EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)5660158

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
16 - 17 July 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/8e3ac056-604d-4213-8685-2589166edf43*

SUMMARY REPORT

The meeting took place via videoconference due to measures taken to contain the COVID-19 outbreak.

A.01 Summary Report of previous meetings:

The Commission informed that the summary record of the meeting held on 16 June 2020 is published and that of the meeting held on 18-19 May 2020 was expected to be published in the coming days.

A.02 New dossiers:

New active substances

The Committee took note of the following admissible dossiers for the approval of new active substances: *Swinglea glutinosa* ext., *Metarhizium brunneum* Cb15-III (I), *Trichoderma atroviride* 77B, and benzobicyclon.
The note taking for fluoxapirolin and *Bacillus amylolyquefaciens* FZB42 (see under Miscellaneous) was postponed on request of one Member State in each case.
Member States were also informed about the withdrawal of the application for the approval of the new active substance tolpyralate and reminded to use the template provided by the Commission, which is available on CIRCA BC, when they notify new admissible dossiers.

Basic substances applications received

a. Yucca Schidigera

The Commission informed that an application for the approval as basic substance of extracts from *Yucca Schidigera*, containing steroid saponins, was received in May 2020. These extracts have antifungal and antibacterial properties as well as surfactant properties and are currently used as soil conditioner and growth stimulant. The *Yucca* extract is intended to be used in spray applications in fields and greenhouses for antifungal and antibacterial protection, as disinfecting dip for potatoes, and for disinfecting the cut of brassica crops post-harvest. The admissibility of the application is currently being assessed.

Amendment of conditions of approval (no news)

No news to discuss.

Article 21 Reviews (no news)

No news to discuss.

A.03 Renewal of approval and general issues:

No news to discuss.

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

New active substances:

1. *Topramezone*

   The Commission informed that the applicant had withdrawn its application for approval and that an Implementing Regulation concerning non-approval was under preparation and would be submitted to the Committee for a possible vote at the next meeting in October.

2. *Bacillus amyloliquefaciens* AH2

   The Commission summarised the EFSA Conclusion.The peer review did not identify any critical area of concern however a number of issues could not be finalised. The peer review identified some uncertainties on the production of metabolites of potential concern, on fate and ecotoxicology, and on the capacity of Bacillus amyloliquefaciens AH2 to transfer genetic material to other organisms. Member States were invited to comment by 11 September 2020.

Renewal of approval:

3. *Akanthomyces muscarius* Ve6

   The Commission informed that for *A. muscarius* Ve6 (formerly *Lecanicillium muscarium* strain Ve6), an insecticide used on fruiting vegetables of cucurbitaceae, fruiting vegetables, strawberries, floriculture crops and tree nurseries, EFSA had identified several data gaps and issues that could not be finalised.

   EFSA concluded that the production of secondary metabolites cannot be excluded and could not finalise the respective risk assessment. The available information on the persistence, the multiplication and the germination in soil and natural surface water was considered insufficient to demonstrate that the fungus is likely to decline. The assessment could not be finalised for fish, aquatic invertebrates, bees, non-target arthropods and soil microorganisms. Member States were invited to comment by 11 September 2020.

4. *Streptomyces K61*

The Commission informed that the EFSA Conclusions and the comments of the applicant to them are available. The Commission intends to present a draft renewal report at the next meeting of this Committee.

The Commission invited Member States to comment on the EFSA conclusion and the applicant's comments by 11 September 2020.

Basic substances

5. *Whey (extension)*

The Commission informed that whey is already approved as a basic substance for the use as a fungicide on cucumber and zucchini squash crops in greenhouses. The extension of use concerns foliar applications by spraying on grape vine and tomato and includes outdoor uses.

Since the extension of use also includes outdoor applications, it is expected to result in a higher environmental exposure than for the existing approval, which is only approved for indoor uses. The provided information was considered insufficient to conclude any environmental exposure assessment.

As was already identified in the initial application, there is a potential health concern related to the use of whey because of food allergies to milk proteins and intolerance to lactose from people with low lactase activity.

Member States were invited to comment by 11 September 2020.

6. *Equisetum avense (extension)*

The Commission informed that *Equisetum* is already approved as a basic substance for the use as a fungicide on fruit trees, grape vine, cucumber, tomato, strawberry, raspberry, potato, ornamental trees and roses, as spray application and in mulch. The extension of use concerns foliar applications by spraying in wheat, vegetables in field and greenhouses, pome fruit, stone fruit and small fruit and ornamental plants. The application is for a third extension of use with application rates in the same ranges as the already approved uses.

Member States were invited to comment by 11 September 2020.

7. *Willow bark and stem extract*

The Commission recalled that the application concerns the use of willow stem infusion as a plant growth regulator in herbaceous plants, fruit trees and woody ornamental plants for stimulation of root growth by dipping of cuttings.

The EFSA Technical Report, published in May 2020, indicated that it could not be concluded that willow stem infusion does not pose any toxicological concern. The consumer risk assessment and an assessment of the risk to terrestrial vertebrates could not be performed. Regarding the environmental fate and behaviour and all other areas of the ecotoxicological assessment, EFSA expected the exposure to be low and within the natural background exposure.

In the reporting table of the EFSA Technical Report, the commenting Member States had raised an issue of the identity of the substance and its eligibility for approval as a basic substance in relation to: (i) an overlap with the existing

approval of *Salix* spp. cortex as a basic substance, (ii) an overlap with the approved active substance indolyl-butyric acid (IBA), (iii) the lack of information about a predominat use of the substance identified as a "willow stem infusion" for purposes other than plant protection.

The Commission indicated that in case of the approved basic substance *Salix* spp. cortex, the used plant part is dried bark of willow, and the substance is used as a fungicide. In case of the willow stem infusion, it is recommended to use fresh branches because the intended use is as a plant growth regulator. Further, the specifications of the active substance IBA and "willow stem infusion" are different; the situation is similar to an approval of acetic acid as regular active substance and vinegar as a basic substance. As regards the predominant use of the substance outside of plant protection, if the substance is identified as "chopped willow stems" instead of "willow stem infusion", the predominant use would be as biomass. The recipe for preparation of home-made infusion/extract could then be included in the Review Report in the section on preparation for use, in case it would be decided to grant an approval.

Member States were invited to comment by 11 September 2020.

Amendment of conditions of approval

8. Prosulfuron

The Commission recalled that the approval of prosulfuron was renewed in 2016 as a candidate for substitution and with a restriction to *one application every three years on the same field at a maximum dose of 20 g active substance per hectare.*

The restriction was necessary since it had been concluded that more frequent use would lead to leaching of prosulfuron into groundwater (in all FOCUS scenarios).

The applicant had submitted an application to amend the conditions of approval and to remove the restriction. Following an assessment and peer review of the additional information EFSA made available its updated conclusion in June in which it was concluded that annual use is not expected to lead to contamination of groundwater by prosulfuron.

The Commission asked Member States for their views on removing the restriction by 11 September 2020.

A.05 Draft Review/Renewal Reports for discussion:

New active substances:

a. Dimethyl disulphide

The Commission informed that few comments have been received so far. The applicant had informed about stewardship programs and suggested a reduced rate of application of 200 kg/ha, limit the use to greenhouses, apply once every 2 years from May to October to limit the release into the environment during rainy periods, and limit the use only to professional applicators duly trained. The plant protection product would be marketed as a "package" solution with the approved barrier film (DAF) and the training / certification of the professional user.

Two Member States indicated they would support a non-approval due to the scarceness of information in the dossier.

Member States were invited to comment by 11 September 2020.

b. Chloropicrin

The Commission informed that ten Member States had commented on the EFSA conclusions, among them the Rapporteur Member State which analysed thoroughly the conclusions and the applicant's comments. This analysis identified a possible restricted approval, provided some concern could be addressed. Several delegations underlined in their comments the importance of the substance for soil fumigation, especially in the Southern zone of the EU, while others highlighted that the substance is not fulfilling the approval criteria. One Member State was concerned about the potential long range transport which, however, does not seem to be an issue according to the EFSA Conclusion.

The Commission informed that it intends to invite EFSA to comment on the analysis of the Rapporteur Member State. Member States were invited to also comment on this analysis by 11 September 2020.

c. 24-Epibrassinolide

The Commission informed that 24-Epibrassinolide is intended to be used as an elicitor on grapes, leafy vegetables and sugar beet. This substance is a brassinosteroid that is naturally occurring in higher and lower plants and some fungi. The EFSA Conclusion is available and no critical areas of concern or issues that could not be finalised were identified. The Commission considers an approval of 24-Epibrassinolide as a low risk substance possible.

Member States were invited to comment by 21 August 2020.

Renewal of approval

d. Clopyralid

The Commission informed that the outcome of the EFSA Conclusion presents uncertainty with regards to the risk to consumers, due to the presence of an unknown plant metabolite and to the fact that the studies on two crops were not presented transparently. However, after the EFSA conclusion was made available, the Rapporteur Member State reassessed the available data and found safe use scenarios. Since this aspect is important for being able to conclude the regulatory decision making on clopyralid, the Commission proposed to mandate EFSA to refine the consumer dietary risk assessment.

e. Famoxadone

The Commission recalled that the earlier proposal for non-renewal had not received support from the majority of Member States. As a consequence, in February 2020 a revised proposal for renewal of approval as a candidate for substitution with risk mitigation measures had been made available to the Member States for comments in writing. This proposal considered re-calculations made by the former Rapporteur Member State (UK) as well as possible risk mitigation measures and, again, was not supported by the majority of Member States.

The Commission found that the situation remains unclear. Besides, since some of the Members States who replied indicated that some aspects of the evaluation

would need to be revised, a detailed discussion on the issues identified by EFSA (the long-term risk for birds and mammals, the risk for workers, the risk to aquatic organisms and the consumer exposure) is still needed. Therefore, given the complex scientific discussion and the diverging positions of Member States in favour of renewal and the Member States in favour of a non-renewal, the Commission indicated that it is still reflecting on the way forward and that it is considering to mandate EFSA to re-evaluate the main controversial areas of the dossier.

f. Cypermethrin

The Commission informed that during a 'tour de table' at the last meeting of this Committee all Member States had expressed their positions with regard to a potential proposal of renewing the approval of cypermethrin as candidate for substitution with restrictions and conditions in line with Art. 6 (i) of the Regulation (EC) 1107/2009, but that no qualified majority in support had been reached. Member States not supporting such an approach considered that the necessary risk mitigation measures set out in the EFSA Statement (2020) are unrealistic and they would not be in condition to implement them in practice. Therefore, given the high risks identified by the 2018 EFSA Opinion to aquatic organisms, non-target organisms (off-field) and bees, the Commission intends to propose a non-renewal of approval for this active substance. The Commission had made available all the comments from the Member States and a supportive letter received since the last meeting.

Member States were invited to comment by 11 September 2020.

g. Bifenazate

The Commission reiterated the reasons for the proposal for non-renewal: two critical areas of concern (high risk to birds and mammals and to non-target arthropods) for all the representative uses and the non-finalised risk assessment for consumers and aquatic organisms.

The Commission had shared comments from three Member States and the applicant's comment received since the last meeting.

The Commission informed that it considers to mandate EFSA to complete the risk assessment.

Member States were invited to comment by 11 September 2020, in particular those 12 Member States who had not yet indicated their positions.

h. Cyazofamid

The Commission informed that EFSA had extended the deadline for responding to the ad-hoc request for an updated risk assessment for non-target arthropods by one month, i.e. till the end of July.

i. Garlic extract

The Commission presented the draft review report for garlic extract, which as specified in the application is of food grade quality and used widely to flavour and season foods. It is not expected that the use of garlic extract as a plant protection product will pose a risk to consumers compared to its use as a food. With particular

regard to residues, no data gaps or areas of concern were identified and no MRLs are required for this active substance.

In addition, no critical areas of concern were identified during the risk assessment. One point could not be finalised by EFSA (risk to aquatic organisms), however did not lead to a concern in the risk assessment and is not relevant for the representative use based on which the renewal of approval is granted (granular product to be applied below the soil surface to potatoes and parsnips, in the field or glasshouse).

Member States were invited to comment by 11 September 2020.

Basic substances

j. Sucrose (extension of use) (amended review report to be noted)

The Commission informed that for the requested extensions of the approval to use as fungicide and insecticide on grape vine and use as insecticide on maize (grain corn) it can be assumed that they also fulfil the criteria of Article 23 and that they can therefore be approved.

The amended review report was noted.

k. Fructose (extension of use) (amended review report to be noted)

The Commission informed that for the requested extensions of the approval to use as fungicide and insecticide on grape vine and use as insecticide on maize (grain corn) it can be assumed that they also fulfil the criteria of Article 23 and that they can therefore be approved.

The amended review report was noted.

l. Vinegar (extension of use) (amended review report to be noted)

The Commission informed that for this second extension for vinegar to be used as an herbicide on non-agricultural areas, the inhalation risks and eco-toxicological risks that were identified in the previous applications, still stand. The proposed application rate is still much higher than the accepted application rate for medicinal, aromatic and perfume crops.

The Commission summarised the comments received from the Member States, noting in particular those from one Member State who indicated that the applicant proposed to lower the application rate and limit the uses. The Commission mentioned that it will verify with EFSA whether this would resolve the issues identified during the risk assessment.

The note-taking of the review report was postponed. Member States were invited to comment by 11 September 2020.

m. Sodium chloride (extension of use) (amended review report to be noted)

Since the last meeting, six Member State had provided comments indicating support for proceeding with decision making without asking for a full risk assessment on the extension from EFSA, and for a restriction to areas of high salinity such as salt marshes. However, the Commission indicated that further clarifications were still required as regards the use of sodium chloride in

combination with the plastic cover needed in the light of the EU's objective to avoid contamination of the environment by plastics. The final decision on the extension will depend on the outcome of the consultation with the applicant.

The note-taking of the review report was postponed. Member States were invited to comment by 11 September 2020.

n. Comfrey steeping

The Commission recalled that it had proposed not to approve this substance as a basic substance.

Since the last meeting, four Member States had provided comments. Three Member States supported the Commission proposal for non-approval. One Member State had submitted further data gathered from scientific literature that had not been presented in the application and may help to support the approval of the substance. Those data were forwarded to EFSA. A decision as regards a potential re-consideration of the proposal, will depend on the outcome of the evaluation by EFSA.

Member State were invited to send comments by 11 September 2020.

o. Clayed charcoal

The Commission had proposed non-approval of an extension of use of clayed charcoal in the form of wettable powder as a basic substance.

The Commission had made available to Member States the comments received from the applicant for approval of clayed charcoal in response to the draft amended Review Report. Furthermore, the Commission summarised the comments submitted by the Member States as follows: four Member States supported the Commission proposal for non-approval, one Member State additionally indicated that there are several reasons why clayed charcoal does no longer fulfil the criteria as a basic substance based on the Commission information note presented during the meeting in May 2020. One Member State informed that at the moment of the first approval of clayed charcoal as a basic substance the substance had been registered and had primary use as a soil improver. However, currently the clayed charcoal is sold solely for purposes of plant protection. That Member State confirmed that clayed charcoal formulated as wettable powder does not have any other primary use.

Member State were invited to comment by 11 September 2020.

p. Capsicum annuum annuum, longum group, cayenne (extract)

The Commission informed that this extract is to be used as a repellent to seed eating mammals and birds. In the EFSA technical report, many questions were raised regarding the genotoxic properties of the active component of the extract, capsaicin. Many data gaps remain for the fate and behaviour section and on the effects on non-target species.

Member States were invited to comment by 21 August 2020.

Amendment of conditions of approval (no news)

No news to discuss.

A.06 Confirmatory Information:

The Commission gave an update on the assessment of confirmatory information for endocrine disrupting properties.

Member States were reminded that 22 active substances had been approved prior to the applicability of the new criteria (November 2018) with a requirement to provide confirmatory information related to endocrine disrupting properties.

For seven substances, a specific deadline had been set in their approval while for others the deadline was linked to the development of EU guidance (with submission of information being required two years later): bromuconazole, paclobutrazol, spirotetramat, amisulbrom, prochloraz, ipconazole and fluopyram. The Commission had written to the respective applicants for the substances to inform them that the legal submission date would be 10 November 2020.

Applicants must submit confirmatory information on endocrine disrupting properties in line with the new criteria by the legal deadline, following which the Rapporteur Member State should carry out an assessment and provide its conclusion/recommendations to the applicant, the Member States, EFSA and the Commission before the renewal evaluation commences (except for paclobutrazol, for which the renewal assessment will begin by 10 November 2020).

If the Rapporteur Member State considers the substance to be an endocrine disruptor based on the information provided or finds concerns, the Commission will consider whether action is required before the completion of the renewal process.

In addition, the following files were discussed:

1. *Triazole derived metabolites (TDMs)*

   – Bromuconzole (amended review report to be noted)

   Member States took note of the amended review report for bromuconazole and were informed that the review reports for several other triazole active substances would also be amended to include the agreed endpoints for the triazole derived metabolites.

2. *Triazine amine (relevant for metsulfuron-methyl, prosulfuron, thifensulfuron-methyl and iodosulfuron)*

   – Metsulfuron-methyl (amended renewal report to be noted)

   The Commission informed the Committee that several Member States had reacted positively to the suggested way for managing triazine amine, as proposed in the meeting of the Committee in May.

   Member States were reminded that taking note of the updated renewal report for metsulfuron-methyl is only one step ahead of the submission of the renewal dossier which is due in September 2020. An in vitro micronucleus study must be provided in the context of the renewal assessment. The rapporteur Member State for renewal indicated that it would evaluate the study as soon as possible during the assessment.

Member States took note of the amended renewal report.

3. *Isoxaben (amended review report to be noted)*

The Commission had provided the revised review report in the light of the assessment of the confirmatory information. The Committee took note with reservation from one Member State which had voted against the renewal of the substance.

4. *Lamda-cyhalothrin (amended review report to be noted)*

The Commission provided the revised review report in the light of the assessment of the confirmatory information. The Committee took note of this report.

5. *Gamma-cyhalothrin*

The Commission proposed to address the two non-finalised issues of the confirmatory information process separately. The toxicological profile of two metabolites that are common with some other pyrethroid substances would need to be reviewed jointly in a harmonized evaluation of all data available for those metabolites. A mandate would be sent to EFSA with this purpose.

As regards the high risk to wild birds and mammals, the Commission invited Member States to send their comments on the possibility of a GAP scenario restricted to single application and to BBCH 30-40 and inform the Commission on any existing national authorisations that are relevant for this restricted use.

Member States were invited to comment by 11 September 2020.

6. *Terbuthylazine*

The Commission recalled that two options were under discussion following the assessment of confirmatory information and the update of the EFSA Conclusion: withdrawal of the approval or a restriction of use.

The Commission summarised the comments received after the May meeting. Some Member States had general concerns about the substance and prefer withdrawal, while the suggested restriction to limit the frequency of use to once every 3 years was supported by other Member States although some have remaining concerns about the consumer risk assessment for metabolites present in groundwater.

One Member State had indicated that a restriction to use every second year only was already in place.

In order to address the issues identified by some Member States a restriction to use every third year at a maximum rate of application of 850 g/ha was suggested by the Commission to reduce the levels of metabolites predicted to occur in groundwater. Member States were invited to provide their final view on a restriction of approval or a withdrawal of approval by 21 August 2020.

7. *Ipconazole*

The Commission recalled that in addition to including ipconazol in the list of candidates for substitution (see point B.11), several Member States had expressed the view that an Article 21 should be initiated due to open issues concerning the risk to birds and the classification of ipconazole as toxic for reproduction, category

1B. One Member State had provided comments expressing some reservations about an early review due to the timing of the assessment and resources required.

The Commission stated that it planned to launch an Article 21 review in the near future, providing time for the applicant to submit information, in particular on negligible exposure and/or essential use (Article 4.7), so that a decision could be taken ahead of the renewal assessment.

8. Sulfoxaflor

The Commission summarised shortly the outcome of the assessment of the confirmatory data regarding bees. The Commission explained that it was still reflecting on the acceptability of risk mitigation measures for possible outdoor use.

Member States were invited to send any comments on the possibility of restricted outdoor use by 11 September 2020.

9. Isofetamid

The Commission recalled that the confirmatory data requested were:

1. The technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities;

2. The compliance of the toxicity and ecotoxicity batches with the confirmed technical specification;

3. The effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface, when surface water is abstracted for drinking water;

The applicant submitted the data for points 1 and 2. Point 3 remains open because the applicant has to submit the relevant information two years after adoption of a guidance document, which is under development.

The Commission summarised the elements of the EFSA technical report and is considering whether the pilot scale specification can be kept or whether the specifications should be updated.

Member States were invited to provide their views on the update of the specifications or not by 11 September 2020.

10. Pyrethrins

The Commission recalled that the technical report summarising the outcome of the consultation process as regards the specification of the technical material as commercially manufactured, was finalised in April 2015.

With regard to the toxicity by inhalation, Pyrethrins were considered unlikely to be genotoxic based on a standard battery of tests in vitro; however, EFSA could not conclude on the toxicity profile of the metabolites (including their genotoxic potential) nor draw a firm conclusion on the consumer risk assessment. This prevents launching the MRL review.

With regard to the representativeness of the major component ‘pyrethrin 1’ as regards the fate and behaviour in soil and water, according to new information

submitted, Pyrethrin 1 is considered the most toxic single molecule to daphnids from all the tested molecules within the submitted studies.

During the last meeting of this Committee, several options had been discussed and Member States had been requested to indicate their preference. Some Member States prefer limiting the supported representative uses to those for which residues are currently at LOQ (and no metabolites of concern identified), which implies that a limitation to ornamental crops would be possible. Other Member States prefer to address the inconclusive issues during the already on-going renewal procedure for reasons of efficiency (in February 2020 the renewal dossier was declared admissibe by the Rapporteur Member State).

Member States were invited to comment by 11 September, to express their willingness to support the Commission's proposal to ask the Rapporteur Member State to perform, during the renewal procedure, the consumer risk assessment and inform the Commission with no delay if they consider that the Commission should trigger an earlier regulatory action based on Article 21.

11. L-ascorbic acid

This agenda point was a duplicate (see point 19 below).

12. Benzovindiflupyr

The Commission recalled that confirmatory data had been required to confirm the technical specification of the active substance as manufactured (on commercial scale), including the relevance of impurities and compliance of the batches with which the (eco)toxicology studies had been conducted. This compliance had been demonstrated.

With regard to mammalian toxicology, the assessment of the confirmatory data led EFSA to consider that the evidence for clastogenicity is weak.

The Commission suggested to amend the approval conditions and the review report by including a maximum concentration for the new relevant impurity. It will be necessary to launch a WTO-TBT notification for the draft Regulation amending the approval conditions.

Meanwhile, the applicant conducted an in-vitro micronucleus test with a negative result, and the renewal dossier including this study is expected by September 2020.

Member States were invited to comment by 11 September 2020.

13. Dithianon

The Commission informed that the Rapporteur Member State had evaluated the new submitted data and issued an Addendum 2 to the DAR in September 2018 and a more recent update in August 2019. The Commission had mandated EFSA to review the assessment of this new information and to revise its conclusions (dated 2015), with the aim to clarify the data gaps on residues and the acute intake concern. On 22 June 2020, EFSA had sent its pre-notification of the updated conclusion on the peer review. The Rapporteur Member State opinion had been uploaded on CIRCABC.

The Commission indicated that it intends to present a proposal for a way forward at the next meeting.

14. Geraniol, Eugenol, Thymol, Clove oil, Orange oil

The Commission informed that the confirmatory data for these 5 substances will be treated together given the similarity of the substances. For all five substances, the renewal procedure has either started or will soon start.

The case of geraniol was discussed in detail. For this substance the confirmatory data requirement relating to groundwater is fulfilled. With regard to the natural background level, a literature search was submitted by the applicant, but was not considered sufficiently robust nor validated by EFSA. However, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) panel has set a maximum level for use of this substance in animal feed and the same substance is furthermore authorised as a food flavouring. The Commission therefore considered to close the file for geraniol and to ask the future Rapporteur Member State to pay particular attention to the consideration of background levels during the renewal procedure.

The Commission informed its consideration to proceed in a similar way the files for eugenol, thymol, clove oil and orange oil due to the advanced stage with respect to the on-going or upcoming renewals processes.

Member States were invited to comment by 11 September 2020.

15. Acibenzolar-methyl

The Commission informed that the applicant had submitted the requested information by June 2017 and that in the EFSA technical report the evaluation on endocrine disruptive properites and the potential link between developmental neurotoxicity effects (DNT) and T-mediated endocrine effect is considered not finally concluded and further discussions would be needed to conclude.

In addition, in light of the implemenation of the new scientific criteria to identify endocrine disruptors, the Commission had sent a letter to the applicant in December 2018, informing that although the assessment of confirmatory information is on-going, there may be the need of a further examination in light of the new criteria.

The Commission therefore suggests that, following the usual procedures, a mandate will be sent to EFSA in order to organize an additional experts' consultation. In this mandate, it will be requested to establish which additional test are needed to conclude on the ED properties on both human health and the environment, in view of a potential request to the applicant to submit further data.

Member States were invited for their comments by 11 of September 2020.

16. Amilsubron

The applicant was required to submit confirmatory information which they did within the deadline and for which a technical report of EFSA is available.

One point (endocrine disruption) remains open due to procedural issues. In light of the implemenation of the new scientific criteria to identify endocrine disruptors, the Commission had sent a letter to the applicant in December 2018, informing that a full assessment according to the new criteria should be submitted as confirmatory information by November 2020.

The Commission is reflecting on the next steps, in particular under consideration that once the additional data will be submitted for endocrine criteria, a clearer picture for this substance will be possible.

Member States were invited for their comments by 11 of September 2020.

17. Spirotetramat

The Commission recalled that spirotetramat was approved on 20 November 2013 and the applicant was required to submit further studies regarding the potential for endocrine disrupting effects in birds and fish within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of a Community agreed test guidelines.

The applicant submitted information in April 2016 for which an EFSA technical report was made available in December 2016, in which it is stated that the information provided was not sufficient for a consideration of endocrine disrupting activities on fish, while the rapporteur Member State had considered the information sufficient.

However, in light of the implemenation of the new scientific criteria to identify endocrine disruptors, the Commission had sent a letter to the applicant in December 2018, informing that a full assessment according to the new criteria should be submitted as confirmatory information by November 2020. In addition, the dossier for renewal for this active substance should be submitted by end of July 2021, leading to a de-facto overlap of two regulatory processes.

The Commission considered that for the moment, no action is needed. The Commission suggested that once the new confirmatory information will be received by November 2020, the former Rapporteur Member States analyses it and forwards it to the Rapporteur Member State for the new renewal process for consideration and feeding into the renewal process.

Member States were invited to comment by 11 September 2020.

18. Tebufenozide

The Commission summarised that the first approval of tebufenozide (1 June 2011) obliged the applicant to submit further data on the relevance of metabolites RH-6595, RH-2651 and M2 and on the degradation of tebufenozide in anaerobic soils and soils of alkaline pH. The required data were submitted within the prescribed period of two years, evaluated by the Rapporteur Member State, and peer reviewed as reflected in the EFSA Technical Report.

The degradation of tebufenozide in anaerobic soils and soils of alkaline pH was addressed successfully. Concerning metabolite RH-2651, however, a further peer review is proposed in particular because the metabolite is predicted to occur above 0.1 µg/L in all FOCUS scenarios for the representative uses considered and based on the data available a genotoxic potential cannot be excluded, therefore the metabolite cannot be considered non-relevant.

According to the foreseen procedures, the Commission suggested to mandate EFSA for carrying out this peer review, including an expert discussion where appropriate.

19. L-ascorbic acid

The Commission summarised the findings of the EFSA Technical Report on the confirmatory information required for L-ascorbic acid: information on the natural background of L-ascorbic acid in the environment and the risk to contaminate groundwater. The required data were submitted, evaluated by the Rapporteur Member State, and peer reviewed as reflected in the EFSA Technical Report.

The first point has been resolved. For the second, the assessment indicated a potential for the representative uses to result in groundwater exposure to L-ascorbic acid above the parametric drinking water limit of 0.1 µg/L in some of the FOCUS groundwater scenarios, however safe FOCUS scenarios were identified so that the point can be considered closed. A submission of the renewal dossier is expected in the third quarter of 2021, however the Commission suggested to amend the review report to close the confirmatory information process.

No Member States commented on this suggestion.

20. Fluometuron

The Commission recalled that the first approval of tebufenazide (27 April 2011) obliged the applicant to submit further data on the toxicological properties of the plant metabolite trifluoroacetic acid (TFAA), the analytical methods for the monitoring of fluometuron in air, the analytical methods for the monitoring of the soil metabolite trifluoromethylaniline in soil and water and the relevance for groundwater of the soil metabolites desmethyl-fluometuron and trifluoromethylaniline, if fluometuron would be classified under Regulation (EC) No 1272/2008 as "suspected of causing cancer".

The Commission recalled that the last point could not be addressed since that classification is still pending and requested the Rapporteur Member State to provide information on the state of this process.

All the other requests were addressed by the applicant except for the toxicological properties of the plant metabolite (TFAA). The Commission pointed out that this information had been provided within the assessment of another active substance (Flurtamone -EFSA Conclusion 10 August 2017, page 9) which allowed to set the acceptable daily intake for TFAA at 0.05 mg/kg bw per day based on the 90-day rat study (uncertainty factor (UF) 200 for the extrapolation from sub chronic to chronic) and to establish that no acute reference dose is needed based on the available toxicological studies. Therefore, the Commission suggested to update the review report and announced that it intends to present it for note-taking during the next meeting of this Committee.

No Member States commented on this suggestion.

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 about the activities carried out so far in the context of the risk manager consultation held in relation to the review of the bee Guidance Document. On 30 June 2020, the Commission organised a virtual workshop attended by risk managers and risk assessors of 22 Member States. EFSA and

ECHA were present. The objective of the workshop was to discuss and agree on the basis of a document prepared by EFSA which of 4 scientific approaches should be used for developing the risk assessment.

Approach 1 is based on scientific data and considers survival of the colony until next season or longer. Model simulations will be used to establish maximum tolerable effects on the colony on which risk managers will be consulted in a second step.

Approach 2 is based on scientific data and considers the magnitude of the effect on the colony size as acceptable when it remains within a range of the expected natural variability considering some beekeeping practices. In a second step Risk Managers define which percentage of the Normal Operating Range is to be used as an acceptable level of effect on colonies.

Approach 3 is based on expert judgement and beekeeper perception which predefined acceptable levels of effect on colony/population size. It is the approach of the EFSA 2013 Bee Guidance Document where the percentages of acceptable level was set at 7% for honeybees. Such expert judgement approaches can be applied to any kind of organism, however a rationale and justification cannot be given to risk managers or stakeholder.

Approach 4 focusses on the levels of acceptable impact on the provision of the ecosystem service 'pollination' by bees. It links the specific protection goal with the ecosystem services provision. For this approach, science is not yet ready and is therefore not feasible within the timeline of the current mandate.

All scientific approaches developed by EFSA are based on honey bees, because only for honey bees a good amount of data are available (for bumble bees some data are available, while for solitary bees scientific data are very scarce for all four approaches).

The Commission informed about the views of the Member States present at the workshop on 30 June 2020 and invited each Member State to express their views in a tour de table. A total of 14 Member States preferred approach 2, 3 Member States opted for approach 2 for honey bees and approach 3 for solitary bees, 4 Member States preferred approach 3, but considered approaches 3 and 2 quite similar and were therefore open to use the insights of approach 2 to refine approach 3. 2 Member States preferred Option 1 and 4 Member States did not indicate any position during the meeting.

The Commission invited Member States who did not indicate a position to do so by 24 July 2020, and all others to confirm or elaborate further on their positions if they so wish.

On the basis of the preferred approach, EFSA will prepare, over the summer, material for further discussions.

2. **Brief procedural updates:**

a. Draft update of Guidance on emergency authorisations according to Article 53

The Commission informed Member States that the stakeholder consultation ended on 26 June 2020 and that comments had been received from several stakeholders. The comments were being reviewed and where appropriate amendments to the existing draft would be made. The Commission indicated that a final draft would be tabled for possible endorsement in the next meeting of this Committee.

b. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance

The Commission informed that the stakeholder consultation ended on 26 June and triggered reactions from three stakeholders. Their comments were analysed and draft replies prepared by the Commission, leading to some minor changes to the guidance document. Member States were invited to comment on these draft replies and on the amended version of the guidance by 11 September 2020.

c. Draft Guidance document on the risk assessment of metabolites produced by micro-organisms

The Commission informed that the stakeholder consultation ended on 26 June and triggered reactions from two stakeholders. Their comments were analysed and draft replies prepared by the Commission, leading to some minor changes to the guidance document. Member States were invited to comment on these draft replies and on the amended version of the guidance by 11 September 2020.

3. **EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers**

The Commission explained that this guidance had been discussed also in the Residue Section of the Standing Committee on Plants, Animals, Food and Feed. Since the last meeting of this Committee the Commission had received comments from two Member States. One Member State had provided a number of technical comments. Another Member State had highlighted the need for a reflection on the application date for the Guidance: on the one hand, the request for clarification submitted by ECPA should be addressed, on the other hand, the industry has been aware since long of the problems emerging with the differential (eco)toxicity of stereoisomers. Thus, any further clarifications should not lead to significant delays in the implementation of the guidance.

The Commission also informed that in March and in May, ECPA had addressed to the Commission a number of questions related to the Guidance. Those requests for clarification had been replied to by EFSA. EFSA will further discuss the issues with ECPA in a dedicated Workshop, which is provisionally scheduled on 1-2 October 2020.

The details of the implementation of the Guidance will be re-discussed during the meeting of this Committee, Residue Section, in September. The proposed provisional implementation date is still 1 August 2021.

The note taking of the Guidance was postponed to the next meeting. However, both dates are provisional, and will be confirmed or modified depending on the outcome

of discussions at the Residues Section of the Committee in September and the outcome of the workshop EFSA-ECPA. Member States were invited to send comments by 11 September 2020.

4. **Additional data for review of EFSA Exposure Guidance Document– for information**

   There were no news to discuss.

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

   The Commission indicated that the work on the update of the two Communications has resumed. Further information will follow at the next meeting of this Committee.

6. **Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching)**

   The Member State coordinating the consultation at this Committee informed that comments had been received from two Member States, and that it will endeavour to resolve the issues raised in the comments with these Member States at technical level.

A.08 Defining Specific Protection Goals for Environmental Risk Assessment, in particular Report on the Workshop on 3-4 February 2020 and way forward:

This point was discussed together with point A.09. The Commission informed on the proposed next steps and invited the Member States to comment on the outline provided and in particular to inform the Commission on the general issues to be addressed with regard to the environmental risk assessment.

In addition, the Commission invited those Member State experts who had been present during the workshops in 2019 and 2020 to join a steering group (first planned meeting on 25 September).

Member States were invited to send nominations and comments by 21 August 2020.

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

Discussed in conjunction with A.08.

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

Article 44(4) (<u>to take note</u>)

No notifications had been received since May 2020.

Article 36(3) (<u>to take note</u>)

One notification had been received and was noted. It concerned a rejection of authorisation under the zonal system for a plant protection product containing cyflumetofen.

A.11 Plant Protection Products Application Management System (PPPAMS):

The Commission provided an update on developments that are planned for implementation later in 2020:

- Implementation of the corrections officer role (enabling Member States to correct mistakes in authorisations/notifications in PPPAMS).
- Additional fields will be added to the Emergency Authorisation notifications as indicated in the revised Guidance Document on Emergency Authorisations.
- Import and export of GAP information - enabling applicants to be able to automatically upload without needing to manually input the data.

Additionally, further work is also underway to develop the other procedure types in the system – further updates will be provided in future meetings of this Committee.

A.12 News from European Food Safety Authority (EFSA), in particular:

1. **Update on EFSA practical arrangements on Transparency/confidentiality (Art. 38/39 GFL Regulation); Pre-submission phase (Art. 32a/32b/32c GFL Regulation)**
2. **Update on EFSA practical arrangements on PPP confidentiality in accordance with 7(3) and 16 of Regulation (EC) No 1107/2009.**

   EFSA provided an overview of the ongoing work on developing the practical arrangements, in particular regarding the consistency of Member State confidentiality assessments under Regulation (EC) No 1107/2009, and indicated that a draft document will be shared with Member States in autumn for consultation.

   Furthermore, EFSA made Member States aware of the link to the practical arrangements on the confidentiality assessments of EFSA (Art 38/39 of the Transparency Regulation) as the screening criteria described therein are envisaged to be also reflected in the said practical arrangements. EFSA also provided an overview of their activities for the other practical arrangements deriving from the Transparency Regulation.

   In addition, EFSA gave an overview of progress in the peer-review process for some active substances and informed that a Pesticide Steering Network meeting focussing on IUCLID is planned for October.

A.13 Improving the efficiency of the process of a.s. approval / renewal:

There was no news to discuss.

A.14 New Transparency rules: General Food Law amendment and implementation:

1. **Update on development of IUCLID as IT tool for notification and submission of application**

   The Commission highlighted the main achievements of the IUCLID pilot project and expressed a favourable view on its progress. It also pointed out that the first mandatory submissions of active substance dossiers in IUCLID will be due as per end of July 2021 (see next paragraph for more details) which gives industry and Member States about one year from now to prepare for the new system. It is also intended to work with real case pilot submissions in a first phase. Furthermore, in the light of the collaboration among the involved players, the Commission suggested that EFSA would organise a common training for the benefit of all the interested applicants and Rapporteur Member States. The form and shape of this training project will have to be agreed in the coming months in order to be ready to start using IUCLID as of the end of October 2020, date of the first release.

EFSA gave a detailed presentation on the progress of the development of IUCLID.

The Commission informed that it is preparing an Implementing Regulation to extend the periods of approval of some active substances that are part of the AIR4 and AIR5 work programmes. This administrative act is needed for two reasons:

1. As a result of the changes to be introduced by the new Regulation governing the renewal process for active substances, the date of submission of the dossiers containing the technical/scientific information will be advanced by three months and it will be required that this information is submitted in the new electronic format IUCLID. For substances for which these dossiers would be due in the time period immediately after the applicability of the new renewal rules, this will not be possible because applicants have not enough time to prepare and submit the dossiers in this new format and 3 months earlier than scheduled so far. The extensions proposed will ensure that applicants have sufficient time (minimum of 3 months) between the entry into applicability of the new rules and submission of their applications. It would apply to substances where dossier submission is due in the period April to November 2021 so that for these active substances the currently planned dates for submission of dossiers are maintained and not brought forward.
2. In addition, for some substances in the AIR5 programme, extensions are already foreseen and have been communicated to stakeholders in the relevant Working Document[1] published on the Commission's website. These extensions were planned together with the Member States to ensure a balance of work over the years but still need to be implemented. No additional time will be given beyond what was already foreseen since there is already sufficient time for applicants to then comply with the new rules. In case no application dossier is received for a substance where an extension is granted, the expiry date will be retracted to the initial expiry date.

Member States were invited to comment by 21 August 2020.

2. Update on Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (SANCO/10363/2012)

The Commission presented an update on the on-going revision of SANCO/10363/2012, which concerns basic substances.

Since the last meeting of this Committee, the Commission had received comments from two Member States. In the reply to these comments, the Commission explained that the work delivered by the Working Group convened in 2017 was taken on board when drafting the current draft revision of SANCO/10363/2012. The Commission explained that the document will be revised in 2 steps: the first step will cover the procedure for approval and the amendments that are necessary to implement the requirements of the new Transparency Regulation; a second step will follow later and cover any other aspects. The two-step approach was needed because of the tight

[1] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_ren-5_sante-2018-10048.pdf

deadline required by the implementation of the Transparency Regulation that does not allow to complete the full revision.

The first version of the revision for the first step had been made available to Member States. The Commission presented shortly the main changes: (a) introduction of optional pre-submission advice to be provided by EFSA and the Commission on the request of an applicant; (b) notification of new studies carried out by the applicant or commissioned to a contract laboratory; (c) use of the IUCLID software package; (d) public consultation on submitted applications; (e) possibility to propose additional uses by the Member States or other parties that are to be included in the risk assessment. Furthermore, a procedure for approval of an extension of use of a basic substance and information on the possibility to withdraw the application were included.

The Member States were invited to provide comments to the revision of SANCO/10363/2012 with the deadline of 11 September 2020.

A.15 Farm to Fork Strategy and REFIT evaluation – update and follow up actions:

The Commission informed that under the Green Deal, the adoption of the Farm to Fork Strategy[2] in May was an important aspect to accelerate the transition to sustainable food systems. As one of the action areas in ensuring food production, the reduction in risk and use of chemical pesticides, based on two ambitious targets, and the review of the Sustainable Use Directive are key action areas. The Commission also explained the targets sets and how they will be measured and achieved.

Together with the Farm to Fork Strategy, the Commission also published two reports, on the outcome of the REFIT evaluation of the pesticides regulations (Regulation (EC) No 1107/2009 and Regulation (EC) No 395/2005)[3] and on the implementation of the Sustainable Use Directive (legal obligation in Art 4 of this Directive)[4]. The Commission presented the reports and the main conclusions.

A.16 Clarifications & questions related to specific active substance:

1. Chlorotalonil monitoring data

The Commission informed of the last comment received on this subject and indicated that it will consider to include in a future revision of the guidance document on groundwater how to consider monitoring data.

The Commission encouraged Member States to inform this Committee should any similar issue arise in future.

2. Potential resistance to azoles with demethylase inhibitor as mode of action

At the last meeting of this Committee, the Commission had asked Member States to submit information on completed or ongoing work related to development of resistance to medical azoles, to help inform on possible action to be initiated by the Commission such as a possible mandate to EFSA and other EU agencies on the subject.

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[2] Available at: https://ec.europa.eu/food/farm2fork_en

[3] Available at: https://ec.europa.eu/food/plant/pesticides/refit_en

[4] Available at: https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

Four Member States had reacted and provided information. Two Member States had provided reports on work carried out and information on ongoing projects. The Commission informed Member States that the reports were undergoing translation and will then be analysed. This information will be fundamental to future work.

One Member State mentioned that their medical experts were very well acquainted with the problem of resistance to medical azoles and that some research had been carried out on environmental samples and that data will be published shortly, also on results from routine diagnostic samples from patients. The research shows that that resistance to azoles exists and is mostly associated with the use of triazole fungicides in agriculture. From previous research, they can conclude that the prevalence of resistant isolates is low for now but that patients are often chronically infected with resistant *Aspergillus fumigatus*.

Another Member State considered that horizontal measures should be taken at EU-level for every azole for which the approval is renewed, in order to avoid further development of resistance to medical azoles. In particular, precautionary mitigating measures should be considered at approval or renewal of approval.

The Commission reminded Member States that if they are rapporteur Member State for the evaluation of azole substances they should ensure that the issue is considered during their assessments.

The Commission informed Member States that the topic will be further discussed with EFSA and discussion on next steps will continue at the next meeting of this Committee.

3. SDHI active substances

The Commission informed Member States about a petition to the European Parliament on succinate dehydrogenase (SDH) inhibitor (SDHIs) fungicides and an addendum to that petition earlier this year.

The Commission informed that it forwarded an article on the effects of boscalid on bees to the Rapporteur Member State in 2018 with the request to consider this publication during the renewal procedure which is currently still ongoing.

One Member State informed that their agency for Food, Environmental and Occupational Health & Safety will update in 2021 the Opinion on the "assessment of a warning signal regarding the toxicity of succinate dehydrogenase inhibitor (SDHI) fungicides" including the latest data which became available. That Member State will keep the Commission and Member States updated on this evaluation.

Member States were invited to send comments by 11 September 2020.

4. Copper compounds

The Commission presented the request from the task force of producers of copper compounds to modify the specifications of the copper compounds in light of the data submitted during the renewal process but eventually not considered in the renewal report and Implementing Regulation renewing the approval. The Rapporteur Member State committed to consider these data and to propose a review of the specifications where relevant to the Commission and this Committee as soon as possible.

In addition, the Commission explained the conclusions of the report delivered by the Human Biomonitoring Project (HBM4EU), which selected copper compounds as a pilot case for non-organic compounds. The aim of this study was to establish whether a link exists between the (dietary and non-dietary) intake levels of copper with observed human biomonitoring data. As a result a bio kinetic model could be developed. However, a validation should be performed on a wider sample of humans from different ages, and exposure scenarios in particular for the non-dietary exposure pathway.

A.17 General issues for information / discussion:

1. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate

The Commission recalled that following previous discussions in this Committee there is an equivalence of functions and modes of action between potassium salts and sodium salts of nitrophenolates. In consequence, both salts fall in the scope of Regulation (EC) No 1107/2009.

The Commission informed that the two Member States, which were considering the potassium salts of nitrophenolates under their national fertilisers regulations, had been informed about the legal situation. These two Member States had recently reacted by considering that nitrophenolates products have claims matching, in their views, the plant biostimulants definition set out in the new EU Fertilising Products Regulation (Regulation (EU) No 2019/1009).

One of the Member States concerned intervened to confirm that they were seeking sound arguments why these products would have to be considered only as plant protection products. The Commission recalled that dual claims (plant protection products and biostimulants) mean that the obligations set out in Regulation (EC) No 1107/2009 must still be fulfilled.

The two concerned Member States were requested to provide arguments justifying their reasoning by 11 September 2020.

2. Active Substances vs. Co-formulants (e.g. Tall oil crude, clove oil,… as co-formulant)

The Commission informed about two recent cases where the applicants proposed in their representative formulations to consider two active substances approved under Regulation (EC) No 1107/2009 as co-formulants. The Commission recalled the discussion on this topic in the context of the draft Regulation setting out a first list of unacceptable co-formulants. Although the Commission had initially considered that it is not legally possible that an active substance can be considered as co-formulant, the majority of Member States had thought otherwise. The Commission recalled that it is up to Member States to assess whether a certain product for which authorisation is sought, contains substances that are considered as active substances under Regulation (EC) No 1107/2009 or whether such substances have indeed another function. The assessment should be case by case and pertinent factors such as the concentration level, intended use and mode of action, and absence of efficacy, shall be taken into account.

In case of doubt, the Commission requested Member States to inform the other Member States via the Post Approval Issues Group to discuss, and where necessary

to consult the Commission and/or EFSA to avoid that one and the same product has different status in the different Member States. Member States were requested to provide information to their representatives in the Post Approval Issues Working Group in view of the meeting in September 2020.

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

a) Scope Document rev.58 (previous border cases – confirmation; adaptation due to new legal status of plant biostimulants, overall review of table, publication on website)

The Commission informed that it had received several suggestions on how to improve the scope document. Some general principles applied to assess previous cases will be recalled in the introduction of the document; special attention will be given to the interpretation of the inter-play with the plant biostimulant definition, while some entries will be removed if considered as obsolete.

b) Ongoing cases:

The Commission suggested that urea (acting via a modification of the soil physical conditions- pH – and affecting the survival of harmful organisms) and paraffin/wax (acting as physical barrier to prevent the dessication of transplant in vines) should not be considered as falling into the scope of the Regulation, while chitinase (an enzyme degrading chitin from fungi) would be considered as falling into the scope. These new entries will be added to the rev. 59 in view of their validation at the next meeting of this Committee.

c) In situ generated active substances: update

The Commission informed that internal discussions are still ongoing on the question of substances generated or released in situ, through the various techniques described in the draft note circulated ahead of the meeting. The preliminary view is that all "starter materials" fall under the definition of plant protection products laid down in Article 2(1) of Regulation (EC) No 1107/2009. By consequence, the authorisation requirement of Article 28(1) of that Regulation also covers such products. The (running of the) machinery itself which generates the active substance or the plant protection product, or the trade with the active substance as such or with its precursor, however, do not require such authorisation under Regulation (EC) No 1107/2009.

The Commission announced that the draft note will be updated and invited the Member States to clearly communicate along this line to potential applicants for in-situ generated or released substances.

The technical aspects will also be discussed in the Post Approval Issues Working Group. A note circulated to the meeting of the competent authorities for Biocidal Products in July 2019 had been made available to Member States via CIRCA BC. Member States were requested to send concrete examples in view of the PAI Working Group in September.

4. **Better Training for Safer Food Training on the Risk Assessment of Microorganisms**

   The Commission informed that the contract for a training programme on the risk assessment for microorganisms used as pesticides or biocides had been signed under the "Better Training for Safer Food" programme. Trainings are aimed at experts from Member States and expected to start in 2021.

A.18 Safeners and Synergists:

The Commission presented an outline for the process to set up a work programme for the review of synergists and safeners on the market in compliance with Article 26 of Regulation (EC) No 1107/2009 and invited Member States to submit comments by 11 September 2020, in particular those Member States which so far had not replied.

A.19 News from Sustainable Use Directive (Directive 2009/128/EC):

The Commission summarised the main findings of the report on the implementation of the Directive 2009/128/EC (SUD) meeting the legal obligation in Article 4 of this Directive (see also A.15), and informed of the upcoming evaluation of the SUD. This evaluation will be combined with an impact assessment for a possible revision. In particular, a combined evaluation roadmap and inception impact assessment for this initiative had been published on the Commission's Better Regulation portal for which public feedback is invited until 7 August 2020. Member States and other stakeholders will be kept updated as the evaluation and impact assessment proceed, including by means of future specific stakeholder workshops and events.

A.20 News from Health and Food Audits and Analysis (SANTE, Directorate F):

No news to discuss.

A.21 Report from Working groups, in particular:

1. **Working group on Biopesticides**

   The Commission informed on progress of the work related to the revision of the data requirements and Uniform Principles for the placing on the market and the evaluation of microbial active substances and plant protection products containing them (i.e. Reg. (EU) No 283/2013, Reg. (EU) No 284/2013, Reg. (EU) No 546/2011). The content of the new regulations is intended to be tailored to the specificities of microorganisms, and suitable for the possible increasing number of applications for approval of microbial substances. The Commission highlighted the efforts to identify which requirements are really needed in all cases to perform a risk assessment and which would be conditional requirements triggered only under certain circumstances, e.g. based on specific biological properties of the microorganisms. The Commission informed that it intended to present first drafts in December 2020 to this Committee.

2. **Working group on Seed Treatments**

   No news to discuss.

3. **Working group Post Approval Issues**

   The Commission informed about the outcome of discussions in the last meeting on 9 and 10 June 2020.

A.22 Minor Uses:

No news to discuss.

A.23 Court cases:

The Commission mentioned that information had been provided in writing on CIRCA BC.

A.24 Ombudsman cases:

The Commission informed Member States that the Ombudsman's had sent its preliminary findings following the inquiries into the complaints 1570/2018 and 1973/2018, both submitted by Pesticides Action Network Europe and had invited the Commission to comment by 30 September 2020.

A.25 Exchange of information from the Pesticide Residues section of the Committee, in particular:

- **possible impact on authorisations**

The Commission informed that the following outcomes of the Residues Section of the Committee held on 15/16 June 2020, have possible impacts on authorisations of plant protection products:

Substance	**Type of change (see above)**	**Agenda item**	**SANTE doc number**
Azinphos-methyl	MRLs were lowered.	B 02	SANTE/12092/2019
Bentazone	MRLs were lowered.	B 02	SANTE/12092/2019
Dimethomorph	MRLs were lowered.	B 02	SANTE/12092/2019
Fludioxonil	MRLs were lowered.	B 02	SANTE/12092/2019
Flufenoxuron	MRLs were lowered.	B 02	SANTE/12092/2019
Oxadiazon	MRLs were lowered.	B 02	SANTE/12092/2019
Phosalone	MRLs were lowered.	B 02	SANTE/12092/2019
Pyraclostrobin	MRLs were lowered.	B 02	SANTE/12092/2019
Repellants: tall oil	MRLs were lowered.	B 02	SANTE/12092/2019
Teflubenzuron	MRLs were lowered.	B 02	SANTE/12092/2019
Bupirimate	MRLs were lowered and residue definition amended.	B 03	SANTE/12558/2019
Carfentrazone-ethyl	Residue definition amended.	B 03	SANTE/12558/2019
Ethirimol	MRLs were lowered and residue definition amended.	B 03	SANTE/12558/2019

The Commission also followed up on the request of Member States to clarify which version of the PRIMo model should be used for national authorisation procedures. The Commission had proposed two options on which Member States were asked to comment by March 2020. All Member States who replied preferred the option to immediately implement the newest version of the PRIMo model (currently rev. 3.1.) also for PPP authorisations, in line with the approach agreed for MRL assessments at the meeting in November 2019[5] .

At the current meeting, the Commission provided further clarifications on mutual recognition and asked Member States to formally endorse the agreed approach. Since there were no objections, the Committee agreed that the latest version of PRIMo should be used when assessing plant protection product authorisations. This information will be communicated to the Post Approval Issues Working Group.

A.26 OECD and EPPO activities, in particular:

- **OECD Pesticides Working group annual meeting, 11-12 June 2020**

  The Commission informed about the WG Pesticides meeting and highlighted the work of the Residues Expert Group, on illegal counterfeited Pesticides (a training for inspectors is planned for October 2020), on drones and that an scoping paper on good manufacturing practices is in preparation.

- **OECD Expert Group on Bio Pesticides annual meeting, 9-10 June 2020**

The Commission informed that the annual EGBP seminar on BioPesticides (concerning efficacy) has been postponed to June 2021 due to the sanitary crisis.
The EGBP agenda listed a number of documents for review and comments. A survey on existing regulatory framework for macrobials in OECD countries was discussed. OECD is also enquiring how Member States are handling antimicrobial resistance and a document providing an overview of existing guidance and test guidelines from the OECD or other sources to address specific data requirements for the submission and evaluation of microbial pesticide test data was presented.
The EU delegation provided updates on the ongoing work as regards microorganisms.

A.27 Scientific publications and information submitted by stakeholders

The Commission raised the attention of Member States to the information available on CIRCA BC on this point, which includes letters from PAN and ECPA concerning several relevant points on the agenda of the current meeting.

A.28 Date of next meeting(s)

The next meeting is scheduled for 22-23 October 2020, subject to confirmation.

[5] available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_primo-imp.pdf

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

The Commission informed that the draft presented had been slightly revised compared to the version presented and discussed at the last meeting of this Committee in order to address the concern expressed by one Member State who had requested to terminate the written procedure for a vote without result.

One Member State highlighted some editorial mistakes in the Annex, which were corrected and a revised version was submitted to a vote during the meeting.

Another Member State supported in principle the rationale of the Annex III update as outlined by the proposed draft Regulation however, given the impact on the authorised products and sequentially its impact on the agricultural sector in view of the current state of play, a grace period defined at the discretion of the Member States is suggested.

Vote taken: favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11254/2018 Rev. 4)

The Commission informed Member States about the applicant's decision to withdraw the application for renewal and indicated that time was needed to make the necessary changes to the documents. The vote was therefore postponed.

Vote postponed.

B.03 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 fenamiphos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11402/2019 Rev. 2)

The Commission explained some minor modifications introduced in the draft Regulation and the renewal report in order to reflect the new expiry date of fenamiphos which was extended by Commission Implementing Regulation (EU) 2020/869 of 24 June 2020. Furthermore, the Commission reminded Member States that the draft Regulation had already been discussed at the meeting of this Committee in May 2020, followed by a vote in written procedure, which had, however, been terminated with no result as on request of one Member State.

The vote on the draft Regulation took place during the meeting.

Vote taken: favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance sodium hydrogen carbonate as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11724/2018 Rev. 2)

The Commission reiterated that all conditions for approval are fulfilled. Following the submission of an application for approval, the Committee had taken note of the admissibility of the application which started the assessment and peer review process. This assessment concluded that the substance fulfils the criteria of Article 4 of Regulation (EC) No 1107/2009. Consequently a decision needs to be taken in line with Article 13(2)(a) and (b) of that Regulation.

The Commission emphasised that a decision to withdraw the current approval of sodium hydrogen carbonate as a basic substance will be discussed at a later point in time in this Committee. The examination procedure will also apply to that decision.

One Member State stated it does not support the draft Regulation as it considers it important that unproblematic active substances such as sodium hydrogen carbonate can be used for plant protection purposes according to Article 23 of Regulation 1107/2009 without any further national authorisation or time restrictions. Basic substances are a necessary alternative for the users also in small markets, where industry might not seek an approval.

Another Member State stated that it does not support the draft Regulation because the notifier failed to provide evidence against the assignment of 'basic substance' status.

A third Member State indicated that it can support the approval of sodium hydrogen carbonate as normal active substance considering that the requirements of Article 4 are met. However, it would disagree with a later withdrawal of the current approval as basic substance, which is not required by Regulation 1107/2009. It is important to keep the approval of sodium hydrogen carbonate as basic substance in order to support public policies in favour of substitution.

The vote on the draft Regulation took place during the meeting.

Vote taken: favourable opinion.

France made the following protocol declaration:

France can support the approval of sodium hydrogen carbonate as normal active substance considering that the requirements of Article 4 are met. However, France would disagree with the withdrawal of the current approbation as basic substance, which is not required by regulation 1107/2009. It is important to keep the approval of sodium hydrogen carbonate as basic substance in order to support public policies in favour of substitution.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance bromoxynil, 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 Renewal Report SANTE/10156/2020 Rev. 1)

The Commission explained some minor modifications introduced in the draft Regulation since the last meeting of this Committee and the renewal report in order to reflect the new expiry date of bromoxynil which had been extended by Commission Implementing Regulation (EU) 2020/869 of 24 June 2020.

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

Outcome: favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance ethametsulfuron-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

The Commissin informed that this is an administrative act due to the fact that the application was withdrawn.

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

Outcome: favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance mancozeb, 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/10326/2019 / Rev. 0)

The Commission recalled the discussion at the last meeting of this Committee and summarised again the main points discussed at previous meetings.

The Commission also informed that contrary to the indication given at the last meeting of this Committee, the new Rapporteur Member State had not yet delivered an assessment of studies that in its view were not fully considered by the former Rapporteur Member State (UK). Furthermore, Malta, because of a delay in submission of new studies by the applicant that are still ongoing, had delayed the submission of a new proposal to modify the harmonised classification opinion. Currently, a classification as toxic to reproduction, Category 1B, is recommend by the Risk Assessment Committee (RAC) of the European Chemicals Agency (March 2019) and in ECHA's registry of intentions to 30 June 2021. A potentially different RAC recommendation would thus not be available before the 2022.

However, despite this ongoing process, the EFSA Conclusion identified the active substance as fulfilling the criteria of endocrine disruptors, and no negligible exposure nor derogations according to Article 4.7 were demonstrated by the applicant. Therefore, the Commission saw no reason to modify the draft Regulation compared to the version discussed at the last meeting.

The new Rapporteur Member State indicated that it now planned to submit its assessment by the end of August 2020.

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

Outcome: The procedure was stopped with no result on request of three Member States.

B.08 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 benalaxyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10240/2020 rev. 1)

The Commission explained some minor modifications introduced in the draft Regulation and the renewal report to reflect the new expiry date of benalaxyl which had been extended by Commission Implementing Regulation (EU) 2020/869 of 24 June 2020. Furthermore, the Commission reminded that the applicant for benalaxyl did neither provide further (requested) information during the peer review nor commented the draft review report when given the possibility.

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

Outcome: favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance azadirachtin (Addendum to the Review Report SANTE/11848/2019 Rev. 0)

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

Outcome: favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of carbon dioxide as a basic substance in accordance with Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

The Commission informed that no opinion would be sought on the draft Regulation as the recent consultation of all Commission services concerned had led to a new version. The Commission explained that the draft Regulation had not changed on substance but was streamlined in several aspects. Article 79(3) was omitted from the list of legal bases.

Four Member States informed that they could not support the draft Regulation because of the underlying rationale brought forward by the Commission that a substance could not be approved as a basic substance as long as it was placed on the market as a regular plant protection product based on an approval as a regular active substance. This was the case for carbon dioxide, and a renewal process was ongoing.

One Member State motivated its position with the reason that the proposal was contrary to the promotion of basic substances. Two other of the four Member States supported the view that a substance could be approved both as a regular active substance and as a basic substance at the same time, even if the substance was placed on the market in a Member State as a plant protection product. One Member State questioned the authorisation status of the substance considering that foodstuff had to be always approved as basic substance.

The Commission emphasised its view that any substance could not be approved as a basic substance if it was available in at least one Member State of the EU as a plant protection product, because of the clear condition in Article 23(1)(d). It recalled that the Regulation provided for mechanisms, that allowed for authorisation in other Member States (parallel authorisation, mutual recognition) and even mechanisms by which authorisations can be requested, under certain conditions, by other actors in the absence of an application and consent of the authorisation holder (see Article 40(2) of Regulation (EC) No 1107/2009).

The Commission also informed that even leaving aside the legal reasons, it was not sure that the substance could be approved as an (inherently safe) basic substance, as its use required proficient users. One Member State enquired whether this rationale could be included in the draft. The Commission informed that this would require an assessment by EFSA. Finally, the Commission mentioned that the decision would open the way for the European Court of Justice to give a binding interpretation of the aspects underlying the discussions.

One Member State declared its intention to abstain, taking the view that Regulation (EC) No 1107/2009 supported the co-existence of a substance as a regular active substance to be marketed as or as part of a plant protection product and at the same time be made available as a basic substance.

One Member State took the view that the drafting was clear in the sense that food stuff was always to be considered as a basic substance and welcomed the explanation by the Commission that the draft Regulation could be the basis for this question to be clarified by the European Court of Justice.

The Commission concluded that further reflections would be needed and continued at subsequent meetings of this Committee.

Vote postponed.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron methyl, ipconazole and tembotrione in the list of candidates for substitution

The Commission reiterated the objective of the proposal, which is to add seven active substances to the list of candidates of substitution by amending Implementing Regulation (EU) 2015/408. Those substances either were classified by ECHA as M1, C1, R1 or the endpoints as ADI, AOEL have been set by EFSA at a level that identify them as candidates of substitution after the time when the preparatory work for Regulation 2015/408 had been concluded.

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

Outcome: favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, blood meal, calcium carbonate, carbon dioxide, extract from tea tree, fat distillation residues, fatty acids C7 to C20, garlic extract, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, kieselgur (diatomaceous earth), Plant oils / rape seed oil, potassium hydrogen carbonate, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, Straight Chain Lepidopteran Pheromones, tebuconazole and urea

The Commission presented this administrative measure, which was required by Article 17 of Regulation 1107/2009 as the evaluation procedures for the substance were all delayed.

Three Member States expressed their concerns on the proposal. One indicated to be in particular against the extension of the approval of kieselgur (diatomaceous earth). Another Member State disagreed with the extension of the approval of tebuconazole.

A third Member State did not agree with the extension of the approval of tebuconazole, due to the risk of resistance development of azoles. Nevertheless, because the draft Regulation covered a package of substances, they expressed their intention to vote in favour of the entire package.

The vote on the draft Regulation took place during the meeting.

Vote taken: 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 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and repealing Commission Implementing Regulation (EU) No 844/2012

The Commission presented the draft Implementing Regulation and responded to some of the comments received from the Member States following the written consultation launched at the last meeting of this Committee. The Commission informed that the consultation of all Commission departments concerned was still on-going and that, therefore, the draft could be subject to some changes following this consultation. The draft Implementing Regulation will also be subject to the feedback mechanism, thus allowing stakeholders to comment. The Commission announced that it intends to submit a draft Regulation for vote at the next meeting of this Committee.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance

benfluralin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020 Rev. 0)

The Commission explained that after it had requested comments on possible risk mitigation measure at the previous meeting it had received five comments from Member States on how to resolve the issue related to the long-term risk to birds and mammals and aquatic organisms. After reviewing these comments it appeared that four Member States find that risk reduction measures such as the product being incorporated into the soil at a depth of 15cm may solve the long-term risk to birds and mammals issue. Furthermore, they consider that refining the assessment would also be possible. Additionally, refining the risk assessment for aquatic organisms with more realistic toxicological values for benfluralin's metabolites would also improve the conclusion on the long term risk for aquatic organisms.

Some Member States expressed their position in favour of a non-renewal for reason related to P and B criteria which present, in the EFSA conclusion, some degree of uncertainty.

Given that the positions of Member States were divergent with no clear preference, the Commission indicated that it will reflect on the way forward and requested all Member States to provide a clear position as regards the draft Regulation made available. Member States were invited to send comments by 21 August 2020.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance pydiflumetofen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10300/2020 Rev. 1)

The Commission presented the draft Regulation. Two Member States opposed, considering that persistence only is not a cut-off criterion and that therefore the persistence properties of this active substance do not preclude an approval. The Commission explained that the draft Regulation was not based on the cut-off criteria but rather the precautionary principle as regards the very long persistence in the environment. It also seemed counterintuitive that a new active substance would be approved as a candidate for substitution (due to persistence and toxicity) – as such substances should be replace wherever possible.

The Rapporteur Member State indicated availability to reassess new data from the applicant (not previously included in the data package), allegedly demonstrating a more favourable outcome for persistence.

Two Member States supported the Commission proposal and one Member State supported a possible restriction of use, which would allow to gain experience in a restricted way with this new active substance which could then be considered in case of renewal (after maximum 7 years).

Member States were invited to comment by 21 August 2020.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the amendment of the conditions of approval of the active substance fenpyrazamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10690/2012 Rev. 3)

The Commission informed that, given that the confirmatory data had been delivered and assessed, the approval conditions and the review report should be amended accordingly, by including a maximum concentration for hydrazine as relevant impurity, which reflects the change in production from pilot to commercial scale. A WTO-TBT notification for the draft Regulation amending the approval conditions will be launched.

Member States were invited to comment by 21 August 2020.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of etoxazole as a candidate for substitution with restrictions in accordance with Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

The Commission summarised its proposal for renewal of approval as candidate for substitution with restriction to non-edible crops in permanent greenhouses (as defined in the PPP Regulation) and shared the comments of the Member States.

The Commission invited Member States to comment on the draft review report, implementing act and its Annex by 11 September 2020.

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 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)

The Commission summarised its proposal and shared the comments of the Member States and a stakeholder received so far. The comments received underline the importance of this substance for Integrated Pest Management (IPM).

In response, the Commission reminded that indoxacarb fulfils 2 of the PBT criteria and should therefore be regarded as a candidate for substitution. Although the use of candidates for substitution is not forbidden under IPM, it is difficult to reconcile with the principle that pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment. Furthermore, there are still alternative insecticidal chemical and biological active substances approved.

One Member State indicated not being convinced that the approval conditions for this substance are met and reminded that the MRLs for several commodities other than the representative uses lead to exceedances of the ARfD for consumers.

One Member State indicated not supporting the Commission’s proposal and supporting a renewal of the active substance given its importance for local agriculture. It considered that the risk to mammals can be addressed at the national level.

Member States were invited to comment by 11 September 2020.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of Blood meal as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11236/2020)

The Commission summarised the proposal and described the comments received from the applicant and from some Member States.

Member States were invited to comment by 11 September 2020.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of extracts from *Allium cepa* L. bulbs 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10842/2020 Rev1)

The Commission recalled that the application for the approval of extracts from *Allium cepa* L. bulbs concerned a new basic substance: a water extract of onion bulbs to be used to control fungi in potatoes, tomatoes and cucumbers. Considering the nature of the substance, the relatively low application rates, and the conditions of use proposed, it can be concluded that the use of extracts from *Allium cepa* L. bulbs can be approved as a basic substance. The Commission also informed that a vote on the draft Regulation is intended at the next meeting of this Committee in October.

Member States were invited to comment by 21 August 2020.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance Kieselgur (Diatomaceous earth) 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/10898/2020)

The Commission informed that a few comments had been received on the draft review report of kieselgur concerning the AOEC value and on the GAP table. They will be taken into account accordingly.

The Commission also informed that the consultation of all Commission departements concerned was still ongoing. The Commission informed further that the applicant would have preferred a renewal as low risk substance. Due to the specific risk mitigation measures needed, i.e. the respiratory protection for operators, the Commission did, however, not propose to renew kieselgur as a low risk substance.

One Member State informed that it opposed the renewal because they do not agree with the proposed AOEL.

Member States were invited to comment by 11 September 2020.

C.10 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 calcium phosphide, denathonium benzoate, haloxyfop-P, imidacloprid, and zeta-cypermethrin

The Commission informed that this draft Regulation intended to retract the extensions granted under the Fourth Renewal Programme of the approval periods of eight active substances (in addition to the seven listed in the agenda item pencycuron). For haloxyfop-p and pencycuron, the new expiry dates will be set back to the original. For calcium phosphide, denathonium benzoate, imidacloprid, plant oils/citronella, tebufenpyrad and zeta-cypermethrin, the original expiry dates were already in 2019. The new expiry date will be set from the applicability of the Regulation, which will be 1 December 2020, with the possibility for Member States to grant periods of grace according to Article 46 when withdrawing product authorisations.

Member States were invited to comment by 21 August 2020.

M.01 Miscellaneous:

1. The Commission informed of a letter received from one Member State on flupyradifurone related to their evaluation of new information pursuant to Article 56 of Regulation (EU) 1107/2009 about potential negative effects of the active substance flupyradifurone on the wild bee species *Osmia bicornis*, *Osmia cornuta* and *Megachile rotundata*. The evaluation of these data resulted in two questions, on which Member States were invited to provide their views by 11 September 2020.
2. The Commission mentioned in relation to point B.12, that another administrative act extending the expiration dates of the approvals of active substances which expire before end of 2020 will be submitted to a vote at the next meeting of the Residue Section of this Committee.
3. The Commission informed in relation to point A.02 about an additional admissible dossier to be taken note of: *Bacillus amylolyquefaciens* FZB42.

   The Commission informed in relation to point A.02 about a dossier for amendment of conditions of approval regarding mecoprop-P, and asked the Rapporteur Member State to confirm the admissibility.
4. Under point A.06, the Commission also gave an update on the assessment of confirmatory information for endocrine disrupting properties.
5. The Commission drew Member States attention to the most recent notice related to BREXIT[6] published on the Commission's website. It also informed about ongoing activities to prepare for the implementation of the Northern Ireland protocol after the end of the transition period.
6. The Commission informed about the publication by the European Court of Auditors of their special report on "Protection of wild pollinators in the EU: Commission initiatives have not borne fruit". The report had been made available to the Committee. The Commission summarised the main findings and especially pointed to recommendation 3 which aims at improving the protection of wild pollinators in the pesticides risk assessment process.

[6] https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/plant_protection_products_en.pdf

Member States were invited to provide comments and/or ideas to address recommendation 3 of this report by 11 September 2020. Member State were especially asked to indicate to the Commission any ongoing development or planning to develop new test methods on bees or other pollinators.