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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
22 - 23 March 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/6943ae5e-7c0e-4659-b9ae-486a92065ded?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meeting in December 2022 was published, while the one of the meeting in January 2023 was still in preparation.

A.02 Applications and withdrawals, in particular basic substances:

1. *Quassia amara*

The Commission informed that an application for an approval of *Quassia amara L.* wood as basic substance is currently being evaluated by EFSA.

2. *Plantago major* extract

The Commission informed that an application of *Plantago major* (ripple-seed) is at the stage of a verification whether it is fit for further assessment.

Plantago major (ripple-seed) is a common weed native in Europe and an ancient medicinal plant used traditionally in wound healing. The application covers the preparation of a water extract – macerate – from dried leaves of *Plantago major*. The extract is to be used as a fungicide against western flower thrips, *Frankliniella occidentalis* on vegetables like tomatoes, cucumbers and legume crops.

3. sodium chloride – extension of use

The Commission informed that two new applications for the extension of use of sodium chloride as a basic substance have been submitted. They are at the stage of a verification whether they are fit for further assessment.

The 1st application proposes an extension of the use as a desiccant on potato crops. The intended use covers application by spraying, in field or post-harvest.

The 2nd application proposes a use of sodium chloride as an herbicide against the exotic and invasive plant species of the genus Ambrosia. The application is by spraying and proposed to be limited to the areas along infrastructures such as roads or railways.

4. chitosan hydrochloride – extension of use

The Commission informed that an application for an extension of use of chitosan hydrochloride is at the stage of a verification whether it is fit for further assessment. It covers application by spraying, dripping and drenching in multiple crops such as grapevine, ornamental plants, perennial plants, in plant breeding, seed production, vegetables, tree nursery and grass and turf in amenity areas.

A.03 General issues on regulatory processes, in particular:

1. Financial assistance to Member States in the context of PPP and BPR between 2023-2027

The Commission reminded that the deadline of the submission of the applications to the call SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA is 25 April 2023, and that if a Member State wishes to apply for both topics, Biocide and Pesticide, it has to submit two separate applications.

2. Renewal process (Regulation (EU) 2020/1740)

The Commission informed that it was still considering the comments received previously regarding agreeing on a process to get access to old studies. Further information will be provided in the meeting in May. Member States were invited to share any further comments on the topic.

There are indications that in some cases agreements had been reached between companies. Member States were encouraged to remind companies of the need to reach agreements in view of the fact that all data must be taken into account at renewal.

One Member State commented about some challenges accessing old studies for an ongoing renewal when not available electronically.

3. IUCLID

The Commission informed of the upcoming new version (7) of IUCLID for pesticides and of the upcoming 6th 'Pesticide Steering Network – IUCLID' inviting them to participate. Moreover, the Commission reminded the Rapporteur Member States (RMS) of the backlog list of admissibility, these dossiers submitted in the second half of 2021 and in 2022 need to be advanced as regards the regulatory processes. Furthermore, the Commission invited the Member States, especially prospective RMS, to take part in the working groups for the drafting of a report generator templates for micro-organisms assessment reports.

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

- New active substances / Amendment of conditions of approval

1. (3E)-dec-3-en-2-one

The Commission summarised the comments received from Member States and informed on a meeting with the applicant. An additional study on the metabolism of (3E)-dec-3-en-2-one, provided by the applicant, was shared with Member States. Member States were invited to comment by 15 April 2023 on this additional study and the outcome of the EFSA Conclusion, in particular as regards the potential of groundwater contamination by the two indirect routes of exposure (critical area of concern) and buffer zones proposed as risk mitigation measures for bystanders/residents.

2. *Aspergillus flavus* MUCL 54911

   The Commission informed that the discussion between the RMS and the applicant is still ongoing, in particular on the provision of new human toxicology data. The Commission will inform the Standing Committee in case of updates from the RMS or the applicant.

- Renewal of approval

3. Clofentezine

   The Commission informed that the internal consultation was in their final stage and that further information was expected soon.

4. Benthiavalicarb

   The Commission informed Member States that the internal consultation was in their final stage and that further information was expected soon.

5. Ethephon

   The Commission summarised the comments received from Member States and shared the applicants' comments on the EFSA Conclusion. The Commission indicated that the proposed values for the ArfD and the AAOEL are based on results from human volunteer studies. The use of these studies is considered appropriate in this case as they lead to more conservative values and date from before EU legislation was available.

   The Commission indicated that a renewal report will be shared ahead of next meeting and invited Member States to send further comments by 24 April 2023.

- Basic substances

6. *Onobrychis viciifolia* var. Perly - sainfoin dried pellets

   The Commission presented the EFSA Technical Report which was published in December 2022. The pellets are to be used in plant protection as a nematicide in grapevines. The Commission highlighted the main issues raised by EFSA and the lack of data on certain elements. The comments from the applicant on the EFSA Technical Report were uploaded on CIRCABC. Member States were invited to comment by 15 April 2023.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval

a) Asulam-sodium

   The Commission informed Member States that the internal consultation was in their final stage and that further information was expected before May. In addition, the Commission referred to a letter from one NGO, who argued that the need to grant derogation to asulam-sodium for certain uses was insufficiently demonstrated by EFSA with regard to the strict requirements of Article 4(7) and the endocrine disrupting properties of Asulam-sodium on human thyroid functions.

- Renewal of approval

b) Aluminium silicate calcined

   This point was discussed together with Point A.09 on substances of natural origin.

The Commission summarised the properties of this naturally occurring active substance and the comments received so far from seven Member States. Five Member States argued against a low-risk status because of the issues for non-target organisms and bees (identified at a Tier 1 level assessment) and the data gaps concerning the impurities respirable crystalline silicia oxid and titanium dioxide. One Member State supported the low-risk status and one Member State remained open on that question. During the meeting, one Member State pointed out the discrepancy that on the one hand several Member States commented against a low-risk status and on the other hand the same substance is marketed as a sunscreen for plants (see point A 13.1.b).

The Commission invited Member States to provide comment, in particular also as regards a potential low risk status of the active substance in consideration of the general discussion under Point A.09.

c) Triflusulfuron-methyl

The Commission reiterated its proposal for a non-renewal, adding that the substance is a PFAS (Per- and polyfluoroalkyl substance) and shared the comments received from seven Member States on the possibility to further explore the application of 1 x 15 g a.s./ha every 2nd year as a safe use. One Member State stated that alternatives are available.

The Commission informed the Committee that further reflections are needed, awaiting the outcome of a more general reflection on implementation of Article 4.7. (see also A.04.3, A.04.4 and A.05.a). The Commission invited the Member States to comment by 15 April 2023.

d) Aluminium ammonium sulfate

The Commission presented the main findings of the EFSA Conclusion. One of the representative formulations appeared to be problematic while for the other safe uses were identified. The Draft Renewal Report is expected to be available for the next meeting.

e) *Cydia pomonella granulovirus* (CpGV)

The Commission presented the draft Renewal Report that proposes renewal of approval of Cydia pomonella granulovirus (CpGV) as low-risk active substance. One Member State expressed its preference that the Renewal Regulation lists the virus at species level, while all isolates are listed in the Renewal Report.

Member States were invited to comment on the draft Renewal Report by 15 April 2023.

f) Fat distillation residues

The Commission presented briefly the main findings of the EFSA Conclusion and informed that the Renewal Report was made available for comments. The applicant was consulted and had just a minor comment on the Renewal Report. Member States were invited to comment by 15 April 2023.

g) Sulphur

The Commission informed that two different task forces submitted applications for the renewal of approval as sulphur as a fungicide and acaricide and that EFSA published its Conclusion on 8 March 2023. Although the EFSA Conclusion

recognizes the ubiquitous presence of sulphur and its compounds in nature, the fact that it is not persistent and that it is of no concern to human health, it identifies several critical areas of concern in the area of ecotoxicology (high risk for sediment-dwelling aquatic organisms for the metabolite sulfate following the use of sulphur dust, high in-field risk for non-target arthropods other than bees for all representative uses; high chronic risk for soil macro-organisms).

The Commission recognised the importance of sulphur in vine-growing and organic agriculture, indicated that the general discussion on Point A.09 has to be considered, and that it had contacted EFSA asking for some clarifications.

Member States were invited to comment by 24 April 2023.

h) S-metolachlor

The Commission presented the main findings of the EFSA Conclusion and informed that the draft renewal report will be made available in the next few days, once the applicant had commented. The Commission anticipated that the proposal will be a non-renewal due to the areas of concerns reported in the EFSA Conclusion. Member States were invited to comment on the draft renewal report by 24 April 2023

- Basic substances

i) Sodium hypochlorite

The Commission summarised the comments received from five Member States, all being reluctant or not be able to support the Commission's proposal for the approval of sodium hypochlorite as basic substance for seed treatment.

The Commission reminded that the proposed use and the use instructions are not different from what already exists in practice, and that consumers are used to dilute the product during e.g., housekeeping activities, and are informed reading the label. Therefore, considering this context of other uses, the Commission sees no reason for non-approving this basic substance and will prepare the draft regulation for the next meeting (Section C).

j) Chitosan hydrochloride (amended review report to endorse)

The Commission summarised the discussions so far on the correction of the GAP table for chitosan hydrochloride and the extension of use covering the uses on hop and amenity grassland.

Three Member States submitted new comments. One Member State re-evaluated its position and does not see the reason for a non-approval of chitosan hydrochloride and the discussed extension of use. The other Member State maintained the position that the current risk envelope is not supported by appropriate data and risk assessment, and that a re-assessment of all uses for both chitosan and chitosan hydrochloride is needed. The third Member State expressed the view that the new data submitted by the applicants should be evaluated as part of the revision of the approval before any new extension of use is granted.

Taking into account all the Member States' comments received so far, the fact that the revision of approval of chitosan and chitosan hydrochloride has been recently launched, and the fact that recently one more application for an extension of use of chitosan hydrochloride has been submitted, the Commission proposed to put on

hold all the on-going applications for extension of use and evaluate them as a part of the revision of an approval.

The Committee endorsed the revision 5 of the Review Report that covered the correction of a GAP table. The correction was proposed because one of the entries was unclear and lead to inconsistent interpretations of the applicable conditions for use. However, one Member State was not in condition to endorse the revised Review Report because it does not see the current risk envelope supported by appropriate data and risk assessment. The Commission intends to correct the GAP table for chitosan in similar way during one of the upcoming meetings of this Committee.

A.06 Confirmatory Information:

1. Pendimethalin

The Commission informed that it has prepared a draft mandate to EFSA and ECHA as a follow up of the EFSA report on the confirmatory data and the potential for bioaccumulation. The intention is to ask the agencies to jointly provide advice on how to derive bioconcentration factor (BCF) values to be used for regulatory purposes considering a weight of evidence approach when experimental data from more than one species are available. Once this is clarified, a follow up mandate to EFSA is proposed to address the points identified in the EFSA Technical Report. The drafts mandates are under discussion with the agencies.

2. Flutianil

The Commission informed that the draft amended Review Report related to the endocrine disruption properties was uploaded on CIRCABC, in view of endorsing at the next meeting. Member States were invited to comment by 15 April 2023.

3. Dithianon

The Commission informed that EFSA considered in its review of the existing maximum residue levels for dithianon, according to Article 12 of Regulation (EC) No 396/2005, the additional data available on the toxicity of the metabolites 1,4-naphthoquinone (Reg. No. 4107273) and phthalic acid (Reg. No. 4005234) for which data gaps were identified during the assessment of the confirmatory data under Regulation (EC) No 1107/2009. Definitive reference values were set for the metabolite phthalic acid and provisional reference values were proposed for metabolite 1,4-naphthoquinone. It is noted that additional information has been submitted as part of the renewal application.

The Standing Committee agreed that no further action is needed with regard to the confirmatory data unless indicated by the Rapporteur Member State (RMS) for the ongoing renewal procedure. If concerns are identified by the RMS during its assessment or during the peer-review, the Commission can take action without further delay. The ongoing procedure for renewal supersedes the confirmatory data evaluation.

Member States were invited to comment by 15 April 2023.

A.07 Guidance Documents:

1. Prioritisation of Guidance Documents (to endorse)

The Commission reminded that the list of prioritised guidance documents was endorsed at the last meeting of this committee. The endorsement of the document outlining the

process for updating this list was postponed due to late comments from two Member States, which were made available on CIRCA BC.

The Commission also announced that it is outlining a short document on the process to follow for drafting guidance documents for which Member States volunteer to take the lead.

2. Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products (to endorse)

The guidance document was endorsed with applicability date of 1 January 2024.

3. Data requirements and list of agreed test methods (Part B - microorganisms) (to endorse)

The Commission informed on the status of the two draft Communications from the Commission in the framework of the implementation of Parts B of Regulations (EU) No 283/2013 and No 284/2013.

The Committee endorsed the two draft communications which will be adopted and published.

4. Data requirements and list of agreed test methods (Part A - chemicals) - Update of the Communications 2013/C 95/01 and 2013/C 95/02

The Commission informed that the revisions of the Parts A from the Communications from the Commission in the framework of the implementation of Regulations (EU) No 283/2013 and No 284/2013 are on-going, and shared the comments from six Member States and two stakeholders on the prototype of a database on '*Guidelines and supporting documents on Active Substances and Plant Protection Products'.*

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

The Commission informed that EFSA has held its last expert meeting and is currently finishing its review of this guidance document. Commission will start the endorsements as soon as the document is published.

6. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil

There was no news to discuss. The Commission mentioned a letter from Crop Life Europe (point A.20) which refers to this point.

7. EFSA Guidance on the use of the benchmark dose approach in risk assessment

The Commission informed about an event held by EFSA on the updated guidance in February 2023, and explained that although the approach was scientifically robust and useful for some situations, it would not replace the standard risk assessment approach, although applicants may choose to use it, if their data is appropriate. It was noted that the BMD approach is not new and is also used in some recent or updated guidance documents (e.g., birds and mammals), although the updated benchmark dose guidance introduces some significant new approaches. Member States were invited to comment on how the guidance could be implemented in the area of plant protection products.

8. EFSA Guidance Risk assessment for Birds and Mammals

EFSA presented its revised Guidance Document for Birds and Mammals and announced an online information session on this revision on 19-20 April 2023.

The Commission invited Member States to comment with regard to the endorsement of this guidance document by 24 April 2023.

9. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – under review

The Commission informed that the guidance would be updated in due course, pending a final position on the ruling in case C-162/21. In the meantime, a watermark indicating the document is under review has been added to the published document.

A.08 Notifications under Regulation (EC) No 1107/2009 (for information):

1. Article 44(4)

The Commission informed that it had received four notifications since the last meeting of this Committee.

One amendment of a bifenazate and rape seed oil based plant protection product (PPP) due to the new renewal restrictions of bifenazate, one withdrawal of authorisation of a carfentrazone ethyl and metsulfuron methyl based PPP following an Article 43 application due to unacceptable risks for aquatic and soil microorganisms, one withdrawal of a spirotetramat based PPP due to the absence of support during the renewal of the active substance, and three withdrawals of cyazofamid based PPP due to risk of leaching of metabolites to groundwater.

2. Article 36(3)

The Commission informed about the two notifications received since the last meeting of this Committee concerning rejections of authorisation under the zonal system. None of the decisions was challenged at national courts.

3. Article 53

See point A.18.

A.09 Microorganism and low risk Active Substances, in particular:

1. Implementation of low-risk criteria for active substances of natural origin

This point was discussed in conjunction with A.05.b, A.05.g, C.05 and C.06 (sulphur, aluminium silicate calcinated, rape seed oil, pelargonic acid).

The Commission noted that there is a growing demand of low-risk active substances, in particular in view of reaching the pesticide reduction goals set until 2030. The Commission reminded that the availability of low-risk active substances is a precondition to authorise low risk products. However, fulfilling point 5 of Annex II of Regulation (EC) No 1107/2009 is not enough to grant low risk status to an active substance, as Articles 22 and 47 are also relevant as regards the representative uses.

As regards the four active substances mentioned above, the Commission recalled that the outcome of the risk assessments are primarily based on tier 1 risk assessments, and wondered if it would be proportionate to expect higher tier (field studies) for such kind of active substances, or if consideration of weight of evidence and expert judgement

which considers the full set of data available would be more adequate and proportionate.

Member States welcomed this discussion. Two Member States asked for consistency in the environmental risk assessments of active substances and that a guideline would be helpful. One Member State raised the question if there is a definition for substances of natural origin, and if for instance an oil or extract which is obtained by processing would still be considered of natural origin. Another Member State stressed the urgency to increase the number of low-risk products and alternatives to chemical products and informed about its on-going reflections regarding a national system of bio control.

A fourth Member State stressed that it is a matter of risk and not hazard, i.e. if there is a safe use or not of the plant protection product (which may include co-formulants), and that more expert judgement should flow into the risk assessment. The way forward could be revising the criteria for low-risk active substances. A fifth Member State suggested considering also the on-going discussion on the draft Sustainable Use Regulation (SUR), and another Member States reminded that under field conditions the use of natural products like plant extracts may also lead to risks. One Member State mentioned that working on the basis of low hazard substances (contrary to low risk ones) could cover active substances of natural origin and might solve the growing tension between the politic and scientific approach.

The Commission thanked for the discussion and invited Member States to comment by 24 April 2023.

A.10 Safeners and Synergists:

The Commission summarized the comments received from Member States on the draft implementing act. The Commission reiterated the invitation to Member States to comment on the draft by the end of March 2023.

A.11 Updates, clarifications & questions on specific active substances:

1. Sodium hydrogen carbonate

See also point A.18.

The Commission summarised the comments received from four Member States.

One Member State indicated not having received yet a request for authorisation and considered priority should be given to the basic substance. Another Member State indicated that the approval of the basic substance needs to be withdrawn. A third Member State preferred an equal approach for all Member States underlining that it should be a legally flawless solution. The fourth Member State did not have a final position yet but indicatively agreed with the draft updated Review Report. They supported the proposal by one Member State to amend the basic substance approval by adding that the removal of the uses is only applicable to Member States where a Plant Protection Product containing sodium hydrogen carbonate as a low risk active substance is authorised and marketed.

One Member State asked if a grace period would be foreseen for the farmers when the use as basic substance in grapevine is withdrawn. The Commission answered that a grace period is currently not foreseen.

The Commission recalled that Article 23(1d) of Regulation (EC) No 1107/2009 clearly states that a basic substance should not be placed on the market as a plant protection

product. The Commission always assumed that an authorisation means a product is on the market. However, an authorisation only means that it may be marketed but there is no proof available that the product authorised in Austria is actually available on the market. The Commission therefore invited Austria to indicate, at the latest by the next meeting of this committee, if the product 'Natrisan' (Register number 4289-0) is on the market in Austria as a Plant Protection Product.

2. Clethodim

The Commission recalled that after the last meeting of this Committee, it was agreed to close the issue on the genotoxic potential of the metabolite 3-chloroallyl alcohol, thanks to the information provided by the Rapporteur Member State (RMS) advancing the toxicological renewal assessment.

In addition, the RMS had informed of a metabolism study on clethodim in apples submitted by a different applicant, evaluated during the procedure of authorisation of a plant protection product in another Member State that seemed to indicate that potential genotoxic chloroallyl metabolites may be formed. The Committee agreed that all available data should be included in the renewal procedure and the RMS was requested include this study in the assessment of the renewal regulatory process.

3. Common metabolites of pyrethroids

There was no news to discuss.

4. Common metabolite TFA

The Commission informed that EFSA was performing a check of the study submitted under REACH in which critical effects were identified, to determine if a full evaluation in view of re-examining the existing toxicological reference values was needed or not.

5. Copper compounds

The Commission informed that EFSA published a Scientific Opinion that reviews the health-Based Guidance Values (e.g., ADI decreased from 10 to 5 mg/kg bw/day) and that recently renewal applications of 5 copper compounds were received, for which one peer review and one EFSA conclusion is intended.

The Commission also informed about the amendment of the CLP Regulation as regards persistency criteria and that new residues data based on the modified GAP are available (from 6 to 4 kg/ha/year).

A.12 Article 21:

1. Pirimicarb

The Commission informed that the EFSA Statement on the outcome of the Article 21 was published in February 2023. The consumer risk assessment could not be finalised for all edible crops and a high risk to birds identified for all field grown uses. For the use on ornamental crops in greenhouses, some issues were also identified (consumer exposure if food crops are grown in rotation, non-dietary risk for upward spraying) but could possibly be solved by applying certain conditions or restrictions of use.

The Commission recalled that the renewal assessment is nearing completion and the EFSA Conclusion is expected in July 2023. Therefore, it would be efficient to wait for the EFSA Conclusion in order to take a final decision taking into account all information.

Member States were invited to comment on this suggested way forward by 24 April 2023.

2. Flupyradifurone

The Commission informed that it has requested Greece to evaluate the additional information on the potential effects of flupyradifurone on bees, which was submitted by the authorisation holder in the context of the review on the approval under Article 21, and to provide within three months its comments.

One Member State commented that there should be a transparent evaluation process with the participation of the national competent authorities. The Commission replied that if further work is necessary Member States and EFSA will be involved. Based on the final outcome of the review under Article 21 it will be decided if and what regulatory measures are necessary.

Member States were invited to comment by 24 April 2023 to the Commission and the Rapporteur Member State on the information submitted by the authorisation holder in the context of review of the approval.

A.13 General issues for information / discussion:

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

a) New cases

The Commission explained the new case concerning a desiccation method involving magnesium sulphate and electric current which falls outside the scope of the Regulation (EC) No 1107/2009. Member States were invited to comment by 24 April 2023 on the revised scope document.

b) FAQ document Fertilising Products Regulation - products out of one single substance + plant biostimulant

The Commission reported the discussion with one Member State concerning products based on kaolin repelling insects (e.g., by confusion). Although it is falling under the scope of the Regulation (EC) No 1107/2009, another function of the product as sunscreen is out of scope. The application as sunscreen would rather fulfil a possible claim for a plant biostimulant (Fertilising Products Regulation). The Commission explained that legal intervention on this secondary claim cannot be made in accordance with the Regulation (EC) No 1107/2009. Member States were invited to comment by 24 April 2023.

c) Phosphonates – update on status according to Fertilising Products Regulation

The Commission informed about the reaction from three Member States concerning the risks associated with the use of phosphonates both as plant protection products and (if demonstrated relevant) as plant biostimulant: residues exceedance, phytotoxicity, difficulties to trace-back due to non-specific residue analytical method. The Commission also informed about the information from EBIC (European Biostimulant Industry Consortium) concerning false positives observed in residues trials due to a non-specific analytical method.

Member States were invited to comment about the claimed use of phosphonates as plant biostimulant.

d) Physical barriers

The Commission explained the reaction of two Member States concerning products acting as physical barrier. A draft decision tree was presented, and Member States were invited to comment by 24 April 2023.

Based on these comments the Commission intends to review, where relevant, the entries to the scope document.

2. Basic substances – general issues

The Commission informed that it is finalising the survey on basic substances. The Commission reassured Member States that their past comments and views have not been forgotten and that some of the questions of the survey were based on the comments received so far. The survey will allow a more complete view on all aspects related to basics and the respective views of Member States, in particular of those that did not contribute so far.

The Commission urged Member States to reply to as many questions as possible, to be able to move the general discussion on basic substances forward.

3. Potential follow ups on incidents with phosphine products

The Commission reported on the activities promoted by the Netherlands. The Netherlands informed that their public consultation was finalised and that it will report on the follow up decisions taken at an upcoming meeting of this committee.

4. Work plan for the development of test methods focusing on wild pollinators

The Commission informed about a meeting with the Joint Research Centre (JRC) on the recognition of test protocols at OECD. JRC included this topic on the agenda of the EU NCM 49 meeting as well as the OECD WNT meeting at the end of April. At this meeting Member States which volunteer to lead and co-lead for these OECD procedures will be asked for. The Commission informed it will contact the Julius Kühn Institute in Germany, which indicted it is developing testing protocols, to confirm which ones are ready to be put forward as draft OECD test protocols.

5. ECI 'Save Bees and Farmers'

The Commission informed that it is preparing a reply in the format of a Communication to this European Citizens Initiative, which is intended to be published before the deadline of 7 April 2023.

The Commission furthermore informed of the discussion of this ECI in the Plenary meeting of the European Parliament on 16 March 2023 of which the recordings are public.

6. Residues on cut-flowers

There was no news to discuss.

7. TARIC codes

The Commission recalled that after the last meeting of this Committee, it had requested from Member States a proposal for the amendment of the TARIC codes under heading 3808, which could be used as a basis for discussions on amendments to Annex 10 of the combined nomenclature in Council Regulation (EEC) No 2658/87.

A.14 Amendment Regulation (EU) No 547/2011:

The Commission summarised the comments received from ten Member States on the draft presented during the last meeting of this Committee. Member States that did comment so far were invited to do so by 15 April 2023.

A.15 Co-formulants and assessment of formulations:

The Commission informed about a series of workshops planned: the first one on 23 May (back-to-back to the May meeting of this Committee, where Member States, EU agencies and stakeholders will be invited), a second one on 21-22 June 2023 organised by EFSA, and potentially a third one in the second half of the year.

Member States were invited to nominate experts to participate to the first workshop by 15 April 2023.

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

The Commission informed about the last meeting of the WG on Biopesticides, where semiochemicals, testing methodologies for micro-organisms, explanatory notes for new data requirements, RAR/dRR templates update, IUCLID, and guidance on virus were discussed.

About semiochemicals the Commission reminded that France recently submitted a proposal to extend the group of straight chain lepidopteran pheromones (SCLP) to cover also other semiochemicals. The Commission informed that it is considering the best way to address this proposal. In addition, the International Biocontrol Manufacturers Association (IBMA) informed it intends to provide an overview of the different regulatory procedures on semiochemicals.

2. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009, in particular:

   i. Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009

   The Commission presented a revised draft document "Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009 and Implementing Regulations (EU) No 283/2013 and No 284/2013" and summarised its context, background, wide consultation with Member States and stakeholders which involved the generation of 23 case studies.

   Member States were invited to comment by 24 April 2023.

3. Working Group Post Approval Issues

The Commission informed about the discussions that took place in the last meeting of the Post Approval Issues Working Group held on 9 and 10 March 2023.

The main points debated were amongst others: inclusion of new application techniques in the risk assessment, co-formulants, in particular the declaration from the manufacturers on formaldehyde releasers and the availability of the full composition of all the co-formulants among Member States, assessment of SCLP mixtures and check on impurities of blends, the necessity to amend the Guidance on the evaluation of new active substance data post-(renewal of) approval following the experience gained with the pilot project on dimethenamid-P, next steps at zonal level on the dimethenamid-P

based plant protection product, importance of notifications to trigger reviews of approval at EU level when new CLH classification makes metabolites become relevant, the impossibility to combine Article 32 and Article 46 when no Article 43 application is submitted, data gaps in EFSA conclusions to be dealt with at plant protection product level, and problems encountered at plant protection product level when endpoints (especially environmental endpoints) are waived.

4. Working Group on Negligible Exposure

Member States were informed that a meeting was held on 14 February 2023 to set the scene and bring together information on the relevant ongoing activities and experiences in assessing negligible exposure so far. The next meeting is scheduled for 30 March 2023.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA provided an update on the on-going peer reviews of active substances and the on-going mandates. EFSA also mentioned the delays in admissibility declarations by Rapporteur Member States (RMS) of dossier submission in IUCLID and offered its availability during this phase to RMS to clarify any issues during the process. EFSA also summarised the feedback received to the survey to collect information on assessment of formulations and for the process for assessments under Article 4.7. EFSA announced a new template for the Conclusions on active substances that are microorganisms.

2. Sustainable Use Directive (Directive 2009/128/EC) / Proposal Regulation on the sustainable use of plant protection products

There was no news to discuss.

3. Health and Food Audits and Analysis (SANTE, Directorate F)

There was no news to discuss.

4. Minor Use Facility (MUCF)

There was no news to discuss.

5. OECD, FAO and EPPO activities

The Commission provided a brief overview on recent activities at OECD.

A.18 Court cases, requests for internal review, Ombudsman cases:

The Commission referred to the earlier discussions[1] with Member States on the consequences for emergency authorisations of the ruling in case C-162/21. While the analysis of the wider ramifications of the ruling was not yet fully concluded – in particular with regard to substances for which an approval was not renewed, the Commission clarified several points for which inquiries had been received from Member States and stakeholders:

- Granting of emergency authorisations for the placing on the market and sowing of seeds treated with the three neonicotinoids clothianidin, thiamethoxam and imidacloprid is no longer possible, and also not for any other outdoor use of the three neonicotinoids. This applies also to imported treated seeds. Seed treatment

[1] https://food.ec.europa.eu/system/files/2023-02/pesticides_aas_neonicotinoids_meeting_20230213_sum.pdf

under emergency authorisations for export only is not possible (it has never been possible as the justification for the use of Article 53 of Regulation (EC) No 1107/2009 relates to combatting a danger to plant health in the EU).

- The judgment establishes an authoritative interpretation of Regulation (EC) No 1107/2009, and thereby immediately affects the legality of existing or envisaged emergency authorisations. The Commission considers that there is no need for any further measures at EU level and Member States need to act immediately to ensure compliance with the judgment. The Commission called on the Member States to withdraw any existing emergency authorisations for the three neonicotinoids, where this is possible under national law.
- The Commission has meanwhile withdrawn the mandate to EFSA from December 2022 for the assessment of the justifications for emergency authorisations for the use of neonicotinoids on sugar beet seeds during the 2022 growing season, as the judgement made the purpose of that verification obsolete.

Seven Member States indicated that they did not agree with a wide interpretation of the ruling, and raised the following aspects for consideration: 1) an interpretation that would in general exclude emergency authorisations for substances for which an approval was not renewed would be discriminatory as for active substances for which there were no applications for renewal, emergency authorisations would remain possible, 2) the Court ruling was limited to seed treatment and not all possible uses of the three neonicotinoids, 3) restrictions should not be set at EU level but left to Member States as they know in detail their environmental and agronomic conditions, 4) the wide interpretation would imply that there are no tools remaining in the EU to tackle certain phytosanitary problems, 5) emergency authorisations are only granted by Member States if there are no other solutions available, 6) the fact that the representative uses on which basis the approval or renewals are granted represent only a fraction of all the potentially uses authorised by Member States after a risk assessment which needs to demonstrate safe use, 7) that new data can be and are made available at Member State level during the foreseen legislative processes that allow a more detailed risk assessment and therefore demonstrating a safe use, and thus the possibility to grant emergency authorisations.

One Member States stressed that all Member States seem to have a much narrower interpretation of the ruling than the Commission. Two Member States indicated that they have no position yet as to the interpretation of the ruling. The Commission noted that ultimately it is for the Court to clarify the scope of its ruling and that further legal action against emergency authorisations granted by Member States might lead to such clarification.

The Commission also informed that it had received several accesses to documents requests related to the judgement in case C-162/21 and asked who should be consulted in the Member States as regards disclosure of documents sent by them, reminding that if there is no reaction before the deadline (5 working days), tacit agreement to disclosure is presumed. Two Member States indicated that they prefer the consultations to be sent to the contact point in the Permanent Representation; nine Member States indicated that they prefer the sender of the document to be consulted directly to the sender of the document. Two Member States suggested that both the sender and the Permanent Representation to be consulted. The Commission indicated it will consult both the sender and the contact point in the Permanent Representation.

The Commission also informed about a new court case T-43/23 on sodium hydrogen carbonate for failure to act under the third paragraph of Article 265 of the Treaty on the Functioning of the European Union ('TFEU'), a new ombudsman complaint 177/2023/VB from an NGO concerning comparative assessment of candidates for substitution, and a new request from a NGO under the Aarhus Regulation for internal review of Commission Implementing Regulation (EU) 2022/2364 concerning the extension of glyphosate approval.

A.19 Exchange of information from the Pesticide Residues section of the Committee, in particular:

1. possible impact on authorisations

The Commission informed that at the last meeting of the Residue Section of this Committee (13-14 February 2023), a draft Regulation lowering the MRLs for phosmet had received a favourable opinion, which may have an impact on authorisation of plant protection products.

2. Setting of Toxicological Reference Values derived via an MRL application or MRL review process (outside an assessment for approval or renewal of an active substance) – <u>to endorse</u>

The Commission informed that since the |last meeting of this Committee two Member States reacted positively to the proposed changes to the process paper which provides details for Member States, EFSA and the Commission on the setting of TRVs and RD-RA. The Committee endorsed the updated document.

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed that it had received from Pesticide Action Network Europe (PAN Europe) a report titled "Weed management: Alternatives to the use of glyphosate". PAN Europe had also submitted a letter with comments on several agenda items that had been made available to the Committee.

A.21 Date of next meeting(s):

The Commission confirmed the 24 and 25 May as dates for the next (hybrid) meeting.

A.22 AoB:

The Commission informed about the following:

- On Isoflucypram, comments of three Member States were received since the last Committee, which supported giving opportunity to the applicant to close data gaps on this new active substance. The substance will not be put on the agenda until they are news to report.
- On Prosulfocarb, the Commission informed of a phone call with the Swedish authorities on three cases of cross-contamination of apple orchards by nearby spraying of plant protection products containing this active substance onto different fields.
- On PFAS (Per- and polyfluoroalkyl substances) one Member State mentioned that it is major topic in their country, that the environmental fate of this group of substances is difficult to investigate due to the usually no labelled moiety, and that the half-life differs among rodents and mammals, a potential mandate to EFSA was

suggested. The results of the questionnaire to Member States were reported, and those Member States who had not yet replied invited to send comments by 24 April 2023. Another Member State wondered about the implications of the REACH restriction on plant protection products.

- As regards the development of guidance on the impact of water treatment processes on residues present in drinking water, EFSA and ECHA are working along with their contractor to finalise the guidance in June. Following discussions between EFSA, ECHA and the European Commission, it was agreed that the publication of the guidance would only take place once the relevant Biocides and Plant Protection Products authorities had the opportunity to provide final feedback on a consolidated draft. This feedback collection and consultation on the consolidated draft will run in parallel for Biocides and Plant Protection Products and is expected to be launched in May/early June 2023 and to last around two weeks. Once all input has been duly considered, the finalised guidance will be published in the EFSA journal and a cross-link and the information on the applicability will be made available on ECHA's webpages. Concerning plant protection products, this Committee will need to agree on the implementation schedule.
- Member Sates asked for an update on the judgment in C-162/21 (see point A.19) and the on-going work on comparative assessment (point taken for upcoming meeting).
- One Member State reminded others about the situation of formaldehyde releasing co-formulants and another offered providing information on the project Phytodrone (postponed to the next meeting).

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus amyloliquefaciens* strain QST713 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10294/2021 - Rev. 1).

SANTE/10292/2021

The Commission summarised the proposal which includes risk mitigation measures for protecting bees and described written comments received by Member States.

One Member State reiterated that restrictions for bees are not needed, while another Member State suggested to add an "unless" clause to the restriction. Two other Member States proposed to amend the restriction adding "daily foraging period", this last proposal was considered and the draft regulation modified accordingly.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis aizawai* strain ABTS-1857 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/10282/2021 Rev. 1)

SANTE/10280/2021

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis aizawai* strain GC-91 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/10286/2021 Rev. 1).

SANTE/10284/2021

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal

calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis israelensis* strain AM65-52 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/10290/2021 Rev. 1).

SANTE/10288/2021

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all

strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.

Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain ABTS-351 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 PLAN/2022/1636 RR Rev. 2).

PLAN/2022/1636

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain EG2348 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 PLAN/2021/11143 RR Rev. 3).

PLAN/2021/11143

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain PB54 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 PLAN/2021/11145 RR Rev. 2).

PLAN/2021/11145

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal

calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-11 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 PLAN/2021/10728 RR Rev. 3).

PLAN/2021/10728
The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu

lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-12 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 PLAN/2021/10753 RR Rev. 3).

PLAN/2021/10753

The Commission summarised the proposal which is based on precautionary minimum time periods that shall elapse between the application of a plant protection product containing this active substance and the harvesting of edible crops meant for fresh consumption; this applies if residues data reported by the EFSA Conclusion showed a Bacillus thuringiensis density above the level of 10^5 CFU/g. In addition, this proposal calls the generation of more data regarding the decline of Bacillus thuringiensis concentration after application, and storage stability data.

The Commission described comments received by the Member States and underlined the agreement on the overall approach proposed.

One Member State disagreed with the way to express the minimum time period elapsing between the application and harvesting.

The Commission proceeded with the vote.

Outcome: favourable opinion.

Vote taken: Favourable opinion.

The following protocol declaration was made by Germany:

"As already explained in detail in our comments of December 2022 and January 2023, Germany could have agreed to the compromise on the renewal of the Bacillus thuringiensis strains only on the condition that a uniform PHI value of 3 days for all strains is set and the threshold of 105 CFU/g is applicable to all Bacillus cereus sensu lato (As the threshold of 105 CFU/g food proposed by EFSA's BIOHAZ Panel is not limited to a specific strain, but applicable to all Bacillus cereus sensu lato.). Against the background of the current data availability, both measures are imperative from the point of view of preventive consumer protection.
Therefore, Germany will abstain for Pt. B 02.00 to Pt. B 09.00."

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance ipconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014.

PLAN/2022/2562

The Commission reminded that the final draft was made available more two weeks before the meeting and explained that the TBT process ended on 11 March 2023 and that no comments had been received.

The Committee was informed that the applicant had submitted a letter to the Commission calling for a longer grace period to enable sowing of treated seeds until the end of 2023, to avoid the forced destruction of treated seeds which would lead to more expense to farmers, logistical challenges across differing Member States, and a greater environmental impact due to the incineration of seed. Euroseeds had also written on the same issue. The letters were available to Member States on CIRCABC.

The Commission recalled that the current draft provides for a maximum grace period of 6 months, implying a final sowing period of approximately late October / early November depending on the completion of the adoption procedure. The Commission asked Member States for final comments and views.

Five Member States asked for the grace period to be extended to cover sowing until end of 2023. One Member State asked for clarification about whether the grace period includes also sowing - the Commission confirmed that in its current view the grace period also includes sowing of treated seeds since the sowing the seed is part of the use of the plant protection product.

Based on the views of Member States, the Commission presented an updated draft with a maximum grace period of 9 months and proceeded to vote.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance oxamyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1836 RR).

PLAN/2022/1836

The Commission informed that the final draft of the Regulation was made available two weeks before the meeting and explained that the TBT process ended on 17 March 2023 and that no comments had been received.

The Commission reminded the issues on dietary and non-dietary risk related to oxamyl. Furthermore, the Commission explained the reasons why, based on the recent EFSA Statement on MRLs, which shows very important health risks with the current MRLs, and based on the comments received by the Member States, the draft Implementing Regulation was updated with a maximum grace period of 6 months.

The Commission proceeded to the vote.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) 2021/1448 renewing the approval of the low-risk active substance calcium carbonate in order to include limestone as additional specification 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 PLAN/2022/2635 - RR).

PLAN/2022/2635

The Commission presented the draft implementing act.

One Member State requested to slightly modify the review report, which was implemented.

The Commission proceeded to the vote.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armigera nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-Metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237.

PLAN/2023/474

The Commission presented this draft Implementing Regulation, extending the approval periods of active substances expiring on 31 May, 30 June and 31 July 2023. These extensions are necessary because it will not be possible to adopt decisions on the renewal or non-renewal of approval of the active substances before the expiry of the current approval. The extensions proposed are calculated on the basis of an estimate of time still needed to complete the respective renewal procedure of each active substance. The remaining regulatory steps depend on where each active substance currently stands in the renewal process and for each of these steps maximum time periods are defined in the legislation.

Three Member States indicated that they do not agree to the extension of one or more of the following active substances: benthiavalicarb, dimethomorph, metribuzin, or flurochloridone. One Member State urged to take a decision as soon as possible on S-Metolachlor.

The Commission proceeded to vote.

Vote taken: Favourable opinion.

Denmark made the following protocol declaration:

"*Denmark votes against the extensions because of benthiavalicarb, which is ED and carcinogenic 1b. Furthermore, we emphasize that the evaluations of dimethomorph and metribuzine should be finalized as soon as possible, because these substances are listed as being ED on EFSA's list*."

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the approval period of the active substance pyridalyl.

PLAN/2023/473

The Commission presented this draft Implementing Regulation, setting back the approval period of the active substance pyridalyl, whose original approval period was extended by 1 year by Regulation (EU) 2020/2007 to take into account procedural changes introduced by Regulation (EU) 2020/1740. Since no application for renewal of approval was submitted by the date required by Regulation (EU) 2020/1740, the expiry date will be replaced by the original expiry date (30 June 2024).

The Commission proceeded to vote.

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 (EU) renewing the approval of the active substance captan 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/12270/2020).

SANTE/12268/2020

The Commission informed about the activities directed towards the identification of a safe field use of the active substance. The Commission clarified that -depending on the outcome of the preliminary assessment, which takes into account certain risk mitigation measures- it will either confirm the current (restricted to greenhouse) proposal or mandate EFSA to validate the proposed risk mitigation measures (and validate the new risk assessment) before sharing a new draft proposal.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance dimoxystrobin 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 PLAN/2022/2636 RR Rev. 1).

PLAN/2022/2636

The Commission presented the draft Renewal Report and an updated draft Implementing Regulation which propose that the approval of dimoxystrobin is not renewed. The TBT notification is on-going and voting on the proposal is planned for the next meeting of this Committee.

One Member State inquired if EFSA will publish an updated statement or conclusion completing the risk assessment. The Commission indicted it will consider how the results of the risk assessment obtained so far can be documented and made public.

The Member States were invited to send further comments by 24 April 2023.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low risk active substance quartz sand 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 PLAN/2022/2457 RR).

PLAN/2022/2457

The Commission summarised the comments received from five Member States and three applicants since the December meeting of this Committee. The Commission invited Member States to comment by 15 April 2023.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Yucca Schidigera* extract a as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft review report SANTE/10236/2022).

SANTE/10234/2022

The Commission summarised the draft Regulation and draft Review Report and informed that one Member State provided comments stating its support for the non-approval of *Yucca schidigera* extract as a basic substance.

The Commission referred to a mutual exclusion of the Fertilising Products Regulation (Regulation (EU) 2019/1009, FPR) and Plant Protection Products Regulation. *Yucca schidigera* extract is available on the market as a fertiliser, biostimulant and adjuvant for plant protection purposes. However, products that fall under the scope of Regulation (EC) No 1107/2009 are automatically excluded from the scope of the FPR. Therefore, if *Yucca schidigera* extract were to be approved as basic substance under Regulation (EC) No 1107/2009, it could not be on the market anymore as a fertiliser or biostimulant. Consequently, another predominant purpose of placing of *Yucca schidigera* extract on the market has not been demonstrated, other than for plant protection.

One Member State opposed to the exclusion of fertilisers from the possibility of approval as basic substances. The same Member State disagreed with the proposal for a non-approval of *Yucca schidigera* extract as basic substance.

The Commission indicated that it will further reflect, and Member States were invited to comment by 15 April 2023.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance rape seed oil 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 PLAN/2022/976 RR).

PLAN/2022/976

The Commission summarised the comments received from seven Member States since the December meeting of this Committee: four Member States support a low risk status and two argued against a low risk status because of the risks identified at Tier 1 level risk assessment for non-target arthropods and bees, and the fact that a buffer zone to protect aquatic organisms is recommended in the EFSA Conclusions. One of the two Member States suggested to mandate EFSA for guidance for active substances of natural origin with a physical mode of action.

The Commission invited Member States to provide their opinion about the kind of renewal for rape seed oil (low risk / non low risk) by 15 April 2023, taking into consideration the general discussion on Point A.09.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance pelargonic acid 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/11124/2021 Rev. 2).

SANTE/11122/2021

The Commission presented the updated draft Renewal Report and draft Implementing Regulation for the renewal of pelargonic acid together with additional comments received by Member States. Amendments made concern the way the active substance's purity is expressed to reflect that the substance should be of food grade quality.

A Member State inquired if all suppliers will be able to reach the required purity. The Commission explained that this specific food grade quality requirement is important as it was prerequisite to complete some parts of the risk assessment.

The Commission also informed that it had a meeting with the applicants upon their request and informed that the supporting information made available is uploaded on CIRCABC.

The Commission reiterated its arguments that at present on the basis of the EFSA Conclusion it could not support a renewal of pelargonic acid as a low-risk active substance because of the risks identified for different groups of non-target terrestrial invertebrates. At the same time, as pelargonic acid is a substance of natural origin, the decision for its renewal should take into account discussions on the implementation of low-risk criteria for active substances of natural origin under agenda item A.09. Member States were invited to provide by 15 April 2023 further comments.