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Section *Phytopharmaceuticals – Legislation*
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SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the report from the meeting of the Committee in October 2018 had been published and that the report from the meeting in December 2018 was being finalised.

A.02 New active substances:

1. New admissible dossiers to be noted

Two new admissible dossiers were noted by the Committee:

- Bixlozone (F9600), a herbicide applied for by FMC Corporation. The rapporteur Member State is the Netherlands and admissibility was reported to the Commission on 28 August 2018.
- BAS 684 H, a herbicide applied for by BASF SE. The rapporteur Member State is the Netherlands and admissibility was reported to the Commission on 30 October 2018.

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

No news to discuss.

3. *Draft Review/Renewal Reports for discussion*

a) Bacillus subtilis IAB/BS03

The Commission summarised the comments received from Member States. Based on these comments, which proposed a low risk status for this active substance and after verifying with EFSA, the Commission changed the draft review report to reflect a low risk status of the new active substance. Member States were invited to send comments by 8 February 2019.

b) Florpyroauxyfen benzyl

The Commission explained the different opinions presented by EFSA in its Conclusion and the comments that had been received from the Member States concerning the acceptability of the 2-generation reproductive toxicity study

dosed until saturation and not until the absolute maximal dose. Member States were invited to send comments by 8 February 2019, in particular whether they could agree with the views of the Rapporteur Member State and the co-Rapporteur Member State that the substance does not have endocrine disrupting properties based on the information available.

c) Sodium hydrogen carbonate

The Commission presented the draft review report and the comments received from Member States. The Commission will further reflect as regards the potential status of this active substance as a basic substance.

One Member State inquired about the control mechanisms on the use of basic substances. The Commission indicated that according to the PPP Regulation, enforcement of the correct use of basic substances is the responsibility of Member States and noted that enforcement via monitoring of residues is not possible as basic substances are only approved if they also can be included in Annex IV of Regulation 396/2005, which lists those substances for which no MRLs are considered necessary.

One Member State indicated that food commodities should always be approved as basic substances. One Member State indicated preference for a dual approval both as a regular and as a basic active substance. One Member State inquired about the practical consequences of a dual approval.

d) Asulam-sodium

The Commission presented a draft review report, which considered previous comments from several Member States, notably about the potential endocrine disrupting properties and the related high long-term risk to birds (i.e. egg-shell thinning). The Commission proposed to mandate EFSA to clarify the potential for endocrine disrupting properties. Member States were invited to react by 8 February 2019 in particular as regards the potential mandate to EFSA.

A.03 Renewal of approval:

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

No news to discuss.

2. *Exchange of view on EFSA Conclusions/EFSA scientific reports:*

a) Bromoxynil/flumioxazin (Article 4.7)

Member States were updated on comments received since December 2018.

For bromoxynil, two Member States had highlighted that in the assessment of negligible exposure an exceedance of the AOEL for workers and for child residents had been concluded using the EFSA Guidance. The Commission reminded Member States that the German model was no longer accepted for assessing the exposure for bystanders and residents since it underestimates exposure and therefore the revised calculations would need to be considered. The impact of this change in non-dietary exposure would also need to be taken into account in the decision-making. The Commission informed Member States that it was reflecting on the next steps.

For flumioxazin Member States were informed that Article 4.7 is currently being considered for the decision-making.

Member States were invited to send comments in particular as regards the implementation of Art 4.7 by 8 February 2019.

b) Clodinafop

The Commission informed that further reflections were needed before a draft renewal report can be presented, taking into account comments from the applicant and Member States. Further views and comments from Member States were invited by 22 February 2019.

c) Clopyralid

The Commission gave an initial summary of the EFSA Conclusion and explained that certain clarifications by EFSA and the Rapporteur Member State were needed before progressing. The applicant had also sent some clarifications. Member States were invited to comment by 8 February 2019.

d) Fenamiphos

The Commission gave an initial summary of the EFSA Conclusion published in December 2018. Whilst no critical concerns were identified, several issues were highlighted that need to be carefully considered: for edible uses a high risk to consumers was identified. The applicant had challenged this conclusion in its comments. A high leaching potential for groundwater was highlighted in the EFSA conclusion based on FOCUS modelling. However, for the Rapporteur Member State the monitoring data provided demonstrate a low leaching potential. Member States were invited to comment by 22 February 2019.

3. *Draft Review/Renewal Reports for discussion*

a) Metalaxyl-M

The Commission briefly recalled the issues identified in the EFSA Conclusion for metalaxyl-M. The applicant had submitted further comments to the Commission on several aspects and had also asked for a meeting. In particular, a solution had been proposed to address the issue of the impurity in the technical material. However, the Commission explained that other issues need to be carefully considered including the risk to birds and mammals for use as seed treatment, the risk to groundwater and the non-dietary exposure assessment.

The Commission asked Member States whether in their view a restricted approval could be supported. Comments were invited by 22 February 2019.

b) Fosetyl

The Commission informed that EFSA was reconsidering some aspects of the Conclusion and that therefore Fosetyl was included for discussion in the EFSA mammalian toxicology expert meeting starting on 28 January 2019. The Commission suggested to await the outcome of that discussion before continuing the discussions on this substance.

c) Etoxazole

The Commission reiterated a possible alternative way forward for this active substance and Member States were again strongly encouraged to communicate

their preferences on the way forward by 8 February 2019. So far only 5 Member States had provided their provisional opinions.

d) Alpha Cypermethrin

The Commission informed about the comments received from the applicant and one Member State. The Commission presented the draft review report for renewal of the approval of alpha-cypermethrin as a candidate for substitution and requested comments by 8 February 2019.

e) Cypermethrin

The Commission informed about the comments received from the applicants, Member States and stakeholders since the last meeting. The Commission presented the draft review report for renewal of the approval of cypermethrin with a restriction to winter/autumn use in order to protect bees. The Commission also informed that in case of renewal the efficiency of drift mitigation measures set at Member State level would need to exceed 95% to mitigate the high risk to aquatic organisms and non-targeted arthropods. So far, four Member States had commented, out of which three indicated their disagreement with the Commission proposal due to the identified potential risks to aquatic organisms, bees and other non-targeted arthropods. The Commission requested further comments by 8 February 2019.

f) Beta cyfluthrin

The Commission reiterated the overview given at the last meeting based on the EFSA Conclusion and informed that comments had been received from only two Member States. The Commission asked Member States to comment as regards a potential renewal or non-renewal, in particular concerning possible risk mitigation measures for workers loading and sowing seeds for the representative use as a seed treatment by 8 February 2019.

g) Methiocarb

The Commission presented the draft review report and proposal for non-renewal and invited Member States to comment by 8 February 2019.

h) Dimethenamid-P

The Commission presented the draft review report and the proposal for renewal and invited Member States to comment by 8 February 2019, especially concerning the two critical areas of concern (specification and groundwater metabolites).

i) Carvone

The Commission presented the draft review report and invited Member States to comment, especially with regard to the identification of impurity 6 as defined in the EFSA Conclusion, by 22 February 2019.

j) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

The Commission informed that, following the discussions at the last meeting, a mandate had been sent to EFSA to assess the ED potential of five active substances (dichlorprop-P, mepanipyrim, phenmedipham, spinosad,

trinexapac-ethyl) in line with the procedures laid down in Commission Regulation (EU) 844/2012 as amended by Regulation (EU) No 2018/1659.

The Commission informed that this point will be kept on the agenda of the next meetings as a standing point. An updated list of active substances for which EFSA had been given mandates for the assessment of the ED potential will be made available, which will also indicate the expected timelines for finalisation of the assessments.

The discussion on other aspects of the active substances that are on this list will be put on hold, as they will be discussed once the assessment of the ED potential of the respective substance is concluded.

However, in order to finalise the previous discussions, the Commission informed that as regards phenmedipham, a draft review report for renewal had been uploaded on CIRCABC under this agenda point. Member States were invited to comment by 8 February 2019. As regards the substance dichlorprop-P, comments were invited by 22 February 2019.

A.04 Confirmatory Information:

1. ***General update (no news)***

   Member States were informed that one Member State had submitted some comments about the timing of the future renewal of prochloraz and bromuconazole and the review of confirmatory information requested on endocrine disrupting properties. The Commission reiterated that confirmatory information must be provided by the deadlines set. A consideration of how information can be reviewed, taking into account any other ongoing process, could be undertaken at that time.

2. ***Metazachlor***

   The Commission updated on Member States comments received since the meeting of the Committee in December 2018.

   Member States were also informed that the applicants who are supporting metazachlor for renewal submitted a paper outlining how the assessment of leaching to groundwater is being addressed in their dossier. The paper had been shared with Member States.

   Given the divergent views amongst Member States on the suggested way forward in the amended review report as tabled in December, the Commission asked Member States to signal their positions. Five Member States were opposed to taking note of the amended review report. The Commission informed Member States that it would reflect further on how to move forward.

3. ***Fluquiconazole (amended review report to take note)***

   Member States took note of a revised version of the review report, confirming that further to the evaluation of confirmatory information, no further regulatory action is required.

   One Member State could not take note due to concerns about the robustness of the confirmatory information submitted, in particular for the dione metabolite and the triazole metabolites.

Member States were also informed that no application for renewal had been received by the prescribed deadline and that the substance approval will therefore expire on 31 December 2021.

4. ***Ipconazole (amended review report to take note)***

   Two Member States did not consider the risk to granivorous birds to be satisfactorily resolved. In addition to the confirmatory information aspect, three Member States expressed their view that an early review under Article 21 of Regulation (EC) No 1107/2009 should be initiated for ipconazole given the classification as toxic for reproduction, Category 1B and the fact that renewal was several years away.

   Given the views expressed, the note taking was put on hold. The Commission informed that it would reflect on the way forward.

5. ***Fluopyram (amended review report to take note)***

   Member States took note of a revised version of the review report, confirming that further to the evaluation of confirmatory information, no further regulatory action is required. The amended review report also confirmed that information to address the point related to endocrine disrupting properties must be submitted by 10 November 2020 (2 years from the date of application of the new criteria and guidance to identify endocrine disruptors).

6. ***Spiroxamine***

   Postponed.

7. ***Dithianon (short update)***

   The Commission explained that discussions were still ongoing with the Rapporteur Member State and EFSA on how to evaluate the new assessment of the Rapporteur Member State of the data submitted by the applicant. Member States will be invited to comment on the second add to the DAR prepared by the Rapporteur Member State as well as on the draft EFSA Conclusion.

8. ***Triazole derived metabolites (TDMs)***

   The EFSA Conclusion on the assessment of exposure to the triazole derived metabolites had been published in July 2018. Member States were informed that the Triazole Derivative Metabolite Group provided comments as did some of the individual applicants on specific active substances.

   The Commission announced that reflections were on-going but welcomed the views of Member States on their preferred way of moving forward by 22 February 2019. Discussions in the Standing Committee section pesticides residues, were being initiated in parallel.

A.05 Article 21 Reviews.

No news to discuss.

A.06 Amendment of the conditions of approval:

No news to discuss.

A.07 Basic substances:

1. ***New dossiers received (for information)***

   The following new applications had been received: vinegar extension (use as herbicide on non-agricultural areas) and potassium metabisulfite (use as fungicide on grapes).

2. ***Exchange of views on EFSA Technical Reports***

   No news to discuss.

3. ***Draft Review Reports for discussion***

   a) *Castanea* and *Schinopsis* tannins

   b) *Vitis vinefera* tannins

   The Commission summarised both EFSA Technical Reports. For both applications concerns regarding the non-dietary risk assessment had been identified for which risk mitigation measures might be necessary. Member States were invited to comment by 22 February 2019.

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 summarised the comments received by 8 Member States in January 2019. The implementation plan made available for this meeting had been revised under consideration of these comments. The main changes are the headings of part A and B of the implementation plan.

   The Commission stressed that this revised implementation plan represented a step forward with respect to the status quo, and that EFSA will be requested to review the 2013 Bee Guidance Document. The only alternative to this procedure is no implementation keeping the current 'old' guidance for bees in place, while mandating EFSA to review the 2013 Bee Guidance Document.

   Upon request from one Member States, the Commission clarified that it expected the mandate to EFSA to be finalised before the next meeting of this Committee in March 2019.

   Member States were asked to indicate their position on the presented version of the implementation plan:

   18 Member States indicated to support the current proposed implementation plan, with some underlining that they did so in a spirit of compromise as they would actually prefer full implementation of the 2013 Bee Guidance Document;

   3 Member States indicated not to support the current proposed implementation plan;

   7 Member States did not have a position yet or were absent.

2. ***Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – (to take note)***

   Postponed.

3. ***Data requirements and list of agreed test methods - Update of the revision of the Communications (no news)***

   No news to discuss.

4. ***Defining Specific Protection Goals for environmental risk assessment – (no news)***

   The Commission thanked Member States for the comments received and indicated that internal reflections are going on. An update to the Committee is intended for the next meeting.

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

   Postponed.

6. ***Draft guidance document on the risk assessment of potential metabolites of concern produced by microbial plant protection products – (no news)***

   No news to discuss.

7. ***Draft guidance document on the approval and low-risk criterion criteria linked to "multiple antimicrobial resistance" (update on progress)***

   Member States were informed about the latest developments related to the draft guidance document on multiple antimicrobial resistence, the low-risk criterion for microorganisms. Next discussion is planned in February at Biopesticides WG.

8. ***Working Document on emergency authorisations according to Article 53***

   Member States were informed that a revised document was almost ready to be circulated and that they would be alerted by email when the document will be available for commenting.

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

1. ***Feedback about notification of additional phrases by MS (no news)***

   No news to discuss.

2. ***Risk Mitigation – update on discussion of EU list of risk reduction measures***

   Member States were informed that the Commission intended to elaborate a repository of risk mitigation measures and their efficiency with the aim to refine the risk assessment during the peer-review process and eventually being reflected in the EFSA Conclusions. Standard risk mitigation measures identified in various projects, activities or in (draft) guidance documents are currently gathered and will be presented in the upcoming meetings for discussion.

3. ***Pictogram 'bee hazardous' (follow-up from feedback received from MS)***

   The Commission presented the information gathered from several Member States and will further reflect on how to harmonise the approach of awareness raising towards bee hazardous substances through a possible future amendment of Commission Regulation (EU) No 547/2011 as regards labelling requirements for plant protection products.

4. ***Low-risk criteria (effects on lactation vs. reprotoxic; eye damage 1 /H318 vs. corrosive) (follow-up from feedback received from MS)***

The Commission informed the Member States about the conclusions of its reflections: Commission Regulation (EU) No 2017/1432 amending the low-risk criteria provides that a substance cannot be considered as low-risk where it is classified as: skin corrosive, category 1A, 1B or 1C, or, as Serious damage to eye category 1.

Several Member States favoured the approach that substances with effects on lactation should be associated to the criterion "toxic to reproduction" excluding substances from being considered low-risk. This should be reflected in a future amendment of the low-risk criteria after consultation of the relevant Commission services.

5. ***Labelling requirements as regards appropriate conditions of storage (follow-up from feedback received from MS)***

The Commission informed that the proposal of one Member State for a precautionary sentence "Store locked-up in a dry and well-ventilated place and protected from sunlight" will be further considered as candidate for a new precautionary sentence through a future amendment of Commission Regulation (EU) No 547/2011 as regards labelling requirements for plant protection products.

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

No notifications received.

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

1. ***New notifications (to be noted)***

The Committee took note of 6 notifications received from 2 Member States, refusing mutual recognition of authorisation of plant protection products containing fludioxinil, sedayane and triticonazole; metham sodium; or metam potassium.

One additional notification was received from one Member State refusing mutual recognition of authorisation of plant protection products containing mild pepino mosaic virus. The Member State who had granted the authorisation was surprised and suggested to discuss bilaterally before taking note. The note taking was postponed.

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

Postponed.

A.12 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009.

1. ***New notifications (to be noted)***

The Committee took note of 9 emergency authorisations received between the 1 December 2018 and the 21 January 2019 via the PPPAMS, which are summarised as follows:

Member State	Active substances	Functions
AT	Thiamethoxam	insecticide
AT	Beta-Cyfluthrin Clothianidin	insecticide
AT	Imidacloprid	insecticide
FI	Chlorpropham	plant growth regulator

FI	Difenacoum	rodenticide
LT	*Beauveria brongniartii*	insecticide
LT	Tefluthrin Thiamethoxam	insecticide
LV	Imidacloprid	insecticide
SI	Lime sulphur (calcium polysulphid)	fungicide

2. *Antimicrobials notified in 2017/2018*

Member States were informed that no emergency authorisations had been received for antimicrobials during 2017 and 2018. However, the Commission invited Member States to confirm this and, if relevant, to update by 18 February 2019 the reference document (SANTE/973/2000 rev. 17) with information about any emergency authorisations for antimicrobials used as plant protection products during 2017-2018.

A.13 Plant Protection Products Application Management System (PPPAMS).

No news to discuss.

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

1. *General update*

EFSA updated the Committee as regards the administrative guidance, which is under consultation of this Committee, the on-going implementation of the new scientific criteria to identify endocrine disruptors, the alignment of ECHA and EFSA procedures, and activities of the PPR Panel. As regards the Panel, EFSA proposes a Standing Working Group on residues and consumers risk assessment, and pilot examples of ad-hoc involvement of the Panel in the Peer Review process.

A.15 Improving the efficiency of the process of a.s. approval – update on on-going activities including feedback of Member States.

The Commission mentioned that the bilateral dialogue with EFSA on the presentation of the Conclusions is progressing, and that activities have been also undertaken to progress on the list of available risk mitigation measures (see also point A.09).

Further, the Commission informed that comments had been received on the documents made available in December from four Member States and that the comments were being considered by EFSA and DG SANTE. The documents will be amended further as appropriate to take into account comments. The documents will be presented again, possibly in the meeting of the Committee in March, for endorsement by Member States.

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

The Commission presented an overview of the activities as regards enforcement and of the official controls carried out by Member States reported under Article 68 of Regulation (EC) No 1107/2009.

The Enforcement Working Group has focused in the last months on how to carry official controls to manufacturers of plant protection products, how to develop reference documents for establishing a minimum number of plant protection products samples for analysis, and on a pilot project to take samples from large scale operators involved in international distribution. Another Working Group dedicated to formulation analysis developed a reference document on analytical strategy and reporting results, aiming to increase cooperation and coordination between laboratories in the EU.

Regarding official controls, 22 Member States had reported their controls conducted in 2017. A total of 16 reports used a specific excel template, which allowed to identify the following emerging trends:

There are very important variations among Member States as regards the controls carried out to certain type of operators (e.g. the majority of controls on ports are reported by only two Member States, controls to re-packers and manufacturers take place in only three and five Member States, respectively). This shows the different approach in the assessment of risks, which was highlighted as a weakness in the respective audit series conducted in 2015 and 2016.

A total of 20000 controls have been conducted. The majority focused on distributors or retailers (16000). The number of controls at ports (1600) increased compared to the previous year. The overall compliance rate for official controls is 88%. The number of formulation analysis reached 1600 with an overall compliance of 94%. The controls to re-packers have increased significantly (tenfold), as well as the controls to transport and storage which has doubled.

The new Official Control Regulation repeals Article 68 and the Commission proposes to discontinue the use of voluntary reporting template under Article 68 in absence of long term legal obligation.

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

No news to discuss.

A.18 Minor Uses.

The EU Minor Uses Coordination Facility (MUCF) informed on the long-term funding. As of 15 April 2018 the Grant Agreement with the European Commission regarding the funding of the MUCF had expired. Therefore, the MUCF is now fully depending on voluntary assessed contributions from Member States. For 2019 all Member States have been approached by the MUCF for a voluntary assessed contribution. Although the MUCF has received positive responses from 14 Member States, funds for 2019 are not yet secured. Lack of funding will have serious consequences for the MUCF and for the minor use work in all Member States. Some Member States indicated they will contact their ministries to follow-up on possible funding of the MUCF.

The Minor Uses Annual General Meeting of all funding countries will be held back-to-back with the Stakeholder Advisory Forum on 26 February 2019 in Brussels.

A.19 Progress Report on Low Risk Active Substances.

Member States were invited to update by 13 February 2019 the last version of the progress report concerning the 40-actions implementing plan to increase the

availability of low-risk products and accelerate implementation of IPM in view of its presentation to the AGRI-FISH Council during the current Romanian Presidency.

A.20 Court cases.

The Commission informed about new cases: T-740/18 R and T-740/18 – annulment of Commission Implementing Regulation (EU) No 2018/2015 not renewing the approval of the active substance thiram and related interim measures (suspension of the Regulation).

The Commission informed about the recent judgment in case T-574/18 R, by which the President of the General Court rejected the application for suspension of operation of Commission Implementing Regulation (EU) No 2018/1019 concerning the non-renewal of approval of oxasulfuron, as urgency had not been demonstrated by the applicant.

A.21 Endocrine Disruptors.

The Commission reminded that a first Better Training for Safer Food (BTSF) event on the application of the ED guidance document will be organised on 6-7 February 2019. There has been great interest from the Member States and nearly all will be present with two experts. The Commission recommended that participants practice in advance on the provided case studies in order to get the utmost benefit from the training.

A second similar event is scheduled for June 2019 in order to allow further Member States experts to be trained.

The Commission explained the on-going activities as regards in-house research by the Joint Research Centre.

The Commission also presented a summary of the eight new research projects funded with 50M € under Horizon 2020, which aim to develop and validate testing and screening methods for endocrine disruptors. These eight projects will form a cluster of more than 70 research groups in 19 EU and non-EU countries, and initiate their work on 1 January 2019.

The Commission referred also to the letter received from one Member State referring to thiacloprid and epoxiconazole, both classified as R1. The Commission explained that the EFSA Conclusion on thiacloprid is expected in few days, and that the Review Assessment Report of epoxiconazole is expected to be sent by the Rapporteur Member State to EFSA by the end of February 2019.

A.22 Rapporteurship glyphosate.

The Commission informed that discussions are progressing with a group of five Member States who consider 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.23 Interpretation issues:

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

    a) New version of scoping document following up on feedback received from MS on case DewSmart (BE), Agrecol Liquid for Aphids (LT)

Comments received from several Member States confirmed that the product DewSmart is falling outside the scope of the PPP Regulation.

Agrecol Liquid would rather be considered as a Plant Protection Product as it contains fatty acids that are considered as active substances with a double role, one of which refers to a more invasive mode of action by interacting with the exoskeleton of the insects.

b) Follow-up in situ generation (update after Member State reaction)

No news to discuss.

c) New case sunflower oil (extension request for basic substance, update after Member States reaction)

No comments had been received from Member States. It was agreed to consider the substance as a normal active substance in PPP for the use as a fungicide. The use as a protectant against weight loss or mechanical damage is regarded as out of scope of the PPP Regulation as this action is purely physical to prevent dehydration of treated fruits and tubers.

A.24 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*

The Commission presented possible changes to Regulation (EU) No 844/2012 to ensure systematic clarification of classification issues. The Commission invited Member States to liaise with the competent authorities for CLP (Regulation (EC) No 1272/2008) and to submit any comments within 1 month.

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

No news to discuss.

A.26 Report from working groups, in particular:

1. *Working Group on Biopesticides (no news)*

No news to discuss.

2. *Working Group on Seed Treatments (no news)*

No news to discuss.

3. *Working Group on Co-formulants*

The Commission informed that comments from three Member States had been received on the draft Regulation presented in December. Comments received from stakeholders on approaches to lists of unacceptable co-formulants had also been uploaded on CIRCABC.

The Commission is preparing a revised draft Regulation populating Annex III to the PPP Regulation, which will be shared with the Member States for further comments via CIRCABC, after consultation of the Commission Legal Service.

4. *Post Approval Issues (no news)*

No news to discuss.

A.27 OECD and EPPO.

Member States were informed about an OECD Seminar planned for 26 June 2019 about the potential roles of drones, robots and IT tools to reduce risks associated with the use of pesticides. Member States were invited to send by 8 February 2019 names of experts from academics, authorities or industries specialised in these topics in view of their participation.

A.28 PEST Committee.

The Commission explained that the European Parliament plenary debate on the PEST Committee report took place on 14 January 2019. The report was adopted two days later with a comfortable majority and is available on the Parliament's website. The Parliament addresses a number of recommendations to Member States and to the Commission. The Commission now needs to answer to the recommendations that are addressed to the institution in the form of a follow-up fiche, which will eventually also be published on the Parliament's website.

One Member State asked whether this report would have an impact on the REFIT exercise (both in terms of content and in terms of timelines). The Commission explained that this report, together with the report from the Environment Committee (prepared by MEP Poc) and other outputs such as the Scientific Advisory Mechanism (SAM) opinion, will be taken into account in the REFIT exercise. This will not lead to any change of the timelines envisaged by the Commission.

Another Member State asked whether there would be a discussion on the recommendations of the PEST Committee in the context of the PAFF meetings. The Commission explained that the recommendations addressed to the Commission will be considered in the response to be prepared for the Parliament (the follow-up fiche to the Resolution). Recommendations addressed to Member States may be discussed in Council Working Group meetings if the Presidency so decides.

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

No news to discuss.

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

Member States were asked to consider and provide comments on the proposal of one Member State to include a new field in the List of Endpoints and the Appendix I of the Review/Renewal Report to provide a reference to the reference specification in order to facilitate the equivalence check process.

A.31 Scientific publications and information submitted by stakeholders.

The Commission invited Member States to check the information available under this point on CIRCABC, which had been submitted by stakeholders for this meeting.

A.32 Date of next meeting(s).

The date of the next meeting was confirmed as 21-22 March 2019.

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.

Germany made the following protocol declaration:

Germany welcomes the fact that the Commission wishes to realise the very demanding task to develop harmonised risk indicators on the application of plant protection products. Despite the fact that Germany is of the opinion that the proposed risk indicators require further improvement, Germany agrees to the submitted draft Directive for the time being.

With its consent to the draft Directive, Germany however expects the Commission to pursue the demanding tasks of developing an improved risk-based indicator on a scientific basis.

At present, indicator (2) (derogations according to Art. 53 of Regulation No 1107/2009) is based on the number of authorisations granted by a Member State. Germany is concerned that the indicator seems inconclusive and could be manipulated. Therefore, Germany asks the Commission to establish adequate provisions as soon as possible in order to calculate the indicator on the amount of active substance granted by the Member State.

On a transitional basis, since the provisions have not yet been established, Germany accepts to calculate the indicator on the number of derogations granted as long as it is adequately stated that this calculation allows no conclusions to be drawn regarding the amount of active substance.

The Commission is asked to submit the risk indicators, calculated annually, to Member States prior to publication in order to give them the opportunity to comment.

In order to make the calculated risk indicators comparable amongst Member States, the Commission is asked to provide a workshop on the calculation of the indicators and clarification of the details.

Italy made the following protocol declaration:

Italy agrees the approach adopted by the Commission in order to set the harmonized risk indicators in the absence of validated statistical data on the use of Plant Protection Products and therefore will vote in favour of the draft Directive setting such indicators.

However, Italy would like to underline the following point: the risk indicator, as proposed by the Commission, is based on a comparison of the trends of the sales over several years, attributing a weight (a multiplier operator) to each sold active substance on the basis of its intrinsic dangerousness. It is foreseen that such a comparison has to be conducted comparing the overall weighting annuity (average of the three-year period 2011-2013) with the ones of the previous years.

It may certainly happen that, over the years, an active substance varies its status, for instance following the renewal of the approval under the (EC) Regulation 1107/2009, a non-approval decision, or because of a new classification under the (EC) Regulation 1272/2008, therefore losing the prerogatives of the original grouping.

Therefore, in order to avoid the application of different criteria by Member States to compare the weights over the years, Italy considers it is necessary that the Commission gives further indication to Member States in the view to guarantee an uniform approach by Member States to the processing of data on sales, by adopting specific guidance documents regarding how to calculate the indicator which also considers the above descripted possible variation of the status of the active substances.

Vote taken: Favourable opinion.

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 Renewal Report SANTE/11966/2017 Rev. 3).

Member States were updated on developments since the meeting of the Committee in December 2018.

Following a request from the rapporteur Member State in December, experts from EFSA and the rapporteur Member State further discussed aspects related to the assessment of residues and consumer risk for the herbicide use in January 2019.

A meeting took place between the Commission and the applicants and their legal representation on 16 January 2019. The applicant continues to consider that a renewal based on the use on onions and flower bulbs would be justified by the existing assessment and that additional data to address issues related to residues and non-target arthropods can be submitted during the renewal of authorisations.

Once again the Commission informed Member States that based on the positions and comments of Member States expressed so far, it still considered that the proposed non-renewal of approval is the approach that respects the legislation and commands the widest possible support of Member States.

Member States were then informed that on 23 January 2019 late in the afternoon, one of the members of the Task Force, UPL Europe Ltd, had written to withdraw support for the renewal of the use of chlorpropham as a sprout suppressant on potatoes.

Given the timing of the letter, the vote had to be postponed because some further amendments to the draft review report and the draft Regulation are required. However, the Commission informed that a vote would be rescheduled as soon as possible.

Member States were asked to confirm their positions. Several Member States indicated that their position was not yet finalised.

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 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 Renewal Report SANTE/10803/2018 Rev. 2).

Italy made the following protocol declaration:

Italy, as the Rapporteur Member State for the active substance ethoprophos, while sharing in principle the concerns expressed in the EFSA final opinion regarding the use of this active substance as well as the identified data gaps and therefore expressing a favourable opinion with regards the proposal of the Commission, however does not agree with the conclusions as regards the genotoxic potential of this compound and is of the opinion that the available data are sufficient to exclude it.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing 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 REV 5).

The Commission presented the draft Regulation and the draft review report, highlighting the changes introduced in the texts since the last meeting of the Committee in December 2018. In particular, a request for confirmatory information on the technical specification of flutianil and its compliance with the toxicological batches was added following a comment from the rapporteur Member State.

Two Member States indicated that they could not support the proposal due to the risk of metabolites leaching to groundwater. Three Member States indicated that they would only support the proposal if a request for confirmatory information was added on the assessment of the ED potential of flutianil. The Commission informed that it will consider adding such request for confirmatory information and that a vote will be rescheduled as soon as possible. Consequently, the vote was postponed.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing 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 point was postponed as in the light of the comments from one Member State, the Commission had identified the need for further modifications in the draft review report and draft Regulation.

Vote postponed.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance mefentrifluconazole 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/11612/2018).

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of 1-methylcyclopropene, mancozeb, methiocarb, methoxyfenozide, pirimicarb, pirimiphos-methyl and thiacloprid for which the United Kingdom is the rapporteur Member State, and amending Commission Regulation (EU) No 1141/2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC, allocating, for the purposes of the renewal procedure, the evaluation of famoxadone for which the United Kingdom is the rapporteur Member State.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azimsulfuron, azoxystrobin, fluazifop p, fluquinconazole, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine.

The Commission informed that no applications for renewal were received for azimsulfuron and fluquiconzale. Therefore, the draft Implementing Regulation was amended: all references to these active substances were deleted and the expiry dates of approval were not extended for these active substances.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the approval periods of the active substances bifenthrin, carboxin, 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.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee 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 was discussed in combination with agenda point A 08.01.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation 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/11254/2018).

The Commission informed that the inter-service consultation was finalised and the WTO TBT notification procedure will be launched soon. Comments from the Member States had been uploaded on CIRCABC.

One Member State expressed that it could not support the proposal. Another Member State could not support the proposal and believed that the concerns identified could be addressed. One Member State requested a shorter grace period for products containing this substance due to its toxicological properties. Another Member State indicated that they would prefer shorter transitional periods rather than shorter grace periods.

The Commission clarified that a shorter transitional period may create problems in the context of the WTO TBT notification procedure.

Member States were invited to provide their views by 8 February 2019, in particular on the appropriateness to set grace periods for PPP containing thiophanate-methyl and their duration.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance dimethoate, 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/11494/2018).

The Commission presented the draft Regulation and indicated that comments had been received from two Member States in support of the Commission proposal.

One Member State requested shorter grace periods for products containing this substance due to its toxicological properties.

Member States were asked to provide their views by 8 February 2019, in particular on the appropriateness to set grace periods for PPP containing dimethoate and their duration.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal 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 Implementing Regulation (EU) No 540/2011.

The Commission presented the draft review report and the related draft Implementing Regulation for renewal with restricted uses to ornamentals and potatoes. Member States were invited to send their comments by 18 February 2019.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 22/2013 and (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen (Draft Review Report SANCO/12618/2012).

Member States were reminded that the outcome of the evaluation of confirmatory information submitted for cyflumetofen was that a genotoxic potential of metabolite B3 could not be excluded and that it is predicted to occur in groundwater above 0.1 ug/L in all or most of the pertinent FOCUS scenarios for all uses. To resolve this issue, the Commission had therefore proposed a restriction to the timing of use through an amendment of the approval conditions.

Member States were informed about comments received concerning the restriction proposed.

Two Member States considered that the restriction was not severe enough and that use should only be allowed in the period from March until June.

One Member State indicated that it did not agree with the proposed restriction, nor a more severe one and that it would prefer to allow Member States to consider each use to ensure an acceptable risk to groundwater. The same Member State commented that if a restriction was considered necessary then it should preclude authorising uses where metabolite B3 is predicted to occur above 0.1 µg/L, rather than restricting the timing of use.

The applicant considered that the currently proposed restriction will preclude uses in the Southern zone where there is no risk to groundwater.

Given the divergent views expressed, Member States were asked to provide their views on the appropriate restriction in view of a possible vote at the meeting of the Committee in March 2019.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance isoxaflutole, 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 Renewal Report SANTE/11653/2017).

Member States were informed that due to a delay in the interservice consultation the draft legal text could not be made available to the Committee before the meeting. However, an updated draft renewal report was available to Member States taking into account comments received from Member States and the applicant. It was recalled that in this case, although the Commission considered isoxaflutole not to be an endocrine disruptor based on the available information, a request for confirmatory information to update the assessment in line with the new guidance document would be made to add further confidence to the decision.

Member States were advised that the draft legal text would be circulated after the meeting and that comments were welcomed by 22 February 2019, with an intention to vote in the next meeting of the Committee in March.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance 1-methylcyclopropene, 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 Renewal Report SANTE/11631/2018).

The Commission presented the draft Implementing Regulation for renewal. Written comments had been received from three Member States and by the two applicants. Changes to the draft renewal report related to the clear distinction of the product generated in situ with respect to the minimum purity level and the associated impurities. Other amendments with respect to the previous versions were linked to the inclusion of a paragraph on the identification of potential endocrine disrupting properties according to the new criteria, while it is explained that 1-methylcyclopropene is unlikely to be an endocrine disrupter as there is no indication of an endocrine mode of action or endocrine disruptive effect.

Member States were invited to comment by 22 February 2019.

C.08 Exchange of views of the Committee 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 Rev. 0) (short update only).

The Commission informed that it had asked EFSA and the Rapporteur Member State for clarifications regarding the risk assessments for mammals and bees and that it will await this requested feedback before being in a position to present an updated draft renewal report and draft Implementing Regulation for this substance.

One Member State informed about the possibility to restrict the use to indoor use only. The Commission explained that a risk to consumers was identified for the only indoor representative use.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation 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).

No discussion as the WTO TBT notification procedure was still ongoing. However Member States were informed that a letter from the International Confederation of European Beet Growers had been received and uploaded on CIRCABC.

C.10 Exchange of views of the Committee on a draft Commission Draft 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10186/2018) (short update only).

No discussion as the WTO TBT notification procedure was still ongoing.