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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
5 - 6 July 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/fc2304e1-ff4f-4880-b8a5-0b875fff71b3*

SUMMARY REPORT

Section A Information and/or discussion

The meeting took place via web conference due to measures taken to contain the COVID-19 pandemic.

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the previous meeting was still in preparation.

A.02 New dossiers (for information):

- New active substances

  The Commission informed that the following application dossiers for new active substances had been declared admissible by the following Rapporteur Member States (RMS): a) Fluazaindolizine (DPX-Q8U80) (RMS MT, nematicide), b) Florylpicoxamid (RMS DK, fungicide), and c) Fenquinotrione (RMS AT, herbicide).

- Basic substances applications

  d) Sodium chloride (extension of use)

  The Commission informed that the verification of admissibility is ongoing. The proposed use is as an herbicide for spot treatment of meadows against an invasive plant water primrose.

  e) *Salix spp* cortex (extension of use)

  The Commission informed that the verification of admissibility is ongoing. The proposed use is as a fungicide to be applied as a spray for foliar treatment, to protect cereals, tomatoes, and potatoes. The application covers also an extension of the application period to additional growth stages and an increase in number of applications for the already approved uses on grapevine and orchards.

- Amendment of conditions of approval

  There were no news to discuss.

A.03 Renewal of approval and general issues.

There were no news to discuss.

A.04 Exchange of views on EFSA conclusions/EFSA scientific reports:

- New active substances

  There were no news to discuss.

- Renewal of approval

  There were no news to discuss.

- Basic substances

  a) Ozone

  The Commission recalled that the intended use of ozone as a basic substance is as a bactericide, fungicide, insecticide, nematicide and viricide. Ozone is produced in-situ by an ozone generator and then diluted in-situ in water to produce ozonated water. The ozonated water is intended to be applied in drip irrigation and spray irrigation on edible and non-edible crops. EFSA had published the Technical Report in May 2021, and identified some concerns such as potential adverse effects of ozone (genotoxicity, neurotoxicity and immunotoxicity, mainly after inhalation exposure) and the fact that no toxicological data were available for the substance as applied (ozonated water). Furthermore, the limited available data did not allow EFSA to conclude on the risk to bystanders and residents for all proposed uses. A potential human health concern could be associated to the presence of by-products that can be generated during chemical interactions between ozone and substances normally occurring in water but the information provided was insufficient to conclude on the toxicological relevance of these by-products in ozonated water used for plant protection. The application contained only limited information in relation to the fate and behaviour of ozone in the environment. As regards effects on non-target organisms, low risk from ozone was concluded for all uses in drip irrigation but this was not the case for spray application. EFSA indicated that no conclusion could be drawn concerning the risk assessment to non-target species from potentially occurring by-products of the chemical interaction between ozone and substances occurring in water.

  The applicant had submitted comments on the EFSA Technical Report which are available to Member States. The applicant had referred to the existing uses of ozonated water in many areas other than agriculture, in particular the fact that ozonated water is already used by farmers for the cleaning of irrigation pipes. Additionally, the applicant had provided views on the concerns raised by EFSA.

  One Member State stated that ozone should not be approved as a basic substance due to its hazardous properties, however, ozonated water could be considered eligible for an approval as a basic substance. Therefore the assessment should focus on ozonated water instead of ozone. Furthermore, it should be taken into account that currently farmers can use ozone generators for cleaning purposes so they should be allowed to use the same equipment to produce ozonated water. The same Member State informed that it would soon submit a note in this sense to the Commission. Another Member State expressed its support for the earlier view. A third Member State questioned whether in situ generation of ozone is in the scope of Regulation (EU) No 1107/2009.

The Commission explained that ozonated water is not in line with the definition of 'substance' as set out in Article 3 of Regulation (EC) No 1107/2009 as it is a mixture of ozone and water and thus not eligible for an approval as a substance. The Commission clarified that basic substances such as beer, vinegar or plant extracts are compliant with the definition of substance as they are produced as such and are so-called UVCB substances (Unknown or Variable composition, Complex reaction products or Biological materials).

The Commission invited Member States to provide comments and positions on the eligibility of ozone to be approved as a basic substance by 10 September 2021.

b) *Urtica* spp (extension of use)

The Commission presented the EFSA Technical Report. The application concerns an extension of use of *Urtica* spp as a fungicide on common bean, cucurbits, strawberry, salad, carrot and potato, as an insecticide in carrot, salad, strawberry, ornamentals, asparagus and potato, as well as plant strengthener in asparagus. Even though the application was for an extension of use of the approved basic substance, there is a difference in the preparation for use, i.e. the addition of *Saccharomyces cerevisiae* to improve fermentation.

Several data gaps have been identified by EFSA, but overall EFSA concludes that *Urtica* species are unlikely to trigger a concern for humans and considering the lower proposed application rates in this extension, also the exposure to non-target organisms is likely to be lower than the already approved applications. There is, however, no information on the usefulness of the *Urtica* spp extract as a plant defence stimulator.

Several Member States had commented on the addition of *Saccharomyces cerevisiae*. The reasons why it is needed is not clear and the applicant has not clarified it upon request and the demonstration of the absence of substantial amounts of yeast in the end product is outstanding. Furthermore, *S. cerevisiae* strain LAS02 is also an approved fungicide under Regulation (EC) No 1107/2009 with a functionality that overlaps with the proposed uses of *Urtica* spp. So it possible that the effects that are seen are due to the presence of the yeast instead of the nettle extract itself.

One Member State expressed its opinion that it should be approved because it is a foodstuff. Member States were invited to provide comments by 10 September 2021.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion.

- New active substances

  a) Dimethyl disulphide

  The Commission recalled that the discussions on this soil fumigant was taking place in parallel with the substances under points b and c below, and also recalled that DMDS is a new active substance which so far was not on the EU market, in contrast to chloropicrin and 1,3-dichloropropene which have been on the market before and dossiers were re-submitted and under discussion.

The Commission also informed that new risk mitigation measures were suggested by the applicant and commented by Rapporteur Member State, and made available via CIRCABC. Two Member States did not consider sufficient the information submitted by the applicant, three Member States expressed their concern about the fact that there is no experience on this new substance.

Member States were invited to reflect on the possibility of a restricted approval or a non-approval and to send their comments by 31 August 2021.

b) Chloropicrin

The Commission thanked the rapporteur Member State for having discussed with the applicant several open points, including the testing protocol for the additional genotoxicity study as well as several other open points identified in the EFSA Conclusion.

The Commission informed that, following internal consultations, it intends to propose non-approval of chloropicrin based on the current EFSA Conclusion. The applicant had been informed and the draft Review Report, once commented by the applicants, is expected to be circulated to Member States before the next meeting of this Committee.

Three Member States expressed their surprise towards the new proposal to not continue with further data generation to address the data gaps of the dossier. The current rapporteur Member State indicated that, should there be a re-submission of an application for approval in the future, it would not wish to accept the role of rapporteur again.

The Commission reminded that the EFSA Conclusion had been adopted already in January 2020 and a decision should normally be proposed within 6 months. Member States were invited to provide their initial positions as regards the proposal for non-approval of the substance by 31 August 2021.

c) 1,3-dichloropropene

The Commission informed that, following internal consultations, it intends to propose non-approval of 1,3-dichloropropene. The applicants had been informed and the draft Review Report, once commented by the applicants, is expected to be circulated to Member States before the next meeting of this Committee.

Three Member States expressed their surprise towards the new proposal to not continue with further data generation to address the data gaps of the dossier.

The Commission reminded that the EFSA conclusion had been adopted already in October 2018 and a decision should normally be proposed within 6 months. Member States were invited to provide their initial positions as regards the proposal for non-approval of the substance by 31 August 2021.

d) *Bacillus amyloliquefaciens IT-45*

The Commission informed that the EFSA conclusion is available and that so far no comments of Member States on the non-finalized issues were received.

The Commission summarised that no concerns were identified, however several issues were not finalised: consumer risk assessment with regard to potential secondary metabolites that might be produced in soil, the likely competitiveness, persistence and multiplication of *Bacillus amyloliquefaciens* strain IT-45 in soil, the

potential for the production of secondary metabolites in soil following application, and the risk assessment to non-target organisms, birds, wild mammals, aquatic organisms, non-target soil arthropods, earthworms, other soil macro- and microorganisms. The applicant' comments to EFSA conclusions have been uploaded on CIRCA BC, the applicant disagrees in particular with the potential infectivity and pathogenicity to birds, soil non-target dwelling arthropods and the issue of secondary metabolites for terrestrial and aquatic non-target organisms.

Member States were invited to send their comments by 31 August 2021.

- Renewal of approval

e) *Metarhizium brunneum* strains BIPESCO 5/F 52

The Commission thanked all Member States that provided comments on the EFSA Conclusion. The Commission informed about some clarifications made by EFSA on its Conclusion. Member States were invited to comment by 31 August 2021.

f) Captan

The Commission informed that, following the request of Member States at the previous meeting of this Committee, the Commission was preparing a mandate to EFSA to assess whether a safe use outdoors at lower application rates is possible. No further comments were requested at this stage.

g) *Bacillus amyloliquefaciens* strain QST 713

No draft review report was made available. Commission reminded that as regards the concern on bees, two Member States had suggested to address this in the review report with the sentence 'MSs should pay particular attention…' while for bumble bees two Member States suggested to set confirmatory information. One Member State indicated to support a renewal as a low-risk substance. Member States were invited to comment by 31 August 2021.

h) *Pseudomonas chlororaphis strain MA342*

The discussion was postponed.

i) *Bacillus thuringiensis (horizontal discussion)*

The Commission summarised the comments received from Member States, applicants, and other stakeholders, on horizontal issues concerning dietary exposure for consumers. The Commission underlined that internal reflections are on-going on how to increase clarity on a possible link between *Bacillus thuringiensis* strains and food intoxication outbreaks.

j) *Pythium oligrandum* strain M1

The Commission informed about a meeting with the applicant and the rapporteur Member State upon request of the applicant following comments on the draft Renewal Report. During this meeting it was explained to the applicant that a non-renewal of the approval of *Pythium oligandrum* M1 would be motivated by the significant data gaps and key issues that could not be finalised, namely regarding the infectivity and the concentration and stability of two metabolites of potential concern.

The Commission reported that the applicant confirmed that all necessary studies to address the data gaps identified in the EFSA Conclusion have been initiated, some

being already available but, in any case, none of them had been submitted during the peer-review which makes a consideration of them not possible. The Commission explained that it intends to submit the comments and arguments provided by the applicant to EFSA for review but that newly generated data cannot be taken into account at this stage of the procedure.

k) Straight Chain Lepidopteran Pheromones

The Commission informed that no draft Renewal Report had yet been made available. EFSA did not find any critical areas of concerns, however there were individual data gaps for some of the in total 35 compounds. Considering all the evidence, the Commission intended to propose renewal as low risk active substances.

The Commission also informed that the additional SCLP compound assessed by the rapporteur Member State ((E,E)-8,10-Dodecadien-1-yl acetate) outside the renewal process will be addressed at the same time as the renewal of the approval of the SCLP group.

Member States were invited to comment by 10 September 2021.

l) Carbon Dioxide

The Commission informed that it intended to propose a renewal of approval as a low risk active substance as the EFSA Conclusion did not find critical areas of concerns. Member States were invited to comment by 31 of August 2021.

- Basic substances

m) Chitosan

The Commission reminded that the application concerns the approval as a basic substance of chitosan from the fungus *Aspergillus niger*, for use as an elicitor in horticulture, olive trees, grapes, grass and post-harvest fruit treatment.

The Commission summarised the comments received from Member States. Two Member States support the proposal for approval. One Member State did not support the approval of chitosan as a basic substance due to lack of data identified in the EU risk assessment and because it is of the opinion that the existing approval of chitosan should be re-evaluated.

As regards the preparation for use of chitosan which requires an adjustment of pH by adding vinegar, one Member State supported the proposal to include two recipes for the preparation in the review report. Another Member State thought that the mixture of vinegar and water can be considered as "a simple diluent" according to Art. 23 1(c). A third Member State was of the opinion that the review report for the basic substance vinegar should not be updated at all. Vinegar used as a simple co-formulant together with another basic substance does not relate to the approval of the basic substance vinegar; therefore, vinegar should be explicitly included in the review report for chitosan - not as a simple diluent but for pH regulation.

The applicant had submitted some additional information on the addition of vinegar that had been sent to EFSA. EFSA confirmed that a quantitative risk assessment was not required based on the toxicological profile of the substance and the low concentration according to the recipe for preparation, and that the exposure of toddlers does not raise concerns. As regards the environmental exposure and risk to non-target organisms, the additional information provided by the applicant did not

change the outcome of the risk assessment, and the identified data gaps still remained.

The applicant requested that the uses already approved for chitosan hydrochloride should also be approved for chitosan and added to the GAP table in Appendix II of the review report. Additionally, the applicant would like to modify and increase the application rate for one use (on grapevine). The Commission informed that the Technical Report of EFSA was prepared for an extension of chitosan hydrochloride and concluded that the outcome of the risk assessment is the same for chitosan and chitosan hydrochloride for all uses. As regards the increase in the application rate it seems to be within the risk envelope for other use of chitosan hydrochloride.

Member States were invited to consider all the documents available and provide comments by 10 September 2021, in particular as regards their position on the approval of chitosan as basic substance, the proposal of one Member State to re-evaluate the approval of chitosan (hydrochloride), and the use of chitosan in combination with vinegar.

n) Caffeine

The Commission reminded that the application concerns an approval of caffeine to be used in plant protection as insecticide in cabbage, potatoes and *Buxus spp.*, and as molluscicide on all edible and non-edible crops.

The Commission informed that it had contacted ECHA concerning the classification of caffeine in a mixture as proposed in the recipe for use as a basic substance. It appears that a 1.5% solution of caffeine in water and 2% in granules would not have to be classified and would not have to be regarded as a substance of concern in the meaning of Art 23 of Regulation (EC) No 1107/2009. Nevertheless, the Technical Report of EFSA identified data gaps in all areas of the risk assessment. Despite the fact that the EFSA Panel on Dietetic Products, Nutrition and Allergies established a value of no concern for caffeine intake, on the basis of the available information, the risk assessment for non-dietary exposure, and the risk assessment for consumers from residues in food could not be concluded. According to EFSA, the information available was also insufficient regarding the environmental exposure assessments and the risks to non-target organisms.

The applicant had submitted some additional information that had been sent to EFSA, who, however found that the provided information is not sufficient to change the conclusion of the risk assessment.

The Commission summarised the positions of Member States: four Member States opposed approval, whereas two Member States thought that caffeine should be approved because it is a foodstuff.

The Commission highlighted that the application for an approval as a basic substance does not concern coffee – a common foodstuff – but caffeine, which is indeed a food additive, but for plant protection purposes it is intended to be purchased in a pure form, and the solution that is intended to be applied has a concentration of 1.5%, whereas typical espresso contains ca 0,0013% caffeine (difference of 3 orders of magnitude). Therefore, the use proposed in the application cannot be directly compared to the use of waste coffee by amateur gardeners, and the proper risk assessment is considered indispensable.

The Commission presented a draft Review Report in view of a non-approval of caffeine as a basic substance. Member States were invited to comment by 10 September 2021.

- Amendment of conditions of approval

  There were no news to discuss.

A.06 Confirmatory Information:

1. Pyriofenone

   The Commission explained that since the last meeting of this Committee, two Member States had indicated that a dedicated peer review procedure on the toxicological relevance of impurities is not considered necessary. They agreed with the evaluation results of the rapporteur Member State and considered that the impurities do not indicate any toxicological concerns at the maximum levels presented in the technical specification.

   Member States were invited to comment on the updated Review Report by 10 September 2021.

2. Pyrethrins

   The Commission informed that the rapporteur Member State had shared the draft renewal assessment with the co-rapporteur Member State in February 2021 and uploaded the draft renewal assessment report in the EFSA peer review workspace on 30 April 2021. According to the rapporteur Member State, the uncertainties highlighted during the confirmatory data procedure remain and, additionally, at least one new study could be necessary to fully address the assessment of endocrine disrupting properties. The Commission informed that it would further reflect on the way forward.

   Member States were invited to comment by 10 September 2021.

A.07 Guidance Documents:

1. Guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 Rev. 11) (to take note)

   The Commission informed that comments had been received from 9 Member States as well as Crop Life Europe and IBMA. Comments were submitted with respect to:

   - the proposed changes regarding genotoxicity
   - the need to update references to legislation
   - the need to update the sections referring to classification of substances
   - other comments on broader points related to assessment of relevance

   The Commission explained that the current update should be limited in scope i.e. primarily related to the genotoxicity assessment. However, based on the comments received some further updates had been made in order to reflect new references to legislation and classification. Other comments will only be considered when the document will be fully revised in the future.

Member States were asked to consider the revised document and provide further comments in view of endorsement at the next meeting of this Committee (October 2021).

2. Updated (errata) Guidance document on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)

   The discussion was postponed.

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

   The Commission informed about the outcome of the discussion on the Specific Protection Goal (SPG) for honeybees by Ministers in the AGRIFISH Council of 28 June 2021. During this public session, a clear majority of Ministers supported the Commission's proposal for an EU wide, specific protection goal which is ambitious but still measurable, and limits the maximum permitted level of honeybee colony size reduction at 10% after the use of a plant protection product. Some Ministers supported a lower or a higher value but were willing to compromise on the 10%. The Commission had, therefore, asked EFSA to complete the update of the Guidance Document on the basis of this 10% maximum permitted level of honeybee colony size reduction as a specific protection goal.

   The Commission furthermore underlined that work will continue to set SPGs for bumble bees and solitary bees. However much less data is available for these type of bees than for honeybees. The Commission will reflect with EFSA on the next steps and invited Member States to send proposals on how to set protection goals for wild bees by 10 September 2021.

   The Commission also indicated that it intends to prepare, upon finalisation of the review of the Bee Guidance Document by EFSA, without delay a draft Regulation to amend the uniform principles for honeybees, bumble bees and solitary bees in order to implement the updated guidance – and also intends to consider if an amendment to Annex II to Regulation 1107/2009 would be needed. The Commission also mentioned the need to set up a work programme for the development of missing test methods for pollinators as recommended by the Court of Auditors in its report last year.

   One Member State inquired about the timeline for the review and adoption of the updated Bee Guidance Document, whether an additional mandate will be send to EFSA and whether the SPG will be mentioned in the updated Bee Guidance Document. The Commission confirmed its intention to update the mandate to EFSA. EFSA indicated needing at least 10 more months for the draft Guidance Document to be ready for public consultation, which may be held in March 2022. After the public consultation the Guidance Document may be finalised by EFSA by September 2022.

   One Member State inquired which value will be included in the Regulation on the uniform principles. The Commission explained that this is currently not known yet as the SPG is set for the reference tier (field studies) and needs to be translated to the lower tiers, this will be reflected in the updated Guidance Document.

4. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009

   The Commission presented the revision 20 of the "Draft guidance document on treatment, placing on the market and use of treated seeds under Regulation (EC) No 1107/2009", which was made available on CIRCA BC. Member States were invited to comment by 10 September 2021.

5. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02

   The Commission updated the Committee on the on-going work on the revision of the Communications. Member States were invited to comments by 10 September 2021.

6. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 Rev. 9) (for information)

   The Commission informed that this Guidance Document had been amended to reflect the changes to residue definitions, based on the comments received from the section Pesticides Residues of this Committee. The amendments also ensure a clear separation of procedures at substance and at product level. The Post Approval Issues Working Group of this Committee will debate this amended version. Member States were invited to submit further comments by 10 September 2021.

7. Guidance document on rules for revision of assessment reports (SANCO/10180/2013– Rev. 2 May 2021) (for information)

   The Commission informed that, depending on the outcome of the discussions explained above, this Guidance Document will be amended accordingly.

8. Guidance document on data matching for applications for authorisation of plant protection products according to article 33/43 (for information)

   The Commission informed that the comments received since the last meeting had been transferred to the Member State leading the revision of this Guidance Document. The Post Approval Issues Working Group of this Committee will debate this amended version.

9. Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 (for information)

   The Commission informed that the comments since the last meeting had been transferred to the Member State leading the revision of this Guidance Document. An updated summary table and a new version of the Guidance Document had been uploaded on CIRCABC. Member States were invited to comment by 10 September 2021 in view of a possible endorsement at the forthcoming meeting of this Committee in October 2021.

A.08 Defining Specific Protection Goals for environmental risk assessment.

The Commission informed about the meetings of the Working Group of this Committee which continued the discussions on the draft document on problem formulation. The Commission informed that a consultation of Member States and stakeholders on this draft document is planned for this autumn.

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

The Commission informed that the update on format and content of the draft list of Risk Mitigation Measures (RMM) that had been presented to Member States in 2019 is in progress. The Commission encouraged Member States to continue reporting about their initiatives regarding RMM or new risk reduction technologies.

The Commission also informed that it will participate as an observer in a Working Group led by Germany that aims to evaluate the possibilities to implement RMM in the regulatory procedures.

A.10 Notifications under Regulation (EC) No 1107/2009 (for information):

- Article 44(4)

No notifications received.

- Article 36(3)

The Commission informed that six notifications had been received. One notification concerned a rejection of authorisation under the zonal system and the remaining five notifications concerned rejections of applications for mutual recognition. For two of the cases the applicants had lodged national appeal procedures, which had been dismissed.

- Article 53

The Commission informed about comments received since the last meeting concerning the addition of a new field in PPPAMS for the actual use of plant protection products after emergency authorisations have expired, to address situations where the actual use is very different from the expected one because of e.g. different environmental conditions not necessitating the uses permitted in the authorisation). The Commission explained that this field would not be mandatory. The Commission informed that analysis was ongoing on how to implement this field in PPPAMS.

A.11 News from European Food Safety Authority (EFSA).

EFSA informed about upcoming Conclusions and their planning for the next months for expert meetings. In particular, EFSA informed that it had received the draft RAR on glyphosate on 15 June 2021 and that the launch of the public consultation is envisaged in September in parallel with the public consultation to be launched by ECHA on the proposal for harmonised classification.

EFSA also reported on the general peer review meeting on residues, which had taken place from 3 to 5 May 2021. A public consultation on a draft scientific opinion on comparative in vitro metabolism studies is open until 25 August 2021, while another on a draft Guidance Document for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals is open until 10 July, 2021. EFSA also informed about an open call for seconded national experts.

A.12 Improving the efficiency of the process of a.s. approval / renewal.

The Commission informed that the discussions with EFSA on an updated general mandate for basic substances were progressing. This mandate will consider the new procedures introduced by the Transparency Regulation (Regulation (EU) No 2019/1381) and aims also to reduce administrative burden by widening the scope of the risk assessment performed.

The Commission also informed that it had initiated discussions with EFSA as regards how to make the Conclusions on micro-organisms more fit-for-purpose for the regulatory decision making, in particular reflecting the central role biological and ecological properties of the respective micro-organisms play in the risk assessment.

The Commission mentioned the on-going prioritisation discussions ongoing among Member States, EFSA, and the Commission, and stressed that this Committee will need to be consulted too due to its role in endorsing the Guidance Documents.

Finally, the Commission reminded of the importance of considering all information and studies submitted in an application dossier, even if no guidance is available and their evaluation during the peer review requires expert judgement. Such situation may in particular arise for active substances where Guidance Documents do not cover the respective modes of action or particular properties of a substance (e.g. volatile active substances). The Commission emphasised that if information cannot be considered, this needs to be justified in a transparent way during the peer review. The Commission recalled the possibility of pre-submission meetings, the possibility of the Rapporteur Member States to discuss with EFSA on particular issues, and ad-hoc consultations of EFSA Panels during the peer review if needed.

A.13 Microorganism Active Substances, in particular:

- update on data requirements
- update on Annex II
- update on uniform principles
- Commission Communications in the framework of the implementation of the data requirements

The Commission presented the main changes in the draft documents compared to the drafts available at the last meeting of this Committee. The Commission informed Member States on the launching of the consultation of the other Commission services concerned on the four Implementing Regulations (update of data requirements for active substances, update of data requirements for plant protection products, update of uniform principles, and amendment to Annex II of Regulation (EC) No 1107/2009). A public consultation via the feedback mechanism will follow after summer, which will give all stakeholders the possibility to comment.

A.14 Safeners and Synergists.

There were no news to discuss.

A.15 Updates, clarifications & questions on specific active substances:

1. Tebufenozide (Art. 21)

   The Commission informed that the mandate under Article 21 of Regulation (EC) No 1107/2009 to assess the genotoxicity of one of the metabolites is ready to be sent to EFSA, and that EFSA is expected to deliver the results within three months from receiving the mandate. The Commission informed Member States that once the output from EFSA is available, discussion in this Committee will resume.

2. Isopyrazam (Art. 21)

   The Commission recalled that in March 2021 it had sent a letter to Syngenta initiating a review of the approval of isopyrazam in accordance with Article 21 of Regulation (EC) No 1107/2009 due to concerns about groundwater contamination by one metabolite and the opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency that isopyrazam meets the criteria to be classified as toxic for reproduction, category 1B. Syngenta had provided its comments to the Commission on 31 May 2021.

   The Commission summarised the position of Syngenta and explained why in the Commission's view an Article 21 review is fully justified. The Commission informed that it intended to mandate EFSA to further review certain aspects of the assessment and to consider the comments provided by Syngenta.

   The Commission also recalled that in March 2021 it had invited Member States to provide comments within 3 months in line with Article 21(2) i.e. by 24 June 2021. One Member States had submitted comments agreeing with the analysis of the Commission.

   Finally, the Commission informed Member States that once an output from EFSA is available, discussion in this Committee will resume.

3. Calcium hydroxide

   The discussion was postponed.

A.16 General issues for information / discussion:

1. Brexit

   There were no news to discuss.

2. Illegal plant protection product use

   The Commission had uploaded on CIRCA BC two tables summarizing the feedback received from the Member States on the implementation of Article 72 and Article 28(2)(d) of Regulation (EC) No 1107/2009. The analysis of the implementation of Article 72 showed that sanctions vary considerably in the different Member States and do not seem to be always effective and proportionate to the infringement. Member States were invited to send their remarks or requests for corrections until 10 September 2021.

   The Commission informed that the tables with the feedback received from the Member States are intended to be published on DG SANTE's webpage. The Commission also stated that discussions on how to improve the implementation of Article 72 and Article 28(2)(d) of Regulation (EC) No 1107/2009 based on the data collected are intended.

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

   The Commission mentioned a letter from the applicant for the renewal of nitrophenolates in which it complained about the interpretation given by some Member States regarding the scope delineation between the Plant Protection Products and the Fertilising Products Regulations.

   The Commission also reported on research projects presented in a recent workshop dedicated to phosphonates, where results are showing some functionalities

matching the definition of plant biostimulants, in particular the observed promotion of root development early in the crop cycle, at lower application rates than those recommended for the fungicidal function falling under the Plant Protection Products Regulation. The Commission confirmed that such a dual claim is not preventing the authorisation of products containing phosphonates as plant protection products.

a) Scope delineation with biocidal products

See Point A.16.b

b) New cases

Two new cases were presented by the Commission: (1) a product based on arachidonic acid with a clear growth regulating mode of action to be considered as falling in the scope of Regulation (EC) No 1107/2009, (2) a product based on quartz creating a physical barrier against the beetle *Hylobius abietis*, proposed not to be considered as a plant protection product.

Member States were invited to provide comments on the revised version of the scope document (rev. 64) including the last changes (e.g. delineation with the Biocidal Products Regulation and the two new entries referred to above) by 31 August 2021.

4. Basic substances – general issues

The Commission gave an update on the general discussion on basic substances.

Reflections on "do it yourself" plant extracts as the example under point C.2 (*Salix spp* stem extracts) are progressing. In addition, the Commission had initiated a discussion with EFSA on how to improve the outcome of the evaluation of basic substances dossiers so that these outputs are better fit for purpose for the decision-making in this Committee. For instance, one option would be a more qualified and comprehensive assessment in order to avoid multiple applications for extension of use. An updated general mandate to EFSA is under preparation which would implement these improvements.

The Commission also recalled that the updated procedure for approval of basic substances to implement the provisions of the Transparency Regulation (Regulation (EU) No 2019/1381) will include public consultations (for applications submitted after 27 March 2021). During this public consultation period, Member States or any interested party could provide information on additional uses of the basic substance which are beyond the uses initially supported by the applicant. These additional uses will then be included in the assessment.

The Commission encouraged Member States to actively participate in these public consultations and to submit as much additional information as possible regarding in particular data on extensions and additional uses. These could cover more crops but also more target pests, or more recipes for preparation for use, so that the approvals are of a wider scope. The Commission emphasised the importance that Member States and other third parties make use of this opportunity, as it would allow to reduce the number of applications for extensions of approval for basic substances and therefore unnecessary administrative burden for all involved parties.

The Commission referred to the suggestion of one Member State to consider so-called "administrative extension", i.e. automatic extension of approval to uses which are within the same risk envelope. An example could be a grouping of crops

for which the conditions of use and the risk envelope are the same. This idea would however still need some more development and reflection.

The Commission invited Member States to provide comments and information as regards if and how they employ administrative extensions for the authorisation of plant protection products, and any other comments on basic substances by 10 September 2021.

5. Development of resistance in *Aspergillus fumigatus* to azoles used as medicines from use of azole fungicides

   The Commission explained that the draft mandate to several European Agencies is in the final stages of development and informed that Member States who had previously submitted information on azole resistance had been consulted on this draft.

   The Commission also explained that based on the comments received a second part to the mandate was being considered – a review of the existing evidence on development of resistance in other types of fungal pathogens due to use of fungicides in the environment. This could then lead to further activities in the future, if needed.

6. Use of groundwater monitoring data in EU regulatory pesticide risk assessment

   The Commission informed Member States that further reflection was ongoing in view of finalising a mandate to EFSA after the summer break.

7. MS updated survey on timing of regulatory procedures

   The Commission thanked all Member States having provided answers to the last survey on compliance with the deadlines for authorisation procedures in Regulation (EC) No 1107/2009. The survey in 2019 (covering the years 2017_2018_2019) is nearly complete as only the response from one Member State is still missing. For the survey in 2021 only 4 Member States have not yet sent back the questionnaire. The Commission asked these Member States to send the questionnaires within the next few days.

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

There were no news to discuss.

A.18 News from Health and Food Audits and Analysis (SANTE, Directorate F).

There were no news to discuss.

A.19 Implementation Art. 67 Regulation (EC) No 1107/2009.

The Commission gave a presentation about the planned Implementing Regulation harmonising the records of the use of plant protection products that must be kept by professional users under Art. 67(1) of Regulation (EC) No 1107/2009. The Commission stressed the distinction between the purposes of the planned act vs the subsequent collection, processing and transmission of the relevant data that would occur under other EU legislation. The Commission specified that the planned Implementing Regulation would harmonise the details of the records, i.e. specify exactly how the elements listed in Art. 67(1) must be recorded, and establish that the records must be kept in an electronic format.

Two Member States gave presentations about their electronic systems for record-keeping and subsequent data collection on PPP use.

The Commission addressed some key points raised in the written comments sent by Member States after the last meeting of this Committee. In particular, the Commission noted that many of the comments received were based on the understanding that the Implementing Regulation would create an obligation for routine collection of data that are then to be transmitted to the Commission, or that it would be focused on the data collection step. The Commission stressed that these aspects are not related to the content of the Implementing Regulation under discussion.

The Commission reiterated the invitation for Member States to provide specific comments on the content of the draft Annex that had been made available at the last meeting of this Committee, following discussions with colleagues responsible for the Regulation on Statistics on Agricultural Input and Output (SAIO), the Directive on the Sustainable Use of Pesticides, and the Common Agricultural Policy. Member States were invited to liaise at national level with all relevant services, including with experts of the SUD Working Group, who had been informed on the planned act. The Commission also asked the Member States to indicate whether they are interested in the development of an EU-IT-tool for record-keeping which could also facilitate the subsequent collection of the records for the purposes of the SAIO Regulation.

In response to questions raised by the Member States, the Commission informed that the intention is to present a first draft of the Implementing Regulation in the meeting of this Committee in October 2021 and clarified that the planned Regulation would not extend the scope of the existing Art. 67(1) record-keeping requirements, but only specify how the elements already listed in this Article are to be recorded.

A.20 Report from Working Groups, in particular:

1. Working Group on Biopesticides

   There were no news to discuss.

2. Working Group on Seed Treatments

   The Commission presented a new draft of the Guidance Document (see point A.07.4) dealing with risk management issues, and informed that it is still waiting for the submission of a revised draft of the guidance on risk assessment issues from the drafting Member State.

3. Working Group Post Approval Issues

   The Commission informed about the outcome of discussions in the last meeting of the Post Approval Issues Working Group of this Committee held on 16 and 17 June 2021.

   The main points treated during the meeting concerned, data protection for data matching dossiers, handling of clethodim and trifloxystrobin based plant protection product authorisations, harmonisation on how to handle data gaps in EFSA conclusions at authorisation level, composition changes of formulations when unacceptable co-formulants are included in the formulation of an authorised PPP or potential creation of a notification system to spread information on new active substance data to be evaluated, among others.

A.21 Minor Uses.

There were no news to discuss.

A.22 Court cases.

There were no news to discuss.

A.23 Ombudsman cases.

There were no news to discuss.

A.24 Exchange of information from the Pesticide Residues section of the Committee, in particular:

– possible impact on authorisations

– residue definition for risk assessment

There Commission informed that the following draft Regulations on MRLs for the following active substances with a possible impact on authorisations, which had been voted at the last meeting (June 2021) of the section Pesticides Residues of this Committee.

Substance	Type of change (see above)	Agenda item
Amisulbrom	MRLs were lowered.	B 06
Flubendiamide	MRLs were lowered.	B 06
Meptyldinocap	MRLs were lowered.	B 06
Metaflumizone	MRLs were lowered.	B 06
Propineb	MRLs were lowered and the residue definition was amended.	B 06
6-benzyladenine	MRLs were lowered.	B 07
Aminopyralid	MRLs were lowered and the residue definition was amended.	B 07
Flupyradifurone	MRLs were lowered.	B 08
Imidacloprid	MRLs were lowered and the residue definition was amended.	B 09

The Commission also informed that the additional comments on a draft document setting out the way of agreeing and updating Residue Definitions for Risk Assessment (RD-RA) provided by Member States after the last meeting of this Committee had been considered and that a revised document had been uploaded to CIRCABC. Member States were invited to provide comments by 31 August 2021, in view of further discussion in in the Residues Section of this Committee in September 2021 and endorsement in this Committee in October 2021.

The Commission underlined that the document is not a Guidance Document, but rather an agreement of a common understanding between Member States to ensure consistency and harmonisation – it can be reviewed and amended based on real cases and experience gained.

A.25 OECD and EPPO activities.

The Commission reported about the week of meetings organised by the OECD (Seminar on efficacy of biopesticides, the Expert Group on Biopesticides, the Working Party on Pesticides) to which several Member States took also part. Member States were invited to provide comments on the Pesticides working programme discussed at the Working Party by 31 August 2021 directly to the OECD Secretariat with copy to the Commission.

One Member State informed about the organisation of a workshop dedicated to illegal pesticides (one agenda point discussed at the OECD Working Party) in autumn 2021 if the pandemic allows it. Member States' enforcement services were kindly invited to participate.

A.26 Scientific publications and information submitted by stakeholders.

The Commission informed it had made available via CIRCABC letters and information submitted by Ecologistas en Accion, PAN Europe, and CropLife Europe.

A.27 Date of next meeting(s).

The Commission informed that the next meeting of this Committee is planned for 21 and 22 October 2021 (to be confirmed).

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance famoxadone, 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/12986/2019 Rev. 2).

The Commission presented the draft Regulation. The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulations (EU) No 540/2011 and (EU) No 563/2014 as regards the CAS number of the basic substance chitosan hydrochloride (Draft Review Report SANCO/12388/2013 – Rev. 4).

The Commission presented the draft Regulation. The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of dimethyl sulphide as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft review report SANTE/10366/2021)

The Commission presented the draft Regulation. The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance calcium carbonate as a low risk active substance 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/10430/2021 Rev. 1).

The Commission presented the draft Regulation. The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance potassium hydrogen carbonate as a low risk active substance 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/10648/2021 Rev. 0).

The Commission presented the draft Regulation. Three Member States asked if the impurity arsenic would be at limit of quantification or limit of detection. The Commission clarified that the limit of detection (LoD) is set at a maximum allowed of 0.75 mg/kg for Arsenic as impurity.

The Committee agreed to vote by written procedure on the modified draft Regulation in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance phosmet, 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/12604/2020 Rev. 3).

The Commission reiterated that, together with the RMS and EFSA, it looked further into one aspect raised by the applicant i.e. the high risk to mammals, in particular the use of the population modelling. As a consequence, EFSA is revising its Conclusion that is expected to be published in July 2021. Therefore, the vote has been postponed to October 2021. Nevertheless, regardless of the outcome of this point, a revision of the

EFSA Conclusion would not alter the overall proposal for non-renewal of the approval of phosmet due to the high risks identified for human health as well as for other non-target organisms.

The Commission shared the comments received from the Member States since the last meeting, the draft implementing act and the revised draft renewal report as well as the correspondence received on behalf of the applicant.

The Commission informed the Committee that the MRL review of this active substance is expected to start this September, and that EFSA and the Commission intend to prioritise the assessment given the consumer concerns identified in the EFSA Conclusion.

One Member State asked the Commission to record in the minutes that they would prefer a shorter grace period of 6 months due to the concerns identified for the substance.

Member States were invited to send their positions and comments by 31 August 2021.

Vote postponed.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus amyloliquefaciens* AH2 as a low risk active substance 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/11938/2020 Rev. 2).

The Commission presented the draft Regulation. Two Member State indicated that they supported renewal but not as a low risk active substance.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Italy made the following protocol declaration:

It is noted that the dossier on this active substance presented different gaps and from both the RAR the EFSA opinion, partly contradictory results emerged in relation to the environmental fate of this substance. Furthermore, a data gap is highlighted with regards to the toxicity of secondary metabolites towards different groups of non-target organisms. Finally, with reference to gene transfer only literature data have been submitted from which it emerges that, although it is a rare event, the gene transfer involving these species may verify in nature. Considering the nature and the characteristic of the substance, Italy is of the opinion that an approval could be proposed but the available data do not completely allow to let this substance being considered as a low risk substance. For these reasons, Italy abstains.

Outcome of the vote via written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron.

The Commission presented the draft Regulation extending the approvals for a number of active substances, which is required by Article 17 of Regulation (EC) No 1107/2009 as the evaluation procedures for the substances were all delayed for reasons beyond the control of the applicant.

One Member State disagreed with the extension of the approval periods in batches and in this case, would not agree to the extension of active substances of concern, in particular substances that meet a cut-off criterion. Another Member State indicated it could not support an extension of the approval of 8-hydroxyquinoline. A third Member State expressed its support for the need for the extensions. However, it would only support the Commission's proposal if it did not include extension of the approval periods for cypermethrin and indoxacarb. In addition, it emphasised the importance of submitting proposals for the renewal or non-renewal of the active substances as soon as possible.

Two Member States expressed their intention to vote in favour because the draft Regulation covered a package of substances, but found the extension of the approvals of clofentezine and 8-hydroxyquinoline controversial. During the meeting, the rapporteur Member State for the renewal of 8-hydroxyquinoline confirmed that it had already finalised the preliminary renewal assessment and that a request for formal evaluation under Article 4 (7) had not been submitted by the applicant. Instead, an assessment of negligible exposure (dietary and not dietary) for humans had been submitted and had been considered for the assessment in the draft renewal assessment report.

The Commission reminded that many active substances on the list are currently under assessment for their endocrine disrupting properties according to the scientific criteria that became applicable in November 2018, and that cypermethrin and indoxacarb had already been discussed in this Committee and the respective draft Regulations will be submitted to a vote in the near future.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

<u>The Netherlands made the following protocol declaration</u>:

The Netherlands does not agree with the extension of the approval period of difenoconazole because of the risks regarding fungal resistance. Nevertheless, because we are faced with a package of substances, we vote in favour of the entire package.

Outcome of the vote via written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances acrinathrin and prochloraz.

The Commission recalled that for the active substances acrinathrin and prochloraz, supplementary dossiers for the renewal had not been submitted by the deadline established. Therefore, it was appropriate to retract the extensions granted to the respective original expiry dates.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and (EU) No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015).

The Commission informed of the further feedback received from eight Member States. When combining this feedback with the outcome of the discussion at the last meeting of this Committee there were 11 Member States supporting the Commission proposal to restrict approval to permanent greenhouses, nine Member States not supporting the Commission proposal and 7 Member States not having a final position yet.

The Commission also made the meeting aware of a letter from a Dutch grower association supporting outdoor uses.

The Commission indicated it will further reflect regarding the next steps. Member States who did not have a position yet during the meeting were invited to send their position by 10 September 2021.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Salix spp* stem extract (willow stem infusion) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/12638/2020 – Rev. 5)

The Commission informed that since the last time the dossier had been discussed, three Member States had indicated support for non-approval of *Salix spp* stem extract as a basic substance.

The Commission referred to the concern raised by one Member State regarding the use of *Salix spp* stem extract as a biostimulant. In accordance with the provisions of the Regulation (EU) No 2019/1009 on Fertilising Products, if the substance has only biostimulant claims and functions, it falls entirely in the scope of the Fertilising Products Regulation. Biostimulant is defined in this Regulation and is related with plant nutrition processes, without being a plant nutrient itself, and with the secondary effects to increase the plant tolerance to non-biotic stress and improve its quality. However, for *Salix spp* stem extract the applicant has claimed a growth-regulating mode of action,

with the effect of root extension and growth. Therefore it should be considered as 'in the scope' of Regulation (EC) No 1107/2009.

The Commission informed of the need for a discussion on a general approach to "home-made" and "do-it-yourself" plant extracts which are not available on the market. *Salix spp* stem extract is supposed to be prepared on the basis of plants which should be freshly harvested by the user and is not based on a product available on the market.

Member States were invited to comment by 10 September 2021.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation approving the active substance *Beauveria bassiana* strain 203 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/10296/2021)

This point was postponed as there were no news to discuss.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance flumioxazin, 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 SANCO/12512/2014 Rev. 3).

The Commission informed of the comments received from four Member States since the last meeting of this Committee and explained the changes made to the wording in the draft Regulation and draft Renewal Report. Also the comments of the applicant on the draft Renewal Report had been made available. The Commission informed that the draft Regulation will now be submitted to the consultation of the Commission services concerned and a vote may be possible at the next meeting of this Committee.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning renewing the approval of the active substance cypermethrin 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 2018-11527 Rev. 7).

The Commission informed the Committee that the interservice consultation was still ongoing and shared the revised draft review report, the latest version of the draft implementing act and one comment from a Member State.

The Commission recalled that so far there was no change in the Member State (MS) positions: 22 MS support the renewal as candidate for substitution with restrictions and conditions regarding a risk mitigation target, 4 MS support non-renewal and 1 MS abstains. The TBT process is expected to be launched by the end of July. Member States are invited to submit positions and comments by 20 July 2021.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of the new active substance *Purpureocillium lilacinum* strain PL11 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/10418/1 Rev.1)

The Commission informed that after the previous meeting of this Committee, comments from two Member States had been received. The Commission proposed an approval of this new active substance as a low risk active substance. Member States were invited to comment by 31 August 2021.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Purpureocillium lilacinum* strain 251 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/12462/2020 Rev.1)

The Commission informed that after the previous meeting of this Committee, comments from two Member States had been received. The Commission proposed a renewal of the approval of this active substance. Member States were invited to comment by 31 August 2021.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2015/2085 as regards the conditions of approval of the active substance mandestrobin (Draft Review Report SANTE/11647/2015 Rev. 3).

Pro memoria – TBT notification (to be) launched

The Commission recalled that this Committee had endorsed the updated Review Report in its meeting in March 2021. Since after the assessment of the confirmatory information, the minimum impurity level is increased and no further relevant impurities or their levels need a change due to the absence of any toxicological or ecotoxicological concern, the appropriateness of amending the Implementing Regulation for mandestrobin had been reconsidered and not deemed necessary. This point is thus considered closed and no further action is needed.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 589/2012 as regards the conditions of approval of the active substance fluxapyroxad (Draft Review Report SANCO/10692/2012 Rev. 2).

Pro memoria – TBT notification (to be) launched

The Commission recalled that this Committee had endorsed the updated Review Report in its meeting in March 2021. Since after the assessment of the confirmatory information, the minimum impurity level is increased and no further relevant impurities or their levels need a change due to the absence of any toxicological or ecotoxicological concern, the appropriateness of amending the Implementing Regulation for

fluxapyroxad had been reconsidered and not deemed necessary. This point is thus considered closed and no further action is needed.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2015/1192 as regards the conditions of approval of the active substance terpenoid blend QRD 460 (Draft Review Report SANTE/00134/2015 Rev. 5)

Pro memoria – TBT notification (to be) launched

The Commission recalled that this Committee had endorsed the updated Review Report in its meeting in March 2021. After the assessment of the confirmatory information, the appropriateness of amending the Implementing Regulation for terpenoid blend QRD 460 had been reconsidered and not deemed necessary. This point is thus considered closed and no further action is needed.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2018/185 as regards the conditions of approval of the active substance penflufen (SANTE/10028/2017 Rev. 1).

Pro memoria – TBT notification (to be) launched

C.12 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. 2).

Pro memoria – TBT notification (to be) launched

Miscellaneous

M.01 Dichlorprop-P

The Commission informed that an application for amendment of conditions of approval (point A.02) for dichlorprop-P had been declared admissible by the Rapporteur Member State Ireland, which concerns the addition of the ester variant to the approved acid variant.

M.02 Sodium hypochlorite

The Commission recalled that the pending application for approval as basic substance is for sodium hypochlorite with a concentration of 13%, which is classified as corrosive for the skin, eye damaging and acutely and chronically toxic for aquatic organisms. As some Member States had correctly pointed out, such classification is not compatible with an approval as a basic substance.

The Commission announced that one Member Sate had sent a proposal for alternative conditions of use as a solution to enable the approval of sodium hypochlorite as a basic substance for a use in seed treatment. A preparation of sodium hypochlorite in water with a final concentration of <1% is proposed. At such concentration there is still a sufficient efficacy according to the users and the corresponding classification is H412

“Harmful to aquatic life with long lasting effects”. Considering a further 3 to 5 times rinsing step with 5/10 L of water per kg of seeds, as proposed by EFSA, it would therefore lead to a concentration of <0,25% active chloride solution, which has no classification.

The proposal would be to consider the possibility to approve sodium hypochlorite at a concentration <1% with an additional statement that "Seeds are rinsed at least 3 times with 5 to 10 litres of water / kg seeds or an abundant rinse under water flow with clean water. Seeds are dried".

Member States were invited to comment by 31 August 2021.

M.03 Abamectin and Benfluralin

The Commission informed that, following the request of Member States during the previous meeting of this Committee, a mandate to EFSA to assess whether for abamectin safe uses would be possible that would avoid the restriction to permanent greenhouses as defined in Art. 3(27) is in preparation.

The Commission also informed that as regards benfluralin a mandate to EFSA had already been sent. The Rapporteur Member State will start preparing a revision of the renewal assessment report (RAR) and the list of end-points (LoEP) by the end of 2021. This will allow EFSA to refine the ecotoxicological risk assessment and to evaluate whether a safe use for benfluralin exists. EFSA is asked to deliver the results of this mandate within six months from receiving the updated RAR and LoEP from the Rapporteur Member State.

The Commission informed that once the respective outputs from EFSA are available, discussions in this Committee will resume.

M.04 Methodological developments by Member States

The Commission informed that it was made aware by EFSA about the request of one national agency to potentially mandate EFSA to review a method related to the assessment of impacts on biodiversity developed by this agency. The Commission asked the concerned Member State for further information. This Member State clarified that there had been a misunderstanding.

The Commission reiterated that proactive initiatives of Member States are welcome, however such initiatives should consider the ongoing discussions on prioritisation of Guidance Documents which are taking place among Member States, EFSA and the Commission.

M.05 Technical equivalence evaluation (source of tolclophos-methyl)

The Commission informed about a question from one Member State concerning the technical equivalence of tolclophos-methyl. Following an up-scaling in the production from pilot to industrial (full-scale) production, the relevant impurity methanol for which a limit of < 1 g/kg was set at the renewal of approval of tolclophos-methyl was in a concentration of 3 g/kg. The requesting Member State was invited to share its assessment of the equivalence via an addendum to Volume 4 of the RAR. The reference specification could then be updated in accordance with the new batch data via an adaptation of the legal act and the Review Report.