EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Brussels
sante.ddg2.g.001(2015)1219194

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 11 DECEMBER 2014 - 12 DECEMBER 2014

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/d4ce9d29-c46c-4975-87aa-c929966856ac*

A.01 Summary Report of previous meetings.

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

A.02 Stage 4 of the review programme under Directive 91/414 – "Green Track".

There are no updates as regards this agenda point.

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.

3. First discussion of a Commission draft review report and Regulation concerning the approval of:

- Sulfoxaflor

The Commission outlined the contents of the draft Review Report, which is uploaded on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). The document was submitted to the applicant

for comments. The European Food Safety Authority (EFSA) conclusions need to be revised as regards endocrine disrupting properties.

Member States were invited to send comments by 31 January 2015.

- COS-OGA

The Commission outlined the contents of the draft Review Report, which is uploaded on CIRCABC. The document was submitted to the applicant for comments.

The Commission proposes to approve the active substance as a low risk substance. Following a comment made by a Member State, the Commission clarified that the criteria for low risk substances are set in the legislation. Although a guidance document needs to be prepared on the topic, in this specific case it is clear that the substance is of low risk and should therefore be approved as such at this stage.

Member States were invited to send comments by 9 January 2015.

- Cerevisane

The Commission outlined the contents of the draft Review Report, which is uploaded on CIRCABC. The document was submitted to the applicant for comments.

In its conclusions, EFSA suggested that the substance should be considered as a potential sensitizer by default, as it consists of the cell walls of a microorganism. However, EFSA clarified that the exposure is quite limited.

At the current meeting, discussions were held as to whether the substance should be approved as a low risk substance, taking into account its particular position between a chemical and a microorganism.

Member States were invited to send comments by 9 January 2015.

A.04 Renewal of approval:

1. Draft Working Document Renewal Programme (Doc. SANCO/11284/2012 Rev.14) (For information)

The Commission prepared a new revision of the working document. The document has been uploaded on CIRCABC.

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. 4) (For information)

There are no updates as regards this agenda point.

3. EFSA conclusions

I Flumioxazin

The point was deleted from the agenda.

II Flupyrsulfuron-methyl

The Commission outlined the main issues identified by EFSA in the conclusions.

Member States were invited to send comments by 15 January 2015.

III Thiabendazole

The Commission outlined the main issues identified by EFSA in the conclusions.

A Member State shared its concerns as regards the possible exceedence of the Acute Reference Dose (ARfD) in the relation to post-harvest treatments on potatoes. The Commission will inform the relevant colleagues dealing with pesticide residues.

Member States are invited to send comments by 15 January 2015.

4. State of play AIR

- 01. 2,4-D

The Commission outlined the main issues reported in the EFSA conclusions. Comments from applicant were uploaded on CIRCABC.

5 Draft Review Reports for discussion

I Lambda-cyhalothrin

The draft Review Report was outlined at the Standing Committee in October 2014. Several Member States submitted comments on that revision.

A Member State reported that there are inconsistencies among the pesticides and biocides areas as regards some endpoints. Moreover, the Member State believes the substance should only be included for 7 years as it fulfils the criteria set for candidates for substitution. Another Member State believes that there is no safe use for workers in greenhouses.

The EFSA conclusions need to be revised as regards endocrine disrupting properties.

Member States were invited to send comments by 15 January 2015.

II. Acybenzolar-S-methyl

The draft Review Report was outlined at the Standing Committee in October 2014. Only two Member States submitted written comments, which generally supported the Commission proposal.

The EFSA conclusions need to be revised as regards endocrine disrupting properties.

III. Amitrole

The Commission prepared a draft Review Report in view of withdrawing the active substance. The EFSA conclusions need to be revised as regards endocrine disrupting properties. No final decision on the renewal of the approval of amitrole will be taken until a revised EFSA-Conclusion has become available.

IV. Pyridate

The Commission prepared a draft Review Report in view of the renewal of the approval of the active substance.

Member States were invited to send comments by 9 January 2015.

V. Flumioxazin

Data submitted by the applicant under Article 4(7) was not taken into account by the Rapporteur Member State (RMS) at the time of the submission of the dossier for renewal. Since a withdrawal proposal is currently envisaged, such data needs to be evaluated.

The RMS will try to assess the data by February 2015. A contribution from other Member States is also required.

Some Member States stressed that the applicant should not be penalised regarding negligible exposure in line with the approach taken for low risk substances. They recommend waiting for the finalisation of the relevant guidance document. In contrast, other Member States indicated that there is sufficient information showing that the substance does not lead to a negligible exposure.

6. Sulfosulfuron

The Commission prepared a draft Review Report in view of the renewal of the approval of the active substance.

Member States were invited to send comments by 15 January 2015.

A.05 Confirmatory data:

1. Flurochloridone (revised report to be noted)

The Commission prepared a draft Review Report. The conclusions of the original risk assessment are not substantially modified by the evaluation of the submitted confirmatory data. Due to the timelines foreseen for the purpose, the amendment of the ISO name of the substance will only be reflected at a later stage.

Following the request from a Member State, the note taking was postponed to provide with some additional time to verify the contents.

2. Metosulam (revised report to be noted)

Recent comments were uploaded on CIRCABC. Most of the issues have been addressed. The ones which are still open are not related to the substance approval, but need to be addressed at Member State level. No modification to the conditions of approval is being proposed.

Two Member States have some concerns regarding the possible leaching of metabolites into groundwater.

The Committee took note of the revised review report together with the reservations expressed by two Member States.

3. Clethodim (revised report to be noted)

All concerns were addressed by the assessment of the confirmatory information. No modification to the conditions of approval is being proposed.

The Committee took note of the revised review report.

4. Tall oil pitch

The RMS confirmed that the data was not submitted within the set deadline. The Commission will therefore draft a non-approval proposal.

5. Pyridaben

The Commission prepared a draft review report, which was uploaded on CIRCABC.

Member States are invited to send comments by 31 January 2015.

6. Bensulfuron (revised report to be noted)

The draft review report was thoroughly discussed at the former Committee. However, the RMS provided further clarifications following a comment made by a Member State. All issues have now been clarified.

The Committee took note of the revised review report.

7. Hymexazol (revised report to be noted)

The draft review report was thoroughly discussed at the last Standing Committee. The RMS provided further clarifications following a comment made by a Member State.

The Committee took note of the revised review report.

8. SCLPs (revised report to be noted)

The draft review report was thoroughly discussed at the last Standing Committee.

The Committee took note of the revised review report.

9. 8-Hydroxiquinoline

There are no updates as regards this agenda point.

10. Etridiazole

The applicant had some concerns regarding the publication of the EFSA technical report. According to the applicant, the Commission should have mandated EFSA to draft that technical report since the substance falls under the old regulatory framework.

The Committee was informed that the technical report was recently published. EFSA and the Commission are currently seeking a solution to prevent future occurrences.

11. Kresoxim-Methyl (revised report to be noted)

All concerns were addressed by the assessment of the confirmatory information. No modification to the conditions of approval is being proposed.

The Committee took note of the revised review report.

AOB:

- 1,2,4-triazole

The Chemicals Regulation Directorate in the United Kingdom (Health and Safety Executive) has included a Regulatory update announcing the new endpoints to be used for 1,2,4-triazole on their website:

http://www.pesticides.gov.uk/guidance/industries/pesticides/News/Collected-Updates/Reg-Updates-2014/October/1-2-4-triazole-endpoints

A.06 Amendment of the conditions of approval.

There are no updates as regards this agenda point.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission informed the Committee about new documentation on calcium hydroxide which has been submitted by the applicant after the finalisation of the technical report from EFSA, in particular to address the area of operator exposure.

2. New dossiers received

No new dossiers were received.

3. EFSA Technical Reports:

- Fructose
- Arctium lappa

The Commission informed the Committee that two technical reports were submitted by EFSA.

4. Draft Review Reports for discussion:

- Salix alba
- Rheum officinale

The Commission prepared two draft Review Reports, which were uploaded on CIRCABC.

Member States were invited to send comments by 15 January 2015.

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

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

A meeting of the working group took place on 27 November 2014. Progress was made in the drafting of the guidance document. A new meeting will take place in spring 2015 in order to finalise a first version on the basis of which stakeholders will be consulted.

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/11251/2012 Rev. 4) (to be noted)

The Commission prepared a new revision of the guidance document, taking into account comments recently submitted. The document was outlined during the meeting.

The procedure regarding dossier submission, sanitisation and publication is described in a separate chapter in the Guidance Document.

It is also clarified in the Guidance Document that a Maximum Residue Level (MRL) application form should be submitted in case the setting of an MRL for a new use or the amendment of an existing MRL is requested. The assessment of these MRLs will be included in the Renewal Assessment Report (RAR) as prepared by the RMS and peer-reviewed by EFSA.

The Committee took note of the guidance document.

3. 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. 3) (to be noted)

The Commission prepared a new revision of the guidance document, taking into account comments recently submitted. Some clarifications and editorial changes were made. Reference to Regulation (EU) No 1136/2014 was added.

A Member State indicated that they needed more time to study the full consequences of the proposed amendment.

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

4. Draft Guidance Document on the assessment of certain applications for which reference is made to Article 34 of Regulation (EC) No 1107/2009 (SANCO/11371/2014 Rev. 3) (for discussion only)

The current Guidance Document is limited to applications:

- for products which are equivalent and comparable to an existing product authorised according to Uniform Principles in the Member State, called the 'Reference product'. Equivalent and comparable products are products which are equivalent according to the Guidance Document SANCO/10597/2003 and which have only non-significant changes according to the Guidance Document SANCO/12638/2011 to the reference product;

- for which access to the protected data is shown or for which data are no longer protected; and

- for which no technical assessment is needed.

Member States were invited to send comments by 9 January 2015.

5. Draft Guidance Document on renewal, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009 (SANCO/13170/2010 Rev. 10) (to be noted)

The Commission is in the process of preparing a new revision of the Guidance Document to better reflect the situation under Regulation (EC) No 1107/2009. As soon as a new revision is prepared, it will be circulated to all Member States and stakeholders for commenting.

The note taking was postponed.

6. Draft Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 Rev. 0)

The Commission outlined the main aspects of the document.

The Committee took note of the template.

7. Draft Guidance Document on Decision Making under points 3.6.3 to 3.6.5, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 (SANCO/12096/2014) (for information)

The Commission informed that the guidance document will be further discussed at an expert meeting on 13 January 2015. The outcome will be reflected in a new revision of the draft guidance document.

A table reporting active substances, which have been classified as C1, R1, C2/R2 and which would be affected by the new provisions was presented and uploaded on CIRCABC. The table also shows in which Member States Plant Protection Products (PPPs) are authorised containing the respective active substance and states for which active substances MRLs are set, which would need to be lowered to the Limit of Determination (LOD).

8. 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. 4) (to be noted)

The Commission outlined the contents of the new revision.

The Committee took note of the guidance document.

9. 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)

The final editorial comments have been included and the guidance document is to be applied as from 1 May 2015. The Committee took note of the Guidance Document together with the reservations expressed by a Member State. That Member State was of the opinion that only a limited part of the Guidance Document should apply to all applications by the set application date. It felt that the compromise proposal from the Commission did not solve all issues.

10. 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 (document SANCO/12184/2014) (to be noted)

Some comments from Member States were recently submitted to the Commission.

The note taking was postponed.

11. Draft Template to be used for the List of Endpoints (SANCO/12483/2014 Rev. 2) (to be noted)

The Commission outlined the latest amendments brought to the new revision.

The Committee took note of the template.

12. Draft Guidance Document for applicants on preparing dossiers for the approval of a new chemical active substance and for the renewal of the approval of a new chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013 Rev. 3) (to be noted)

The revised list of endpoints (see point 08.11) will be included when noted.

The Committee took note of the guidance document.

13. Draft Guidance Document for applicants on preparing dossiers for the approval or renewal of the approval of microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/12545/2014 Rev. 1) (to be noted)

Some editorials amendments were brought to the new revision.

The Committee took note of the guidance document.

14. EFSA Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874 (EFSA presentation and follow-up discussion)

EFSA made a presentation, which was uploaded on CIRCABC.

The Commission gave an update on the state of play and mentioned two letters from stakeholders which are uploaded on CIRCABC.

Some Member States urged the Commission to take note of the guidance document as soon as possible.

Member States were invited to send comments to guidance document and/or stakeholder letters by 15 January 2015.

A.09 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Metalaxyl-M (Belgium)
Hydroxyquinoline (Germany)
Pyraclostrobin/Boscalid (Spain)
1,3-dichloropropene (Spain)
Chloropicrin (Spain)
Gibberellic acid (Spain)

Azoxystrobin/Difenoconazole (Spain)
Chlorantraniliprole (Spain)
Chlorthalonil (Spain)
Ethephon (Spain)
Fosthiazate (Spain)
Metazachlor (Spain)
Saponins (Spain)
Tau-fluvalinate (Spain)
Thiabendazole (Spain)
Chlorpropham (Finland)
Asulam (France)
Azoxystrobin/Difenoconazole (France)
Chlorantraniliprole (France)
Chlorothalonil/Metalaxyl-M (France)
Copper compounds (France)
Cyazofamid (France)
Ethephon (France)
Fluopyram/Trifloxystrobin (France)
Milbemectin (France)
Phenmedipham (France)
Picoxystrobin(France)
Spinetoram (France)
Spinosad (France)
Tebufenpyrad (France)
Tefluthrin (France)
Prochloraz (the Netherlands)
Thiram (the Netherlands)
Chlorantraniliprole (the Netherlands)
Spinosad (the Netherlands)
Abamectin (the Netherlands)
Formetanate (the Netherlands)
Chlorophacinone (Romania)
Captan (Sweden)
Fosetyl (Sweden)
Paraffin oil (Sweden)
Phenmedipham (Sweden)
Pirimicarb (Sweden)

The Committee took note of the notifications submitted by Belgium, Germany, Spain, Finland, France, the Netherlands, Romania and Sweden.

Some Member States urged the Commission to provide further clarifications regarding seed treatment, in the framework of Article 53 of Regulation (EC) No 1107/2009 in the Q&A document on interpretation issues.

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).

There are no notifications under Article 44(4) of Regulation (EC) No 1107/2009.

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

Germany refused to recognise the authorisation of Dauphin 45 WG and Moximate 725 WG, both from Austria. The Commission refused the second notification and requested Germany to sufficiently motivate its decision.

The Committee took note of the first notification.

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 gave an update on the state of play. In particular, Member States were informed on the Better Training for Safer Food (BTSF) workshops in the process of being organised and on the need to cooperate to identify relevant participants, dealing with training coordination under the Sustainable use directive to ensure adequate participation and future dissemination.

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

EFSA gave an update on the state of play.

A.15 Report from working groups:

1. Authorisation database

There are no updates as regards this agenda point.

2. Post Approval Issues

The Commission gave an update on the state of play.

The Commission will explore the possibility to organise a workshop to evaluate the zonal system and mutual recognition in June 2015 hosted by Ireland.

3. OECD

There are no updates as regards this agenda point.

4. Low Risk

A meeting of the expert group is scheduled for 17th December 2014. The aim of the meeting is to discuss the state of play and the way forward especially as regards possible criteria for the different groups of substances (chemicals, micro-organisms, semiochemicals, etc.).

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

The Commission gave an update on the state of play.

The Commission was consulted on this topic and it was decided to proceed with a recommendation for Member States to implement the guidance document in accordance with the implementation plan (SANCO/10606/2014). It is not yet decided which kind of document will be drafted to cover this issue. One of the available tools is a Commission Communication. The Commission, as already announced in the past, will soon request EFSA to organise a call for data for all relevant stakeholders and not only industry.

EFSA invited the authors of Bee-have model. The validity of the model will be checked as of the beginning of 2015 to verify the compliance with the specific EFSA Guidance on modelling.

During the meeting where the Commission was also represented, the authors made clear that no formal pesticide exposure module exists yet. Moreover, to use the model

for regulatory risk assessment purposes, a new approach should be studied to use toxicological endpoints instead of the mortality rate (i.e. a conversion of the existing endpoints will be needed). It is not possible at this stage to foresee the timeline of this process (it is excluded to have this available in the next 2 years in any case).

3. Uniform principles – Amendment to Regulation (EU) No 546/2011 as regards the trigger value for honeybees to align to the EFSA Guidance Document.

The uniform principles need to be amended so as to reflect the current trigger values on bees. A draft will be prepared in the near future.

4. AOB

There are no updates as regards this agenda point.

A.17 Court cases.

The Commission informed the Committee on the outcome of Court Case T-269/11.

A.18 Endocrine disruptors – state of play.

The Commission updated on the progress of the on-going impact assessment for defining the criteria. A public consultation is running until 16th of January. Member States are invited to forward the questionnaire to the relevant people. The first study is under progress and is managed by the Joint Research Centre (JRC). A dedicated section on endocrine disruptors will be created on the Commission's website, allowing for more transparency.

A draft document for supporting EFSA regarding the interpretation of "may" in the second interim criterion for endocrine disruption was uploaded on CIRCABC. Once agreed, this document may be included in the Q&A document.

Member States were invited to send comments by 15 January 2015.

A.19 Minor Uses – state of play.

The Financial Decision which allocates the co-funding by the Commission for the Coordination Facility on minor uses was published last November. A proposal to set up this facility has been received and is currently under evaluation. If this proposal is considered acceptable the technical secretariat can be established as of the first half of 2015.

A.20 Interpretation issues:

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

- Fertiliser products containing phosphonates

There are no updates as regards this agenda point.

2. Questions and Answers

A new revision was uploaded on the Commission's website. The Commission outlined the latest amendments brought to the document.

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 uploaded an updated table on CIRCABC.

2. 'To be classified' - Role of the Member States (MS)

There are no updates as regards this agenda point.

A.22 Glyphosate:

There are no updates as regards this agenda point.

A.23 Chlorpyrifos - state of the dossier.

The Commission presented a draft review report restricting the condition of approval to wine grapes at a maximum application rate for a first discussion. The need to review the toxicological reference values to prioritise the review of MRLs was also restated as in previous meetings. Only a few Member States have up to now expressed their views.

Some Member States reiterated that they believe safe uses of the active substance exist beyond the restriction proposed by the Commission.

Member States were invited to send comments by 15 January 2015.

A.24 Chlorpyrifos-methyl – state of the dossier.

The Commission presented the finalised reporting table concerning the assessment of post Annex I data submitted by the notifier in order to support evidence for the confirmation of the acute reference value.

The results of the assessment of the new study confirm the value of the ARfD based it on the toxicological effect of AChE inhibition in red blood cells.

Member States were invited to send comments by 15 January 2015.

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

EFSA gave an update on the state of play.

The responses of the Plant Protection Products and their Residues (PPR) Panel to the reports on the potential DNT of acetamiprid and imidacloprid were uploaded on CIRCABC.

The Commission clarified that a decision will need to be taken as regards the new reference values proposed by EFSA in their Opinion. In case these new reference values are agreed upon within this Standing Committee, they will have an impact also on MRLs.

A.26 Data requirements and acceptance of waivers/implementation of SANCO/10181/2013 Rev 2.1.

The agenda point was postponed to next meeting.

A.27 Follow-up workshop "Harmonisation in toxicology".

Member States are invited to nominate experts attending the workshop to be held in Austria by 15 January 2015.

A.28 Acequinocyl (amended review report to be noted).

The Commission presented the first draft of the amended review report. One Member State commented that the Good Agricultural Practice (GAP) table should not be amended as there is not enough data to support those uses.

The Committee took note of the amended review report together with the reservations expressed by a Member State.

A.29 Imidacloprid (revised review report for discussion).

There are no updates as regards this agenda point.

A.30 Update on the Trans-Atlantic Trade and Investment Partnership (TTIP) talks on pesticides.

There are no updates as regards this agenda point.

A.31 Fertilizers containing nitrophenolates.

There are no updates as regards this agenda point.

A.32 European Union Pesticide Database – update of national authorisations.

The Commission reminded Member States to send the tables reporting their updated national authorisations by 16 January 2015.

A.33 CIRCABC's Survey.

The Commission asked for Member States participation in a survey of all CIRCABC members to ensure that the membership for each Member State is up-to-date. Forms can be returned in paper or by e-mail to the Commission.

On this occasion, the Commission recalled that access can only be granted to representatives of competent authorities in Member States.

A.34 New voting rules for qualified majority.

The Commission presented the new voting rules required by the Lisbon Treaty, which are applicable from 1 November 2014.

The Commission stressed that Member States who intend using the old voting system during the transitional phase should request to do so by the beginning of the voting session, at the latest.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl, propamocarb and Spodoptera exigua nuclear polyhedrosis virus.

The Commission proposes to extend the approval period for the above mentioned substances to provide for sufficient time to complete the renewal procedure in accordance with Regulation (EU) No 844/2012. Spodoptera exigua nuclear polyhedrosis virus was withdrawn from the proposal as no application was submitted.

A Member State does not support the extension of the approval period for glufosinate as it is one of the 21 substances for which that Member State asked the Commission to prioritise the review. Another Member State is not in favour of the proposal as it contains 8 substances for which they did not support the approval.

Vote taken: Favourable opinion.

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 Z-13-hexadecen-11-yn-1-yl-acetate (Draft Review Report Doc. SANCO/2649/2008 Rev. 3)

The proposal was already presented at the last Standing Committee.

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 540/2011 as regards the conditions of approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate (Draft Review Report Doc. SANCO/2650/2008 Rev. 3)

The proposal was already presented at the last Standing Committee.

Vote taken: Favourable opinion.

B.04 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. 2)

The Commission proposes to renew the approval of Isaria fumosorosea strain Apopka 97 as a low risk substance. A new recital was added to justify this approach.

A Member State supports the renewal, but would have preferred to classify the substance as a "low risk substance" at a later stage, since discussions are still on-going on low risk substances. Another Member State is not sure whether the substance should be classified as a "low risk substance" as it believes the substance may be a potential sensitizer.

The Commission clarifies that there is no legitimate exclusion criterion, as all microorganisms may be considered as potential sensitizers by default. This is also reflected in the criteria for low risk substances in Annex II to Regulation (EC) No 1107/2009.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation confirming the conditions of approval of the active substance Triclopyr (Draft Review Report Doc. SANCO/10010/2006 Rev. 4)

The Commission proposes to restrict the approval of triclopyr to herbicide uses only with a maximum of one application per year at a maximum rate of 480 g active substance per hectare. Following comments made by some Member States, the Standing Committee agreed to delete the reference to a single application.

A Member State has concerns regarding the potential leaching of metabolites into groundwater. Another Member State does not support restricted approvals in cases like this as a matter of principle and believes Member States should ensure that appropriate risk mitigation measures are applied.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation confirming the conditions of approval of the active substance fenazaquin, as set out in Implementing Regulation (EU) No 540/2011 (Draft Review Report Doc. SANCO/10324/2011 final Rev. 2, 17 September 2013)

The Commission proposes to confirm the current conditions of approval of the active substance fenazaquin.

Some Member States reacted by stating that a safe use exists and that current restriction on ornamentals should be lifted. Moreover, they believe that the risk to aquatic organisms can be mitigated at national level. In contrast, other Member States support the current proposal, as it is in line with EFSA recommendations.

Italy made the following declaration:

"The Italian delegation expresses its concerns regarding the proposed decision. In fact the approval decisions taken on active substances have been insofar based on the safe use concept: with the current proposal maintaining the use limitations, this concept has not been followed, leaving room for legal discussion on unequal treatment for this molecule. Italy could be favourable to a proposal allowing at least the uses on citrus fruit."

Vote postponed

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

The FVO made a presentation, which was uploaded on CIRCABC.

Following a comment from a Member State, the FVO clarified the procedure on audits and reminded that competent authorities are informed by the FVO well in advance to agree upon the dates. The official request is sent afterwards.

M.02 New scientific publications.

There are no updates as regards this agenda point.

M.03 AOB

1. MAgPIE Update

The Commission informed the Committee on a workshop for Regulatory Authorities, held by the Organising Committee of MAgPIE, on mitigating the risk of PPPs in the environment.

2. Green Deal (the Netherlands)

The Netherlands updated the Committee on the Dutch "Green Deal" programme.

Member States were invited to send comments by 15 January 2015.

3. Adjuvant

One Member State enquired whether it was acceptable for a product to contain an adjuvant consisting in an active substance (either approved or non-approved).

The Commission indicated that it is the responsibility of the applicant to demonstrate that in this particular case the substance used as an adjuvant is not falling in the definition of an active substance (e.g. because of the low dose applied). The substance should not “have a general or specific action against harmful organisms or on plants, parts of plants or plant products”. This will be assessed by the Member State. The Member State should assess this product in accordance with Article 58 and the substance should comply with the criteria of Article 27 on co-formulants.

Member States were invited to send comments by 15 January 2015.

After that the Commission will update the Question and Answer document with this additional question.

4. Clarification on the note taking procedure

The Commission explained the approach to be taken in the note-taking procedure when there is no unanimous agreement and where a compromise cannot be reached. Following the request of several Member States, the Commission will prepare a position paper on this topic.

5. Discussion on the official control regulation (the United Kingdom)

The United Kingdom asked other Member States to send to the Commission any concerns they have on the regulation under preparation.

6. Website link with PAFF dates

Member States were invited to consult the following website reporting the indicative planning of Standing Committees:

http://ec.europa.eu/dgs/health_consumer/dgs_consultations/docs/planning_sc_meetings_2015.pdf

7. Extension of the deadline for flufenacet for which Poland is RMS (Austria)

Austria informed the Committee on its availability to become RMS for flufenacet as of 2017. The Commission clarified that the Polish Parliament recently adopted a law stating that the dossiers can be submitted also in English. In view of this, it might not be necessary to re-attribute responsibilities for flufenacet.

8. Candidates for substitution

At the next Standing Committee, the list of candidates for substitution, as presented in May 2014, will be put for a vote. The proposal provides for an application date of 1 August 2015, as well as transitional measures, where necessary. The Commission clarified that the list covers substances which have been approved until 1 January 2013. The list will be updated in a second stage as regards substances approved after that date.

Some Member States urged the Commission to proactively communicate information on the list of candidates for substitution, the process of identification of those substances as candidates for substitution, and the regulatory consequences, to prevent misunderstandings. The Commission is currently preparing such communication materials.

Member States are invited to submit comments on the proposed transitional measures, but not on the list itself, as no further changes can be made to the list.

9. Reorganisation Commission/Directorate General for Health and Food Safety (DG SANTE)/Unit E3

The Commission outlined the main changes to the re-organisation in the relevant areas linked to the establishment of the new Commission.