
Diclorvos (Spain)  
Dimethoate (Spain)  
Diquat (Spain)  
Dodine (Spain)  
Emamectin Benzoate (Spain)  
Ethephon (Spain)  
Ethoxyquin (Spain)  
Ethylene (Spain)  
Flonicamide (Spain)  
Fludioxonil (Spain)  
Fosetyl-aluminium (Spain)  
Lambda-cyhalothrin (Spain)  
Linuron (Spain)  
Methomyl (Spain)  
Pymetrozine (Spain)  
Pyraclostrobin (Spain)  
Pyrethrins (Spain)  
Quinclorac (Spain)  
Saponins (Spain)  
Spinetoram (Spain)  
Spinosad (Spain)  
Spirodiclofen (Spain)  
Spiromesifen (Spain)  
Spirotetramat (Spain)  
Spitotetramat/Chlorpyrifos-methyl (Spain)  
Spodoptera exigua nuclear polyhedrosis virus (Spain)  
Tau-fluvalinate (Spain)  
Thiabendazole (Spain)  
Thiacloprid (Spain)  
Thiophanate-methyl (Spain)  
Trifloxystrobin (Spain)  
Difenacoum (Finland)  
1,3-dichloropropene (Greece)  
Abamectin (Greece)  
Ethephon (Greece)  
Iprodione (Greece)  
Azadirachtin (Croatia)  
Chlorpropham (Croatia)  
Difenacoum (Croatia)  
Imazalil (Croatia)  
Imazalil/2-phenylphenol (Croatia)  
Prochloraz (Croatia)  
Abamectin (Italy)  
Acibenzolar-S-methyl (Italy)  
Aclonifen (Italy)

Copper compounds (Italy)  
Deltamethrin (Italy)  
Fludioxonil (Italy)  
Isoxaflutole (Italy)  
Pretilachlor (Italy)  
Propanil (Italy)  
Prothioconazole/Tebuconazole (Italy)  
Quinclorac (Italy)  
Spinetoram (Italy)  
Sulfur (Italy)  
Tricyclazole (Italy)  
Spinosad (Luxembourg)  
Sodium Silver Thiosulphate (Latvia)  
1,3-dichloropropene (Malta)  
Chloropicrin (Malta)  
Clothianidin (Romania)  
Imidacloprid (Romania)  
Abamectin (Sweden)  
Boscalid/Kresoxim-methyl (Sweden)  
Spirotetramat (Sweden)  
Dimethoate (Slovenia)  
Aluminium phosphide (Slovakia)  
Fenoxycarb (Slovakia)  
Fludioxonil (Slovakia)  
Spirodiclofen (Slovakia)  
Tefluthrin (Slovakia)  
Zinc phosphide (Slovakia)  
Acetamiprid (the United Kingdom)  
Chloropicrin (the United Kingdom)

The Committee took note of the notifications submitted by Belgium, Germany, Denmark, Spain, Finland, Greece, Croatia, Italy, Luxembourg, Latvia, Malta, Romania, Sweden, Slovenia, Slovakia 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.

**A.10 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (To be noted).**

Belgium notified three PPPs containing thiabendazole for which they withdrew or amended the authorisation in view of the exceedence of the Acute Reference Dose (ARfD) established in the framework of the renewal of the active substance.

*The Committee took note of the notifications.*

**A.11 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (To be noted).**

Belgium notified the refusal of a PPP containing flumioxazin from the Netherlands. Spain resubmitted the notifications distributed at the Standing Committee in March 2014.

*The Committee took note of the notifications.*

**A.12 Notifications under Article 56 of Regulation (EC) No 1107/2009 (To be noted).**

There are no notifications under Article 56 of Regulation (EC) No 1107/2009.

**A.13 Sustainable Use Directive (Directive 2009/128/EC).**

- State of play

The Commission outlined the main issues discussed during the experts working group on the sustainable use of pesticides, which was held on 22 and 23 September 2014. Information on current status of ongoing projects under the Better Training for Safer Food frame was provided.

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

A call for proposals for grants planned under the "EFSA 2014 Work Programme for Grants and Procurement in science" was made on endocrine disruptors to review the available information.

The EFSA extranet will migrate to a new platform. An interruption of the service during a week is foreseen.

EFSA informed Member States that only those experts who contributed in the past will be invited to the next Peer Review meetings.

## **A.15 Report from working groups:**

### 1. Authorisation database

The Commission gave a short update on the state of play.

### 2. Post Approval Issues

The United Kingdom has prepared a preliminary draft of a Guidance Document on the preparation of procedural guidance documents.

A new revision of the guidance document on data protection is under preparation.

It is planned to organise a workshop to evaluate the zonal system and mutual recognition in June 2015 in Ireland.

### 3. Interzonal Steering Committee

There are no updates as regards this agenda point.

### 4. Feedback BfR / COM EU Conference of Safe Use of PPP

The Commission outlined main issues discussed at the conference held in June 2014.

### 5. Negligible exposure

This agenda point was discussed under Pt. A 08.06.

### 6. OECD

#### *i) Survey on product chemistry requirements*

The questionnaire was circulated among Member States and the compiled comments were submitted to the Organisation for Economic Co-operation and Development (OECD) by the deadline of 1 October 2014.

#### *ii) GHSTS*

Member States are invited to send comments on the questionnaire, which was prepared at the first expert group.

#### *iii) Survey risk indicators*

There are no updates as regards this agenda point.

#### *iv) Workshop non-professional uses*

There are no updates as regards this agenda point.

v) Upcoming meetings

The Commission informed of the risk reduction and registration steering group, which is scheduled in mid-December 2014 in Paris.

**A.16 Bees**

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

There are no updates as regards this agenda point.

2. EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (SANCO/10606/2014) state of play

EFSA will check the quality of the BEEHAVE model and see whether it can be included in the guidance document. EFSA cannot commit on a deadline at this stage.

3. International symposium on the hazard of pesticides to bees

The Commission outlined the main issues discussed at the symposium, which took place mid-September 2014 in Ghent (Belgium). The abstracts of the presentations are uploaded on CIRCABC.

4. AOB

Finland informed the Committee on their interim report: "Impact of use of neonicotinoid insecticides on honey bees in the cultivation on spring oilseed crops in Finland" and asked to establish a workshop to address the issue.

**A.17 Court cases.**

There are no updates as regards this agenda point.

**A.18 Endocrine disruptors – state of play.**

A public consultation to gather data on the impact assessment for the criteria has been published on 26 September 2014 on the Commission's website and is open until 16th January 2015. The outcome of the call will feed into the on-going impact assessment for which a roadmap has been published in June 2014.

An administrative arrangement will be signed soon between the Directorate General for Health and Consumers (DG SANCO) and the Joint Research Centre (JRC) to develop a methodology to screen a set of substances against the various options for the criteria. The methodology will then be applied to the set of substances by a contractor in the course of 2015. In the first half of 2015, further studies will be launched to assess the impacts of the options for the criteria on health, environment,

agriculture, trade and socio-economy. The completion of this comprehensive impact assessment is expected by end of 2016.

Bilateral discussions are on-going between the Commission and EFSA on how to report issues regarding endocrine disruption in the conclusions and on how to interpret the second interim criterion.

#### **A.19 Minor Uses – state of play.**

It is envisaged that the Financial Decision will be adopted by October 2014 and published before the end of 2014. If an acceptable proposal by an interested party will be submitted by the end of November 2014, then the technical secretariat may be established in the first half of 2015.

The Netherlands, France and Germany urged the Commission to proceed as soon as possible and invited other Member States to provide a contribution for the 2016 financial input. The Commission re-iterated that in kind contributions should also be possible.

#### **A.20 Interpretation issues:**

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

###### *i Fertiliser products containing phosphonates*

There are no updates as regards this agenda point.

###### *ii BlocCade*

This is a wound healing preparation through the generation of a physical barrier. It does not contain active substances, and only a very low level of an essential oil as fragrance. In line with similar cases, this is not considered as a plant protection product.

##### 2. Questions and answers

A new revision of the document was prepared and uploaded on the Commission's website.

#### **A.21 Status of harmonised classifications under Regulation (EC) No 1272/2008.**

##### 1. Status of harmonised classifications under Regulation (EC) No 1272/2008

The Commission updated the table reporting requests for classification which have been submitted to European Chemicals Agency (ECHA). The document was uploaded on CIRCABC.

## 2. 'To be classified' - Role of the Member States

One Member State asked some clarification on the role of MS' competent authorities for the classification of the plant protection products. The Commission will clarify in the *Questions and Answers* document that the classification of the product is in the authorisation and therefore the competent authority may impose a classification different from the one proposed by the applicant.

The Commission confirmed that for substances, it is preferable that a harmonised classification is decided under Regulation (EC) No 1272/2008 or an opinion of the Risk Assessment Committee of ECHA is published before the active substance is approved or renewed. EFSA indicated that they state in the conclusions how the substance should be classified, according to their evaluation.

The Commission is planning to clarify in the *Questions and Answers* document the terms "*active substances which are classified*" and "*active substances which have to be classified*". DG SANCO considers that the terms "*active substances which are classified*" designate substances for which a harmonised classification was adopted under Regulation (EC) No 1272/2008.

### **A.22 Measures taken on products containing metam-sodium or dazomet in NL and notified under Article 71 of Regulation (EC) No 1107/2009 (Follow-up)**

The Commission does not agree that this notification would qualify as a notification under Article 71 for formal reasons. However, the Commission does not contest the decision taken by the Netherlands in principle, as it is in line with the precautionary principle.

### **A.23 Glyphosate:**

#### 1. State of the dossier

The Commission reported on the status of the evaluation as regards the possible renewal of the approval of the active substance. A large number of comments were received during the public consultation on the Draft Assessment Report, many of which are not substance-specific but of a general nature. These comments should be addressed in a suitable forum. The Commission considered the Advisory Group on the Food Chain and Animal and Plant Health as one possible option.

#### 2. Court case T 545-2011

There are no updates as regards this agenda point.

### **A.24 Chlorpyrifos - state of the dossier.**

After the finalisation of the EFSA Conclusion on chlorpyrifos and following an initial discussion in the PAFF Committee in July, the Commission consulted the Member



States concerning the possible amendment of the toxicological reference values(i) for chlorpyrifos, with a view to prioritising the review of the current EU MRLs for the substance.

The Commission seeks agreement of the PAFF Committee in order to formally endorse the new toxicological values and to proceed with prioritising the review of the current EU consumers' exposure and MRLs definition.

Several Member States expressed their agreement with this approach.

In view of the concerns highlighted by EFSA in the conclusions, in particular as regards the consumer and operator exposure in some scenarios, the Commission proposes to amend the conditions of approval and restrict the use of chlorpyrifos to wine grapes at the maximum rate of application of 245 g/ha per year. An addendum to the review report was uploaded on CIRCABC. A draft proposal will be circulated in the coming days.

According to the Rapporteur Member State (RMS) further uses are considered safe. Several Member States believe the current proposal is too strict and that the risk could be mitigated at national level. They are also concerned about the absence of viable agricultural alternatives. Some Member State expressed support for the current proposal as being in line with the outcome of EFSA conclusions.

The Commission urgently asks all Member States to send their position concerning the draft Addendum to the Review Report by the end of October 2014 at the latest.

(i) ADI and AOEL: 0.001 mg/kg bw per day, ARfD: 0.005 mg/kg bw.

#### **A.25 EFSA Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid.**

EFSA is investigating whether the new data submitted by the notifiers are relevant.

#### **A.26 Trade in illegal pesticides:**

1. Presentation of OLAF (European Anti-Fraud Office) on the fight against trade in illegal pesticides

OLAF made a presentation.

Member States were asked to submit comments by the end of October 2014.

2. On-going SANCO Study on trade in illegal and counterfeit pesticides

The Commission presented the current status of the work done by the contractor so far.

Member States were reminded to fill in the survey.

**A.27 Uniform principles – Amendment to the Regulation EU No 546/2011 to align to the Bee guidelines.**

The Commission will initiate the procedure to amend Regulation (EU) No 546/2011 to align the uniform principles with the relevant bee guidelines.

**A.28 Data requirements and acceptance of waivers/implementation of SANCO/10181/2013 Rev. 2.1**

The Commission reminded Member States of the statement according to the SANCO document (SANCO/10181/2013 Rev. 2.1, 13 May 2013): “In some cases, agreed test methods or guidance documents are not yet available for particular data requirements. In these cases, waiving of these particular data requirement points is considered acceptable as long as no test methods or guidance documents are published in the form of an update of the Commission Communications 2013/C 95/01 and 2013/C 95/02. Applicants should follow on a routine basis the current developments, e.g. activities of the European Food Safety Authority for guidance documents and in particular publications in the Official Journal.

**A.29 TTIP - update on pesticides.**

The Commission reminded Member States to submit their position concerning Global Joint Reviews by e-mail within the deadline set for 17 October 2014.

**A.30 Acequinocyl (amended review report to be noted)**

(Additional point to the agenda)

The Commission amended the list of uses supported by available data in the review report. It was agreed to postpone the note taking.

**A.31 Imidacloprid**

(Additional point to the agenda)

EFSA recently published its conclusions on the confirmatory data submitted for the active substance and its conclusions on the risk assessment for aquatic organisms.

**A.32 Carbendazim – expiry of approval**

(Additional point to the agenda)

The Commission refers to carbendazim for which Member States have to withdraw authorisations as from 1 December 2014. For this substance, the provisions laid down in Article 46 of Regulation (EC) No 1107/2009 ("Grace period") apply.

In consistency with previous similar cases, the period of grace should be as short as possible and, in any case, not exceed 6 months as from 1 December 2014, for the sale and distribution, followed by an additional maximum of 1 year for the disposal, storage and use of existing stocks of the products concerned.

*The Committee took note of the above statement.*

**A.33 Follow-up workshop "Harmonisation in toxicology" (information from Austria)**

(Additional point to the agenda)

Austria informed the Committee of the workshop scheduled in June 2015. The announcement was uploaded on CIRCABC.

Member States are invited to send their feedback on participation by mid November 2014.

**A.34 Fertilizers containing nitrophenolates**

(Additional point to the agenda)

A company made a complaint to the national authorities of Czech Republic regarding the placing on the market of a fertilizer containing nitrophenolates.

The Commission believes the product is not used as a fertilizer and should therefore be treated as a Plant Protection Product. The applicant intends to extend the demand to other countries. The Commission recommends Member States to be vigilant and to provide feedback on future occurrences.

**B.01 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 period of the active substances ethephon and fenamiphos.**

The expiration of approval of the above substances is set for 31 July 2017. The Commission proposes to extend the expiry dates until 31 July 2018.

A Member State expressed some concerns regarding the acute consumer exposure where the assessment of the residues intake is calculated using the PRIMo Rev. 3.

**Vote taken:** Favourable opinion.

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EU) No 1197/2012 as regards the expiry date of the approval of the active substance tepraloxydim.**

For the active substance tepraloxydim, Commission Regulation (EU) No 1197/2012 postponed the expiry of the approval period, as set out in Commission Implementing Regulation (EU) No 540/2011 to 31 July 2017.

The sole applicant for the renewal of the approval of the active substance tepraloxydim informed the Commission and the rapporteur Member State of its choice not to pursue further the application for renewal. Therefore it is appropriate to set the expiry date at the original date of expiry as set before the adoption of Regulation (EU) No 1197/2012.

**Vote taken:** Favourable opinion.

**B.03 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 rapporteur Member State for the active substance mecoprop-P.**

Commission Implementing Regulation (EU) No 686/2012 allocates the evaluation of each active substance to a rapporteur Member State and a co-rapporteur Member State. Upon request of the applicant and in agreement with the Member States concerned, it is considered necessary to change the rapporteur Member State for mecoprop-P while respecting the balance as regards the distribution of the responsibilities and the work between Member States. The evaluation for the purposes of the renewal procedures for mecoprop-P should from now on be allocated 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 withdrawing the approval of the active substance Z-13-hexadecen-11-yn-1-yl-acetate, 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. SANCO/11571/2014 Rev. 1)**

The Commission outlined the contents of the current proposal. As the Inter-Service Consultation (ISC) is still on-going, the voting session for this proposal needs to be postponed.

**Vote postponed**

**B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANCO/11620/2014 Rev. 1)**

The Commission outlined the contents of the current proposal. As the ISC is still on-going, the voting session for this proposal needs to be postponed.

**Vote postponed**

**B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance cerevisane, 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.**

The Commission prepared a non-approval proposal in view of the fact that the applicant had withdrawn its interest for the active substance. The EFSA conclusions were however published showing that there are no major concerns in relation to the active substance's profile.

The applicant contacted the RMS expressing its willingness to support the active substance. The Commission plans to schedule a meeting where the applicant is to formally state its intentions. The purpose is to optimise in terms of efficiency.

**Vote postponed**

**B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance Isaria fumosorosea strain Apopka 97, 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. SANCO/11393/2014 Rev. 1)**

The Commission prepared a renewal of approval proposal with a view to including the active substance in Regulation (EU) No 540/2011 as a "low risk substance". As the ISC is still on-going, the voting session for this proposal needs to be postponed.

Following some comments made by Member States, the Commission will revise the review report in line with decisions on other micro-organisms.

**Vote postponed**

**B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance meptyldinocap, 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. SANCO/10742/2014 Rev. 1).**

The Commission clarified that meptyldinocap is a mixture E/Z and R/S-isomers. Although the current ISO common name 'meptyldinocap' only refers to the E-isomer, ISO has agreed with an amendment of the definition of meptyldinocap. The amendment allows retention of the name 'meptyldinocap' but with the new underlying chemical definition which now embraces both the major (E)-isomer and the minor (Z)-isomer and specifies content ranges for each isomer of 75-100% (E-isomer) and 0-25% (Z-isomer).

Risk mitigation measures are set for Member States to pay particular attention to the risk to operators and the risk to aquatic invertebrates. Moreover, the applicant is requested to submit confirmatory information as regards the groundwater exposure assessment for metabolites, as well as for the possible impact of any preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment.

Two Member States believe that the risk to aquatic organisms has not been addressed. Two other Member States believe data is missing regarding a metabolite and that the risk to aquatic organisms and workers has not been addressed. Another Member State believes that the long term and reproduction studies submitted by the applicant are not acceptable. Those Member States cannot support the proposal.

**Vote taken:** Favourable opinion.

**B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance topramezone, 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. SANCO/10168/2014).**

The proposal was already presented in previous Standing Committees. The title was recently amended so as to allow Member States to extend provisional authorisations granted for that active substance.

Some Member States expressed reservations regarding the possible leaching of the active substance into groundwater and the classification proposed by EFSA.

The Commission added a set of risk mitigation measures and confirmatory information requests to address the critical area of concerns identified by EFSA. The proposal was however withdrawn from the voting session as no qualified majority could be achieved.

**Vote postponed**

**B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance chromafenozide, 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. SANCO/12127/2014).**

The proposal was already presented during previous Standing Committees. The title was recently amended so as to allow Member States to extend provisional authorisations granted for that active substance.

Four Member States do not support the proposal due to the possible leaching of some metabolites into groundwater.

**Vote taken:** Favourable opinion.

**B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance gamma-cyhalothrin, 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. SANCO/10606/2014).**

The proposal was already presented in previous Standing Committees. The title was recently amended so as to allow Member States to extend provisional authorisations granted for that active substance.

Some Member States expressed reservations either on the risk to aquatic organisms, non-target arthropods, wild mammals or workers. Those Member States cannot support the proposal.

**Vote taken:** Favourable opinion.

**B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747, 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. SANCO/11391/2014 Rev. 1).**

The proposal was already presented in previous Standing Committees. The title was recently amended so as to allow Member States to extend provisional authorisations granted for that active substance. The Commission clarified that the active substance cannot be approved as a "low risk substance" because it falls under the transitional rules of Article 80 of Regulation (EC) No 1107/2009.

**Vote taken:** Favourable opinion.

**B.13 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 copper compounds (Draft Review Report doc. SANCO/150/2008).**

The conditions of approval are being amended by adding provisions for the notifier to present a monitoring programme for areas where the contamination of soil and water by copper is a concern or may become one, in order to verify whether further limitations of use are necessary to prevent any unacceptable environmental effect.

Moreover, a correction is being brought to the measurement unit used for the maximum levels set for certain heavy metals.

A Member State expressed reservations already at the time of the approval of the substance. Another Member State believes that the risk to the environment has not been addressed. Another Member State believes there are some redundant provisions within the current proposal. Those Member States cannot support the proposal.

**Vote taken:** Favourable opinion.

**M.01 News from Food and Veterinary Office (FVO)**

There are no updates as regards this agenda point.

**M.02 New scientific publications**

Topic covered by other relevant points in the agenda.