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Health and Food Safety Directorate General

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

**Section *Phytopharmaceuticals - Legislation***

**12 – 13 December 2018**

***CIRCABC Link:*** *https://circabc.europa.eu/w/browse/600fab43-5805-410c-9a18-27e79d9802f1*

# SUMMARY REPORT

## A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the last meeting was submitted for publication and should be publicly available soon.

## A.02 New active substances:

1. New admissible dossiers to be noted:
   a) Bixlozone (F9600)
   b) BAS 684 H

   Not all Member States had yet received the relevant information for neither Bixlozone (F9600) nor BAS 684 H. Consequently, the note taking was postponed.
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
   a) Sodium hydrogen carbonate

      The Commission briefly presented the EFSA conclusion and invited Member States to send their comments, especially with regard to the current approval as a basic substances and its possible withdrawal of approval. Four Member State did not agree that the approval of this substance as a basic substance should be withdrawn.
3. Draft Review/Renewal Reports for discussion:
   a) Bacillus subtilis IAB/BS03

      The Commission presented the draft review report and the draft Regulation, and invited comments from the Member States by 4 January 2019.

   b) Florpyrauxyfen benzyl

      The Commission presented the EFSA conclusion and invited comments from the Member States by 4 January 2019. The main issue discussed was the validity of the 2-generation reproductive toxicity study, which is important for the assessment of the endocrine disrupting potential of the substance.

c) Mefentrifluconazole

The Commission briefly presented the draft review report and invited Member States to provide comments, especially with regard to the potential endocrine disrupting activity on fish. It was also pointed out that mefentrifluconazole is expected to replace epoxiconazole for the treatment of winter wheat, hence providing a safer alternative. Comments should be sent by 4 January 2019.

**A.03 Renewal of approval:**

1. Annex I Renewal Projects: State of play (no news)

   No discussion.

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

   a) Bromoxynil/flumioxazin (Article 4.7)

   The Commission informed the Committee about the comments received from Member States following the meeting of the Committee in October. Two Member States had stated that they could not support renewal under the conditions of Article 4.7. Another Member State had reacted more favourably.

   The Commission explained that a proposal for both bromoxynil and flumioxazin would be developed on the basis of the Scientific Reports issued by EFSA.

   Concerning negligible exposure for bromoxynil, the Commission reminded Member States that the EFSA Conclusion and comments from the applicant were available.

   Member States were invited to provide comments on the proposal for a renewal under the conditions of Article 4.7.

   b) Carvone

   The Commission briefly presented the EFSA conclusion and invited Member States to send comments, especially with regard to the risk to non-target terrestrial plants, by 18 January 2019.

   c) Dimethoate

   The Commission presented the proposal for non-renewal and requested comments by 18 January 2019. One Member State requested to shorten the grace period from 12 to 6 months, for consistency with what had been decided in the past for very hazardous substances such as iprodione. The Commission indicated that it will reflect.

   d) Clodinafop

   The Commission informed the Committee that comments of the applicant on the EFSA Conclusion were available and that a draft renewal report would be presented in due course once the Commission had reviewed all information. Member States were invited to send early views or comments, in particular concerning the non-dietary exposure assessment.

   The rapporteur Member States recalled that they did not support the derivation of the AOEL in the EFSA Conclusion.

e) Clopyralid

The Commission briefly presented the EFSA Conclusion and invited comments from the Member States by 18 January 2019.

f) Dichlorprop P

The Commission presented the draft renewal report and clarified the difference in the proposed uses as an herbicide and as a plant growth regulator. Furthermore, Commission Regulation (EU) 2018/605 sets new scientific criteria to identify endocrine disruptors to be applied from 10 November 2018 onwards. This Regulation also foresees that the new criteria are applicable to ongoing applications.

The Commission informed that, due to the questions remaining open on endocrine disruption as reported in the EFSA Conclusion, it intended to mandate EFSA to reassess this active substance under consideration of Commission Regulation (EU) No 844/2012 (as amended by Commission Regulation (EU) 2018/1659). The mandate to EFSA is expected to be sent early 2019.

g) Alpha Cypermethrin

The Commission summarised the EFSA Conclusion and Member States were invited to provide their comments by 4 January 2019.

h) Cypermethrin

The Commission summarised the EFSA Conclusion and Member States were invited to provide their comments by 4 January 2019.

i) Beta cyfluthrin

The Commission summarised the EFSA Conclusion and Member States were invited to provide their comments by 4 January 2019.

3. Draft Review/Renewal Reports for discussion:

a) Isoxaflutole

The Commission recalled that in 2016 non-renewal had been proposed due to the substance meeting the interim criteria for endocrine disruption based on is classification as R2 (harmonised) and C2 (proposed).

Commission Regulation (EU) 2018/605 sets new scientific criteria to identify endocrine disruptors to be applied from 10 November 2018 onwards and, therefore, isoxaflutole no longer falls under the interim criteria.

Based on the scientific assessment of data available for renewal, the EFSA Conclusions states that isoxaflutole is unlikely to be an endocrine disruptor under the new criteria. The draft renewal report presented proposes renewal of approval; in order to be prudent a requirement for confirmatory data is proposed to provide an updated ED assessment according to the new criteria, where necessary submitting additional information in particular in relation to non-target organisms.

Member States were asked to provide comments on the draft renewal report by 4 January 2019.

b) Metalaxyl-M

The Commission informed that it intends to continue the regulatory procedure for this substance with no modification of the current proposal for non-renewal of approval.

One Member State indicated its disagreement with this proposal. Another Member State considered a renewal of approval with confirmatory data requirement appropriate.

c) 1-MCP

The Commission briefly presented the draft review report and invited Member States to send comments, especially with regard to a possible approval of this substance as a low risk substance. Two Member States questioned the eligibility of 1-methylcyclopropene as low risk substance considering that risk mitigation measures are proposed which appears to be contradictory to the provisions of Art. 47 (1) of Regulation 1107/2009. The Commission indicated that the proposed measures should be considered as normal practice for this kind of product as these are reflected in the GAP.

d) Mecoprop-P

The Commission informed that it had sent a mandate to EFSA on 4 December 2018 to update the worker exposure assessment by 15 March 2019.

e) Spinosad

The Commission informed that the proposal for renewal of approval was presented at the last meeting in October and had not changed substantially. Comments had been received from 3 Member States and they were mostly taken on board. A request for confirmatory information on the nature of residues in drinking water following water treatment was added to the draft renewal report. Comments on this draft report were invited by 18 January 2019.

Commission Regulation (EU) 2018/605 sets new scientific criteria to identify endocrine disruptors to be applied from 10 November 2018 onwards. This Regulation also foresees that the new criteria are applicable to ongoing applications.

Due to the questions remaining open on endocrine disruption as reported in the EFSA Conclusion, the Commission informed that it intends to mandate EFSA to reassess this active substance under consideration of Commission Regulation (EU) No 844/2012 (as amended by Commission Regulation (EU) 2018/1659). It is expected to send this mandate early in 2019.

f) Trinexapac-ethyl

The Commission informed that an amended draft review report had been made available to take into account comments received by Member States and the applicant on the initial version.

Furthermore, Commission Regulation (EU) 2018/605 sets new scientific criteria to identify endocrine disruptors to be applied from 10 November 2018 onwards. This Regulation also foresees that the new criteria are applicable to ongoing applications.

Due to the questions remaining open on endocrine disruption as reported in the EFSA Conclusion, the Commission informed that it intends to mandate EFSA to reassess this active substance under consideration of Commission Regulation (EU) No 844/2012 (as amended by Commission Regulation (EU) 2018/1659). It is expected to send this mandate early in 2019.

g) Fosetyl

The Commission informed about the comments received from the applicant and stakeholders, especially with regard to setting of the reference values for human toxicity. Due to risks and data gaps identified in the section on residues, only the use in mandarins seems acceptable.

Member States were invited to send their views to the Commission by 18 January 2019.

h) Etoxazole

The Commission informed of a possible alternative way forward for this substance and Member States were strongly encouraged to communicate their preferences by 4 January 2019.

**A.04 Confirmatory Data:**

1. General update, status and prioritisation

The Committee was updated on: 1) General update on managing ongoing confirmatory information files and 2) Follow-up to substances currently approved with confirmatory information related to endocrine disrupting properties. Member States were invited to send specific questions on individual files to the Commission.

2. Metazachlor

The Commission informed that since the meeting of the Committee in October two Member States had sent comments opposing the proposed way forward. One Member State referenced national monitoring data that indicated contamination of groundwater and another indicated concerns about lack of information on the impact of water treatment processes on metabolites and on drinking water.

The Commission explained that based on all of the views expressed so far (from 2017 up until now) there appears to be a preference for continued approval, allowing Member States to consider monitoring data when authorising products and for a further final examination of groundwater at renewal.

Two additional Member States indicated during the meeting that they could not support continued approval due to the risk to groundwater.

The Commission reiterated that it was seeking to find a solution that could be supported by Member States but that this was a complex case. Since the renewal assessment was due to start in 2019, it was suggested that it would be better to allow for a full-scale reassessment and then take a final decision rather than acting now.

The Commission invited further comments in writing and asked all Member States to come to the meeting of the Committee in January with a clear position to decide on the way ahead.

3. Fluquiconazole
4. Ipconazole
5. Fluopyram

   Points 3, 4 and 5 were discussed together.

   The Commission informed that revised review reports for all three substances had been prepared and made available taking into account comments from Member States.

   Concerning ipconazole, two Member States had asked whether an Article 21 Review should be undertaken given that the substance had been classified as toxic for reproduction (R1B) earlier in 2018.

   The Commission explained that cut-off criteria are applied at the renewal of the substance in order to ensure a fair and consistent approach and in line with the intentions expressed in recital 10 of Regulation (EC) No 1107/2009.

   Member States were invited to consider the amended reports and provide comments with a view of taking note at the next meeting of the Committee in January.

6. Bupirimate (amended review report to take note)

   The Commission informed that since the meeting of the Committee in October two Member States had sent comment with respect to the fate of one metabolite and the specifications of the technical material. The Commission indicated that a solution had been found on the first point. On the second point, one Member State still expressed disagreement with the proposed way forward. The Committee took note of the revised renewal report with one Member State abstaining.

7. Spiroxamine

   The Commission informed that it was analysing the file and intended to present a possible way forward in 2019.

8. Trifloxystrobin

   The Commission informed about a request received from the applicant to extend the deadline for the confirmatory information set in the renewal Regulation voted in May 2018. The reason for the request is that, in order to submit the confirmatory information within the current deadline, the applicant would need to start testing on vertebrate animals before the RAC Opinion on the classification of the substance will be published, even if such data would possibly not be needed. Under these circumstances, the Dutch Competent Authority had not given the permission to start those vertebrate studies. The Commission recalled that the outcome of the RAC Opinion is known at adoption (3 months before publication) and informally even before adoption. Therefore, the Commission proposed to take the decision on whether or not to amend the deadline for the submission of the confirmatory information in the Regulation when the outcome and date of publication of the RAC Opinion will be known.

9. Dithianon

   The Commission informed it was preparing a mandate to EFSA to evaluate the new assessment of the rapporteur Member State of the data submitted by the applicant. Member States will also get the opportunity to comment on this second

addendum to the draft assessment report prepared by the rapporteur Member State as well as on the draft EFSA conclusion.

**A.05 Article 21 Reviews.**

No news.

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

No news.

**A.07 Basic substances:**

1. New dossiers received (for information)

   Member States were informed that applications for the extensions of the approval of the following basic substances had been received: chitosan hydrochloride, salix, sodium hydrogen carbonate, sunflower oil, and hydrogen peroxide.

2. Exchange of views on EFSA Technical Reports

   None.

3. Draft Review Reports for discussion:

   a) *Castanea* and *Schinopsis* tannins

      The discussion was postponed.

   b) *Vitis vinefera* tannins

      The discussion was postponed.

**A.08 Guidance Documents:**

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

   The Commission informed of the comments received since the last meeting of the Committee and introduced the revised implementation plan which takes into account these comments. The postponement of the implementation of the chronic risks to bees was kept. The Commission also introduced the revised Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 as regards uniform principles related to bees for the evaluation and authorisation of plant protection products in which the trigger values for chronic risk to bees were deleted (See point C01).

   The Commission also informed about its intention to mandate EFSA to review the EFSA Guidance Document on the risk assessment of plant protection products for bees (*Apis mellifera, Bombus* spp. and solitary bees).

   Member States had diverging views on the proposal of the Commission. One Member State disagreed with the comments of other Member States and proposed to adopt the original implementation plan (with acute and chronic risk assessment for honeybees to be implemented immediately) for the approval/renewal of active substances but to delay the chronic risk assessment for the authorisation of Plant Protection Products (PPPs). This Member State further reminded the Committee that the need for a chronic risk assessment for bees is already included in

Regulation (EC) No 1107/2009 and in the Regulations describing the data requirements.

Member States were invited to send in comments and positions by 18 January 2019.

2. 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 comments received from stakeholders on the draft document are currently being analysed, with the intention to endorse the document in the Committee meeting of March 2019.

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

   The Commission informed that comments from stakeholders following the Advisory Forum Meeting held on 21 September 2018 had been received until 23 November 2018. An overview of the comments received will be presented in early 2019.

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

   The Commission informed that comments to the outline made available in July 2018 have been received from three Member States, which are in general supportive. The Commission is now reflecting on a more detailed outline for the next steps, which will be presented to the Committee in due time.

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

   No news to report.

6. Draft guidance document on the risk assessment of potential metabolites of concern produced by microbial plant protection products – update on progress

   The Commission informed about the most recent progress: the document was restructured reflecting a stepwise approach. A final technical discussion is planned for the meeting of the WG Biopesticides in February 2019, covering in particular the assessment of natural background exposure.

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

1. Feedback on notification of additional phrases notified by Member States

   The Commission explained that there is no significant progress so far but that a draft list of harmonised sentences is expected to be presented in 2019.

2. Risk Mitigation – workplan

   The Commission presented an outline to set up a “list” of risk mitigation measures that could be considered by Member States and EFSA during the peer review of substances, implemented in the authorisation process, and applied by the final users. This plan is in line with the conclusions of the high level meeting on improving cooperation between EFSA, Member States and Commission, organised in September, as regards risk mitigation measures and safe use (see point A.15).

The Commission also informed about the ongoing research project INNOSETA (http://www.innoseta.eu/) it is funding via Horizon2020 and where progress in the area is expected.

3. Pictogram 'bee hazardous'

   The Commission explained the question raised by an EEA country concerning a pictogram that was in use at national level. The Commission asked for the criteria triggering the affixing of the pictogram. Member States were invited to inform the Commission about similar pictograms and to react on the additional information that will be provided by the EEA country.

4. Low-risk criteria (effects on lactation vs. reprotoxic; eye damage 1 /H318 vs. corrosive)

   The Commission explained the questions raised about the interpretation of the low-risk criteria, as regards:

   - substances labelled with "may cause harm to breast-fed children" which is a separate category of reprotoxic substances (1A, 1B, 2) and as such not excluded from being a low-risk substance;
   - substances labelled with "causing severe damage to eyes" which are not falling in the CLP corrosive class, hence they are also not excluded them from being low-risk.

   Member States were invited to send their reactions in order to clarify the status of those substances by 18 January 2019.

5. Labelling requirements as regards appropriate conditions of storage

   The Commission reported about the observations made by one Member State control authorities about the absence of clear 'directions for appropriate conditions of storage'. Another Member State provided its labelling requirements.

   Member States were invited to comment by 18 January 2019 on the general sentence "Store locked up in a dry and well-ventilated place and protected from the sunlight" which combines several existing precautionary statements.

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

The Committee took note of 15 notifications as regards withdrawals received until the 5 December 2018, which are summarised as follows:

| Notifying Member State | Active Substance | No of plant protection products concerned | |
|---|---|---|---|
| UK | pymetrozine | 12 | withdrawal |
| UK | clothianidin | 4 | withdrawal |
| UK | imidacloprid | 4 | withdrawal |
| UK | thiram | 6 | withdrawal |
| UK | thiamethoxam | 7 | withdrawal |
| RO | clothianidin | 2 | withdrawal |
| RO | diquat | 5 | withdrawal |
| RO | fenamidone | 2 | withdrawal |
| RO | imidacloprid | 23 | withrawal/GAP change |

| | | | |
|---|---|---|---|
| RO | malthion | 1 | withdrawal |
| RO | propineb | 2 | withdrawal |
| RO | pymetrozine | 1 | withdrawal |
| RO | thiamethoxam | 3 | withdrawal |
| RO | thiram | 6 | withdrawal |
| PL | several AS, single & multiple AS | 23 | withdrawal/GAP change |

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

1. New notifications (to be noted)

The Committee took note of one notification of a refusal of mutual recognition received until the 5 December 2018, which is summarised as follows:

| Notifying Member State | Reference Member State | Active Substance |
|---|---|---|
| FR | ES | pyrimethanil |

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

Postponed.

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

Member States were informed that an update would be presented in early 2019.

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

1. New notifications (to be noted)

The Committee took note of 6 emergency authorisations received between the 23 October and the 30 November 2018 via the PPPAMS, which are summarised as follows:

| MS | Active substances | Functions |
|---|---|---|
| CY | Abamectin (aka avermectin) | acaricide |
| FR | Metalaxyl-M | fungicide |
| FR | Potassium hydrogen carbonate | fungicide |
| FR | Beauveria bassiana 203 | insecticide |
| PL | Beta-Cyfluthrin; Imidacloprid; | insecticide |
| PL | Thiamethoxam | insecticide |

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

1. General update

EFSA highlighted the relevance of the accordance check process proposed by the Pesticides Steering Network as part of the peer review improvement plan. Its implementation will improve the quality of the dossiers and DAR/RARs, covering also the concerns expressed by NGOs and interested parties on transparency. EFSA proposed a discussion regarding the implementation of the additional clock stop for getting information on endocrine disruption. The discussion should also cover residues. Finally, EFSA updated the Committee on information regarding ongoing peer reviews, the PPR Panel work plan, and the new EFSA structure for pesticides with two units: one dedicated to the assessment of pesticides residues and risk for

consumers and another covering toxicology, non-dietary health risks and environmental assessments.

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

The Commission informed that the conclusion of the high level meeting of improving cooperation between EFSA, Member States and Commission, organised by some Member States the 24 September 2018, are available on CIRCABC. The Commission invited Member States to consider this conclusion in order to improve the efficiency of the peer review process and the decision making at this Committee.

Further, it was recalled that EFSA and Member States, in the context of the Pesticide Steering Network, have been discussing the need for an accordance check of Assessment Reports before acceptance into the peer review to ensure that assessment reports are of high quality and fit for purpose.

Linked to this work, EFSA has prepared guidance for applicants and Member States when preparing dossiers and assessment reports. This guidance will form part of a bigger Administrative Guidance document covering all administrative aspects related to the pesticide approval processes. This is part of EFSA's customer-orientated approach for regulated products.

As a result of the proposed guidance there is a need to make some changes to existing SANTE guidance documents or templates. EFSA has already proposed changes to these documents.

Member States were invited to provide comments on the Guidance and the amended SANTE guidance documents by 18 January 2019. It was noted that Member States as well as the associations ECPA, ECCA and IBMA had already commented on the guidance in an earlier form via an EFSA Consultation and therefore Member States are asked to not repeat those comments again.

**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.**

Since on 15 April 2018 the Grant Agreement with the European Commission regarding the funding of the EU Minor Uses Coordination Facility (MUCF), the MUCF is now fully depending on voluntary assessed contributions from Member States. At the end of October 2018 all Member States had been approached by the MUCF for a voluntary assessed contribution for 2019. However, funds for 2019 are not yet secured.

The new Minor Uses Steering Group comprises representatives from Germany, Italy, Netherlands, Sweden and Switzerland. The European Commission attends meetings of the Steering Group as permanent observer.

Regarding the governance of the MUCF, the Steering Group will supervise and support the work of the Coordination Facility. The governing body, comprising all funding countries, will meet once a year for the 'Annual General Meeting' (AGM). The role of the AGM will be to approve the budget, and consider the annual work programme and reports of the MUCF. The Annual General Meeting will be held back-to-back with the Stakeholder Advisory Forum on 26 February 2019 in Brussels.

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

1. Working Group on Biopesticides

   The Commission reported about the recent activities and the progress on the draft guidance documents (1) on metabolites of concern, (2) on exclusion and low-risk criteria linked to multiple anti-microbial resistance properties, (3) on Straight-Chain Lepidopteran Pheromones. It explained as well the discussion initiated in view of the need to revise the current data requirements and uniform principles for microbial plant protection products.

2. Working Group on Seed Treatments

   The Commission reported about the Revision 16 of the draft Guidance Document on seed-treatments and the background document which had been made available to the Committee in July 2018. Stakeholders had also been consulted on the document via the Advisory Forum. Comments had been received, but no progress has been made so far.

3. Working Group on Co-formulants

   The Commission informed of its intention to progress first with the Regulation establishing a list of unacceptable co-formulants and thus populating Annex III to Reg. 1107/2009 before continuing the work on an Implementing Regulation setting out a process for nominating further unacceptable co-formulants. The drafts uploaded on CIRCABC before the meeting of the Committee reflected a significantly simpler approach by cross-referencing to substances with harmonised classifications listed in Annex VI to the CLP Regulation and to substances included in the candidate list under REACH. However, internal discussion are still on-going, also with the Commission Legal Service, who considered that there was a need to actually list the names of substances and that the empowerment for the Commission in Article 27 does not allow to list co-formulants the use of which is merely restricted for some uses while other uses of the same substances would remain allowed. Consequently, only co-formulants found unacceptable in all plant protection products can be listed in Annex III. Other co-formulants (i.e. those found only unacceptable in some products and/or above certain conditions) can still be restricted at national level.

   The Commission asked the Member States who had earlier notified unacceptable co-formulants to verify whether the concentration limits and the restrictions reported in the national lists of unacceptable co-formulants submitted to the Commission are necessary for enforcement or only reflect limits coming from the CLP Regulation.

   One Member State pointed out that petrol oil is a substance which can be classified as CMR based on some of its impurities present above a certain small percentage in the overall oil. A solution to list this kind of substances in Annex III to Reg. 1107/2009 should be explored. Another Member States opined that it

should well be possible to list co-formulants in Annex III that are unacceptable only in some products or under certain conditions, given that Article 27 of Regulation 1107/2009 specifically referred to ‘use in a PPP’ and not to ‘use in all PPP’.

**A.20 OECD and EPPO:**

1. First review of the new draft Guidance Document for Flammability testing of Plant Protection and Biocidal Products

   The Commission reminded Member States about the invitation from the OECD Secretariat to comment on this draft Guidance Document by 18 December 2018.

2. Call for leads or co-leads for Joint EGBP and EGMU projects

   The Commission reminded Member States about the OECD call for expression of interest addressed to delegations to identify leaders and co-leaders for future activities of the Expert Groups on Biopesticides and Minor Uses. Three topics were identified: (1) Data requirements concerning biopesticides, (2) Incentives for risk reduction, (3) Capacity building activities.

   The Committee was also updated on the work of the OECD Expert Group on RNAi (of the Working Group on Pesticides). The expert group is currently working on data requirements and a risk assessment approach for externally applied dsRNA. EFSA, the BVL and the Julius Kühn Institute are involved in the drafting of the document. The Commission and the Minor Uses Coordination Facility also participate in the meetings/teleconferences.

   Parallel to this, a conference on the “Regulation of Externally Applied dsRNA-based Products for Management of Pests” will be organised. Provisionally, the conference is scheduled for 10-12 April 2019 at OECD Headquarters in Paris.

**A.21 Court cases.**

The Commission presented the Judgment of the General Court of 21 November 2018 in case T-545/11 RENV “Pesticides Action Network Europe and Stichting Greenpeace Nederland vs. Commission“.

**A.22 Endocrine Disruptors.**

The Commission informed about the recently published Commission Communication titled "Towards a more comprehensive EU framework on endocrine disruptors" (7 November 2018).

The Commission reminded that a Better Training for Safer Food (BTSF) on the application of the criteria and guidance for endocrine disruptors is scheduled for 6-7 February 2019. Member States are invited to nominate as soon as possible two experts per Member State who will be fully reimbursed. An official invitation with a draft agenda will be sent soon. Nominated experts will be invited to download two case studies from the CIRCABC link provided with the invitation. The Commission informed that a 2nd training is already scheduled for the 2nd quarter of 2019, due to the high interest.

**A.23 Neonicotinoids.**

The Commission informed of the comments received concerning the restrictions on the use of clothianidin, thiamethoxam and imidacloprid adopted in May 2018 and that it does not intend to amend the wording of the restriction.

**A.24 Rapporteurship glyphosate.**

The Commission informed that discussions are progressing with a group of five Member States who would be prepared to assume jointly the rapporteurship for the next evaluation of glyphosate. The Commission invited other Member States to consider joining the group in order to share the expected high workload.

**A.25 Interpretation issues:**

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

   a) *New case DewSmart (BE)*

      The Commission provided explanations and suggested to consider this case out of the scope of Regulation 1107/2009, subject to comments from Member States.

   b) *New case Agrecol Liquid for Aphids (LT)*

      The Commission provided explanations and suggested to consider this case within the scope of Regulation 1107/2009, subject to comments from Member States.

   c) *Follow-up Frost Armour (FR)*

      The Commission reported that, as the applicant did not provide the requested information, the request is on hold.

   d) *Follow-up Palm tree Protector INO128 (FR)*

      The Commission reported that the tests of efficacy are not very positive and that the request should be considered as abandoned.

   e) *Follow-up in situ generation (EL – July PAFF)*

      The Commission explained that several Member States are challenging the interpretation of in situ generated active substances outlined in the Q&A document SANCO/12415/2013 (Rev. 6 of 15 November 2015). Member States were invited to comment.

   f) *New case sunflower oil (request for extension of approval as basic substance)*

      The Commission stated that the mode of action as a fungicide can be considered as a plant protection use but the mode of action leading to reduction of weight loss and mechanical damage should be not considered as plant protection because the oil acts as physical barrier. Member States were invited to send comments by 18 January 2019.

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

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. General 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).**

No news to report.

**A.28 PEST Committee.**

The Commission informed that the European Parliament's PEST Committee had adopted its report on 6 December 2018. Following the publication of the draft report by the two rapporteurs, members had tabled 1142 amendments, which led to 59 compromise amendments that had been supported by all major political groups. The final report will be adopted in the plenary session of the Parliament in January 2019.

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

The Commission thanked Member States for the comments on grace periods and MRL transition periods and explained that it would further reflect, also taking into account Member States views expressed in the residues section of the PAFF Committee. Grace periods are set on a case-by-case basis, taking into account concerns raised and the specificities of the use of a substance.

**A.30 Reference to significant impurities in List of Endpoints and Renewal Report (DE).**

Postponed.

**A.31 Scientific publications and information submitted by stakeholders.**

The Commission reminded that documentation is available to Member States for their information.

**A.32 Date of next meeting(s).**

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 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 amendments made to the draft Directive since the last meeting of the Committee.

One Member State expressed concerns as regards how grace periods would be implemented and the consideration of inert gases used as active substances. Two Member States have significant concerns as regards the second indicator proposed, as it is not built on risk but on hazard. Two Member States indicated concerns because one of the indicators proposed is based on sales data, while consideration of the application rate would be preferred. Three Member States mentioned that the indicators proposed cannot be used to compare Member States, in particular because there is no correction as regards the area dedicated to farming. One Member State asked for a longer period for transposition into national law and another Member State wondered how it would be ensured that the calculation at national level would be harmonised. On the latter point, the Commission mentioned that it is intended to develop a guidance document.

Several Member States indicated that they support the draft as a first step forward, but expect that better indicators would be developed in the future.

An indicative tour de table showed support of Member States for the draft. A vote on the draft is intended for the meeting of the Committee in January 2019.

**Vote postponed.**

**B.02 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 of the Committee in October, explaining that several letters had been received from stakeholders and that the Commission had met with the potato sector and with growers from the Netherlands and the United Kingdom. All correspondence had been made available via CIRCABC. The Commission asked all Member States for the final position.

The positions revealed that the current draft for non-renewal of approval is supported by more than 50% of Member States and that it is so far the widest possible support. Member States not in favour of the Commission's draft had diverging views: some support a restricted renewal for use as herbicide, one Member State supported a restriction to non-edible uses only and several could not support anything other than an unrestricted renewal since they had no alternative products for use on potatoes.

The Commission considered therefore that in line with the Comitology rules it had submitted a draft that had the widest possible support of Member States.

*The Netherlands submitted the following declaration to be included in the minutes:*

*As Rapporteur Member State this dossier is important to us. Even that important that our parliament had a (intense) discussion on this substance on Tuesday and yesterday afternoon. For the Netherlands it is very difficult to accept the difference in views between our competent authority and the Commission on the possibility of safe uses. Therefore, The Netherlands calls out to the Commission for a last attempt to work on a consensus with our competent authority on the dossier of chlorpropham. Until then, we will abstain.*

The Commission explained that the formal vote will be postponed as further time was needed to analyse the positions of Member States and to determine the appropriate way forward.

**Vote postponed.**

**B.03 Exchange of views and possible opinion of the Committee 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).**

**Vote taken:** Favourable opinion.

**B.04 Exchange of views and possible opinion of the Committee 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).**

**Vote taken:** Favourable opinion.

**B.05 Exchange of views and possible opinion of the Committee 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).**

**Vote taken:** Favourable opinion.

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

**Vote taken:** Favourable opinion.

**B.07 Exchange of views and possible opinion of the Committee 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 Commission informed that Commission Regulation (EU) 2018/605 sets new scientific criteria to identify endocrine disruptors to be applied from 10 November

2018 onwards. This Regulation also foresees that the new criteria are applicable to ongoing applications.

Due to the questions remaining open on endocrine disruption as reported in the EFSA Conclusion, the Commission informed that it intends to mandate EFSA to reassess this active substance under consideration of Commission Regulation (EU) No 844/2012 (as amended by Commission Regulation (EU) 2018/1659). The mandate to EFSA is expected to be sent early in 2019.

**Vote postponed.**

**B.08 Exchange of views and possible opinion of the Committee 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).**

**Vote taken:** Favourable opinion.

**B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2015/1108 of 8 July 2015 approving the basic substance Vinegar in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANCO/12896/2014– rev. 3).**

**Vote taken:** Favourable opinion.

**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 abamectin, *Bacillus subtilis* (Cohn 1872) Strain QST 713, *Bacillus thuringiensis* subsp. Aizawai, *Bacillus thuringiensis* subsp. israeliensis, *Bacillus thuringiensis* subsp. kurstaki, *Beauveria bassiana*, benfluralin, clodinafop, clopyralid, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, *Lecanicillium muscarium*, mepanipyrim, mepiquat, *Metarhizium anisopliae* var. Anisopliae, metconazole, metrafenone, *Phlebiopsis gigantea*, pirimicarb, *Pseudomonas chlororaphis* strain: MA 342, pyrimethanil, *Pythium oligandrum*, rimsulfuron, spinosad, *Streptomyces* K61, thiacloprid, tolclofos-methyl, *Trichoderma asperellum*, *Trichoderma atroviride*, *Trichoderma gamsii*, *Trichoderma harzianum*, triclopyr, trinexapac, triticonazole, *Verticillium albo-atrum* and ziram**

*The Netherlands submitted the following declaration to be included in the minutes:*

*We cannot agree with the procedural extensions of the approval periods of thiacloprid - because of the risks to bees - and epoxiconazole – because of the risks regarding fungal resistance. Nevertheless, because we are faced with one package of 42 substances, we will vote in favour of the whole package.*

**Vote taken:** Favourable opinion.

**B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 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**

**Vote taken:** Favourable opinion.

**C.01 Exchange of views on a 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 bees principles for evaluation and authorisation of plant protection products.**

This point is covered under Point A 08.01.

**C.02 Exchange of views on a draft Commission Draft 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).**

The Commission presented the draft Regulation for approval of the active substance. It proposed to set confirmatory information on the nature of residues in drinking water following water treatment to be submitted once relevant guidance will be available.

One Member State indicated that, in their view, no safe use was identified in grapes and therefore approval should be restricted to greenhouse uses only.

One Member State indicated that they would prefer seeing the endocrine disrupting properties reassessed by EFSA.

One Member State asked about the Commission's position on the request of the applicant to update the reference endpoints following the publication of the RAC Opinion on flutianil. The Commission informed the applicant can submit an application after the approval of flutianil asking for an amendment of the conditions of approval. EFSA added that the recently published EFSA Statement already considered this question concluding that the reference endpoints would remain the same even considering the RAC Opinion on flutianil.

**C.03 Exchange of views on a draft Commission Draft 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 Commission presented the draft Regulation for non-renewal of approval which remained unchanged since the meeting of the Committee in October 2018. The Commission informed that many letters from sugar beet growers had been received. They highlighted the importance of desmedipham and phenmedipham for sugar beet

production due to their compliance with Integrated Pest Management and avoidance of resistance.

The Commission mentioned that up to now only few comments from Member States had been received and encouraged submission of comments by 4 January 2019.

Four Member States indicated that they would support the Commission proposal, while two would prefer waiting for the RAC Opinion before taking any decision on desmedipham.

**C.04 Exchange of views on a draft Commission Draft 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 Commission indicated that the draft Regulation for harmonised classification and labelling (CLH) under the CLP Regulation had recently been published for public consultation and is uploaded on CIRCABC. In the CLH proposal, the rapporteur Member States clearly indicates that the overall evidence suggests that phenmedipham is unlikely to be genotoxic in vivo. Considering that the potential genotoxicity of phenmedipham was the main concern in the EFSA conclusion, the Commission is now considering preparing a new draft Renewal Report proposing renewal of approval. In that case, the endocrine disrupting properties would need to be reassessed by EFSA and the Commission would then send a mandate in that sense to EFSA.

Five Member States indicated that they might support the new Commission intention, but that they would first need to see the written proposal, while two Member States indicated that they would prefer waiting for the RAC Opinion before taking any decision on phenmedipham. One Member State mentioned that they had also received several letters from sugar beet growers asking for the renewal of approval of the two substances desmedipham and phenmedipham.

Member States were invited to provide comments by 4 January 2019.

**C.05 Exchange of views on a draft Commission Draft Regulation concerning the approval of the active substance ABE IT 56 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/11228/2018 rev 1).**

The Commission presented the draft Regulation and a slightly revised draft review report based on comments from one Member State. Member States were invited to provide further comments by 4 January 2019.

**C.06 Exchange of views on a draft Commission Draft Implementing Regulation (EU) concerning the non-renewal of approval of the active substance thiophanate-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 the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11253/2018).**

The Commission presented the draft Regulation for non-renewal of approval of the active substance. Written comments had been received from two Member States and from the applicant. One Member State requested to wait for the RAC Opinion before taking any decision on this substance. The rapporteur Member State indicated that in the submitted draft for harmonised classification and labelling, based on new data submitted by the applicant, they have now proposed classification of thiophanate-methyl as mutagen category 2 (M2) and not anymore mutagen category 1 (M1), as proposed during the renewal peer review. The Commission indicated that even if the classification of the parent would remain M2 (which is the current harmonised classification), the overall concerns still justify a draft for non-renewal.

One Member State requested to shorten the grace period from 12 to 6 months, consistent with what had been decided in the past for very hazardous substances such as iprodione and linuron. The Commission indicated that it will reflect on the proposal. Member States were invited to provide comments by 4 January 2019.

**C.07 Exchange of views on a draft Commission Draft Implementing Regulation (EU) as regards the approval periods of the active substances bifenthrin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate amending the Annex to Implementing Regulation (EU) No 540/2011**

The Commission presented the draft Regulation to retract the expiry dates of several active substances for which the applicants had withdrawn their support of renewal of approval. The Commission informed that also carboxin will be included in the draft Regulation when presented for a vote in January 2019. Member States were invited to provide comments by 4 January 2019.