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**Standing Committee on Plants, Animals, Food and Feed**

**Section *Phytopharmaceuticals - Legislation***

**23 – 24 October 2018**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/d4213216-e1cc-420f-b513-bc4ac32d94a9>

**SUMMARY REPORT**

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

The Commission informed that the summary report of the previous meeting had been published.

**A.02 New active substances:**

1. New admissible dossiers to be noted:

Two new admissible dossiers were noted:

- Elemental Iron, a molluscicide applied for by ADAMA Agriculture B.V. The rapporteur Member State is Austria and the admissibility was reported to the Commission on 9 August 2018.
- *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), an insecticide applied for by Andermatt Biocontrol GmbH. The rapporteur Member State is Spain and the admissibility was reported to the Commission on 24 September 2018.

As regards Bixlozone (F9600), not all Member States had received the relevant information. The note taking was postponed.

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

The Commission informed about two new EFSA Conclusions:

- Propanil (withdrawal of application following EFSA conclusion): EFSA Conclusion was made available to the Commission on 6 September 2018. By letter of 14 September 2018 the applicant UPL Europe Ltd withdrew its application for the approval of propanil. The Commission will draft a Regulation for non-approval of the substance with a vote expected for December 2018.
- Mefentrifluconazole: in the EFSA Conclusion no critical area of concern had been identified, however two issues could not be fully finalised: 1) the potential effects of water treatment for which no guidance exist and 2) the new criteria to identify endocrine disrupting properties which apply from 10 November 2018. The EFSA Conclusion states clearly that as regards human

health Mefenitrifluconazole is not to be considered to have endocrine disruption (ED) properties (EATS modalities). EFSA did not finalise the assessment as regards fish but an initial review seems to indicate that the scientific approach taken for testing, which includes higher tier fish tests, would confirm the absence of ED potential in fish. Based on this, an approval of Mefetrifluconazole would be possible. The Rapporteur Member State clarified that for fish level 4 / level 5 studies are available, which implies that there is no relevant data gap. Member States were invited to communicate their views to the Commission by 12 November 2018.

### 3. Draft Review Reports for discussion:

The Commission informed about one draft Review Report made available for discussion:

- ABE IT 56: EFSA conclusion is available since July 2018. It is proposed to approve ABE-IT 56 as low risk active substance. Member States were invited to communicate their views to the Commission by 12 November 2018.

The discussion on *Bacillus subtilis* IAB/BS03 was postponed.

## **A.03 Renewal of approval:**

### 1. Annex I Renewal Projects: State of play

The Commission informed that it is preparing an act to retract the extension of the expiry dates for three active substances in the AIR 4 programme which are no longer supported in the EU: bifenthrin, pepper and sodium aluminium silicate.

### 2. Exchange of view on EFSA conclusions/EFSA scientific report:

The Commission informed about new EFSA Conclusions/EFSA scientific reports:

The EFSA Conclusion on bromoxynil had proposed that the active substance should be classified as toxic for reproduction, category 1, however so far no CLH dossier has been submitted to ECHA in order to confirm this. Consequently, the assessment of whether bromoxynil can be used such that exposure to humans is negligible and as to whether bromoxynil meets the conditions of Article 4.7 of Regulation (EC) No 1107/2009 was mandated to EFSA, without prejudice to the need to consider other issues identified during the renewal assessment. The Commission informed that the draft EFSA Conclusion on negligible exposure was available and indicates that non-dietary exposure is unlikely to be negligible. The Commission reminded that the Scientific Report on Article 4.7 was published in August 2018. There are several uses in Member States where insufficient chemical alternatives are available. It was however noted that a combination of chemical and non-chemical methods seems possible.

Flumioxazin is classified as toxic for reproduction, category 1B. The Commission informed that the EFSA Conclusion on negligible exposure is published since 8 October 2018 and indicates that acute exposure for operators for both representative uses cannot be considered negligible. The Commission reminded of the Scientific Report on Article 4.7 published in January 2017. There are several uses in Member States where insufficient chemical alternatives are available. It was however noted that a combination of chemical and non-chemical methods seems possible.

Member States were invited to communicate their views to the Commission by 26 November 2018, in particular on whether they consider renewal of certain uses identified in the EFSA Article 4.7 Scientific Report.

3. Draft Review/Renewal Reports for discussion:

The Commission informed about draft Review/Renewal Reports made available for discussion, which had also been made available to the applicants for commenting.

a) Rimsulfuron

The EFSA conclusion was adopted on 23 April 2018. One critical concern with respect to the genotoxic potential of one of the metabolites of rimsulfuron could not be concluded on.

The Commission received feedback from several Member States on the EFSA Conclusions: one Member State supported a non-renewal of rimsulfuron, two Member States disputed the EFSA conclusions and the concerns identified, one Member State pointed to some concerns with respect to the groundwater modelling of the metabolite.

Following the review of the evidence available in particular as regards the genotoxic potential of the metabolite, the Commission considered that it is not possible to make a recommendation on the renewal or non-renewal of Rimsulfuron. Therefore the Commission intends to mandate EFSA to clarify this point.

b) Mecoprop-P

Following the EFSA Conclusion adopted in April 2017, a proposal for non-renewal had been presented in October 2017. Meanwhile it was shown that the worker exposure risk assessment had been performed using different parameters with respect to what had been done for the same representative use for other active substances, creating inconsistencies. Therefore, the Commission suggests mandating EFSA to revise the workers exposure assessment in order to ensure a consistent approach. In case the worker exposure risk assessment is acceptable, then EFSA would also be requested to update the ED assessment in line with the new ED criteria. One Member State indicated that also concerns for consumers, groundwater and ecotoxicology were highlighted in the EFSA Conclusion. Member States were invited to communicate their views to the Commission by 12 November 2018.

c) Spinosad

The EFSA conclusions had been published in March 2018. In the draft review report for renewal available to Member States some supported uses are removed from the GAP table based on the residue definition and ultimately the consumer risk assessment. The assessment of the endocrine disrupting properties under the new criteria is still to be discussed.

Comments from several associations of growers from five Member States belonging to the Southern and Central Zone had been received, which highlight the need of this active substance in particular also for organic farming. Member States were invited to communicate their views to the Commission by 12 November 2018.

d) Thiophanate-methyl

The EFSA conclusions had been published in January 2018. The Commission had prepared a draft renewal report proposing non-renewal of approval of thiophanate-methyl, based on several areas of critical concern and issues not finalised: the main metabolite carbendazim is classified as mutagen, category 1B; genotoxicity concerns regarding thiophanate-methyl; consumer and non-dietary risk assessment not finalised due to concerns about the parent compound and the metabolite carbendazim; risk to birds and mammals; groundwater assessment not finalised for various metabolites; potential endocrine disrupting properties (EFSA Conclusions indicate that thiophanate-methyl is likely to be an endocrine disruptor based on available scientific evidence). Additionally, while thiophanate-methyl is currently classified as mutagen, category 2, EFSA proposes classification of as mutagen, category 1B. The RMS informed that its proposal for classification of thiophanate-methyl is not mutagen, category 1B, but mutagen, category 2 confirming the current harmonized classification. Member States were invited to communicate their views to the Commission by 26 November 2018.

e) Trinexapac-ethyl

The Commission has proposed the renewal of approval of trinexapac-ethyl in the draft renewal report as the issues related to the specification and consumer risk assessment identified in the EFSA Conclusion could be addressed. There was no specific concern to indicate that trinexapac-ethyl is an endocrine disruptor, however, EFSA concluded that some elements of the assessment could not be finalised. Further consideration of how to complete the assessment of endocrine disrupting potential is ongoing. Member States were invited to provide comments by 26 November 2018.

f) Fosetyl

The discussion was postponed.

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

1. General update, status and prioritisation

The discussion was postponed.

2. Isofetamid (short update only)

The discussion was postponed.

3. Metazachlor

The Commission recalled that in October 2017 a draft updated review report proposing the withdrawal of approval of metazachlor had been presented. Eleven Member States submitted written comments on this draft report, and only one Member State considered that a withdrawal of approval would be justified. The other Member States broadly acknowledged that whilst the groundwater monitoring data did not meet all the quality criteria they were sufficiently reassuring to indicate that the two relevant metabolites of metazachlor will not contaminate groundwater under the foreseen conditions of use. Taking into account these comments and further examination, the draft updated review report had been amended to propose maintaining approval, but highlighting the need to

address in details the issue of groundwater in the evaluations of product authorisations. Member States were invited to send comments on the draft updated review report by 12 November 2018.

4. Fluquiconazole

A revised draft review report was made available for Member States and there is no need to amend the approval conditions since the additional data provided addressed the confirmatory requirements. Member States were invited to provide comments by 12 November 2018.

5. Ipconazole

The Member States were informed that as regards the risk to granivorous birds, a use showing no unacceptable effects was demonstrated for some focal species and scenarios. The draft revised review report made available to Member States allows Member States to consider each use during assessments for product authorisation, but indicates that this issue needs more attention at renewal. Member States were invited to provide comments to the draft amended review report by 12 November 2018.

One Member State commented that ipconazole had recently been classified as toxic for reproduction, category 1B by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) and asked if the approval should be reconsidered now rather than waiting for the renewal assessment.

6. Fluopyram

Member States were informed that the key issue related to the risk to birds. For the use on grapes no unacceptable risk was identified therefore there is no need to amend the approval. The draft amended review report flags that the risk to birds from the use on tomato and strawberry was not confirmed as being acceptable. Member States were invited to provide comments to the draft amended review report by 12 November 2018.

7. Sulfoxamid

This agenda item had been added erroneously and was thus not discussed.

8. Bupirimate (amended review report to take note)

The discussion was postponed.

9. Sulfoxaflor

The Commission informed that EFSA had been mandated to organise a peer review on the outcome of the assessment of the confirmatory data with deadline end of February 2019.

**A.05 Article 21 Reviews.**

No news to report.

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

1. New admissible dossiers to be noted:

No news to report.

2. Exchange of view on EFSA conclusions:  
No news to report.
3. Draft Review/Renewal Reports and Regulations for discussion:  
No news to report.

#### **A.07 Basic substances:**

1. *Quassia amara* L. wood extract (withdrawal)

The Commission informed that the applicant had withdrawn its application and intends to come back with a completed dossier to fill the data gaps identified earlier by EFSA.

2. New dossiers received (for information)

Member States were informed that applications for the following basic substances had been received:

- a) caffein
- b) L cysteine
- c) oleoresins capsicum
- d) *Allium cepa* extract
- e) sucrose (extension)

3. Exchange of views on EFSA Technical Reports

The Commission informed that EFSA approved on 22 August the technical report regarding the use of cow milk as basic substance, applied by foliar spray after dilution with water, against powdery mildew in grapes, vegetables and ornamentals, as well as liquid for disinfection of cutting tools. The EFSA report underlined the potential allergenic concerns caused by the possible presence of residues of milk on treated crops. The applicant had proposed labelling of treated commodities to warn the consumers. The Commission recalled that a similar concern had been identified for whey. Member States were invited to send their comments, in particular about the effectiveness of the proposed risk mitigation measure by 26 November 2018.

4. Draft Review Reports for discussion:

- a) Extension of approval of vinegar

The draft amended review report for an extension of use of vinegar as herbicide for medicinal aromatic and for perfume crops had been made available. The Commission proposed not to grant extension for the use in non-agricultural areas because of inhalation risks to humans and eco-toxicological risks. The applicant had been consulted on the draft amended review report and submitted a new GAP – with lower concentration and application rates - for the non-agricultural uses; however these changes cannot be considered at this point of the regulatory procedure. The Commission intends to propose a draft Regulation amending the conditions of approval of vinegar for opinion of the Committee at the next meeting.

b) *Castanea* and *Schinopsis* tannins

The discussion was postponed.

c) *Vitis vinefera* tannins

The discussion was postponed.

#### **A.08 Guidance Documents:**

1. General update and stakeholder consultation via the Advisory Group on the Food Chain and Animal and Plant Health

The Commission informed that it aims to consult stakeholders on draft guidance documents in future via the Advisory Group on the Food Chain and Animal and Plant Health. Invitations will be extended also to ad hoc stakeholders who are not members of this Advisory Group.

A meeting of the Advisory Group was organised on 21 September 2018 on guidance documents related to Regulation (EC) No 1107/2009. Similar meetings will be organised more frequently in the future, and written consultation on specific documents could also be envisaged. The minutes of the meetings of the Advisory Forum are public via the SANTE website.

2. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

The Commission informed on the written comments received from Member States since the last meeting. Many of the received comments questioned the chronic trigger value and the technical difficulties with higher tier testing. A "tour de table" indicated the following positions of the Member States:

- 16 Member States indicated the need to revise the Bee Guidance Document first before it being implemented.
- 9 Member States could support the current implementation plan. Six of these Member States asked for an immediate start of a revision of the Bee Guidance Document after implementation.
- 2 Member States did not have a position.
- 1 Member State was absent and not represented.

In the light of the positions of Member States, the Commission proposed as a compromise revising the implementation plan by moving the parts related to chronic risk to honeybees to part B (with a later implementation date) and mandating EFSA to update certain elements of the Bee Guidance Document. This would imply no delays in implementing the acute risk to honeybees and would be a step forward given that exposure can be assessed for different exposure routes. The draft regulation to amend the trigger values would be amended accordingly (see Point C2).

Some Member States indicated the need for involvement of risk managers when the Bee Guidance Document is revised and EFSA indicated being open to this. One Member State indicated that the need to assess the chronic risk to bees is already mentioned in the implementation of Regulation (EC) No 1107/2009.

The Commission invited Member States to provide comments on the amended draft Commission Notice (moving chronic risk assessment to bees to part B of the implementation plan) by 12 November 2018.

3. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – final consultation before adoption

The Commission informed that the interservice consultation on the draft Commission Notice is currently ongoing. Comments from three Member States had been received regarding the transitional provisions on data protection (Art. 80). During the advisory group meeting on 21 September, stakeholders asked to be consulted on this guidance document and comments are expected by 24 October 2018. Pending the comments from stakeholders, a revised version will be presented to the Standing Committee as soon as possible for final commenting.

4. Data requirements and list of agreed test methods - Update of the revision of the Communications (short update)

The excel file containing the updated test guidelines and guidance documents had already been shared with Member States and EFSA. Comments were received and are considered. The revised excel file was used to draft the two updated Communications, which were shared with stakeholders at the advisory group meeting on 21 September. The feedback of stakeholders is expected by 23 November at the latest.

It is planned to have the two Communications adopted as Commission Notices. Once comments are considered, the draft Commission Notices will be subjected to inter-service consultation and presented to the Committee.

5. Defining Specific Protection Goals for environmental risk assessment – update

The Commission informed that two Member States had send comments on the outline presented at the last meeting, and invited Member States to send any comments by 26 November 2018.

6. Corrigendum of cover page of the Guidance Document on Dermal Absorption

The Committee took note of a minor corrigendum on the cover page for the EFSA Guidance on dermal absorption, which had been noted at the meeting of the Committee on 25 May 2018.

7. Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil

The Commission informed that the Guidance Document for evaluating dissipation studies to obtain DegT50 values in soil was published by EFSA in October 2017 but it is not yet possible to take note of the guidance document. The reason is that the tool designed by EFSA which is essential to implement the guidance will not be ready before March 2019, and would then need to be tested. It is expected that the note taking will be possible mid-2019, once the tool is fully available.

8. Draft guidance document on Consideration of Soil Photodegradates in FOCUS-PELMO 5.5.3 – update and discussion on next steps



One Member State informed that it prepared this draft guidance document in cooperation with other Member States and EFSA. It wondered about the next steps for finalising the guidance document, and hoped for a smooth process to have this guidance document available soon.

The Commission thanked the Member State(s) which volunteered to prepare this draft guidance document and will reflect on the best and most efficient way forward to consult and adopt this draft guidance document.

**A.09 Commission Regulation (EU) No 547/2011 and risk mitigation:**

The discussion was postponed.

One Member State raised an additional point as regards labelling and appropriate conditions of storage, which will be discussed at the next meeting of this Committee.

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

The Committee took note of one notification which amended the classification and adapted the personal protective equipment for one plant protection product.

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

1. New notifications (to be noted)

The Committee took note of 7 notifications in 3 Member States, where authorisations have been refused.

2. Differences in application of Article 36(3) amongst Member States

The discussion was postponed.

**A.12 Plant Protection Products Application Management System (PPPAMS).**

Member States were informed that discussions are ongoing about how to move ahead with a full implementation of PPPAMS as quickly as possible by finding an alternative to the data migration related to existing authorisations which seems to block full implementation.

The Commission presented the state of play in using PPPAMS to manage emergency authorisations. Member States did good progress as regards using PPPAMS for notifying emergency authorisations. However, there are differences as regards how Member States handle the emergency authorisation process and this process needs to be harmonised. Further discussions are needed.

**A.13 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:**

1. New notifications (to be noted)

A total of 90 emergency authorisations were notified between the 7th of July and the 22nd of October 2018 by 20 Member States concerning the active substances listed below. The Committee took note of these notifications.

MS	Active substances	Functions
MT	1 3-Dichloropropene	nematicide
HR	6-Benzyladenine	plant growth regulator
GR IE	Abamectin (aka avermectin)	insecticide
FI	Acetamiprid	insecticide

FI	Alpha-Cypermethrin (aka alphamethrin)	insecticide
DE FR HR	Azadirachtin (Margosa extract)	Acaricide, insecticide
ES	Azoxystrobin	fungicide
SE	Azoxystrobin, Difenoconazole	fungicide
FI	Bacillus thuringiensis subsp. aizawai strains ABTS-1857 and GC-91	insecticide
BE PL	Beta-Cyfluthrin, Clothianidin	insecticide
NO	Bifenazate	acaricide
FR	Boscalid (formerly nicobifen), Pyraclostrobin	fungicide
ES HR	Captan	plant growth regulator
GR	Carboxin, Thiram	fungicide
AT ES FR	Chlorantraniliprole	insecticide
HU	Chlorophacinone	rodenticide
GR HU MT	Chloropicrin	
AT	Chlorotoluron	herbicide
HR	Chlorpropham	plant growth regulator
AT DE	Copper hydroxide	fungicide
UK	Copper oxychloride	fungicide
BE FR HU IE NL UK	Cyantraniliprole	insecticide
FR	Dichlorprop-P	plant growth regulator
ES	Dichlorvos	attractant
FR GR	Dimethenamid-P, Metazachlor	herbicide
AT	Diquat (dibromide)	herbicide
FI	Esfenvalerate	insecticide
BE	Ethylene	
PT	Fludioxonil	fungicide
PL	Fludioxonil, Metalaxyl-M, Thiamethoxam	insecticide
GR	Fluopyram	Fungicide, nematicide
GR	Fluxapyroxad	fungicide
FI	Indoxacarb	insecticide
LT	Iprodione	fungicide
FR	lambda-Cyhalothrin	insecticide
DE	Lime sulphur (calcium polysulphid)	fungicide
FR	Mandipropamid	fungicide
PT	Metaflumizone	insecticide
GR	Napropamide	herbicide
FR	Paraffin oil/(CAS 64742-46-7)	fungicide
SE	Prochloraz	fungicide
GR	Prochloraz, Propiconazole	fungicide
FR	Sodium hypochlorite	bactericide
LV	Sodium silver thiosulphate	plant growth regulator
ES	Spinetoram	insecticide
ES FR	Spinosad	insecticide
ES	Spirodiclofen	acaricide
DE PT	Spirotetramat	insecticide
PT	Sulphur	fungicide
GR	Tebufenpyrad	acaricide

BE HU PL RO	Thiamethoxam	insecticide
ES	Thidiazuron	plant growth regulator
ES	Thiram	fungicide
AT	Tribasic copper sulfate	fungicide
BG SK	Zinc phosphide	rodenticide

## 2. Update on emergency authorisations for neonicotinoid active substances

The Commission informed about the replies received from Romania, Hungary, Lithuania and Bulgaria on the letters sent by Commissioner Andriukaitis asking to confirm that emergency authorisations found not justified by EFSA will not be repeated. These replies are currently considered together with the emergency authorisations given in 2018, in order to evaluate if a Commission decision, in line with Art. 53.3 to prohibit the repetition of these emergency authorisations, is warranted.

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

#### 1. General update

EFSA updated the Committee via a presentation, in particular informing about the implementation of the action plan of the pesticide steering network, the on-going work on the alignment of CLH and PPP processes, a new independence policy for peer review experts, the Scientific Opinion on TK/TD modelling adopted in July. Ongoing consultations are the launch of a call for data on exposure guidance (PPR Panel), and public consultations of the Scientific Committee on genotoxicity and on the mixtox guidance. The final version with editorial corrections of the guidance document on endocrine disruption will soon be published in the EFSA Journal. A new PPR Panel is operational since July 2018.

### **A.15 Improving the efficiency of the process of a.s. approval – update on on-going activities.**

The Commission informed about on-going activities which aim to improve the efficiency of the active substances approval process. The Commission and EFSA had held several bilateral meetings to identify how to make the EFSA outputs more targeted to the needs of the risk management decision making. Several aspects have been identified based on the experience of the last years. Follow-up actions are expected in the next few months.

One Member State informed about a meeting held on 24 September on initiative of some Member States with EFSA and the Commission with the aim to identify issues to improve the approval and authorisation processes. The outcome of the meeting will be summarised in a short document which will identify the points which should be addressed for improving the process. This document will be shared with the Committee once finalised.

EFSA also informed about a guidance document developed by Member States in the Peer Review Network of EFSA, which provides guidance on some aspects which need improvement by rapporteur Member States when doing their assessments. The Commission welcomed this draft guidance, but mentioned that some reflections as regards the format are still on-going. The draft is expected to be presented to the Committee at the next meeting.

**A.16 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO).**

No news to report.

**A.17 News from Sustainable Use Directive (Directive 2009/128/EC).**

No news to report.

**A.18 Minor Uses.**

The discussion was postponed.

**A.19 Report from Working Groups:**

The discussion was postponed.

**A.20 OECD and EPPO:**

1. Declassification of Guidance document on secondary metabolites

The Commission informed that this Guidance Document had been circulated by the OECD secretariat for a final check and that the Working Group on Biopesticides has been informed.

**A.21 Court cases.**

The Commission informed about the new case T-574/18 (R) (main application and interim measures) for annulment of Commission Implementing Regulation (EU) 2018/1019 on the non-renewal of the active substance *oxasulfuron*.

A Dutch court had referred questions for preliminary ruling on the interpretation of Article 52 of Regulation (EC) No 1107/2009.

Judgment T-429/2013 of 17 May was appealed by Bayer CropScience and Bayer AG regarding the conditions of approval of *clothianidin* and *imidacloprid* (Reference C-499/18 P).

The hearing in Case C-616/17 (Blaise and others) was scheduled for 20 November 2018.

The Commission debriefed on the judgment in case T-12/17 (Mellifera vs European Commission) regarding a request for internal review of the Regulation extending the approval for glyphosate, where the Court had upheld the Commission decision to not carry out an internal review under the Aarhus Regulation (Regulation (EC) No 1367/2006).

**A.22 Endocrine Disruptors:**

1. Member States views on the draft Commission Regulation amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge (SANTE/12011/2016, as discussed under point B.02 at the meeting the 21 December 2016)

A final discussion on the draft Commission Regulation took place. Although some Member States insisted on proceeding and would support this amendment, there was insufficient support by the Committee and no qualified majority would be

possible. Consequently, the Commission closed the discussions on this draft Commission Regulation.

Further, the Commission informed on the following:

- 1) The Commission analysed in March 2018 the 27 active substances which had been identified as potential endocrine disruptors in the screening for the impact assessment accompanying the proposal for setting criteria for the identification of EDs (substances falling under option 2 in the impact assessment, i.e. under the option equivalent to the new criteria) as regards whether it was appropriate to trigger any early regulatory review. Such an early review does not seem proportionate for any of the active substances because of the following reasons:
  - a) 8 substances had already been not approved for other reasons (e.g. classified or proposed for classification as R1B or C1/R2);
  - b) 2 substances (maneb and spirodiclofen) were not anymore supported and their approval expired or will soon expire;
  - c) 13 substances had an application for renewal submitted by the applicant before 10 November 2018 and fall under the amendment to Reg 844/2012, i.e. the regulatory process for renewal has started and the active substances will be assessed under the new criteria (pending evaluations);
  - d) 4 substances will have an application submitted at the latest in August 2021 (i.e. in 3 years) and will fall under the new criteria. Triggering an early review would not add any benefit in terms of timing as any decision on an early review would need to foresee the necessary time to generate new data which may easily take two years, which would mean having data in 2020-2021.

A similar exercise has been conducted for biocidal active substances. In that case, for 3 substances an early review will be triggered as their approval expires significantly later.

The Commission mentioned also a letter from a Member State requesting to conduct early reviews for a number of approved substances to verify whether they are endocrine disruptors. The Commission considered that this would be disproportionate referring to the analysis above. The Commission reminded that if a Member State considers that scientific evidence is available to justify an early review of an active substance, it can request this at any time in accordance with Article 21 of Regulation (EC) No 1107/2009.

- 2) The Commission informed of its intention to support Member States in applying the new EFSA/ECHA guidance on endocrine disruptors with a "Better Training for Safer Food" workshop.

The 2-day training is addressed to the national Competent Authorities and is scheduled for the first week of February 2019. The precise dates will be communicated as soon as possible. Two experts per Member State (one for PPP and one for BP) will be reimbursed (travelling and accommodation). Other similar trainings could be foreseen in the future.

EFSA and ECHA staff will be the trainers. Member States will be asked to submit case studies on assessment of active substances for which they are

currently acting as RMS. The case studies may regard the overall assessment of the endocrine disrupting properties of the substance or focus on specific more complex aspects of that assessment. EFSA and ECHA will then use those case studies as a basis for the training.

- 3) The Horizon 2020 topic ‘New testing and screening methods to identify endocrine disrupting chemicals’ has been evaluated. A total of 8 proposals are in the grant agreement preparation (GAP) phase. Those who successfully complete the GAP are expected to start on 1 January 2018.
- 4) A Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions has been developed under the lead of the Secretariat General to update the 1999 ED strategy on endocrine disruptors. The Communication is entitled “Towards a comprehensive European Union framework on endocrine disruptors” and it is expected to be adopted by the College on 7 November 2018.

#### **A.23 Neonicotinoids.**

The feedback received from Member States on the need for potentially clarifying the wording of the restriction on the use of clothianidin, thiamethoxam and imidacloprid had been made available on CIRCABC. Discussion of this feedback was postponed to the next meeting.

#### **A.24 Rapporteurship glyphosate.**

The Commission inquired which Member States would volunteer to become (co-) rapporteur for the next evaluation of glyphosate. No Member State volunteered to act as Rapporteur Member State, but a few indicated willingness to consider to become part of a group of Member States acting jointly as rapporteurs. The Commission agreed to accommodate such a solution by proposing the necessary changes to Regulations 844/2012 and 686/2012, and to facilitate further contacts between the Member States.

#### **A.25 Interpretation issues:**

Scope of Regulation (EC) No 1107/2009: the discussion was postponed.

#### **A.26 Classifications under Regulation (EC) No 1272/2008 / REACH:**

- 1) Status of harmonised classifications (summary table for info)

An updated table on the status of submitted proposal for classification and labelling had been made available on CIRCABC.

- 2) Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation 844/2012 in view of the harmonised classification of active substances + Report on the alignment of the classification and peer-review processes (short update)

No news to report.

**A.27 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 informed that the external evaluation study commissioned by DG SANTE is now publicly available online at: <https://ec.europa.eu/food/plant/pesticides/refit>.

The Commission informed that it is currently working to finalise the Staff Working Document. The expected deadline for adoption is first half of 2019. The external study will be the basis of a Staff Working Document. In addition, the Commission is using other sources such as the Commission's audit reports, the reports from the European Parliament PEST and ENVI Committees. The Commission is also considering the contributions from stakeholders collected in the framework of the external study.

**A.28 PEST Committee.**

Three meetings of the PEST Committee took place since July 2018:

- 30 August 2018, with authorities from third countries (e.g. Australia, Canada) with the aim to understand how their regulatory system works
- 6 September 2018 on "Environmental Impacts of Pesticides, including Mitigation Measures at Member State Level" and "Stakeholders Recommendations on the Current EU Regulation on the Approval of PPP"
- 27 September 2018 for a discussion on the draft report produced by PEST

The draft report is available on the EP website. The report is structured according to the different steps of the EU's approval and authorisation procedures for active substances and plant protection products and contains general observations. Several of the draft recommendations of the PEST committee are directed to Member States. Many of the draft recommendations are addressed by the proposal to amend the General Food Law (i.e. increase of transparency). The report is still to be finalised. During the debate, many MEPs announced their intention to table amendments to the draft report, which will need to be considered. The next PEST meeting is scheduled for 8 November 2018.

**A.29 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.**

The Commission informed that the following outcomes of the PAFF Committee – phytopharmaceuticals - section Residues held on 18/19 September 2018 have possible impacts on authorisations of plant protection products:

Substance	Type of change (see above)	Agenda item	SANTE doc number
Acetamiprid	MRLs were lowered.	B 02	SANTE/10617/2018
Bromadiolone	MRLs were lowered.	B 03	SANTE/11715/2017
Etofenprox	MRLs were lowered.	B 03	SANTE/11715/2017
Paclobutrazol	MRLs were lowered and the residue definition was amended.	B 03	SANTE/11715/2017
Penconazole	MRLs were lowered and the residue definition was amended.	B 03	SANTE/11715/2017
Bromuconazole	MRLs were lowered.	B 04	SANTE/10154/2018

Carboxin	MRLs were lowered and the residue definition was amended.	B 04	SANTE/10154/2018
Fenbutatin oxide	MRLs were lowered.	B 04	SANTE/10154/2018
Fenpyrazamine	MRLs were lowered.	B 04	SANTE/10154/2018
Pyridaben	MRLs were lowered.	B 04	SANTE/10154/2018
Linuron	MRLs were lowered.	B 05	SANTE/10145/2017
Iprodione	MRLs were lowered.	B 06	SANTE/11836/2017
Buprofezin	MRLs were lowered.	B 07	SANTE/10151/2018
Diflubenzuron	MRLs were lowered.	B 07	SANTE/10151/2018
Ethoxysulfuron	MRLs were lowered.	B 07	SANTE/10151/2018
Ioxynil	MRLs were lowered and the residue definition was amended.	B 07	SANTE/10151/2018
Molinate	MRLs were lowered.	B 07	SANTE/10151/2018
Picoxystrobin	MRLs were lowered.	B 07	SANTE/10151/2018
Tepraloxydim	MRLs were lowered.	B 07	SANTE/10151/2018

The Commission also reported that at that meeting several draft acts lowering MRLs for non-approved substances, or substances whose approval was restricted to non-edible crops, were discussed. In the context of these discussions, two Member States requested that the maximum length of grace periods allowed following restriction of approval or non-approval should be proportionate to the concerns identified and be as short as possible and based on an alignment of the level of stringency applied in decisions on the approval and the MRLs setting of the same substance. The Commission requested Member States to ensure coordinated positions between their representatives in the Legislation and Residues sections of the Committee.

Two Member States stressed the importance of transitional periods for food products with long shelf life, pointed to the possibility for Member States to set shorter grace periods than the maximum grace periods provided for in acts not renewing or restricting the approval of an active substance, and referred to the discussions on import tolerances for non-approved substances.

### **A.30 Information concerning Brexit:**

#### 1) Re-allocation of ongoing assessments

The Commission informed about the changes made in the draft working document since the last meeting. Member States asked for further clarifications. The note taking was postponed to the next meeting. Member States were invited to send comments by 12 November 2018.

#### 2) Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of deltamethrin, diflufenican, epoxiconazole, fluoxastrobin, prothioconazole and tebuconazole for which the United Kingdom is rapporteur Member State.

The Commission presented the draft act re-allocating six active substances currently being assessed under the AIR 3 and AIR 4 programmes and where the United Kingdom is the rapporteur Member State and EFSA will not finalise the Conclusions before 29 March 2019. Member States were invited to send comments by 26 November 2018.



**A.31 Reference to significant impurities in List of Endpoints and Renewal Report (DE).**

The discussion was postponed.

**A.32 Human Biomonitoring in Europe (presentation Directorate General RTD).**

The Commission informed about the "Human Biomonitoring for Europe" ("HB4EU", <https://www.hbm4eu.eu/>) project, co-funded by the EU. Member States, EU agencies, and the Commission are involved in the EU policy board and priority substances have been already selected. Copper compounds had recently been submitted as candidate priority substance for HB4EU; the case is currently screened by the project scientific body.

Member States asked about how the collected biomonitoring data could be used from the toxicological point of view and how to communicate the results.

**A.33 Scientific publications and information submitted by stakeholders.**

Feedback received from stakeholders for this meeting are made available to Member States via CIRCA BC.

**A.34 Date of next meeting(s).**

The next meeting of 12-13 December 2018 is confirmed. The planning for the meetings of 2019 is as follows - subject to confirmation:

- 24-25 January
- 21-22 March
- 20-21 May
- 16-17 July
- 21-22 October
- 5-6 December

**B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 844/2012 in view of the implementation of Commission Regulation (EU) 2018/605 setting out scientific criteria for the determination of endocrine disrupting properties.**

**Vote taken:** Favourable opinion.

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance copper compounds, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10506/2018).**

The Commission explained the modifications made to the earlier version of the draft:

- a renewal for 7 years as EFSA had confirmed that it would need about two years to elaborate a guidance for an environmental exposure assessment – thereafter applicants need time to prepare a new dossier
- the maximum application rates are set over the period of 7 years as requested by several Member States at the earlier meeting to allow for flexibility in the light of highly variable pest pressure depending on climatic conditions in different years.

The Commission inquired about the positions of Member States:

- 2 Member States were against any renewal of approval;
- 2 Member States were against greater flexibility in the new proposal and requested a fixed maximum application rate of 4 kg/ha/year;
- 2 Member States had no position yet and requested assurance that they would not be forced into 'mutual recognition' of authorisations granted in another Member States for application rates higher than 4 kg/ha/year. The Commission considered that this could be addressed through amending the list of issues to which Member States must pay particular attention by stating explicitly that Member States can set an upper limit of 4 kg/ha/year or even lower.
- One Member State preferred to keep a renewal for 5 years and requested to add an obligation for Member States to also consider other sources of copper input (such as fertilisers) during product authorisation. This was opposed by three other Member States who pointed to the absence of quantified information on such other sources.
- One Member States urged the Commission to consider whether there is a need to amend the Regulation on organic agriculture, which sets a maximum of 6 kg/ha/year on average over a period of 5 years.

**Vote postponed.**

**B.03 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 flurtamone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11585/2016 Rev. 2).**

The Committee was informed that some minor editorial changes had been made to the draft Regulation and draft Renewal Report.

**Vote taken:** Favourable opinion.

**B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance propiconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11932/2017 Rev. 1).**

Member States were informed that the text made available in July had been updated to include the reference to the published ATP establishing the classification as toxic for reproduction, category 1B.

**Vote taken:** Favourable opinion.

**B.05 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 chlorpropham, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11966/2017 Rev. 2).**

The Commission updated on the developments since the meeting in July. Following comments received from the applicant, the rapporteur Member State and from other Member States regarding the consumer assessment for the use as a herbicide (on lettuce and onions), the Commission had asked EFSA to consider the comments. EFSA had reiterated its view that based on the information available in the dossier the consumer risk assessment cannot be finalised for the herbicide uses given the deficiencies in the data package and the uncertainties that remain, in particular in relation to exposure to the metabolite 3-chloroaniline.

The Committee was informed that the Rapporteur Member State had already reacted by submitting an updated position paper, taking into account EFSA's additional comments. Several other Member States had also submitted comments.

In addition to Member State comments, a further letter from the law firm representing the applicant had been received asking the Commission to reconsider its proposal and restating arguments from previous correspondence.

The Commission explained that having carefully examined all comments raised, it considered that given the risks identified, in particular for the use on potatoes, and the uncertainties and large number of data gaps for the herbicide uses, that the appropriate proposal remains non-renewal of approval. The Commission also recalled that aside from the consumer risk other issues identified for one or more uses e.g. the risk assessment for non-target arthropods (NTAs) remained unresolved as did the ED potential, whilst for potatoes the risk assessment for residents and bystanders was also not finalised.

Member States were asked for their positions in view of a possible vote. Based on the positions expressed the vote was postponed.

**Vote postponed.**

**B.06 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 etoxazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10184/2018 rev 2).**

Several Member States expressed that they would not be able to support a non-renewal. They were convinced that risk mitigation measures, defined at Member State level would address the ecotoxicological concerns identified by EFSA. Several Member States would be able to support a restricted approval combined with a request for confirmatory data.

Member States were asked for their positions in view of a possible vote. Based on the positions expressed the vote was postponed.

**Vote postponed.**

**B.07 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 quinoxifen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10214/2018 rev 1).**

**Vote taken:** Favourable opinion.

**B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance tribenuron, 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/11859/2017 Rev 3).**

**Vote taken:** Favourable opinion.

**B.09 Exchange of views and possible opinion of the Committee on a draft Commission Review Report and Regulation concerning the approval of the active substance *Metschnikowia fructicola* strain NRRL Y-27328 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/10472/2018 – rev 2).**

The Committee was informed that written comments from four Member States were received and that minor changes to the draft review report and the draft annex were made.

**Vote taken:** Favourable opinion.

**B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, pethoxamid, picloram, propiconazole, pyraclostrobin, pyriproxyfen and tritosulfuron amending the Annex to Implementing Regulation (EU) No 540/2011**

The active substances pethoxamid and propiconazole were removed from the draft act and the vote was taken on:

Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron amending the Annex to Implementing Regulation (EU) No 540/2011 . (SANTE/10798/2018 Rev. 2)

**Vote taken:** Favourable opinion.

**B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances bispyribac and triazoxide amending the Annex to Implementing Regulation (EU) No 540/2011**

The active substances triazoxide was removed from the act prior the vote as no application supporting the renewal had been submitted.

**Vote taken:** Favourable opinion.

**C.01 Exchange of views on a draft Commission Directive amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators.**

The Commission summarised the progress to establish harmonised risk indicators under Directive 2009/128/EC. The Inter-Service Consultation had been launched on 17 October and the feedback mechanism will be conducted during November. The Commission plans to ask Member States to give their indicative voting position at the next meeting of the Committee and to vote on the draft Directive at the meeting in January 2019.

Following the Committee meeting of 19 July, 11 Member States had provided written comments. Most comments dealt with Article 53 authorisations. There were also comments relating to confidentiality issues, the legal basis for low-risk active substances and candidates for substitution, statistical issues and seeking a correction factor to be included in the proposed indicator based on the typical rate of use of each active substance.

The revised version of the draft act was explained and questions and comments of the Member States clarified. The draft Directive had been revised to have now two indicators. In indicator 1, Article 53 authorisations relating to approved active substances are now excluded. The second indicator is based on the number of Article 53 authorisations. The lists of low-risk active substances and candidates for

substitution had been revised. The Commission explained that there is no single source of EU data on the rate of use of each active substance. The Commission invited further written comments until 30 October 2018.

**C.02 Exchange of views on draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.**

Not discussed in detail but covered under Point A 08.02.

**C.03 Exchange of views on a draft Commission Regulation concerning the approval of the active substance Flutianil 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/11948/2017).**

In 2014, EFSA published the conclusion for flutianil, where a classification as carcinogen and toxic for reproduction, category 2 had been proposed. In 2016, the ECHA Risk Assessment Committee finalised its opinion, concluding that no harmonised classification as carcinogen or toxic for reproduction was warranted. In July 2018, EFSA published a Statement acknowledging the new harmonised classification.

The Commission presented a new draft review report for the approval of flutianil. No confirmatory information is requested on the potential endocrine disrupting properties of flutianil, due to the fact that it was considered that there are no adverse effects raising concern for endocrine disruption in view of the new information (new historical control data) assessed in the RAC Opinion, and that therefore the new ED criteria would not be fulfilled.

As regards two metabolites relevant for potential uptake in crops and for groundwater, EFSA had carried out a preliminary consumer assessment concluding total chronic intakes < 0.2% ADI for one metabolite and below 0.02 µg/kg bw per day (conservative threshold of toxicological concern for metabolites occurring in groundwater at levels up to 0.75 µg/l), which makes an approval possible.

One Member State would like to see the endocrine disrupting properties reassessed by EFSA or set as confirmatory information.

Comments from Member States are expected by 26 November 2018.

**C.04 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance desmedipham, 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/10556/2018).**

The draft Regulation for non-renewal of approval is based on the following concerns identified by EFSA: the potential exposure to consumers to aniline and 4-aminophenol, both classified as mutagen category 2; a high long-term risk to mammals for all representative uses and to birds for some representative uses;

endocrine disrupting properties of desmedipham cannot be excluded; the residue definition could not be finalised; the potential groundwater contamination by soil metabolite EHPC could not be evaluated.

Three Member States had submitted comments: one Member State considered a renewal of approval with confirmatory information for endocrine disrupting properties more appropriate. Another Member State would prefer to await the harmonised classification before taking any decision on desmedipham. The third Member State indicated that they will submit a CLH dossier for classification as toxic for reproduction, category 2 (due to developmental effects). Comments from associations of sugar beet growers had also been received.

During the meeting one Member State indicated that they would prefer to wait for the ECHA RAC opinion before taking any decision because the active substance is particularly important for resistance management. Another Member State would prefer to renew desmedipham with a request for confirmatory information. Another Member State asked for clarification on whether the overall inconclusive risk assessment would be sufficient to justify a proposal for non-renewal, irrespective from the conclusion on the endocrine disrupting properties.

Comments from Member States are expected by 26 November 2018.

**C.05 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance phenmedipham, 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/10558/2018).**

The draft Regulation for non-renewal is based on the following concerns identified by EFSA: the potential clastogenic effects observed in vitro which were not adequately followed up in vivo and consequently toxicological reference values could not be established; missing data to address the toxicological relevance of most impurities present in the technical specifications; endocrine disrupting properties of phenmedipham cannot be excluded; data gaps with regard to processed commodities and a comprehensive livestock assessment; long-term risk to mammals and aquatic risk assessment to algae that could not be finalised.

Comments were received from the five Member States: three Member States submitted the same comments as for desmedipham. One Member State commented that they supported the non-renewal of phenmedipham because the applicant did not provide valid scientific argumentation to the concerns highlighted in the peer review; and another Member State submitted a comment on the draft renewal report concerning the formulations containing both desmedipham and phenmedipham.

Comments from associations of sugar beet growers have also been received.

Comments from Member States are expected by 26 November 2018.

**C.06 Exchange of views on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance ethoprophos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10803/2018).**

The Committee was informed that the applicant had submitted comments on the draft renewal report proposing non-renewal of approval by submitting an extensive set of comments and additional data and studies. The applicant considers that all of the concerns in the EFSA Conclusion are unfounded and that a renewal of approval is warranted, taking into account evaluation of new data and expert opinions.

However, the Commission considered that the number and the nature of the issues are such that a non-renewal of approval is appropriate. Furthermore, new studies cannot be taken into account especially since the issues concerned are key areas, which should have been fully addressed in the renewal dossier, in particular since many issues had already been identified as problematic in the first EU review and following assessment of confirmatory information.

Therefore the Commission confirmed that a draft act concerning non-renewal of approval is being advanced through the inter-service consultation and will be followed by a notification to the WTO under the Technical Barriers to Trade (TBT) agreement. A vote will be scheduled once this procedure is completed. It was also pointed out that a period of grace of 12 months was suggested in the draft Regulation. This would allow for a further season of use plus time for disposal of stocks.

Member States were asked for comments by 26 November 2018.

**C.07 Exchange of views on a draft Commission Implementing Regulation renewing the approval of the active substance mepanipyrim 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/11620/2017) (short update only).**

The discussion was postponed.

**C.08 Exchange of views on a draft Commission Implementing Regulation renewing the approval of the active substance methoxyfenozide, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10295/2018) (short update only).**

The discussion was postponed.



**C.09 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance chlorothalonil, 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/10186/2018) (short update only).**

No new document was presented. The Commission informed on the comments received from Member States since the last meeting.

Three Member States indicated to support the non-renewal of approval. One of these indicated that they could also support a renewal under Article 4(7) of Regulation (EC) No 1107/2009. Two Member States did not support the draft.

Two Member States requested to apply Article 4(7). Commission did not consider it appropriate to apply this article due to the risks identified. This Article is intended to be applied for substances for which the approval is not renewed only based on their meeting the cut-off criteria. One Member State indicated not having an issue with this substance in their national groundwater monitoring programme and underlined the importance of this substance with regard to resistance to other fungicides.

The Commission indicated that it intended to present this draft Regulation for vote in the meeting of the Committee in March 2019.

**C.10 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10730/2018) (short update only).**

No new document was presented. The Commission informed on the comments received from Member States since the last meeting.

One Member State agreed that Article 4 of Regulation (EC) No 1107/2009 is not complied with for the risk to mammals but pointed to the importance of this substance for horticulture. This Member State considered risk mitigation at national level for bees possible. Two Member States did not support the current proposal. One Member State indicated that despite not having a final position the proposal seemed disproportionate and regretted that EFSA did not discuss the updated conclusion regarding the risk to bees with Member States before publication. One Member State indicated not having a final position but understood the reasons for the proposal. This Member State underlined the importance of this substance for IPM.

The Commission indicated that it intended to present this draft Regulation for vote in the meeting of the Committee in March 2019.

**C.11 Exchange of views on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen.**

The discussion was postponed.

**C.12 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance tolclofos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11272/2018).**

The Commission reminded that tolclofos-methyl had been discussed already at the last meeting. Several Member States had sent comments. Based on these comments and new information, the Commission now proposes to renew the approval because of the following reasons:

The applicant decided not to support anymore the uses on lettuce because the issues related to residues for the uses on lettuces could not be solved in the short term. Furthermore, EFSA had corrected an inconsistency in the EFSA Conclusion as regards the effects on aquatic organisms, identifying now one out of 3 FOCUS scenarios where the risks to water compartments could be considered as acceptable. In consequence, a renewal of the approval of tolclofos-methyl with a restriction to uses on ornamentals and on potatoes (tuber dressing), in combination with risk mitigation measures and some areas where the Member States should pay attention when reviewing their authorisations of products containing the active substance seemed now justified.

Member States were invited to comment on the draft by 12 November 2018.

**C.13 Exchange of views on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk substance *Clonostachys rosea* strain J1446 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11655/2017).**

The Commission presented the draft renewal report as well as the draft for renewal of approval. This microbial biopesticide, formerly known as *Gliocladium catenulatum* is applied as seed treatment in many crops, including vegetables, wheat, ornamentals, against seed and soil borne fungal diseases.

Conclusions of EFSA dated from June 2017 and a first presentation of the draft renewal report had been made in October 2017. There were two issues underlined by EFSA that are discussed in the renewal report but do not preclude a renewal of approval (persistence in soil, however the microorganism is ubiquitous; and the potential metabolite of concern gliotoxin, which is of transient production under particular conditions and was not detected above the LOQ of 50 µg/kg, so not constituting a major risk). The status of 'low-risk' can be maintained as the absence of multiple antimicrobial resistance could be excluded.

Member States were invited to comment on the draft by 12 November 2018.

**C.14 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance *Beauveria bassiana* strain IMI389521, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11650/2017).**

The EFSA conclusion had already been discussed in the course of 2017 and a first draft was discussed at the end of 2017. An external scientific report procured by EFSA to elucidate the in-vivo genotoxicity of beauvericin was published in May 2018. The Commission considered that the other outstanding points (efficacy, updated literature search, identification method, storage stability) in the EFSA conclusion for this *Beauveria* strain and the supported use as an insecticide in empty grain storage facilities do not prevent the approval.

Member States were invited to comment on the draft and on the status (no low-risk due to the uncertainty concerning the genotoxicity of beauvericin) by 12 November 2018.

**C.15 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance *Beauveria bassiana* strain PPRI5339, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11265/2018).**

The situation is similar to the previous *Beauveria* case (point C.14). The Commission considered that the other outstanding points in the EFSA conclusion (updated literature search, identification method, analytical aspects of typical formulation) for this *Beauveria* strain and the supported use as an insecticide in protected crops do not prevent the approval.

Member States were invited to comment on the draft and on the status (no low-risk due to the uncertainty concerning the genotoxicity of beauvericin) by 12 November 2018.

**M.01 Dithianon: Update on the status on the assessment of the confirmatory data**

The RMS Greece had sent an addendum 2 to the DAR at the beginning of October 2018 where the new data provided by the applicant were assessed and by which the uncertainties expressed by EFSA would be solved. The Commission will reflect on the way forward.