# **EUROPEAN COMMISSION**



Health and Food Safety Directorate General

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# Standing Committee on Plants, Animals, Food and Feed Section *Pesticides Legislation* 22-23 MARCH 2018

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### **SUMMARY REPORT**

## A.01 Summary Report of previous meetings.

The Committee was informed that the report from the December meeting was due to be published imminently and that the report from January would be published in due course.

### A.02 New active substances:

- 1. New admissible dossiers to be noted:
  - a. Bacillus amyloliquefaciens IT-45
    - A new admissible dossier was noted, *Bacillus amyloliquefaciens* IT-45, which is a fungicide. The rapporteur Member State is France and the applicant is a Taskforce formed by Danstar Ferment AG and Comercial Quimica Masso. Admissibility was reported to the Commission on 12 January 2018.
    - b. *Pepino mosaic virus* (*PepMV*) Chilean (CH2) strain, mild isolate Abp2 (PEPMVO)
      - See subpoint below.
  - c. *Pepino mosaic virus* (PepMV) European (EU) strain, mild isolate Abp1 (PEPMVO)
    - Two new admissible dossiers were also noted concerning Pepino mosaic virus Chilean strain, mild isolate Abp2 and European strain, mild isolate Abp1. The active substances are elicitors. The rapporteur Member State is Spain and the applicant is Abiopep for both active substances. Admissibility was reported to the Commission on 15 February 2018.
  - d. Limestone Postponed.
- 2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
  - a. Pasteuria nishizawae Pn1
    - Moved to section B.
  - b. Metschnikowia fructicola NRRL Y-27328 (NAS 1107)
    - The Commission informed the Committee about the main concerns expressed in the EFSA conclusion and on comments received by the applicant. Member States were invited to send their views by 20 April 2018.

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

#### a. Flutianil

For flutianil, initially a non-approval had been prepared as EFSA had suggested that the substance would not meet the approval criteria due to the need for classification as carcinogenic and toxic to reproduction. As a dossier for a harmonised classification under CLP was under preparation, the Commission had postponed the final decision-making to wait for the outcome of the process led by the European Chemicals Agency (ECHA). This process was finalised and it was established that the substance shall not be classified in one of the aforementioned hazard classes. The Commission therefore will revise the draft Review Report and Regulation. Working documents were presented to the Member States for discussion and commenting by 20 April.

### b. Fenpicoxamid (XDE-777)

The Commission informed Member States that a proposal for approval of fenpicoxamid had been made and a brief summary of the draft review report and Regulation that had been made available to Member States was provided. Member States were invited to provide comments on these drafts before they will be finalised and presented for vote.

# A.03 Renewal of approval:

1. Annex I Renewal: State of play

The Commission informed Member States that two active substances, imazamox and pendimethalin, that were recently approved for seven years as Candidates for Substitution are included in the 5<sup>th</sup> renewal programme as their approvals expire in 2024. The work to allocate new RMSs and co-RMSs was recently finalised and a draft Regulation will be presented to the Standing Committee at the next meeting.

a. 5<sup>th</sup> renewal programme

The Commission informed that the draft working document for the 5<sup>th</sup> renewal programme will be published online on the Europa webpage once the Commission Implementing Decision (Point B.03) is published in the Official Journal.

### 2. Exchange of view on EFSA conclusions:

a. Desmedipham

The Commission informed the Committee about the main concerns expressed in the EFSA conclusion. Member States were invited to send their views by 20 April 2018.

b. Phenmedipham

The Commission informed the Committee about the main concerns expressed in the EFSA conclusion. Member States were invited to send their views by 20 April 2018.

c. Copper compounds

The Commission informed the Committee about the main concerns expressed in the EFSA conclusion and on comments received by the task force and various stakeholders. Member States were invited to send their views by 30 April 2018.

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

# a. Chlorpropham

The Commission informed the Committee about the state of play for the non-renewal as the internal consultation has been recently finalised and TBT (Technical Barriers to Trade) notification needs to be launched. Positions from Member States and RMSs were presented as well as several stakeholders positions on the importance of the substance in the horticultural sector. Member States were invited to send their views by 20 April 2018.

# b. *Pseudomonas chlororaphis* strain MA342 Discussion postponed.

## c. Quinoxyfen

The Commission presented the draft renewal report and the draft Regulation for the non-renewal of approval of quinoxyfen. Member States were invited to provide their comments by 13 April 2018.

## d. Diquat (short update only)

The Commission informed the Committee about a mandate send to the EFSA to update the peer review concerning the non-dietary exposure risk assessment of diquat. Feedback from EFSA is expected by 13 April 2018.

## e. Mecoprop-P

The Commission informed the Committee that there has been little progress made on this file, due to time constraints. Comments received from Member States will be considered and the draft renewal report and the draft renewal Regulation will be updated.

## f. Carfentrazone-ethyl

The Commission presented to the Member States a revised draft renewal report and Regulation concerning the renewal of approval of carfentrazone-ethyl. Two requests for confirmatory information were added to the drafts. Member States were asked to provide any final written comments on these updated drafts.

### g. Propyzamide

Moved to section B.

### h. Silthiofam

Moved to section B.

# i. Mepanipyrim

The Commission presented the draft renewal report and the draft regulation for the restricted approval of mepanipyrim. Member States were invited to provide their comments by 13 April 2018.

# j. Tribenuron (short update only)

The Commission informed the Member States that the Commission will reconsider the EFSA conclusion and comments from the applicant, rapporteur Member State and other Member States before continuing with the TBT notification. Member States were invited to provide their comments by 13 April 2018.

### k. Flurtamone

The Commission informed the Committee that further to the previous discussions on this substance the draft for non-renewal of approval was being progressed given the issues identified.

## 1. Propiconazole

The Commission informed the Committee that the proposal for classification as toxic for reproduction category 1B obtained a favourable opinion by qualified majority at the REACH Committee held on 20 February 2018.

Given the issues identified other than the classification (e.g. residues assessment and groundwater) the draft for non-renewal of approval was maintained.

#### m. Etoxazole

The Commission presented the draft renewal report and the draft Regulation for the non-renewal of approval of etoxazole. Member States were invited to provide their comments by 13 April 2018.

#### n. Fenamidone

The Commission informed the Committee that the draft Regulation for the non-renewal of approval would be notified to third countries via the TBT process in the coming weeks and that a vote on the draft was foreseen in the May meeting.

# o. Trifloxystrobin

The Commission presented the draft review report in view of the renewal of approval of trifloxystrobin. All Member States were invited to provide their comments by 13 April 2018.

## p. Pethoxamid

The Commission informed the Committee that there has been little progress made on this file, due to time constraints. Comments received from Member States will be considered and the renewal report and the draft renewal Regulation will be updated.

# q. Methoxyfenozide

The Commission informed the Committee that the draft renewal report was not yet available for the meeting. In any case, Member States were invited to provide their opinions by 20 April 2018

## r. Ampelomyces quisqualis AQ10

The Commission presented the review report and the draft Regulation for approving the active substance as low risk substance. Comments from Member States are welcome until 13 April. The draft Regulation will to be proposed for voting in May 2018.

## **A.04** Confirmatory Data:

#### 1. Dithianon (short update only)

The Commission informed the Member States that the TBT notification had been launched, and that the draft Regulation amending the approval of dithianon would be scheduled for vote at the meeting after the TBT procedure had been finalised.

#### 2. Terbuthylazine

No discussion – this point was postponed.

# 3. Iprovalicarb ( review report to be noted) Postponed.

- 4. Thiencarbazone-methyl (review report to be noted)
  The Committee took note of the amended Review Report.
- Mandipropamid (review report to be noted)
   The Committee took note of the amended Review Report.
- 6. Bupimirate (review report to be noted) Postponed.
- 7. Azimsulfuron (review report to be noted)
  The Committee took note of the amended Review Report.
- 8. Tau-fluvalinate (review report to be noted)
  The Committee took note of the amended Review Report.
- 9. Disodium phosphonate (review report to be noted)
  The Committee took note of the amended Review Report.
- 10. Ipconazole (review report) Postponed.
- 11. Urea (review report) Postponed.

#### A.05 Article 21 Reviews.

Reports from EFSA on imidacloprid, clothianidin and thiamethoxam

The European Food Safety Authority (EFSA) presented the conclusions (published on 28 February 2018) on the updated risk assessment for imidacloprid, clothianidin and thiamethoxam.

EFSA explained that the conclusions explore new ways for presenting the outcome of the risk assessment. This new approach presents the risk characterisation with a high level of detail, in order to facilitate the assessment by the Commission and Member States in their decision-making processes. EFSA would appreciate feedback from the Commission and Member States on these approaches (e.g. summary table, graphical representations and description of uncertainties). Comments will be welcome until end of May 2018.

Several Member States inquired about the availability of risk mitigation measures for the use in sugar beet. One Member State wanted to continue the use in winter cereals. One Member State inquired if the current draft Regulations will be maintained and indicated to support further restrictions.

Several Member States, which have granted Article 53 authorizations since 2013, asked for risk mitigation measures in oilseed rape and/or sunflower. One Member State indicated that it will reject Article 53 applications for 2018.

EFSA explained that in the conclusions all EU validated risk mitigation options had been used but recognised that certain Member State specific risk mitigation measures might not have been taken into account. EFSA could assess such measures if mandated by the Commission.

The Commission underlined that no data had been submitted during the call for data on succeeding crops for sugar beets which demonstrated that the risk to bees would be low. Therefore, no such information is available in the conclusions.

The Commission had analysed the EFSA reports and maintains its draft Regulations (apart from updating some recitals) as the data now evaluated by EFSA do not allow to conclude that there is a safe succeeding crop for sugar beets. If such data became available in the future and were to be validated by EFSA, the approval conditions could be modified again.

The Commission announced that it intends to table the drafts for vote in the Standing Committee scheduled in May.

(Post meeting note: The Commission scheduled the vote in another Committee meeting on 27 April)

# A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

No new admissible dossiers to be noted.

2. Exchange of view on EFSA conclusions: No new EFSA conclusions.

3. Draft Review/Renewal Reports and Regulations for discussion: No drafts for discussion.

## A.07 Basic substances:

1. Pilot projects: state of play No news since the last meeting.

- 2. New dossiers received (only for information)
  - a. L-cystein See below.
  - b. Wheat flour

The Commission informed about two new applications for basic substances, L-cysteine and wheat flour, that had been submitted. The target pest is leaf-cutting ants in tropical climates.

- c. Clayed charcoal (extension) Postponed.
- 3. Exchange of views on EFSA Technical Reports No new technical report to be discussed.
- 4. Draft Review Reports for discussion:
  - a. Landes pine tar (short update only) Postponed.
  - b. Lecithin extension

The Commission informed the Standing Committee that following a new application for extension of uses of lecithin as basic substance on strawberries, potato and raspberries, a draft amended review report had been made available for comments. Member States were asked to provide comments on the amended review report by 30 April 2018. The updated revised report will be tabled for taking note at the next meeting.

## **A.08** Exchange of views on Guidance Documents:

1. Draft revised Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (for discussion)

The Commission informed the Standing Committee that comments had been

The Commission informed the Standing Committee that comments had been received from some Member States. The updated revised guidance document will be tabled for the next meeting.

- 2. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 Rev. 11, feedback on comments received) The Commission informed the Standing Committee that comments had been received from some Member States. The Post Approval Issue group urged the Commission and the Standing Committee to endorse the outstanding revised guidance document as it addresses the conclusions of the workshop held in Dublin in 2015. An update of the document in place is urgently needed. The updated revised guidance document will be tabled for the next meeting, possibly for endorsement.
- 3. Draft Mandate for a Technical Guideline on the Structure of the Biological Assessment Dossier (for discussion)

  The Commission informed the Standing Committee of the suggestion from a group of Member States led by France to draft guidelines on the Structure of the Biological Assessment Dossier. Member States were invited to provide comments by 13 April.
- 4. EFSA Guidance of the Residue Definition for Risk Assessment (feedback from the Residue Section of the PAFF Committee meeting).

  At the meeting of the PAFF Committee on Residues held in February 2018, the Commission and EFSA made proposals on how to proceed with the implementation of the guidance document on the establishment of the residue definition for dietary risk assessment. Two options for a possible way forward were submitted to Member States for a final decision on the approach. Member States provided feedback to the Commission.
  - Some Member States believe the impact of the GD should be assessed before implementation (Option 1)
  - Some Member States believed that the GD should be implemented as soon as possible (Option 2)
  - Another Member State saw merits in both approaches

The majority of Member States who provided feedback expressed their support for option 1. An impact assessment will therefore be carried out before implementation of the GD by developing a set of cases studies. In parallel, discussions will take place at international level.

5. Draft revised template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 rev. 1, feedback on comments received and discussion in the Post Approvals Issues expert group). The Commission reported on the discussion in the Post Approval Issue group on the revised template to notify zonal applications under Article 33. The section related to the overview on similar products will be deleted as this is not relevant for notifications under Article 33. The revised template will be noted in May.

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

One notification from Germany was submitted concerning the active substance diquat.

The Committee took note of the notification submitted by Germany.

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

- 1. New notifications (to be noted)
  No notifications received from Member States.
- 2. Differences in application of Article 36(3) amongst Member States Postponed.

### 3. On-board fumigation of grain

Comments from two Member States had been received. As the treatment does not take place within the territory of a Member State the rules of Regulation (EC) No 1107/2009 do not apply automatically, but different Member States might have adopted different practices, also with a view to implementation of international obligations.

As only few comments had been received, the Commission extended the commenting period and asks the remaining Member States to describe their practice.

Member States were invited to provide comments in writing before the next meeting.

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

Plant oils/ Rape seed oil, Pyrethrins (Austria)

Copper hydroxide (Austria

Cypermethrin (Austria)

Potassium hydrogen carbonate (Austria)

Beauveria bassiana PPRI 5339 (Austria)

Metarhizium brunneum strain Cb15-III (Austria)

Ethoprophos (Austria)

Quassia (Austria)

Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Austria)

Beauveria brongniartii (Austria)

(E,Z)-2,13-Octadecadien-1-yl acetate,E,Z-3,13-Octadecadienyl Acetate" (Austria)

Metarhizium anisopliae var. anisopliae strain BIPESCO 5/F52 (Austria)

Penoxsulam (Belgium)

Cyantraniliprole (Belgium)

Flonicamid (IKI-220) (Belgium)

Spirotetramat (Belgium)

Metam (incl. -potassium and -sodium) (Belgium)

Pyridate (Bulgaria)

Metobromuron (Germany)

Fludioxonil, Metalaxyl-M, Thiamethoxam (Estonia)E

Beta-Cyfluthrin, Clothianidin (Estonia)

Azadirachtin (Spain)

Aluminium silicate (aka kaolin) (Spain)

Emamectin (Spain)

Mancozeb, Metalaxyl-M (Spain)

Cymoxanil, Famoxadone (Spain)

Tembotrione (Spain)

Clethodim (Spain)

Oxadiazon (Spain)

Quinoclamine (Finland)

Captan (Finland)

Metalaxyl-M (France)

Ethoprophos (France)

Azadirachtin (France)

Sodium hypochlorite (France)

Lime sulphur (France)

Pyrethrins (France)

Potassium hydrogen carbonate (France)

Acibenzolar-S-methyl (Greece)

Iprodione (Greece)

Beta-Cyfluthrin, Clothianidin (Hungary)

Kasugamycin (Hungary)

Clothianidin (Hungary)

Pythium oligandrum M1 (Hungary)

Chloropicrin (Hungary)

Penoxsulam (Hungary)

Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and G 2348 (Italy)

Azoxystrobin (Italy)

Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Italy

Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Italy)

Lavandulyl senecioate (Italy)

Napropamide (Italy)

Beta-Cyfluthrin, Clothianidin (Lithuania)

Fludioxonil, Metalaxyl-M, Thiamethoxam (Lithuania)

Bromoxynil (Latvia)

2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene (alpha-Pinen), 2-Methyl-6-methylene-2,7-octadien-4-ol (ipsdienol), 4,6,6-Trimethyl-bicyclo[3.1.1]hept-3-en-ol ((S)-cisverbenol) (Latvia)

Asulam (Netherlands)L

Plant oils/ Rape seed oil, Pyrethrins (Netherlands)

Bifenox (Netherlands)

Imazalil (aka enilconazole) (Norway)

Copper oxide (Norway)

Deltamethrin, Thiacloprid (Poland)

Paclobutrazol (Portugal)

Azoxystrobin (Portugal)

Cypermethrin (Portugal)

Spinetoram (Portugal)

Propiconazole (Portugal)

1,3-Dichloropropene (Portugal)

Aluminium phosphide (Portugal)

Bentazone (Portugal)

1-Naphthylacetic acid (1-NAA), 6-Benzyladenine (Portugal)

Spirotetramat (Porugal)

Oxadiazon (Portugal)

Bromoxynil (Sweden)

Phosmet (Slovenia)

Lime sulphur (calcium polysulphid) (Slovenia)

Chlorpyrifos (Slovakia)

Tefluthrin (Slovakia)

Lime sulphur (calcium polysulphid) (Slovakia)

Azadirachtin (Margosa extract) (Slovakia)

Trichoderma harzianum strains T-22 and ITEM 908 (Slovakia)

The Committee took note of the notifications submitted by Austria, Belgium, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden.

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

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

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

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

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

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

Concerning the authorisation of kasugamycin, the Commission recalled its strict policy vis-a-vis antimicrobial resistance and requested Hungary to report by the end of the year the amount of kasugamycin used in practice.

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

1. List of End-Points – update of the residue section

The updated list of endpoints – template was discussed with experts and all comments received from Member States have been addressed. EFSA and the Commission invited Member States to take note of the amended template.

Concerning the implementation of the action plan of the Pesticide Steering Network (PSN), EFSA reported an increasing interest in pre-submission meetings with rapporteur Member States and including the applicant.

The work on the improved accordance check is ongoing and well on track.

Following discussions in the PSN and with the Commission, EFSA will in future in more detail document disagreements between EFSA, the rapporteur Member State and other Member States during the peer review.

EFSA would like to be more involved in the evaluation of studies at authorisation level, but at the same time reminded that this would go along with a need for an increase in resources.

As to the new Guidance document on the residue definition, EFSA was keen to provide evidence about possible impacts of its application. The new guidance document has so far been used for two dossier submissions and EFSA will report about the outcome once the review is more advanced.

The Committee took note of the amended template (section residues) for the list of endpoints.

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

No new information under this agenda point

## A.14 Report from working groups:

Plant Protection Products Application Management System (PPPAMS)
 Member States were informed that a new release of PPPAMS had been made on
 12 March – users had been informed via a newsletter.

For emergency applications and authorisations Member States were reminded to process these as quickly as possible in PPPAMS. The Commission informed that webinars would be set up with those Member States with the highest volumes of applications to ensure these were managed effectively.

# 2. Post Approvals Issues group (PAI)

a. Update on the November meeting – products containing 2,4D Revision 5 of the 2,4D renewal report was noted. Member States having renewed the authorisations of products containing 2,4D before the change of the toxicological reference values should review these authorisations according to the newest values. The check may be performed within a year under the zonal system.

# b. Update on the March meeting

The group clarified provisions in the guidance documents on Article 43, on the draft registration report (dRR) and zonal evaluation and mutual recognition. It asked the Commission to provide advice on the acceptance of vertebrate studies generated for other regimes. It agreed that the interzonal steering committee might be a relevant forum to coordinate the evaluation of active substance data submitted after the approval/renewal of an active substance. A first pilot case will be started.

### 3. Working group on Biopesticides

No meeting was held but the working group will be reconvened later in May. Comments were received on the draft guidance document on secondary metabolites.

4. Working group on Seed Treatments (no update) No news.

## 5. Working Group on Co-formulants

The Commission thanked the Standing Committee for the comments received on the two draft Regulations. The comments had been considered by the Working Group during two teleconferences. The formal internal consultation within the Commission will now start before the acts are published for feedback from stakeholders.

6. Working Group on Low-risk criteria

The Commission informed the Standing Committee that the comments received on the draft guidance for implementation of the low risk criteria are being examined and as soon as possible a new meeting of the working group will be organised to follow up also on the resistance issue discussed under the Biopesticides expert group.

### A.15 OECD.

- 1. Pesticide Notification Information System (OECD secretariat)
  The Commission informed the Standing Committee about the notification of New Zealand regarding a tainted source of mancozeb technical grade.
- 2. Update on the new development about the Global Harmonised Submission Transport Standard (EFSA)

  No new information following the discussion in January; point will be closed.
- 3. News on the work of the WGP and the related groups
  - Registration for the WGP (Working Group on Pesticides)
     The Commission informed the Standing Committee about the upcoming meetings of the Working Group on Pesticides (WGP) and its related expert groups.
  - Call for experts for the RCEG
     The Commission informed the Standing Committee about the deadline to submit expert names to the OECD secretariat for the next meeting of the Residue Chemistry Expert Group (RCEG).

### A.16 Court cases.

- Case T-719/17- annulment of Commission Implementing Regulation (EU) No 2017/11496 concerning the non-renewal of the approval of the active substance flupyrsulfuron-methyl No news.
- 2. Case T- 67/18, Probelte v Commission- annulment of Commission Implementing Regulation (EU) No 2017/2065 Confirming the conditions of approval of the active substance 8-HYDROXYQUINOLINE

  The Commission gave a short update on this case.
- 3. Case T- 25/18, PAN Europe v Commission- annulment of Commission decision C(2017) 7604 final of 9 November 2017, partially refusing to grant the applicant access to documents relating to the drafting of Delegated Regulations on scientific criteria for the assessment of endocrine disrupting substances. The Commission gave a short update on this case.

# **A.17** Endocrine Disruptors.

1. State of play: ED criteria and draft EFSA/ECHA guidance document

The Commission informed that the scrutiny for the Regulation setting the endocrine disruptior (ED) criteria is to end on 9 April 2018. Council has already decided not to oppose (27 February) and two statements were made: one from the Netherlands, Latvia, Portugal, and the Czech Republic and another one from Denmark and Sweden. As regards the position of the Parliament, the end of the scrutiny period has to be awaited but so far there are no indications that the Parliament would oppose.

In case of no opposition, the Commission will proceed to adopt the criteria swiftly (end of April) and they will be published one day after adoption. Then they will enter into force 20 days after publication (May) and be applicable six months later (November).

One Member State asked how to evaluate endocrine disruptors for the cases where a draft Renewal Report (DRR) has to be submitted before the new criteria are applicable. In such a case the interim criteria are legally applicable, however it is evident that the new criteria will need to be considered at the peer review level at EFSA. The Commission suggested that in such cases (between entry into force and applicability of the criteria), the rapporteur Member State (RMS) may either conclude if the active substance (AS) is an ED or not on the basis of the interim criteria, or alternatively justify that no conclusion is made as regards the interim criteria but the RMS should then evaluate the AS according to the new criteria and propose, if applicable, which additional data would be needed to conclude if the AS is an ED or not according to the new criteria.

The Commission informed the Member States about the workshop held on 1-2 February 2018 and thanked the Member States who had prepared case studies on the applicability of the draft guidance to identify endocrine disruptors. The Commission reminded that, taking into account the comments received during the public consultation (7 December 2017 - 31 January 2018) and during the workshop held on 1-2 February 2018, the draft guidance is now being revised by the drafting group (EFSA and ECHA with the support of the Joint Research Center JRC).

Risk assessors for the PPP sector (via the pesticide steering network) and the BP sector (via the Biocidal Product Committee in ECHA) will be consulted on this new revision of the draft guidance document around mid-April 2018 via a list of questions. The time for Member States to comment/answer the questions will be limited to two weeks. Risk managers will be consulted on the final draft via the PPP and the BP Standing Committees in May, but time for commenting will be limited to one week. This is why the Commission asked risk managers in each Member State to liaise with their risk assessors, in order to raise any major comments during the consultation for risk assessors foreseen in April.

The final guidance document is expected to be adopted in June 2018, when the criteria to identify endocrine disruptors for biocidal products will become applicable.

The Commission also informed that it will make available in the next days on CIRCABC the draft guidance document which was submitted for public consultation (since it is not available on-line anymore) and all the presentations given at the workshop on 1-2 February 2018, which include several case studies prepared by some Member States on the applicability of the draft guidance.

2. Implementation of the new ED Criteria renewal active substances: Amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties

The Commission gave a presentation on a new version of the draft act Amending Implementing Regulation (EC) No 844/2012, where the implementation of the new criteria to pending applications is detailed, introducing the main changes compared to the version already discussed in the previous meeting. The draft Regulation will be uploaded on CIRCABC as soon as the discussion with the

Legal Service will be finalised and Member States will be informed and asked to provide their comments.

#### A.18 Minor Uses.

The Second Stakeholder Advisory Forum of the Minor Uses Coordination Facility (MUCF) took place on 6 February 2018 in Brussels. The event was well attended with around 50 stakeholders from a diverse range of Member States and organisations. The report of the Forum will be published soon.

The spring meetings of the Commodity Expert Groups (CEG) and Horizontal Expert Group (HEG) which took place in Brussels on 13-15 March 2018 were attended by approximately 110 participants from more than 20 Member States and a plenary session dedicated to Integrated Pest Management (IPM) was organised.

A priority for the Coordination Facility is to ensure long-term financial sustainability, beyond the first three years. Requests for voluntary assessed contributions have been sent out and already twelve Member States plus Switzerland responded positively to this request. Future arrangements will be discussed for a Steering Group to be appointed by the whole body of funders, in the next Minor Uses Steering Group meeting on 4-5 April 2018.

A 'Guidance Document on Minor Uses' on the implementation of Article 51 and other provisions related to minor uses, is in preparation. The next meeting of the drafting group is scheduled for April 2018. After this meeting it is envisaged to have a draft available that can be circulated to all Member States and stakeholders for commenting. It is envisaged that eventually the 'Guidance Document on Minor Uses' will be noted in the PAFF Committee meeting.

## **A.19 Interpretation issues:**

- 1. Scope of Regulation (EC) No 1107/2009:
  - a. Lava meal (Belgium)
  - b. Salvis freeze (Belgium)
  - c. Straw pellets (Belgium)
  - d. Moss control / fertilizers (Denmark)
  - e. Uses against lichens on trees (Austria)

The discussion on this agenda point was postponed.

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

- Status of harmonised classifications No item raised.
- Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances No item raised.
- 3. Report on the alignment of the classification and peer-review processes
  The Commission informed the Standing Committee that discussion is still ongoing between EFSA, ECHA and the Commission. Once progress is made, the
  Working Group with both Agencies, volunteer Member States and the
  Commission will be reconvened.

## A.21 Glyphosate.

The Commission informed Member States about:

- a court case lodged by a region in one Member State, who decided to challenge the renewal decision. It remains to be seen whether this case will be considered admissible by the Court as it is a region and not a Member State challenging the decision.
- a regional draft measure in one Member State proposing to ban the use of plant protection products containing glyphosate and the clarifications brought forward by the Commission to this region, which will now amend its draft measure.
- the work of EFSA on MRLs and its expected publication for April 2018
- the first meeting of the EP PEST Committee (12 April 2018). The Committee will meet twice per month and Member States, EFSA and the Commission are expected to be invited for hearings.
- the upcoming adoption of the "transparency proposal" to amend the General Food Law in response to the citizens' initiative on glyphosate
- the need to find a rapporteur for the next evaluation of glyphosate. The Commission is ready to accept the concept of a consortium of Member States acting as rapporteur and co-rapporteurs so that the burden could be shared amongst several Member States.

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

No item raised.

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

The Commission thanked the Member States for responding to the very extensive questionnaire for the external evaluation study. The Commission informed that the second workshop will be held on 16 May 2018 in Brussels. One participant per Member State is invited, thus Member States are requested to coordinate with colleagues working on pesticide residues. In the workshop the main findings of the contractor will be discussed and validated. A thought-starter will be sent out before the workshop that will form the basis for the discussion.

## A.24 Information concerning Brexit.

No item raised.

# A.25 Draft Commission Notice concerning a list of potentially low-risk substances (presentation).

The Commission informed the Standing Committee that the Commission Notice is under inter-service consultation. Some Member States asked to be informed as soon as the Notice will be adopted and published.

### A.26 Scientific publications and information submitted by stakeholders.

All information received ahead of the meeting had been uploaded on CIRCABC.

# A.27 Confirmatory data pending and renewal ongoing – Clofentezine and Difeconazole (RMS ES).

Postponed.

# A.28 Summary of the Workshop on Toxicological Risk Assessment of Plant Protection Products (Paris, 13-14 March 2018).

The workshop was held on 13-14 March at the ANSES headquarters in Paris. The Commission thanked ANSES and the organisation committee for their excellent organisation of this event. The workshop was a great success and included participants from almost all Member States, from industry, from EFSA and from JRC and ECHA. A number of key issues were discussed and whilst progress was noted on harmonisation of risk assessment, there is still more to be done. Of note is that the update of guidance document on non-dietary exposure would be undertaken by EFSA following a mandate from the EC. This work would take 3 years to complete. A report of the workshop will follow.

## A.29 Update on acetamiprid.

The Commission informed the Member States about the different conclusions of EFSA and ECHA on the persistency of acetamiprid. The Commission explained that the difference comes from a different evaluation methodology between pesticides and biocides which in this case lead to a different conclusion for the same active substance.

# A.30 Iprodione: updated toxicological reference values for a non-renewed substance (request from Belgium, for note taking).

The new reference values identified by EFSA were endorsed in the form of an updated renewal report.

# A.31 Propargite: new toxicological reference values for setting of import tolerances (for note taking).

The Commission outlined a preliminary strategy to address future import tolerance requests where new toxicological data are submitted in support of the establishment of toxicological reference values. This includes cases of substances that were never authorised in the EU but for which import tolerance requests are made.

- The Evaluating Member State assesses the new toxicological data and drafts an Evaluation Report (ER);
- The Commission forwards the ER to EFSA who is to deliver a Reasoned Opinion within 6 months;
- EFSA launches a Member States' consultation on the ER with a focus on the toxicological assessment only (4 weeks);
- Following the comments received, EFSA might decide that there is a need to request additional data (stop-the-clock letter);
- Following submission of the updated ER and considering the comments received, EFSA will consider the need to discuss the outstanding issues in a physical meeting or in an *ad hoc* telephone conference;
- Following publication of the Reasoned Opinion, the PAFF-legislation is responsible for taking note of the new reference values;
- Once noted, the new reference values will be considered in MRL assessments.

The Committee took note of the new toxicological reference values proposed by EFSA in the framework of the Reasoned Opinion establishing import tolerance requests for propargite in citrus fruits and tea, published on 26 February 2018.

#### A.32 Revision CIRCABC Account users.

In the frame of the recurrent revision of access to the Interest Group Plant Protection Products and their Residues, the Commission asked all Member States to verify that all users of that Interest Group are still eligible for access. As the Interest Group is shared with the Committee section "Pesticides Residues", the Commission asked the participants to liaise with the national contact points for residues and submit only one common reply per Member State, covering all competent authorities. To this end, the Commission will approach the residues contact points after the meeting by e-mail.

# A.33 New AGM system for the organisation of meetings and reimbursement of participants.

A new system for proceeding with invitations and reimbursement for meetings has been rolled out by the Commission and information packages were sent to the contact points for the Committee.

Member States were invited to ask for clarifications, where necessary.

## A.34 Date of next meeting.

The next regular meeting is planned for 24-25 May 2018.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing approval of active substance bentazone in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12012/2015 rev. 7).

Vote taken: Favourable opinion.

*Reasons for abstention/negative opinion:* 

- Findings of bentazone in Member States' national groundwater monitoring programmes.
- Renewal period of five years cannot be supported.
- B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance Talc E553B in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11639/2017 Rev1).

Vote taken: Favourable opinion.

## *Reasons for abstention/negative opinion:*

- Inclusion of risk mitigation measures.
- B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the establishment of a work programme for the renewal of active substances expiring in 2022, 2023 and 2024 in accordance with Article 18 of Regulation (EC) No 1107/2009.

**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 propyzamide, as a candidate for substitution, 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 11797/2016 Rev. 3).

Vote taken: Favourable opinion.

# Reasons for abstention/negative opinion:

- Lack of data on risk assessment related to groundwater and ecotoxicology.
- Lack of data on non-target organisms, consumer risk assessment and ED properties.
- B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance silthiofam in accordance with Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11799/2016 Rev. 2).

Vote taken: Favourable opinion.

## *Reasons for abstention/negative opinion:*

- Data gap on ecotoxicology and groundwater risk assessment.
- Potential risk of leaching and data gap on eco-toxicological and groundwater risk assessment.
- B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance forchlorfenuron 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/11643/2017 Rev 2).

Vote taken: Favourable opinion.

B.07 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 malathion.

Several Member States indicated not to support the draft Commission Regulation. For some of them, the provisions are too restrictive, as some outdoor uses are essential for agriculture. For one Member State, the measure was not restrictive enough.

# **Vote Postponed**

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenazaquin (Draft addendum to the review report SANTE/11781/2017 rev 0).

Vote taken: Favourable opinion.

## *Reasons for abstention/negative opinion:*

- Issues as regards aquatic organisms can be dealt with by risk mitigation at Member State level.
- A safe use in citrus was demonstrated by EFSA.
- No safe use on an edible crop grown in a greenhouse has been demonstrated as regards consumer exposure.
- B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Pasteuria nishizawae* Pn1, 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/10160/2018 rev. 0.1).

The inter-service consultation was not finalised.

Member States were asked for their positions.

## **Vote Postponed**

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bromuconazole, buprofezin, haloxyfop-P and napropamide.

Vote taken: Favourable opinion.

### *Reasons for abstention/negative opinion:*

- The act includes two active substances that are listed as Candidates for Substitution which should be evaluated without delay.
- B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance zoxamide 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/10052/2018).

Vote taken: Favourable opinion.

# *Reasons for abstention/negative opinion:*

- Potential leaching of metabolites in groundwater.
- Lack of data on consumer risk assessment, non-target organisms and equivalence of technical specifications.
- More data needed on certain metabolites potentially relevant for consumer risk assessment.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiram 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/11020/2017 Rev 2).

A notification to the WTO under the TBT agreement was still ongoing, meaning that a formal vote could not take place.

Member States were asked for their positions.

## **Vote Postponed**

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance pymetrozine 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/00103/2015 Rev 3).

A notification to the WTO under the TBT agreement was still ongoing, meaning that a formal vote could not take place.

Member States were asked for their positions.

# **Vote Postponed**

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance oxasulfuron 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/10886/2017 Rev 0).

A notification to the WTO under the TBT agreement was still ongoing, meaning that a formal vote could not take place.

Vote rescheduled for the next Committee meeting.

# **Vote Postponed**

## M.01 Seed treatment for export of seeds only (in conjunction with point B.12- thiram).

As part of the discussions on thiram it was raised whether products containing thiram could be used to treat seeds for export only in the case of the non-renewal of approval of the substance. This question is not, however, only relevant to the case of thiram but also to other substances which may be used as seed treatments and where an approval is withdrawn or restricted.

Different views were expressed by Member States.

## M.02 Aspergillus flavus.

Denmark shared some information about *Aspergillus flavus* strains with multiple antiobiotic resistance occurring in Denmark. The Commission invited the other Member States to share any information on this topic in writing after the meeting.