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 23 JANUARY 2017 - 24 JANUARY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/1e12a062-e870-4e3b-bac7-73981b4685f0*

A.01 Summary Report of previous meetings.

The Committee was informed that the December 2016 summary report was under preparation.

A.02 New active substances:

1. New admissible dossiers to be noted:

(No new dossiers.)

No discussion required.

2. Exchange of views on new European Food Safety Authority (EFSA) conclusions

(No specific conclusions identified.)

No discussion required.

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

Beta-cypermethrin (No detailed discussion; Member States are requested to send in comments after the meeting)

No discussion in the meeting. Member States were informed that a proposal for non-approval was being taken forward.

Bacillus amyloliquefaciens FZB24

No detailed discussion; Member States were requested to send final comments by 17 February 2017.

Beauveria bassiana strain 147

The Commission informed the Member States of a new revision of the Draft Regulation and Draft Review Report. The maximum level of the secondary metabolite beauvericin under Purity was changed to the value specified by the applicant (24µg/L). The applicant confirmed that they are able to produce the substance according to this specification. The review report was updated to reflect this. Because of an inoculation step in the production process for the product, a point of attention for Member States was added on the level of beauvericin in the product. Member States were invited to send in comments by 17 February 2017 at the latest.

Beauveria bassiana NPP 11B005

The Commission informed the Member States of a new revision of the draft regulation and draft review report. The maximum level of the secondary metabolite beauvericin under Purity was changed to the value specified by the applicant (24µg/L). The applicant confirmed that they are able to produce the substance according to this specification. The Review Report was updated to reflect this. Because of an inoculation step in the production process for the product, a point of attention for Member States was added on the level of beauvericin in the product. Member States are invited to send in comments by 17 February 2017 at the latest.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

The Commission once again raised the issue of the delays in the renewal assessment of active substances included in the AIR III (Annex I Renewal) programme and showed a graphical overview of the delays in the submission of the dRARs (Renewal Assessment Reports) from Member States to EFSA. The delays are problematic since a decision on the renewal of an active substance cannot be taken without a risk assessment, which leads to additional extensions of the approval periods of active substances included in the renewal programme. Although raised at numerous Standing Committees, the delays reported do not seem to decrease. Therefore, the Commission has decided to act in order to gain clarity of the reasons for the delays and find ways to remedy the situation.

2. Exchange of view on EFSA conclusions

(No specific conclusions identified)

No discussion required.

3. Draft Review/Renewal Reports and Regulations for discussion:

i. Flupyrsulfuron-methyl

Member States were informed that a revised proposal (concerning non-renewal of approval, replacing the earlier proposal also for non-renewal of approval) had been prepared and comments were requested by 17th February 2017.

ii. Pymetrozine

Member States were updated on comments received on the EFSA Statement on negligible exposure since the December meeting. A limited number of Member States had submitted comments. All Member States' comments were not supportive of considering negligible exposure to be demonstrated due to the lack of final guidance on the subject and/or some more fundamental concerns about what constitutes negligible exposure and what types of uses can be considered.

Further comments from other Member States were requested.

The Commission updated Member States on the ongoing process to develop the protocol to consider insecticide substances under Article 4.7 of Regulation (EC) No 1107/2009. Once this was completed the assessment of Article 4.7 would continue.

iii. Imazamox

The Commission presented the revised version of the draft renewal report for imazamox in which the Commission proposed the renewal of approval. No detailed discussion on the proposal took place during the Standing Committee meeting. Member States were asked to submit their comments by 10 March 2017.

iv. Maleic hydrazide

The Commission presented the revised version of the draft renewal report for maleic hydrazide. In this report, the Commission proposed the renewal under some specific conditions. No detailed discussion on the proposal took place during the Standing Committee meeting. Member States were asked to submit their comments by 10 March 2017.

v. Flazasulfuron

The Commission referred to comments received from Member States and the applicant. The Commission presented the revised version of the draft renewal report (minor changes). Member States were asked to submit their comments by 17 February 2017.

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

The Commission referred to comments received from Member States and the applicant. Member States were asked to submit their comments by 17 February 2017.

vii. Mesosulfuron-methyl (No detailed discussion; Member States are requested to send in comments after the meeting)

No discussion took place in the meeting.

viii. Mesotrione

The Commission presented a revised Draft Review Report with respect to possible identification of mesotrione as candidate for substitution. Considering the overall properties of the substance and the information on its behaviour in examined environmental compartments, it is concluded that the criteria of persistency of mesotrione is not fulfilled also in view of the diverging results of OECD tests 308 and 309. The Commission invited Member States to submit comments by 17 February 2017.

ix. Pendimethalin

The Commission referred to comments received by Member States and applicant uploaded in CIRCABC. The Rapporteur Member States (RMS) and one Member State disagree with identification of pendimethalin as candidate for substitution, in particular they did not agree with the conclusions on persistency. On the contrary, three other Member States commented supporting the identification of the substance as candidate for substitution. One Member State agreed with the comment of the German UBA and considered pendimethalin fulfilling bioaccumulation criteria. The Commission invited Member States to submit comments on the draft review report by 17 February 2017.

x. 2,4-DB

The Commission presented a revised draft review report in favour of approval of the substance. In line with the general views of the Member States, it is considered to retain the reference toxicological endpoints proposed by EFSA in the current Conclusion regarding 2,4-DB, and not, as suggested by the applicants, to refer back to the (less strict) endpoints appearing in the former 2,4-D Conclusion. It is moreover possible that the latter will be revised in due course and aligned. Other issues, in the fields of consumer exposure from commodities from animal origin and ecotoxicology can be completed by further refinements at national level and/or adequate risk mitigation measures. The Commission invited Member States to submit comments by 17 February 2017.

xi. Carfentrazone-ethyl

The Commission presented a revised draft review report in favour of approval of the substance. A matter of principle relates to the future methodology to assess the impact on consumers from the treatment of surface or groundwater to generate drinking water. Provisionally, the report proposes to handle the matter via confirmatory data. A similar recourse to confirmatory data would apply for the assessment of the relevance of metabolites in groundwater, once a classification of the parent substance as Carc 2 would be adopted by the Commission. Other issues, such as the aquatic risk, the risk to non-target soil macro-organisms and to non-target plants, can be completed by further refinements at national level and/or adequate risk mitigation measures. The Commission invited Member States to submit comments by 17 February 2017.

xii. Acetamiprid

The Commission presented the draft review report for acetamiprid in which a renewal of approval is proposed. No detailed discussion on the proposal took place during the meeting and Member States were asked to submit their comments by 17 February 2017.

xiii. Propyzamide

The Commission referred to comments received by the applicant arguing against the proposed identification as candidate for substitution, in particular with respect to fulfilment of toxicity criteria. Comments from the RMS and other Member States have been uploaded in CIRCABC. Two of the PBT (Persistent Bioaccumulative Toxic) criteria are considered to be fulfilled, the persistency in water and the specific criteria of long term toxicity to aquatic organisms due to the NOEC 0.000634 mg/L for Myriophyllum spicatum. One Member State considered propyzamide should not be renewed due to groundwater and non-target organisms risk assessment. Two Member States expressed agreement on identification of propyzamide as candidate for substitution. The Commission invited Member States to submit comments on the draft review report by 17 February 2017.

xiv. Propoxycarbazone-sodium (No detailed discussion; Member States are requested to send in comments after the meeting)

No discussion took place in the meeting.

xv. Benzoic acid (No detailed discussion; Member States are requested to send in comments after the meeting)

No discussion took place in the meeting.

xvi. Diquat

The Commission uploaded all letters received since July 2016 from EFSA and Syngenta on diquat on CIRCABC together with comments from Member States received during that time period. The Commission will also upload an overview document prepared by the EFSA regarding the different discussion points brought up by the applicant together with EFSA's reply.

Three Member States indicated having identified safe uses at national level.

Two Member States indicated providing further comments.

Member States were invited to send in further comments by 10 March 2017.

A.04 Confirmatory Data:

1. Bifenthrin

Views of Member States are quite diverging as regards the manner in which to deal with the two remaining issues (non-target arthropods and bioaccumulation). In any case, the Commission, in addition to possible risk mitigation or further refinement at national level, is of the opinion that at least regulatory restrictions should be set. Uses should therefore not exceed 10 g/ha and 2 applications per season. This seemed acceptable to several Member States while others preferred applications in greenhouse only.

Member States were invited to send in further comments by 10 March 2017.

2. Thiamethoxam

10 Member States support a restriction to permanent greenhouses. 3 Member States indicated that certain outdoor uses could be maintained. 1 Member State did not have a position yet.

Member States who did not submit their position yet were requested to provide this position by 10 February 2017.

3. Clothianidin

The Commission referred to comments received by Member States uploaded on CIRCABC. The Commission further explore the issue of crop rotation systems with sugar beets and it appears that all common rotation systems foresee a succeeding crop that may be bee attractive (it is recalled that EFSA confirmed that it cannot be excluded that potatoes and cereals are attractive to bees). Member States were invited to send any comments or suggestions regarding crop rotation systems with sugar beets, not posing problems for the succeeding crop by 17 February 2017.

4. Imidacloprid

The Commission referred to comments received by Member States uploaded on CIRCABC. The Commission further explored the issue of crop rotation systems with sugar beets and it appears that all common rotation systems foresee a succeeding crop that may be bee attractive (it is recalled that EFSA confirmed that it cannot be excluded that potatoes and cereals are attractive to bees). Member States were invited to send any comments or suggestions regarding crop rotation systems with sugar beets, not posing problems for the succeeding crop by 17/2/2017.

5. Tetraconazole

Dossier under examination. The additional information by RMS Italy has been well received.

6. Diclofop (revised Review Report to be noted)

The proposal in the Review Report to avoid that treated straw or hay is fed to livestock raised for food is commonly agreed. The Review Report is noted accordingly.

7. Cyflumetofen

The Commission brought to the attention of the Committee new pieces of information sent in by the notifier in order to clarify the data gaps identified during the assessment of the confirmatory data. The Commission further indicated that the issues flagged by EFSA in their peer-review can only be addressed through a restriction to non-edible crops (or crops not intended for food production) and other restrictions for the representative uses. Member States were invited to submit comments by 10 March 2017.

8. 8-hydroxyquinoline (revised Review Report to be noted)

The Commission presented the revised review report putting an end to the confirmatory data process. The Committee took note of the revised Review Report, with the exemption of Denmark.

9. AOB :

The Commission brought to the attention of the Committee a letter from the Copper Task Force asking more time to finalise the monitoring interim report due by the end of 2016. The Commission proposed to accept to allow until mid February to permit the task force to duly address comments received by the Rapporteur Member State France in the context of renewal assessment which is running in parallel.

A.05 Article 21 Reviews:

i. Diflubenzuron (Draft Review Report and draft Implementing Regulation for discussion)

The Commission presented a revised draft act and invited Member States to submit comments by 17 February 2017.

ii. Thiametoxam, other uses than seed treatments and granules (revised Review Report to be noted)

An addendum to the Review Report was presented. Several Member States asked postponing the note-taking in order to get more time to study the text.

The Commission accepted to postpone the note-taking.

iii. Clothianidin, other uses than seed treatments and granules (revised Review Report to be noted)

An addendum to the Review Report was presented. Several Member States asked postponing the note-taking in order to get more time to study the text.

The Commission accepted to postpone the note-taking.

iv. Imidacloprid, other uses than seed treatments and granules (revised Review Report to be noted)

An addendum to the Review Report was presented. Several Member States asked postponing the note-taking in order to get more time to study the text.

The Commission accepted to postpone the note-taking.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted

i. Paraffin oils

Member States took note of this new admissible dossier.

2. 8-Hydroxyquinoline

The Commission informed that the notifier for 8-hydroxyquinoline was seeking a revision of the harmonised classification. The Commission works on a draft Regulation which will undergo the usual process. The point may be on the agenda for the May Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) under points B. Member States were invited to send in comments by 10 March 2017.

3. Penflufen

The Commission informed the Committee about their intention to lift the restriction to crops in the condition of approval of penflufen. At the same time, the Commission wants to address the confirmatory data which were submitted and assessed in parallel to the request to amend the conditions of approval. The notifier will be invited to comment on the draft review report and the point might be back on the agenda for the May PAFF Committee under point B. Member States were invited to send in comments by 10 March 2017.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission reminded Member States to send nominations for the reorganisation of experts group on basic substances.

2. New dossiers received (only for information):

i. Fructose (extension of use)
ii. Propolis
iii. Onion oil

The Commission informed the Member States about the new dossier for onion oil. The applicant was informed that the application was not complete and requested the applicant to send in a completed application.

3. Exchange of view on EFSA Technical Reports (No specific report identified)

No discussion required.

4. Draft Review Reports for discussion:

Capsicum spice

Member States were invited to send in comments by 10 March 2017.

Millefolii herba

Member States were invited to send in comments by 10 March 2017.

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 assessments 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. Germany did not wish to take note of the document and provided detailed comments.

The Committee took note of the guidance document. Germany did not take note of the document.

2. 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)

The Commission reminded the Committee that according to the Guidance Document mentioned above, the European reference specification for the technical active substance should not be changed during the renewal process. Such a change is only acceptable where strong concerns about human or animal health or to the environment are identified. Changing the reference specification has major impact on the renewal of national authorisations of products already on the market.

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

No notifications uploaded due to a technical error.

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

No notifications uploaded due to a technical error.

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

Asulam (Belgium)
Ethylene (Belgium)
Metalaxyl-M (Belgium)
Fludioxonil (Belgium)
Trichoderma atroviride strain SC1 (Belgium)
Prpyzamide (Denmark)
Chlorpropham (Finland)
Beta-Cyfluthrin, Clothianidin (Finland)
Fludioxonil, Metalaxyl-M, Thiamethoxam (Finland)
Lambda-Cyhalothrin (Germany)
Mancozeb (Italy)
Chlorpyrifos-methyl (Italy)
Propyzamide (Italy)
Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348 (Italy)
Deltamethrin (Italy)
Propiconazole (Portugal)
Aclonifen (Portugal)
Metalaxyl-M (Portugal)
Beauveria bassiana strains ATCC 74040 and GHA (Portugal)
Pyrethrins (Portugal)
Deltamethrin (Spain)
Azoxystrobin, Diquat (dibromide), Trifloxystrobin (Spain)
Bentazone, Spinosad (Spain)
Chlorantraniliprole, Spinosad (Spain)
Chlorantraniliprole (Spain)
Copper hydroxide (Spain)
Chlorpyrifos (Spain)
Spinosad (Spain)

The Committee took note of the notifications submitted by Belgium, Denmark, Finland, Germany, Italy, Portugal, Spain,

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).

EFSA gave a presentation on the Scientific Guidance Document of the Plant Protection Products and their Residues (PPR) Panel on the establishment of the residue definition to be used for dietary risk assessment.

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

1. Follow up workshop formulation laboratories

A follow-up workshop will take place on 15th/16th February in the Netherlands. Member States are invited to participate.

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

No new information.

3. Article 68 Enforcement Working group

The Commission is currently preparing a form to be filled in by Member States in submission of Article 68 – information. Member States will be kept informed about any progress.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

The Committee was informed that some further resource had become available for support tasks and that there would be a review of online materials to assist users.

The Committee was informed that the next release (scheduled for first quarter 2017) would include a simplified user management process and the movement of the justification tab from authorisation to application (applicants would complete and the Member States would check, amend and agree).

An update on the data collection exercise was given; 23 teleconferences had been held. The remaining Member States would be progressed in early 2017. Once data was collected it would be used for two purposes: to feed into the public database on authorisations and to enable further implementation of other application types in PPPAMS.

The Northern Zone Member States had written to the Commission with concerns about the resource required to complete the exercise and future requirements. The Commission acknowledged the resource required but emphasised the need for collaboration to ensure the project could continue apace.

Member States were informed that the Commission intended to meet with European and Mediterranean Plant Protection Organisation (EPPO) on 6th February to discuss the need for new EPPO codes with regards to PPPAMS. The meeting would also include the Minor Use Coordination Facility as cooperation between the European Minor Use Database (EUMUDA) and PPPAMS databases was seen as useful.

Member States were also thanked for providing details of uses where they considered EPPO codes were not available and were invited to provide further examples by 1st February 2017.

2. Post Approvals Issues group (PAI) (no meeting since December)

No discussion required.

3. Sustainable plant protection experts group Dutch proposal

No update on the work of the working group. The Commission informed the Member States on the oral question on biological low-risk pesticides adopted by the European Parliament (EP) and of the draft resolution worked on by MEP's and discussed in the Environment, Public Health and Food Safety (ENVI) Committee of the EP.

(Point added to original agenda):

4. Drift Risk Assessment Workshop (DRAW). Improving Representation, Management and Mitigation of Spray Drift for Plant Protection Products in Arable Crops (8-9 February, Torino, Italy).

The Commission informed about this workshop, and invited Member States to appoint experts as the participation of regulators is welcome.

A.15 OECD.

No new information.

A.16 Bees:

1. Review of Fipronil – state of play

The Commission informed the Committee about a letter sent to EFSA to withdraw the mandate for the review of the restrictions and to withdraw the task of providing a technical report on confirmatory data.

No renewal dossier was submitted for fipronil. The approval of fipronil will expire on 30 September 2017.

2. Review of the Uniform Principles for Decision Making as laid down in Commission Regulation (EU) No 546/2011

Comments were received from 2 Member States and discussed.

Two Member States indicated their concern for the number of dossiers that would fail at first tier.

3. 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).

Comments were received from 2 Member States.

The Commission is still reflecting on some comments received and will further discuss internally. A new version of the draft Notice will be circulated for comments to the Member States as soon as available.

One Member State indicated the need fora working group to discuss the Bee Guidance Document. This was supported by another Member State.

4. AOB

No discussion.

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 annulment of Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate dismissed.
- Cases C-442/14 and C-673/13 - Judgements announced for 23/11/2016

These cases were presented at the meeting of 6 and 7 December 2016. No update was provided.

A.18 Endocrine disruptors.

The Commission explained that there is no news on the file with respect to the last Committee held the 21 of December 2016.

Three Member States asked details about the on-going development of the guidance document by EFSA and ECHA, in particular at which stage Member States and this Committee would be involved. EFSA and the Commission clarified in line with the details provided in the outline document.

One Member States asked if the next discussions will be held on the basis of the split texts provided for the last Committee, another Member State mentioned it welcomed the split. The Commission explained that reflections on how to best proceed are still on-going.

A.19 Minor Uses.

The coordinator informed the meeting about the state of affairs concerning the continued funding of the Coordination Facility: So far, some Member States expressed some interest, but more committing messages would be necessary in order to provide planning security.

Several Member States agree to the need for continued funding but expect problems in convincing the government as a whole. They ask the Commission to step in and to request Member State Governments in an official letter to contribute to the fund.

The Commission will explore this possibility. The Commission, however wonders why such a letter would be necessary given the broad recognition of the work of the Coordination facility amongst delegations in the Standing Committee, the importance of the Minor Uses problem as expressed by many member States and the comparably modest contribution expected from Member States.

The coordinator informed the meeting about a Stakeholder Conference in Brussels, which will take place on 25th January. All member States were invited to participate.

A.20 Interpretation issues:

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

i. Larvex (Question from Belgium)

The product is composed of dried and chopped garlic bulb. The legal analysis by the producer that this is not a Plant Protection Product (PPP) application is not supported: clearly the intention is to market this product for plant protection purposes and claims in that sense are being made. Possibly, the product could come under the basic substances regime or be considered similar to already authorised garlic derivatives but this would need further examination.

ii. Siltac (Question from BE)

This product is at the limit between products that only have sticking properties and those of which the mode of action is more invasive (suffocation). From the elements of the dossier (i.e. the molecular structure) it shows that the action is rather

immobilisation (trapping) until death follows, than suffocation. As a consequence, this product is not considered a PPP, which is in line with other similar decisions taken in the past.

iii. Colour spray

The matter will be studied in more detail with Commission legal advisers and will be brought back on the agenda at the next meeting.

2. Questions and answers

No new information.

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

1. Status of harmonised classifications

An updated table was made available on CIRCABC.

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

The Commission updated the Member States about its plans concerning an amendment to the legislation regarding the renewal programmes. In line with requests from several Member States, a provision should be added which obliges Member States to regularly prepare classification proposals for active substances under renewal.

The Commission will keep Member States updated on the progress in drafting.

3. Report from the WG on Assessment Reports (AR) template (merging CLH and xAR templates)

An update on the state of play was provided. EFSA and ECHA proposed a merged template for pesticide active substances. Member States were informed that the template is almost finalised but the guidance about how to apply it needs further discussion between EFSA/ECHA and the Commission. The finalised template and guideline will be forwarded to the Working Group on DAR then to the Standing Committee for endorsement, once finalised.

A.22 Glyphosate:

- State of the dossier

EFSA and the Commission updated the Committee on the ongoing assessments. The Commission informed the Committee about a European Citizens' Initiative and thanked Member States who had provided information on the implementation of the provisions of Commission Implementing Regulation (EU) 2016/1313. It drew the

Committee's attention to two scientific articles available on CIRCABC and asked the Rapporteur Member State to assess their relevance.

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

No news, because no meeting of the section Pesticide Residues has taken place since December 2016.

A.24 Proposal on amendment of criteria for the approval of low risk active substances (SANTE/12376/2015).

The Commission informed Member States on the new revision of the draft Regulation which aims to take into account some of the Member States comments expressed in December 2016. In addition, the Commission referred Member States to the documents uploaded in CIRCABC concerning the comments collated from stakeholders through the Feedback Mechanism and a conclusive report. The Commission underlined that the proposal reflects the discussion held in the previous years and has been welcomed by majority of stakeholders which considers it an important step forward. In order to progress further, the Commission proposed to organise a low risk expert group to proceed with a Guidance on the implementation of the criteria to be built up with Member State experts. For this purpose, the Commission asked Member States to nominate an expert. Finally, the Commission asked for comments by 17 February as the vote on the proposal is scheduled for March.

A.25 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

Public consultation of the roadmap ongoing. No further news.

A.26 Commission Communications amending Commission Communications (2013/C 95/01-95/02) – General update.

The Commission brought to the attention of the Committee that the revision of the two Commission Communications was launched. The draft (track-changed) revised communications will be circulated by end of February. Member States and EFSA were invited to send in comments by 31 March.

B.01 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 SANTE/11617/2016)

The draft regulation was presented for vote.

Vote taken: Favourable opinion.

B.02 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. 7)

The draft regulation was presented for vote. One Member State voted against because it felt that setting (or, as in this case: maintaining) restrictions in uses is of the competence of the Member States.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance Mild Pepino Mosaic Virus isolate VC1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/11998/2016 Rev. 0)

The draft Regulation was presented for vote. One Member State abstained because it asks a supplementary fee to provide comments during the peer review, which the applicant refused to pay. In consequence, the Member State cannot support the approval of the substance.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance Mild Pepino Mosaic Virus isolate VX1, 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 SANCO/11980/2016 Rev. 0)

The draft regulation was presented for vote. One Member State abstained because it asks a supplementary fee to provide comments during the peer review, which the applicant refused to pay. In consequence, the Member State cannot support the approval of the substance.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance clayed charcoal in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection

products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/11267/2011 Rev. 0)

The draft regulation was presented for vote. One Member State abstained because of lack of efficacy and phytotoxicity data.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance *Urtica* spp. in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/11809/2016 Rev. 1)

The draft Regulation was presented for vote. One Member State voted against because it felt the risk to non-target arthropods and aquatic organisms were insufficiently addressed. One Member State abstained because it felt the skin irritation and skin sensibilization potential of this compound has not been adequately assessed.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance hydrogen peroxide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/11900/2016 Rev. 1)

The draft Regulation was presented for vote. One Member State voted against, because it felt it cannot be assured that the solutions used would be below the concentration for which there would be no classification for harmful effects. One Member State abstained, because the substance is classified for harmful effects and it felt it is not sufficiently clear that a solution with a concentration below 5% which does not need to be classified, would not have these harmful effects.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance prosulfuron, 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 SANTE/10682/2015 Rev. 3)

The draft Regulation was presented for vote. Two Member States voted against due to the risk of leaching of parent and metabolites into groundwater. One Member State abstained due to concerns about groundwater contamination. One Member State abstained as they considered the restriction to be against the principle of subsidiarity.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance cyclaniliprole, 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 draft Regulation was presented for vote. One Member State voted against, because it considered that the conclusions do not reflect the peculiar nature of biological substance.

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 the active substance *Pseudozyma flocculosa* ATTC 64874 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 SANTE/10615/2016 Rev. 1)

The draft Regulation was presented for vote.

Vote taken: Favourable opinion.

B.11 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 buprofezin (Draft Review Report SANCO/12256/2010 Final).

The draft Regulation was presented for vote. One Member State abstained as they considered that the restriction would prevent some special situations, where residues would not be expected, to be authorised. One Member State abstained as they considered that a safe use could be demonstrated taking into account the Margin of Exposure methodology.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen (Draft Review Report SANCO/11136/2011 Rev. 3).

The draft Regulation was presented for vote. One Member State abstained as they considered that an acceptable peer-reviewed use had not been fully demonstrated. One Member State abstained as they considered the risk to aquatic organisms to be unresolved even with the rate restriction. One Member State abstained as they considered the restriction to be against the principle of subsidiarity. One Member State voted against for consistency reasons as they did not originally support the approval of the substance. One Member State voted against as they considered the

risk to aquatic organisms to be unacceptable even taking into account the restriction and enhanced mitigation measures.

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 extension of the approval periods of several active substances part of the AIR IV renewal programme and listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012

The draft regulation was presented but the vote postponed until the next meeting.

Vote taken: Favourable opinion.

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

Information submitted by Pesticide Action Network and COPA COGECA was uploaded on CIRCABC.

M.02 Antibiotics – Yearly reporting by Member States

The Commission recalled the duty by Member States to yearly report on the nature and quantities of antibiotics that have been used for emergency reasons, should this have been the case. On the basis of that information (to be provided by 17 February) the ad hoc Commission report will be updated and made available on CIRCABC.

M.03 Date of next meeting.

The next regular meeting will take place on 22nd/23rd March 2017.

M.04 AOB

Germany informed the meeting about plans for a workshop concerning harmonised health risk assessment. The workshop is planned for September/October 2017. The workshop will not overlap with a similar event planned by France. Further information will follow.