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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

19 - 20 May 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/8aa708bc-2a69-47d1-81f4-6c112a65d068*

SUMMARY REPORT

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 all outstanding summary reports of previous meetings had been published.

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) Choline Hydrogen Phosphonate (RMS BE, fungicide in grapevine and turf grass), b) *Metharhizium pingshaense* CF62 (RMS NL, insecticide against aphids in strawberries), c) *Metharhizium pingshaense* CF69 (RMS NL, insecticide against trips in strawberries), d) *Metharhizium pingshaense* CF78 (RMS NL, insecticide against spider mites in strawberries), e) *Pythium oligandrum* strain B301 (RMS BE, systemic resistance inducer and elicitor against several diseases).

- Basic substances applications

  f) *Psidium guajava* L. leaf extract

  The Commission informed that the verification of admissibility is ongoing. The proposed use of *Psidium guajava* L. leaf extract is as fungicide on all crops. It can be used for spray applications, for seed treatment or as a liquid for disinfection of agricultural mechanical cutting tools.

  g) Sainfoin (*Onobrychis viciifolia* var. Perly) dried pellets

  The Commission informed that the verification of admissibility is ongoing. The proposed use of *Onobrychis viciifolia* var. Perly (Sainfoin) dried pellets is as nematicide on grapevine. It is to be used as soil treatment.

  h) Organic polyphenolic botanical compost

  The Commission informed that the verification of admissibility is ongoing. The substance is a compost of defined composition primarily registered as a fertiliser.

The intended use is in inhibition of growth of *Fusarium*-related diseases in watercress, basil, linseed.

i) *Ocium gratissimum* extract

The Commission informed that the verification of admissibility is ongoing. The proposed use of *Ocium gratissimum* extract is as fungicide, to be used as spray application on vegetable crops.

j) Chabazite

The Commission informed that the verification of admissibility is ongoing. Chabazite is a common name for sodium aluminium silicate - a volcanic rock which is also a food additive. The proposed use is as a physical barrier against fungal pathogens, as a spray in preventive treatment on grapevine, wheat, sugar beets, potato.

k) *Allium fistulosum* extract

The Commission informed that the verification of admissibility is ongoing. The proposed use of *Allium fistulosum* extract is as fungicide and bactericide for vegetable production (tomatoes). It is to be used as soil treatment.

l) *Urtica* spp (extension of use)

The Commission informed that the verification of admissibility is ongoing. The proposed extension of use of *Urtica* spp is as bactericide on cantaloupe. It is to be used as foliar spray.

- Amendment of conditions of approval

m) Maleic Hydrazide

The Commission informed that an application for amendment of conditions of approval of Maleic Hydrazide had been received by the Rapporteur Member State and declared admissible. It focuses on the provision related to exposure to livestock and aims at lifting the corresponding restriction.

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

a) *Bacillus amyloliquefaciens* IT-45

The Commission informed that the EFSA Conclusion is available. 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 after application, the 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 for non-target organisms.

The applicant's comments on the EFSA conclusions had been uploaded on CIRCABC. The applicant disagrees in particular with the potential infectivity and

pathogenicity to birds, soil non-target dwelling arthropods and the relevance of secondary metabolites for terrestrial and aquatic non-target organisms.

Member States were invited to comment by 18 June 2021.

- Renewal of approval

b) *Bacillus thuringiensis ssp. kurstaki* strain PB 54

The Commission summarised the comments received on this micro-organism, and in particular on the horizontal issue concerning dietary exposure for consumers. Due to the current uncertainties linked to foodborne outbreak events, and based on comments received and discussions in previous meetings of this Committee, the Commission indicated that it is exploring the possibility of setting certain risk mitigation measures as a precaution to maintain the concentration of *Bacillus thuringiensis* spores below the threshold of 105 CFU/g suggested by EFSA, while the factor triggering such consideration for risk mitigation measures was not the presence of data gaps, but rather the uncertainties identified for some foodborne outbreaks. However, in applying a precautionary approach, the Commission underlined the need to be proportionate to the actual risks identified, acknowledging that the causality link between *Bacillus thuringiensis* strains and the foodborne outbreaks was still uncertain.

c) *Bacillus thuringiensis ssp. kurstaki* strain EG2348

The Commission summarised the comments received on this micro-organism, and in particular on the horizontal issue concerning dietary exposure for consumers as described in point A.04.b.

d) Potassium hydrogen carbonate

The Commission informed that the EFSA Conclusion is available and applicants had been invited to submit comments. One of the applicants replied, mainly not agreeing with the proposed function (fungicide), compared to the previous authorisation (fungicide, insecticide, growth regulator). Another comment related to the predicted exposure to arsenic as possible impurity. These comments had been uploaded on CIRCABC. Member States were invited to comment by 18 June 2021.

- Basic substances

e) Sunflower oil

The Commission informed that after the previous meeting of this Committee, three Member States had provided comments.

For one Member State, the approval of the extension of use of sunflower oil in plant protection may be issued, but further studies concerning relevant residues would be necessary.

Another Member State suggested to draw conclusions for sunflower oil on the basis of the outcome of the risk assessment of the ongoing assessment on rape seed oil.

The third Member State proposed to wait for the EFSA Conclusion on rape seed oil, in order to proceed with a decision on the extension of approval of sunflower oil.

Member States were invited to comment by 18 June 2021.

f) Caffeine

The Commission informed 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 in all edible and non-edible crops. EFSA had published the Technical Report in January 2021. Five Member States had submitted comments.

One Member State was of the opinion that caffeine could be regarded as a basic substance because it complies with the definition of foodstuff. The four other commenting Member States had reservations as regards approval of caffeine as a basic substance. The main reason is that the information provided in the application is insufficient, in particular as regards the risk assessment to non-target organisms and dietary and non-dietary exposure. Although caffeine is naturally occurring and approved as a food additive, it can still be hazardous and pose a risk. There are indications that caffeine is a substance of concern and non-compliant with the criteria set in Article 23 of Regulation (EC) No 1107/2009. Additionally, it is unclear to what extent medicinal caffeine is available on the market in its pure form.

The Commission summarised that it seems that without additional data it will be difficult to propose an approval of caffeine as a basic substance. Member States were invited to provide views and comments by 18 June 2021 on whether caffeine could be approved as a basic substance.

g) *Urtica* spp (extension of use)

The Commission informed that this application for extension of use of *Urtica* spp concerned the use as a fungicide on common bean, cucurbits, strawberry, all salads, carrots and potatoes, as an insecticide in carrots, all salads, strawberry, ornamentals, asparagus and potato, as well as plant strengthener in asparagus. An in-depth analysis of the EFSA Technical Report is expected to be presented at the next meeting.

- 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 fumigants was taking place in parallel with the substances under points b and c below, and informed about a meeting with the applicant which had taken place on its request where the applicant had suggested possible additional risk mitigation measures. The applicant had submitted a presentation and a document addressing the data gaps identified by EFSA and these documents are available on CIRCABC. The risk mitigation measures suggested concerned the applied quantity (40 g/m2 by band application via dripping irrigation, max 200 g/ha), uses only in protected structures or permanent glasshouses, and a limited application period from May to October.

  Member States were invited to comment by 4 June 2021, in particular on these risk mitigation measures.

b) Chloropicrin

The Commission informed about a meeting which had taken place with the applicant on its request to discuss a potential new genotoxicity study for which a discussion about the testing protocol with the rapporteur Member State is planned and the assessment of endocrine disrupting properties according to the criteria which are applicable since 2018.

c) 1,3-dichloropropene

The Commission informed about a meeting which had taken place with the applicant on its request to take stock of the progress made regarding the submission of a new dossier for harmonised classification and labelling to ECHA to address genotoxicity. The Commission further reported about the applicant's intention regarding the assessment of endocrine disrupting properties according to the criteria which are applicable since 2018 and the risk mitigation measures applied under the emergency authorisations granted by Member States.

The rapporteur Member State asked whether a mandate to EFSA would be necessary to peer-review any additional data like those under discussion. The Commission suggested that is such cases the Rapporteur Member States would have to prepare an addendum to the RAR followed by a peer review to be organised by EFSA. One Member State informed about an ongoing national Court case linked to an illegal use of 1,3-dichloropropene.

d) *Purpureocillium lilacinum* strain PL11

The Commission informed about the latest comments received as regards a possible approval of this active substance. The Commission presented the main aspects of the EFSA Conclusion, as well as the diverging opinion of the second Rapporteur Member State and the applicant.

Member States were invited to comment by 4 June 2021. The Commission indicated that a vote is intended for the next meeting of this Committee.

- Renewal of approval

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

The Commission presented the main characteristics of the micro-organism, its representative uses and the outcomes of the risk assessment. According to the EFSA Conclusion, the outcome is favourable and no critical area of concerns were identified. However, parts of the risk assessment could not be finalised due to data gaps concerning the production of secondary metabolites. The Commission explained that, in its view, these do not preclude the renewal of approval since the likelihood of production of these metabolites is very low because of the mode of action of the microorganism and because it is already naturally occurring in the environment. So far, the applicants and one Member State had provided comments on the EFSA Conclusion.

Member States were invited to comment by 4 June 2021.

f) Captan

The Commission reminded that the current proposal is for a restricted renewal (protected structures). The Commission informed about the prospect to explore with EFSA the possibility to assess whether the use on cherry at the lowest application

rate (not yet assessed), including risk mitigation measures, would lead to acceptable ecotoxicological risks. Member States were invited to comment on this possible approach by 4 June 2021.

g) *Purpureocillium lilacinum* strain 251

The Commission reiterated the main characteristics of the micro-organism and the main results of the EFSA Conclusion, followed by a summary of the new comments received from Member States. Member States were invited to comment by 4 June 2021. The Commission indicated that a vote may be possible in the next meeting of this Committee in July.

h) *Bacillus amyloliquefaciens* strain QST 713

The Commission summarised the comments received from three Member States on the EFSA Conclusion. One Member State supported the renewal as a low-risk substance, another Member State recommended to perform a new earthworm study in accordance with the Canadian Test Guideline "Environment and Climate Change Canada GD EPS 1/RM/44 (2016),13.3.2 Earthworms" or OECD Test Guideline No. 222 "Earthworm Reproduction Test".

Additional comments had been received from four Member States. For the bumble bee test, two Member States suggested to request data as confirmatory information and specify this issue in the Review Report.

Member States invited to comment by 4 June 2021.

i) *Bacillus amyloliquefaciens* AH2

The Commission clarified that this micro-organism is a new active substance and not a renewal. In November 2020 the applicant had provided comments on the draft Review Report and the active substance had been discussed since December 2020. Slightly revised versions of the draft Review Report and the draft Regulation had been made available to Member States and the consultation of the Commission services concerned had been launched, with the intention to vote at the next meeting of this Committee.

One Member State agreed with the Commission proposal for approval of *Bacillus amyloliquefaciens* AH2 as a low-risk substance.

Member States were invited to comment by 4 June 2021.

j) *Pseudomonas chlororaphis* strain MA342

The Commission reminded that the discussion on the renewal of approval of Pseudomonas chlororaphis MA342 had re-started following the adoption of an EFSA statement in 2020 which confirmed concerns identified in the original EFSA Conclusion.

Two Member States had submitted comments. One Member State indicated that the newly submitted studies for strain MA342 did not show a relation to the species Pseudomonas chlororaphis. Thus, the argumentation in the dossier which refers to „read across" and „bridging" has to be put into question. Furthermore, there is insufficient data available in the dossier as regards the risk to bees, however, for seed treatment uses this risk can be considered manageable. This Member State supported non-renewal of approval.

The second commenting Member State agreed with the proposal for non-renewal of approval of Pseudomonas chlororaphis MA342 due to concerns identified in the consumer risk assessment and the risk assessment for workers and residents.

The Commission had received letters from the applicant containing additional information on several aspects of the risk assessment. The applicant believes that the dossier provides sufficient information to conclude on safe uses of Pseudomonas chlororaphis strain MA342. One of the main points raised is about the study demonstrating the rapid degradation of the genotoxic metabolite DDR and the resulting possibility of a refinement of the consumer risk assessment. Although the updated RAR (in 2018) had taken into account the results of this study, it had not been considered in the preparation of the EFSA Statement of 2020.

The applicant also put into question the choice of default values for genotoxicity endpoints by EFSA and disagreed with the statement of EFSA as regards the identified potential for translocation of Pseudomonas chlororaphis MA342 to edible parts of plants following seed treatment, proposing calculations showing that even in the case of translocation, the concentration of DDR in edible parts of plants would be of no concern.

The applicant submitted also a statement concerning antimicrobial resistance of Pseudomonas chlororaphis MA342, according to the procedure described in the relevant guidance document (2020), and concluded that there is no concern and the strain may be approved. The applicant also evoked letters from many stakeholders supporting the renewal of approval, and a history of use of the substance which did not raise any immediate concerns. All the documents had been made available to the Member States.

Member States were invited to comment on the documents provided by the applicant by 18 June 2021.

k) *Bacillus thuringiensis subsp. kurstaki* strain SA-11

The Commission summarised the comments specifically received on this substance, and in particular on the horizontal issue concerning dietary exposure as described in point A.04.b.

The Commission informed Member States that the first draft of the Review Report on this active substance had been made available for comments, but a detailed discussion on this draft is postponed to the next meeting to allow for consideration of other comments (including those of the applicant).

l) *Bacillus thuringiensis subsp. kurstaki* strain SA-12

The Commission summarised the comments specifically received on this substance, and in particular on the horizontal issue concerning dietary exposure as described in point A.04.b.

The Commission informed Member States that the first draft of the Review Report on this substance is made available for comments, but a detailed discussion on this draft is postponed to the next meeting, when other comments may be available (including those of the applicant).

m) *Bacillus thuringiensis subsp. Israelensis* (serotype H-14) strain AM65-52

The Commission informed about similar concerns as regards the dietary exposure as described in point A.04.b.

n) *Bacillus thuringiensis subsp. aizawai* strain ABTS-1857

The Commission informed about similar concerns as regards the dietary exposure as described in point A.04.b.

o) *Bacillus thuringiensis subsp. aizawai* strain GC-91

The Commission informed about similar concerns as regards the dietary exposure as described in point A.04.b.

p) Rimsulfuron

The Commission informed that it had recently sent a mandate to EFSA to review two aspects related to the metabolite IN-E9260.

The rapporteur Member State had agreed to carry out the necessary groundwater modelling calculations (including for bi and triannual use). A further consideration of the genotoxic potential of the metabolite and the possibility to set reference values would also be undertaken.

Member States were informed that depending on the outcome of this mandate a further mandate to finalise the assessment as regards endocrine disrupting properties may be needed.

- Basic substances

q) *Equisetum arvense* (extension of use)

The Commission informed that after the last meeting one Member State had commented that it would agree with a request for supplementary information from the applicant regarding a clarification of the identity of Equisetum arvense and that the first approval had to be reviewed.

In the meantime EFSA had provided a response on the new information submitted by the applicant. This reply was available on CIRCABC for Member States' consideration. The Commission was still assessing this information in more detail before a proposal can be made.

Member States were invited to comment by 4 June 2021.

r) Chitosan

The Commission recalled that the application concerned the use of chitosan extracted from Aspergillus niger as an elicitor in horticulture, olive trees, grapes, grass and post-harvest fruit treatment. The application had been submitted as an extension of use of the approved basic substance chitosan hydrochloride. However, it appears that it is rather an application for approval of a new basic substance – chitosan – with different CAS number, different source and specification.

The Commission presented a draft Review Report in view of approval of chitosan as a new basic substance. The Appendix to the draft review report included two recipes for the preparation of use of chitosan – one with water only, and a second one with addition of vinegar as a pH regulator. Member States were asked to provide views whether they supported the proposed approach. One Member State mentioned that vinegar should be rather regarded as an adjuvant in this context.

One Member State had submitted comments, providing calculations for exposure of toddlers from the proposed uses on lawns and for post-harvest treatment of fruits, concluding that safe uses could be demonstrated. However, this Member State

indicated also that the current risk envelope for the basic substance chitosan hydrochloride is not well supported by the risk assessment, therefore, all uses for chitosan hydrochloride and chitosan should be re-evaluated.

The applicant had provided new information as regards classification of chitosan and to support the environmental risk assessment. The proposal for an approval of chitosan as a basic substance is based on the authorised uses of chitosan and its derivatives as foodstuff, on the low toxicity confirmed by EFSA, on the natural occurrence of the substance, its biodegradability and the indications that the exposure resulting for the proposed uses as a basic substance will be lower than the background exposure.

Member States were invited to consult the information provided by the applicant and the draft Review Report and provide comments by 18 June 2021, in particular as regards eligibility of chitosan for approval as basic substance, the proposal from one Member State for the review of the current approval, and the proposal for the use of chitosan in combination with vinegar.

s) Sodium hypochlorite

The Commission informed that after the last meeting two Member States had commented. One Member State had opined that sodium hypochlorite does not meet the criteria of Article 23 of Regulation (EC) No 1107/2009 and should therefore not be approved as a basic substance. The second Member State had agreed with a non-approval as the substance is not regarded as a food item. However they were ready to accept an approval limited to seed treatment as proposed by a third Member State.

This third Member State confirmed during the meeting that it was working with the applicant and users on the conditions of use to explore how to overcome the issues identified by EFSA in the technical report. The Commission said that it intended to await the outcome of these discussions as regards a possible solution for seed treatments.

Member States were invited to comment by 4 June 2021.

- Amendment of conditions of approval

  There were no news to discuss.

A.06 Confirmatory Information:

1. Gamma cyhalothrin (amended review report to take note)

   The Commission briefly summarised the amendments in the revised Review Report and the Committee endorsed it.

2. Flupyradifurone

   The Commission informed that the confirmatory information as regards the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification, had been addressed. However, a disagreement between EFSA and the Rapporteur Member State as regards the relevance of some individual impurities leaves open this part of the confirmatory data. During the commenting period, several Member States backed the conclusion of the Rapporteur Member State.

In the opinion of one Member State, the Review Report should sufficiently clarify the toxicity of the impurities, highlighting the conclusion of the Rapporteur Member State.

An updated toxicological assessment of the technical specification submitted by the main applicant was made available before the meeting.

One Member State reminded during the meeting that the active substance is currently undergoing a parallel review by EFSA following a mandate from the Commission under the provisions of Article 69 of Regulation (EC) No 1107/2009. In its view, closing the confirmatory data procedure would imply confirming the approval of the active substance, which would contradict the ongoing Article 69 procedure, which might lead to measures to restrict or prohibit the use and/or sale of that substance or products containing it. Therefore, in its opinion the confirmatory data process should remain open until a conclusion in the context of Article 69 is reached.

Member States were invited to comment on the Review Report by 18 June 2021.

3. Spiroxamine

The Commission recalled that one Member State had requested additional measures needed to reduce the risk to aquatic organisms and that, meanwhile, a renewal dossier had been submitted on 24 March 2021.

The Commission suggested to wait for the outcome of the renewal, asking the Rapporteur Member State to inform this Committee without delay in case the issue related to the confirmatory information would not be solved.

Member States were invited to comment by 4 June 2021, particularly on the Rapporteur Member State's opinion about the possibility of taking into account the use of the Hazard Index method for assessing the mother substance together with the metabolites, as suggested by some Member States during the peer review of the confirmatory information.

4. Dithianon

At the meeting of this Committee in March 2021, the Commission had invited Member States to express their preferred way forward. Several Member States showed their preference to wait to the finalisation of the current review of the MRLs and the submission of the renewal dossier, while a few others would support the Commission to restrict, or even withdraw the approval, as soon as possible.

The Commission informed that it would reflect on the comments received in view of determining the next steps.

5. Pyriofenone

The information presented in the Rapporteur Member State's assessment of the identity of the two impurities covered the confirmatory data requirement and are considered appropriate by EFSA. Further details as requested by Member States and EFSA during the consultation process have been included in a revised addendum to the draft assessment report (Vol.4 United Kingdom, 2016a, 2016b). Vol.4 has also been revised to include evaluations of the relevance of five impurities. The evaluations are based on the submitted data, QSAR analysis and the Guidance Document on the Equivalence of Technical Materials.

Member States were invited to comment on the need of a dedicated peer review to decide on the toxicological relevance of the impurities present in the proposed technical specification by 18 June 2021.

A.07 Guidance Documents:

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

   The Commission informed of a letter sent by Commissioner Kyriakides to the Portuguese Presidency and the chair of the European Parliament's Committee on the Environment, Public Health and Food Safety suggesting to discuss the specific protection goal for honeybees among Ministers at the June AGRIFISH Council, and that meanwhile this discussion was confirmed for the AGRIFISH Council on 28-29 June 2021. The Commission indicated that the letter is publically available on its website (https://ec.europa.eu/food/plant/pesticides/protection-bees_en).

   One Member State underlined its preference for a specific protection goal per regulatory zone and the consideration of the full range of the normal variability of honeybee colony size development as simulated by EFSA.

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

   There were no news to discuss.

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

   The Commission shared the comments received from four Member States on the document 'General remarks with regards the revision of the Communications' which had been presented previously at this Committee, and provided some explanation to the questions and comments raised. The Commission shared an updated version of this document which includes some new points. Member States were invited to comment by 18 June 2021.

4. Draft technical guidance on points 3.6.3. to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the demonstration of negligible exposure to an active substance in a plant protection product under realistic conditions of use

   The Commission explained that it is currently reflecting on how to proceed following the comments received from Member States, including on how to assess the assessment of negligible exposure in the environment.

   The Commission also informed Member States that some further comments had been received since March and were available on CIRCABC.

5. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (follow up discussion)

   There were no news to discuss.

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 still needed to be updated to reflect the changes to residue definitions and/or provisional definitions, as

requested by comments received since February from Member States delegates in the section Pesticides Residue of this Committee.

The Commission intends, in cooperation with Member States in the framework of the Post Approval Issues Working Group of this Committee, to draft a proposal to be included in the Guidance Document to ensure a clear separation of the regulatory procedures.

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 in the previous point A.07.6, this Guidance Document will be amended accordingly.

8. Guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 Rev 11)

   The Commission recalled the discussion in the meeting of this Committee in March about the need to amend the section related to genotoxicity screening in the existing guidance document.

   The Commission also reminded Member States to be vigilant for any ongoing applications, ensuring that sufficient data is provided by applicants to address the three genotoxicity endpoints (noting that the existing version of the guidance provides the minimum requirements). Applicants must provide the necessary data to rule out a genotoxic potential.

   The Commission also informed the Committee that it had announced its intention to revise the genotoxicity screening section in the existing guidance document during the meeting of the Advisory Group on the Food Chain and Animal and Plant Health on 7 May. Subsequently, on Monday 17 May 2021, the Commission had sent the revised version to the three major plant protection products industry associations for comments.

   Member States were invited to comment by 4 June 2021 with a view to endorse the revised guidance document in the meeting of this Committee in July.

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

   The Commission informed about the comments received during the commenting round that took place in 2019 and provided a summary table and an updated version of the guidance document. Some open issues had already been debated in the Post Approval Issues Working Group of this Committee at its meeting in March 2021. The Commission informed that it is considering to include in the Guidance Document, as an Annex, the Template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step (SANTE/2016/11449, 7 December 2016). However, there are practical disadvantages, because applicants may then need to adapt the template of the Guidance Document. Member States were invited to send their views on this guidance by 18 June 2021.

10. 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 this Guidance Document had first been drafted by the United Kingdom and had undergone several commenting rounds. The Commission had opened a final consultation of six weeks, which had finalised on 8 May 2020. A summary table and an updated version of the Guidance Document had been uploaded on CIRCABC.

Member States were invited to comment by 18 June 2021.

A.08 Defining Specific Protection Goals for environmental risk assessment, in particular:

– Terms of Reference (to take note)

The Commission informed that one meeting of the Working Group had taken place since the last meeting of this Committee and that a possible re-orientation of the draft working document on generic pesticide scenarios towards a more flexible methodological approach to make the problem formulation more prominent and the risk assessment more fit for purpose for "ad-hoc" scenarios had been discussed.

The Committee endorsed the Terms of Reference of the Working Group that will be published as soon as the specific website dedicated to the topic will be available.

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

The Commission encouraged Member States to continue reporting about their initiatives regarding risk mitigation measures or new risk reduction technologies.

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

– Article 44(4)

The Commission informed the Committee that two notifications had been received.

– Article 36(3)

The Commission informed the Committee that 13 notifications had been received. Nine notifications concerned rejections of mutual recognition applications, two from Member States belonging to different zones and 3 related to products containing active substances approved as candidates for substitution. Four concerned rejections of authorisations under the zonal system.

– Article 53

The Commission informed Member States about several recent questions from Member States concerning the use of PPPAMS, in particular about the field 'Area permitted to be treated' which is required as part of the notification of emergency authorisations.

In one case a Member State had granted an authorisation for use of a plant protection product on a limited number of hectares. However, due to the weather conditions no use was eventually required since the pest infestation for which this emergency authorisation had been granted did not occur and no phytosanitary measures were required. The Member State asked how to reflect this situation given that the information was relevant in the context of the Harmonised Risk Indicator 2.

Another Member State had raised a more general question about the field and how to reflect actual use (noting that an authorisation does not mean use will take place and that use of the plant protection product for which an emergency authorisation had been granted should be the last resort).

The Commission noted the issue and explained that one possible solution would be to add another field to PPPAMS that would reflect the actual use, which would be completed after the expiry of the authorisation. This would ensure accurate data collection for calculation of HRI2.

Member States were invited to provide comments on the suggestion, or on an alternative solution. Several Member States already welcome the proposal during the meeting.

The Commission further informed that it had updated the mandate to EFSA on the assessment of emergency authorisations for neonicotinoids to be used during the 2020 growing season of sugar beet. This update requested EFSA to also assess the emergency authorisations granted by France and Germany for these substances for the 2021 growing season, in addition to the emergency authorisations already included in the original mandate.

– Article 69

The Commission informed that it had received two comments from two Member States supporting a mandate to be sent to EFSA following the request from France to take measures under Article 69 of Regulation (EC) No 1107/2009 for the active substances flupyradifurone and acetamiprid.

The Commission indicated that the mandate would also cover the notification under Article 56 by the Netherlands, who had provided 3 study reports on flupyradifurone to the EFSA.

– Article 71

The Commission informed that further to the discussions held at the earlier meetings of this Committee on the notification of national measures by France, reflections were ongoing internally on the next steps to take.

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

EFSA informed about upcoming Conclusions and their planning for the next months for expert meetings. EFSA also informed that a new public consultation tool is available for consulting on draft assessment reports and renewal assessment reports, that a webinar with competent authorities of Member States is planned for 22 June 2021, and that Member States are being consulted on the prioritisation of work related to guidance documents. EFSA also informed Member States about an open call for preparatory scientific work for the risk assessment of pesticides.

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

The Commission informed that it had initiated discussions with EFSA on how to make the format of the EFSA Conclusions on active substances which are microorganisms more fit for purpose for the decision-making process, also under consideration of the forthcoming new data requirements for this kind of active substances (see also point A.13 below). Discussions had also been initiated with EFSA on a new general mandate for basic substances, which would address the new procedures as required by Regulation (EU) No 2019/1381 (Transparency Regulation).

Finally, the Commission reminded Member States of the importance to close all points during the peer review of the risk assessment, in order to avoid ad-hoc mandates to

EFSA, which are triggered by the discussions at this Committee on issues which were not fully finalised during the peer review.

A.13 Microorganism Active Substances, in particular:

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

The Commission summarised the comments received from Member States on the draft documents made available at the last meeting of this Committee, and presented revised versions in which these comments had been considered. The Commission also mentioned that the work was progressing according to the planned schedule, and that as the next step the other Commission services concerned will be consulted, followed by a public consultation via the feedback mechanism which will give stakeholders the possibility to provide comments.

A.14 Safeners and Synergists.

The Commission informed about the intention to present at the next meeting of this Committee a position paper containing the main points for discussion.

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

1. Copper compounds

The Commission informed that the EFSA statement on Environmental Risk Assessment for transition metals and the technical stakeholder report had been published at the end of March. EFSA presented the main elements of the statement in view of future risk assessment of iron- or copper-based plant protection products, taking into account their non-degradability and the specific conditions affecting their fate and behaviour as well as their toxicity.

2. Tebufenozide (Art. 21 procedure)

The Commission informed that the applicant had sent on 11 May 2021 new studies about the presence in the bone marrow of the metabolite whose genotoxicity could not be excluded by EFSA during the confirmatory information assessment. The Commission invited the Member States to indicate by 4 June 2021 whether they consider it acceptable to amend the review report based on this information or whether a mandate to EFSA would be needed to review the submitted information.

3. Calcium hydroxide

This point 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 informed that it had still not received the information required under Article 72 from Bulgaria, Croatia, Cyprus, Latvia, Hungary and Romania. Neither had

the Commission received information about controls related to compliance with requirements under Article 28(2)(d) from Belgium, Bulgaria, Denmark, Estonia, Croatia, Cyprus, Latvia, Hungary and Romania.

The Commission requested these Member States once again to provide the necessary information before the next meeting of this Committee in July 2021.

3. Nitrophenolates salts (Na/K) - new active substance vs. technical concentrate

The Commission informed about new information received from another company than the applicant for the renewal of the nitrophenolates compounds, claiming that products based on nitrophenols (not nitrophenolates) are equivalent to nitrophenolates and are as well not falling under the scope of Regulation (EC) No 1107/2009 but are rather fulfilling the claims associated with the new definition of plant biostimulants under the Regulation (EU) No 2019/1009 on Fertilising Products. The Commission invited the rapporteur Member State to integrate these data in its ongoing review of the application for renewal of approval.

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

   a) Scope delineation with biocidal products

   The Commission informed about reactions received from two Member States supporting the rationale presented at the previous meeting of this Committee that delineates the claims falling under the biocidal and plant protection products regulatory frameworks, respectively.

   The Commission invited the Member States to comment on a revised version by 18 June 2021, and indicated that this rationale will be incorporated in the Scope Document.

   b) Scope Document rev. 62

   The Commission informed about the publication of the Scope Document on the Europa Website (https://ec.europa.eu/food/system/files/2021-05/pesticides_ppp_app-proc_guide_scope_reg-1107-2019.pdf) and about the intention to regularly update it in function of the decisions taken regarding new cases.

   The Commission also encouraged the Member States to refer to the latest version of the scope document when they are questioned about new situations/cases.

   c) New cases

   The Commission presented three new cases for which Member States were invited to send comments about the proposed conclusions by 18 June 2021.

5. Basic substances – general issues

There were no news to discuss.

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

The Commission informed that a draft joint mandate to four European agencies is well advanced and that internal consultations are ongoing within the Commission before the mandate will be sent to the agencies.

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

The Commission informed that it was working with EFSA to develop the mandate to address the request from the Pesticides Steering Network on this topic.

8. Trifluoroacetic acid (TFA)

The Commission updated on the comments received since the meeting of this Committee in March. One Member State had indicated that it was working to set a health-based limit value for TFA in drinking water by the end of 2021.

The Commission explained that the final results of the studies being carried out under the REACH process will be considered (when available) before determining the next steps in the context of the assessment of active substances and/or plant protection products.

9. MS updated survey on timing of regulatory procedures

The Commission informed Member States that it intended to update the information on their compliance with deadlines for completing the evaluations for the authorisation of plant protection products, following on from the surveys which had been done in 2017 and 2019 in the context of the REFIT evaluation of the pesticides legislation.

Member States were invited to answer to the latest survey by 30 May 2021, but may extend the deadline to 18 June 2021 in case they needed more time.

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

The Commission reminded about the invitation to participate to the 2nd remote SUD stakeholder event on 25 June 2021.

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 presented a draft harmonised format of the records to be kept by professional users under Article 67(1) of Regulation (EC) No 1107/2009 of their use of plant protection products. The intention is that this format would constitute the Annex of an Implementing Regulation under Article 67(4) of Regulation (EC) No 1107/2009. The objective of the planned Implementing Regulation is to increase comparability of data on plant protection product use under the proposed Regulation on statistics on agricultural input and output (SAIO) and, by requiring record keeping in electronic format, facilitate collection of the data by Member States.

Nine Member States asked for clarifications or provided comments, which covered the following points:

- The timing with respect to the SAIO Regulation, with a Member State in favour of waiting until the SAIO Regulation is finalised before harmonising the format of PPP use records.
- Whether a transitional period would be foreseen.
- Scope of the planned Implementing Regulation: whether it would focus on use records only and whether it would cover all professional users (also non-farmers).
- Whether the records would concern daily record-keeping or annual records.

- The reasons justifying the requirement of recording geo-location and the fact that recording geo-location could be challenging for professional users
- The development of a harmonised EU tool for the collection of PPP use records, which was favoured by three Member States.
- Issues linked to the introduction of mandatory electronic record-keeping, in particular the potential additional costs for farmers, the potential financial support to help farmers face such costs, the fact that some farmers are already recording data digitally using private tools, and the risk of creating additional burden for those users.
- The question of coherence with the cross-compliance system under the Common Agricultural Policy (in particular the Statutory Management Requirement 10), and the risk of creating increased burden for professional users already keeping records for cross-compliance purposes if coherence is not ensured.
- The high number of such professional users and the differences among Member States concerning the notion of "professional user" as defined in Directive 2009/128/EC.
- The issue of compulsory transmission of data.

In response to the points raised, the Commission

- Confirmed that a transition period would be foreseen before the harmonised format and electronic record keeping would become applicable and invited Member States to provide feedback on how long such a transition period should be.
- Clarified that the Implementing Regulation will concern the recording of the actual use as foreseen under Art. 67(1) of Regulation 1107/2009 and will cover all professional users.
- Stressed that feedback from the Member States is that electronic record keeping/reporting is necessary to reduce the burden under SAIO. Therefore the Commission considers that mandatory electronic record keeping will help Member States to meet SAIO obligations while reducing the administrative burden on them.
- Explained that, based on feedback to date, its understanding was that the majority of Member States do not favour a single mandatory EU-wide electronic tool to record PPP use. However, if this is not the case, the Commission would take this into consideration considering the currently available limited financial resources to assist professional users in switching to electronic record keeping.
- Indicated that it is expected that once the Implementing Regulation is in place, the private suppliers of electronic record-keeping tools will adapt the tools to reflect the new legal requirements.
- Mentioned that coherence with the CAP cross-compliance system is certainly something to be discussed both at EU and national levels between relevant services.
- Mentioned that data on geo-location of PPP use will provide useful data on PPP use adjacent to water courses, housing, playgrounds etc., and in Natura 2000 areas etc.
- Recalled that the proposed SAIO Regulation foresees an obligation to annually collect the use data and highlighted the advantages of the creation at Member State

level of a database system where information is recorded directly by the record-keeper.

Two Member States indicated that they have already in place electronic data collection systems on plant protection product use and offered to present their approaches at the next meeting.

Member States were invited to consult with their colleagues responsible for the Regulation on statistics on agricultural input and output (SAIO) and their colleagues responsible for the implementation of the Common Agricultural Policy, and comment on the draft harmonised format and presentation by 18 June 2021.

A.20 Report from Working Groups, in particular:

1. Working group on Biopesticides

The Commission reported about the ongoing discussion with EFSA regarding the most appropriate way forward regarding the horizontal mandate on particular species and/or topics.

Member States were invited to comment by 18 June 2021 on two presentations provided by stakeholders (Croplife Europe and International Biocontrol Manufacturers Association IBMA) which had been invited (together with People for Ethical Treatment of Animals PETA) to participate at the last meeting of the Working Group.

2. Working group on Seed Treatments

There were no news to report.

3. Working group Post Approval Issues

There were no news to report as no meeting took place since the last meeting of this Committee.

On request of one Member State, the Commission informed that a first meeting with Member States to initiate discussions about a possible update of Annex IV to Regulation (EC) No 1107/2009 on comparative assessment is planned for 27 May 2021.

A.21 Minor Uses:

There were no news to report.

A.22 Court cases:

The Commission informed about the pending case C-189/21. It is a preliminary reference by a Dutch court. The action in the national proceedings concerns a cross-compliance reduction of direct payments under the Common Agricultural Policy due to the use of an unauthorised plant protection product. The relevant Management requirement in Regulation (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy refers only to Article 55, first and second sentences, of Regulation No 1107/2009, which provides that plant protection products must be used properly. The referring court asks whether that Management requirement must be interpreted as covering the situation in which use is made of a plant protection product which is not authorised in the Member State concerned.

A.23 Ombudsman cases.

There were no news to report.

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

– possible impact on authorisations

– residue definition for risk assessment

The Commission thanked Member States for the additional comments received since the last meeting of this Committee and explained that further time is needed to consider these comments and to review the proposal on how to manage changes to residue definitions and/or provisional definitions.

Furthermore, further time is needed to ensure alignment with the Guidance on new active substance data post-approval which is currently under review.

A.25 OECD and EPPO activities.

The Commission informed about various ongoing activities in the OECD:

- Biopesticides conference (2022):
- Seminar on efficacy of biopesticides (June 2021).
- The Expert Group on Biopesticides (June 2021) and the Working Group on Pesticides (July 2021) for which the Commission will organise a coordination meeting on 23 June 2021.
- Drafting of guidance documents:
    - Pesticide residues in honey
    - Nanopesticides: OECD call regarding risk assessment of nanoforms of pesticides
    - Working Party on Exposure Assessment (WPEA): survey concerning children-specific parameters used in exposure assessment (EFSA follow-up)
    - The Expert Group on Drones
    - Expert Group on the Electronic Exchange of Pesticides Data (EGEEPD)

A.26 Scientific publications and information submitted by stakeholders.

The Commission informed that a letter, a published editorial, and a position paper from the stakeholder association CropLife Europe (CLE) had been made available to this Committee via CIRCABC. CLE was advocating for a transition period of 11 years for crop protection products, seed treatments and coatings in the ongoing process for restricting the use of microplastics under the REACH Regulation that would allow sufficient time for the supply chain to formulate new materials and have them approved under the EU regulatory system.

A.27 Date of next meeting(s).

The Commission confirmed the date of the next meeting of this Committee, which will take place virtually on 5 and 6 July 2021.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance clopyralid, 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 rev 1 SANTE/10206/2021).

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 by 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 and an amended Review Report to correct the CAS number in the current approval of chitosan hydrochloride (currently the CAS number indicated in the Regulation does not correspond to the name of the approved active substance). The vote will take place at the next meeting as the consultation of the Commission services concerned was not yet finalised. Member States were invited to submit comments by 4 June 2021.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2015/408 as regards the deletion of propoxycarbazone from the list of active substances to be considered as candidates for substitution.

The Commission explained that propoxycarbone has to be removed from the list of candidates for substitution (CfS) established by Commission Implementing Regulation (EU) 2015/408 as following the renewal of the approval of the substance in 2017 it no longer meets the CfS criteria. The Commission shared the comments from two Member States.

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

Outcome of the vote by written procedure: Favourable opinion.

B.04 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 discussion was postponed because the consultation of the Commission services concerned was not yet finalised.

Vote postponed.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance abamectin 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 rev 0 SANTE/12068/2020 Rev. 0).

The Commission reminded about the current proposal for a renewal restricted to permanent greenhouses (as defined in Art. 3(27) of Regulation (EC) No 1107/2009). The Commission informed about the possibility to mandate EFSA to assess the environmental risks derived for the supported uses considering only the lowest application rate, for which no assessment is available so far in the EFSA Conclusion.

The Member States were invited to comment on this approach by 4 June 2021.

C.02 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 recalled the proposal made to restrict the approval to permanent greenhouses. The Commission informed of new scientific information submitted by the applicant which had been made available via CIRCABC. Furthermore, the Commission informed of comments from five Member States which had not yet been available at the last meeting of this Committee, and which all considered restricted outdoor uses possible.

The Commission had also made available on CIRCABC numerous letters from grower associations from various crops in support of outdoor uses as well as one letter from the European Citizens Initiative ‘Save Bees and Farmers’ asking for a ban of outdoor uses.

The Commission further informed that Commissioner Kyriakides requested, in letters sent to all Member States, to support the Commission proposal to restrict the uses to indoor uses only. Member States were therefore asked for their positions during the meeting: 8 Member States supported the Commission proposal, 9 Member States indicated not supporting the Commission proposal and 10 Member States did not have a final position yet.

The Commission indicated that it will further reflect regarding the next steps. Member States were invited to send further views and in particular positions by 4 June 2021.

C.03 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. 0).

The discussion was postponed. The Commission informed that the comments received from Member States had been shared on CIRCABC.

C.04 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).

The Commission informed about the comments received from two Member States supporting the proposed maximal content for beauvericin and the argumentation provided concerning the potential effects on bees, as well as the restriction to ornamental palm trees and the qualification of the micro-organism as not low-risk.

The Commission also informed that the applicant indicated that the new 5-batches GLP analysis regarding the beauvericin content are in progress.

One further Member State expressed support during the meeting, while another Member State expressed concerns regarding the effects on non-target organisms.

C.05 Exchange of views 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 informed that the deadline for third countries to comment following the notifications to the WTO under the TBT/SPS agreements was extended to 1 June 2021 at the request of the USA. The Commission shared the comments received from the Member States and the revised draft Implementing Regulation, which included a revised maximum grace period of 9 months (rather than 6 months in the previous version) on request of some Member States, as well as the revised draft Renewal Report.

Four Member States requested a further extension of the maximum grace period to 12 months.

The Commission also shared the correspondence with two firms that act on behalf of the applicant. The Commission informed the Committee that together with the Rapporteur Member State and EFSA, it was looking further into one aspect raised by the applicant (high risk to mammals, in particular the use of the population modelling). However, given that the population modelling is only relevant for the risk assessment for wild mammals, the overall outcome of the assessment and the Commission's proposal for non-renewal will not be impacted as there are also risks identified for human health as well as for other non-target organisms.

Member States were invited to submit positions and comments by 4 June 2021.

C.06 Exchange of views 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 implementing Regulation and indicated that a vote is foreseen for the next meeting of this Committee. Member States were invited to submit comments by 4 June 2021.

C.07 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 SANTE/12512/2014 Rev. 3).

The Commission had shared the draft Renewal Report and the draft Implementing Regulation proposing to renew the approval of flumioxazin with the requirement for the applicant to submit data to confirm the assessment of endocrine disrupting properties in line with the criteria which became applicable in 2018. The Commission shared and discussed also the comments received from four Member States: one Member State preferred giving additional time to the applicant for the submission of the requested information before deciding on the renewal while the other three Member States indicated support for the proposal.

The Commission informed of a meeting with the applicant at their request and shared a presentation provided by the applicant at that meeting and of a Draft Motion for a Resolution in the European Parliament objecting to the extension of the approval periods of 44 active substances, in particular that of flumioxazin, which is scheduled for vote without debate in the Parliament's Committee on the Environment, Public Health and Food Safety on 27 May 2021.

Member States were invited to comment on the draft Renewal Report and draft Regulation by 18 June 2021.

C.08 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. 6).

The Commission had shared the revised draft Renewal Report, the draft implementing act, the draft notification to the WTO under the TBT agreement and the comments received from 11 Member States, and informed the Committee that there is no change in the Member States positions. A total of 22 Member States support the renewal as candidate for substitution with restrictions and conditions regarding the risk mitigation target, four Member States support non-renewal while one Member State intends to abstain. The consultation of the Commission services concerned had recently been launched.

Member States were invited to submit positions and comments by 4 June 2021.

C.09 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)

The Commission reported that, following the last meeting of this Committee, a Regulation had been drafted to increase the minimum purity level. The Commission informed that the consultation of the Commission services concerned was not yet finalised and that a possible vote could only be expected in the last quarter of 2021.

C.10 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)

The Commission reported that, following the last meeting of this Committee, a Regulation had been drafted to increase the minimum purity level. The Commission informed that the consultation of the Commission services concerned was not yet finalised and that a possible vote could only be expected in the last quarter of 2021.

C.11 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)

The Commission reported that, following the last meeting of this Committee, a Regulation had been drafted to incorporate the new reference specification as commercially manufactured. The Commission informed that the consultation of the Commission services concerned was not yet finalised and that a possible vote could only be expected in the last quarter of 2021.

C.12 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)

The Commission reported that, following the last meeting of this Committee, a Regulation had been drafted to restrict the conditions of the approval of the active substance, since the confirmatory information required in the approval of penflufen in accordance with Article 6(f) of that Regulation on potatoes had not been provided. Member States were invited to comment by 18 June 2021 in particular on the clarity of the wording proposed.

The Commission informed that the consultation of the Commission services concerned was not yet finalised and that a possible vote could only be expected in the last quarter of 2021.

C.13 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance *Pythium oligrandum* strain M1, 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/10332/2021 Rev. 0).

The point was postponed.

C.14 Exchange of views 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. 0).

The Commission presented the draft Renewal Report and the draft Implementing Regulation, for which the consultation of the Commission services concerned was still ongoing, and indicated its intention to proceed to the vote at the next meeting of this Committee. Member States were invited to comment by 4 June 2021.

C.15 Exchange of views 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 explained that the AIR 4 renewal programme had extended the approval periods for active substances for which the approval expired between 31 July 2019 and 31 December 2021, by two years, in order to distribute the workload for Member States. However, for the active substances specified, no supplementary dossiers had been submitted at the deadlines established. Therefore, there is no longer any support at EU level and the draft Regulation would retract the extensions given earlier.

C.16 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 New compound in the Straight Chain Lepidopteran Pheromones group:

The Commission informed about an ongoing assessment to add a new compound as part of the group of Straight Chain Lepidopteran Pheromones (SCLP). As SCLP are currently under peer-review by EFSA, the Commission is reflecting on the best way forward as it appears that the screening carried out by the rapporteur Member State

seemed to indicate that this new compound fulfils the criteria of the group and was supported by a dossier in conformity with the guidance document on semiochemicals.

M.02 Better Training for Safer Food (BTSF) programme on risk assessment for micro-organisms:

The Commission informed about the start of training under the Better Training for Safer Food (BTSF) programme on risk assessment for micro-organisms, with the first online training planned for the period 28 June to 2 July 2021, and encouraged Member States to nominate participants.

The Commission also informed that on request of Member States a further training on the criteria to identify endocrine disputing properties is planned either for 15 and 16 December 2021 (2 full days), or for 15 to 17 December 2021 (3 half days). More information will be provided once the training is confirmed.