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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*

24 - 25 May 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/7e7381fd-d3cb-41ea-b5bf-8799966a1b90?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

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

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

The Commission informed it uploaded on CIRCA BC an overview table, organised by renewal programmes, compiling the no-longer defended active substances for renewal, the non-renewed active substances and the withdrawn applications. An overview of the applications for new active substances as of 2021 was also uploaded.

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 informed the Committee that applications from 6 Member States for plant protection topics and 10 Member States for biocide topics were received by the deadline of 25 April 2023 of the call SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA. The evaluation of the applications is ongoing. The signature of the grants is expected in October/November 2023.

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

There was no news to report.

3. IUCLID

There was no news to report.

In addition, the Commission informed about the planned workshop “Zonal Authorisation Procedure - Improvements and Development (ZAPID)”, which is planned to take place in Braunschweig, Germany on 5-7 December 2023, hosted by the German Federal Office of Consumer Protection and Food Safety. A draft agenda was uploaded on CIRCA BC. The workshop is expected to be interactive, with plenary and breakout groups. Member States were invited to nominate two participants per Member State.

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

- New active substances / Amendment of conditions of approval
- Renewal of approval

1. Metiram

The Commission informed that the EFSA conclusion was published on March 2023 and that the applicants' comments to the EFSA conclusion were uploaded on CIRCABC A non-renewal is foreseen, because of the several areas of concerns identified together with a long list of issues that were not finalized. A draft non-Renewal Report has been sent to the applicant for comments which will be uploaded on CIRCABC once received.

Member States were invited to comment by 12 of June 2023.

2. Flutolanil

The Commission informed that the EFSA Conclusion is available and that the active substances has some persistent properties and is also a per- and polyfluoroalkyl substance (PFAS). See also Pt. A 13.08. Member States were invited to comment by 23 June 2023.

- Basic substances

3. Magnesium hydroxide

The Commission informed about the publication of the EFSA technical report and summarised the conclusions of this report. Member States were invited to comment by 12 June 2023 on the EFSA Technical Report and the applicant's comments.

4. Caffeine

The Commission explained that the evaluation of an application for approval of caffeine as a basic substance had been put on hold upon request of an applicant and was discussed for the last time at the meeting of this Committee in October 2021.

The Commission informed that the applicant has now submitted additional information to support his application. That information was made available to EFSA and the Member States for comments. Member States were invited to comment by 23 June 2023.

A.05 Draft Review/Renewal Reports for discussion:

Before the discussions on the individual substances asulam-sodium (A.05.b), benthiavalicarb (A.05.c) and clofentezine (A.05.d) and triflusulfuron-methyl (point C.06), the Commission recalled that it had been discussing the potential application of Article 4.7 both with Member States and internally, and that the EFSA protocols state that "*the decision on the classification of impacts on plant health as 'serious' should be taken by the risk managers (e.g. European Commission) on a case by case basis"*. The availability of alternatives (chemical or non-chemical) should also be considered for decision making and Article 4.7 refers to 'other available means' and does not mention economic or other considerations. Given the hazard of the substances concerned, Article 4.7 must be used very restrictively and reserved for exceptional cases of dangers to plant health for which no other means are available, and the consideration of serious danger and alternatives must be taken into account.

One Member State asked for further clarity on the type of situation where Article 4.7 would be possible. The Commission underlined that it was a case-by-case consideration but that both a serious danger and no other available means of control must be demonstrated.

Several Member States asked how such an approach would be reflected in actual assessments, in view of avoiding unnecessary resources. The Commission agreed to reflect on that point.

- New active substances / Amendment of conditions of approval

  a) (3E)-dec-3-en-2-one

  The Commission summarised the comments received from one Member State and EFSA on the additional study on the metabolism of (3E)-dec-3-en-2-one, provided by the applicant. The Commission informed that a meeting with the applicant was scheduled in the following days. Member States were invited to comment by 23 June 2023 on the additional study and the information provided by EFSA.

  b) Asulam-sodium

  The Commission reminded the issues of concern identified for asulam-sodium: (1) T-modality for ED, (2) the observed effects on thinning of birds' eggshells, (3) a high long-term risk to birds and mammals (tier-1 risk assessment), hence only uses in permanent greenhouses could be considered acceptable. There were also gaps to allow conclusions on the (4) consumer risk assessment for sulfanilamide metabolites, leading to provisional estimates of acute consumer exposure close to the ARfD for the main representative use in spinach; (5) the EAS endocrine disrupting modalities both for wild mammals, and non-mammalian species; (6) the long-term risk to soil organisms from non-extractable soil residues.

  The Commission explained that the applicant is challenging the ED T-modality arguing that observations in test animals are not conclusive enough for human beings and believes that further data could change that conclusion.

  The Committee was informed that the draft Review Report for non-approval had been made available to the applicant and to Member States and that the applicant had already submitted comments, which are made available to Member States on CIRCA BC.

  Member States were invited to comment by 12 June 2023.

- Renewal of approval

  c) Benthiavalicarb

  The Commission informed that the EFSA Conclusion identified the following critical areas of concern: 1) Carcinogenic potential observed in the liver and uterus in two different species and that benthiavalicarb is classified as cancerogenic Category 1B (RAC opinion adopted on 18.03.2022); 2) The criteria for endocrine disruption (ED) for humans for the T and EAS modalities are met. Negligible exposure cannot be confirmed since exposure through residues in food cannot be excluded. In addition, some parts of the risk assessment could not be finalised by EFSA, such as, among others, the non-dietary risk assessment and the consumer dietary risk assessment.

The EFSA evaluation concluded that in general a wide range of alternative fungicide active substances to benthiavalicarb are available; however, for one use and only in one Member State, no sufficient chemical alternatives are available. However, in this case serious danger is not identified and alternatives appear to exist as mutual recognition would contribute to fill any needs. Therefore, the approval of benthiavalicarb should not be renewed. A draft Review Report was uploaded on CIRCABC as well as the applicants' comments to it.

Some Member States asked to vote as soon as possible, and one Member State requested a slight change in the draft Review Report.

Member States were invited to comment by 12 June 2023.

d) Clofentezine

The Commission explained that in addition to the conclusion that clofentezine is identified as an endocrine disruptor (ED), a number of issues or risks were identified that already limited a possible derogation under Article 4.7 i.e., only non-edible crops in greenhouses. In particular, negligible exposure to consumers is not demonstrated. The Commission also stressed that the applicant contests the conclusion that clofentezine is an ED and believes that further data could change that conclusion.

The Commission informed that a draft Renewal Report for non-renewal of approval had been made available to the applicant and to the Member States. The applicant had already submitted comments on this draft in which he asks for the conclusion on ED to be modified to state that it is a default position without taking into account new data that could be requested to provide clarity on human relevance.

The Commission informed that it is carefully considering the comments of the applicant, and welcomed the comments and positions of Member States by 12 June 2023.

e) Aluminium silicate calcined

The Commission informed about one more comment received from Member States after the last Committee in March 2023. A Member State reiterated that an active substance has to fulfil article 22 and 47 of Regulation (EC) No 1107/2009 as well as the criteria included in point 5 of Annex II to qualify as a low-risk substance. Furthermore, the compliance of the specifications of the respirable fraction (≤10 μm) of crystalline silica in the quartz sand does not guarantee the compliance of these specifications in products due to subsequent processes that occur in the preparation of the product such as grinding. Consequently, in formulated products with uses triggering inhalation Member States should control the maximum amount of 0.1% of respirable crystalline silica (≤10 μm).

The Commission suggested to mandate EFSA to clarify based on weight of evidence the level of expected ecotoxicological effects under field conditions in view of the available lower tier studies and fate/behaviour for some naturally occurring active substances (see also point A.09). Member States were invited to comment on this possible suggestion by 12 June 2023.

f) Aluminium ammonium sulfate

The Commission presented the main points of the draft Renewal Report for aluminium ammonium sulfate and informed about the comments from the

applicant. Considering the physico-chemical properties of the active substance, which are influenced by the soil pH, Member States may need to pay particular attention to the protection of the environment and to aquatic species and they may need to apply risk mitigation measures for bees in order to ensure safe uses for this substance. Furthermore, the Commission reminded the participants that the toxicological relevant component (aluminium ion) is naturally present and used also for other human uses such as food contact materials and cosmetics. Member States were invited to comment by 12 June 2023.

g) Sulphur

The Commission informed that the discussion about the identified areas of concern (high risk for non-target arthropods and soil macro-organisms) is common also to other naturally occurring substance and/or essential elements (see also point A.09). The Commission also reminded the historical relevance of this substance, mostly used in grape growing and horticulture, in organic production and following Integrated Pest Management, as fungicide. Exchange of views are currently ongoing with the Rapporteur Member State and EFSA to clarify some technical points.

One Member State sent comments about the possibility of setting confirmatory information (for the risk for soil macro-organisms) and to assess at authorization level the issues identified for non-target arthropods. Another Member State agreed with the view of the Commission.

Member States were invited to comment by 12 June 2023.

h) Ethephon

The Commission presented the main points of the draft Renewal Report and a comment from a Member State.

One Member State indicated that there was a clear outcome of the expert meeting on endocrine disrupting properties which was later changed by the EFSA in the Conclusion. The Commission underlined that the EFSA reflected the outcome of the discussion on endocrine disrupting properties that was held during teleconference 88 correctly in the conclusion, however an EFSA conclusion reflects the view of EFSA on the whole peer review process and is not merely a report of the expert meetings. The Commission regards the Conclusion by EFSA as the final outcome of the risk assessment.

Member States were invited to send in comments on the Renewal Report by 23 June 2023.

i) Metrafenone

The Commission summarised the EFSA Conclusions: there are no critical areas of concern and few issues that could not be finalised, in particular missing data on phototoxicity, and a partly unfinished or provisional consumer risk assessment. Although metrafenone is not endocrine disruptor for humans neither for non-mammalian non target organisms via the EAS modalities, equivocal results in the available XETA test led to an unfinished assessment of the endocrine disruption potential (T-modality) for non-target organisms. The applicant provided several arguments against these data gaps which were uploaded on CIRCA BC.

Member States were invited to comment by 12 June 2023.

- Basic substances

  j) *Onobrychis viciifolia* var. Perly - sainfoin dried pellets

  The Commission informed that this file is on hold due to internal reflections as regards the interplay between the fertilizer regulation and the rules regarding basic substances.

  k) Chitosan (amended Review Report to endorse)

  The Committee endorsed revision 2 of the Review Report for chitosan that covered a correction of the GAP table. The correction was proposed because one of the entries was unclear and lead to inconsistent interpretations of the applicable conditions for use.

  One Member State did not agree as a matter of principle because it is of the opinion that the current risk envelope is not supported by appropriate data and risk assessment and the approval of this basic substance needs to be revised.

A.06 Confirmatory Information:

1. Flutianil (amended Review Report to endorse)

An amended draft Review Report was available for potential endorsement, however one Member State preferred to have more data, another agreed with the proposal, and a third Member State disagreed with the amended report.

The Commission suggested to postpone the endorsement to the next meeting and invited Member States to comment by 12 June 20223.

2. Pendimethalin

The Commission informed that a draft mandate on the potential for bioaccumulation as a follow up of the EFSA report on the confirmatory data is under discussion with EFSA and ECHA. However, ECHA informed it is planning to develop guidance on the application of the CLP criteria that will be ready earliest by mid of 2024. Therefore, mandating the agencies to jointly provide advice on how to derive the bioconcentration factor (BCF) values when experimental data from more than one species are available may result in duplication of work and possibly inconsistencies. The Commission is considering about the best way to proceed.

Member States were invited to comment on how to address the issue of bioaccumulation studies from multiple species by 12 June 2023.

3. Dithianon

The Commission informed that, based on the comments received, Member States supported the closing of this confirmatory data, which are superseded by the already on-going renewal procedure.

Furthermore, the rapporteur Member State for the renewal confirmed the reception in the renewal dossier of additional data on mutagenicity on the metabolite 1,4-napthoquinone.

A.07 Guidance Documents:

The Commission recalled that for the January meeting of this Committee one Member State had submitted a proposal for a method to assess effects on biodiversity, which had

been made available on CIRCA BC together with other relevant biodiversity reports[1], and on which Member States were invited to comment. So far two Member States reacted, suggesting that biodiversity should be considered in combination with the upcoming update of the Terrestrial Ecotoxicology Guidance Document, which had been prioritised.

The Commission reiterated the invitation to Member States to comment on the possible way forward by 24 June 2023.

1. Prioritisation of Guidance Documents (to endorse)

The endorsement of the document outlining the process for updating this list was postponed as one Member State indicated to need more time for its consideration.

The Commission also informed that the draft document on the process to follow for drafting guidance documents for which Member States volunteer to take the lead is still in preparation.

2. Data requirements and list of agreed test methods (Part A - chemicals) – Revised versions of Communications 2013/C 95/01 and 2013/C 95/02 (to endorse)

The Commission shared the draft revised Communications concerning Parts A of Regulations (EU) No 283/2013 and 284/2013, the updated rationale-document, and the excel table with the individual comments from Member States and stakeholders, as well as a comment from one Member State. It informed that the internal process is still ongoing and that the endorsement can take place in July. It also explained that the new database on *Guidelines and supporting documents on Active Substances and Plant Protection Product**s*** is under development. Stakeholders will be consulted following the endorsement of the documents.

Member States were invited to comment by 24 June 2023.

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

The European Food Safety Authority (EFSA) presented the revised guidance document on the risk assessment of plant protection products on bees and announced an online information session on 13 June 2023.

The Commission explained that amendments of the Regulations (EU) No 546/2011, No 283/2013 and 283/2013 seem necessary before the revised guidance document can be endorsed. The Commission indicated that it is already working on the necessary amendments and that it intends to initiate discussions in the Standing Committee soon. Upon request of a Member State, the Commission explained that the endorsement of this Guidance Document may be via a Commission Notice given the complexity of the file. Comments on the revised guidance document received from third parties were made available on CIRCABC under agenda point A.20.

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[1] Nationale Akademie der Wissenschaften Leopoldina, acatech – Deutsche Akademie der Technikwissenschaften, Union der deutschen Akademien der Wissenschaften (2020): Biodiversität und Management von Agrarlandschaften – Umfassendes Handeln ist jetzt wichtig.
KEMI PM2/21 Methods for assessing the effects of plant protection products on biodiversity
KEMI PM 7/21 Resilience of biodiversity to plant protection product use – the modifying influence of landscape and interventions
Alix, Bylemans, Dauber, Dohmen, Knauer, Maltby, Mayer, Pepiette, Smith, 2022. Optimising agricultural food production and biodiversity in European landscapes. Report of an online-Workshop. Tünen Report 98.

Member States were invited to comment in view of the endorsement and any necessary changes to the Regulations mentioned above by 23 June 2023.

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

The Commission informed that no comments had been received from Member States since the last meeting. However, a position paper was received from CropLife Europe, in which concerns were outlined about the use of the Guidance in the regulatory framework for pesticides in a meaningful way.

In addition, the Dutch National Institute for Public Health and Environment (RIVM) has raised objections to the Guidance and is currently corresponding with EFSA on the topic - a procedure under Article 30 of the General Food Law may be launched. The Commission suggested to wait for the outcome of this ongoing discussion between EFSA and RIVM before discussing further implementation of the Guidance. Member States views were welcomed by 23 June 2023.

5. EFSA Guidance Risk assessment for Birds and Mammals

The Commission discussed the comments received by four Member States on the endorsement of this Guidance document and explained it will take up the points brought forward either internally or with the EFSA. Comments on the revised guidance document received from CropLife Europe were made available on CIRCABC under agenda point A.20.

The Commission explained that an amendment of Regulation (EU) No 546/2011 seem necessary before the revised guidance document can be endorsed. The Commission indicated that it is already working on the necessary amendments and that it intends to initiate discussions in the Standing Committee soon.

Member States were invited to comment in view of the endorsement and any necessary changes to the Regulation mentioned above by 23 June 2023.

6. Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

The Commission recalled that in March 2023 it had informed Member States that they would be offered a final short period to provide comments to EFSA and ECHA on the final consolidated draft before its adoption and publication.

The final draft was expected at the end of May, following which the Commission would launch a short commenting period. 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 then discuss the implementation schedule.

The Commission noted that CropLife Europe had submitted a position paper outlining its views and concerns about the draft that is commented on as part of the public consultation.

7. Explanatory notes on data requirements on micro-organisms

The Commission recalled that these Explanatory Notes were prepared by the Biopesticide Working Group (see point A.16) and provide guidance in view of

a harmonized implementation of the new data requirements on micro-organisms. The Commission highlighted that the draft is now under consultation by stakeholders.

8. Superseded Guidance documents SANCO/12116/2012 (on contaminating micro-organisms) and SANCO/10754/2005 (on taxonomic level of micro-organisms)

The Commission informed that the guidance document SANCO/12116/2012 is now to be considered superseded by the OECD issue paper on microbial contaminant limits for microbial pest control products series on Pesticides No. 65. The Commission underlined that this is due to the fact that an updated version of the OECD document will be published soon (however, the list of relevant contaminating micro-organisms and their quantitative limits will be kept unchanged).

The Commission informed that the guidance document SANCO/10754/2005 concerning taxonomic levels of micro-organisms is to be considered obsolete as the new data requirements on micro-organisms already provide clear provisions on this regard.

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

1. Article 44(4)

The Commission informed that it had received an update on the modelling data, accompanying the notification of the last meeting of this Committee, concerning the withdrawal of three cyazofamid based plant protection products due to the risk of the leaching of metabolites to groundwater.

2. Article 36(3)

The Commission informed about the nine notifications received since the last meeting of this Committee: five notifications concerned rejections of mutual recognition applications and four concerned rejections of authorisations under the zonal system. Two of the decisions were challenged at national level, however they were dismissed.

3. Article 53

See agenda point A.18 for the discussion on the judgment in case C -162/21.

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

The Commission informed that procurements are to be launched under the framework contract SANTE/2021/OP/0002, asking for studies which would collect and assess available information on some micro-organisms species that are currently approved in the EU (horizontal review and information on background population levels). These studies are aimed at facilitating dossier preparation and assessment.

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

The Commission informed that twelve Member States and Norway reacted after the meeting of this Committee in March as follows.

There was a general agreement, that a plant protection product can only be “low risk” if the active substance(s) contained in it is low risk. Nonetheless, all other ingredients (e.g., co-formulants) should qualify as “low-risk” as well. As the representative use for the approval of the active substance should have no need for specific risk mitigation, the question was raised if one “low risk” representative use is enough for an active substance to qualify as low risk. There was also a general recognition that low-risk plant protection products are necessary to reach the EU targets of the Green Deal and

Farm to Fork Strategy and that low-risk plant protection products are equally important for amateur and professional users.

Member States had indicated that the risk assessment should be based on sound science and on a case-by-case approach for all kind of active substances, regardless of their nature. Although general assumptions based on common knowledge alone should be avoided, certain aspects/parts of the risk assessment may be superfluous due to the identification of certain properties of an active substance on a case-by-case basis. The consideration of 'need-to-know', 'weight of evidence', and/or 'expert judgement' approaches are important in such cases, and the draft guidance for the problem formulation (see point A.16.2.1), might help distinguishing 'need-to-know' and 'nice-to-know' data requirements of potential low-risk substances.

Finally, there was a general agreement that generic risk mitigation measures (RMM) may be applicable also for low-risk plant protection products for professional or non-professional uses. Some RMM should be considered as generic and without impact on a potential low-risk status, like for instance RMM which are considered as 'basic hygiene' or general good practice (e.g., wearing gloves during mixing and loading, wearing workwear, goggles, etc.). However, if RMM are triggered by the exposure assessment indicating an exceedance of the AOEL, this use and as a consequence the plant protection product cannot be considered as low risk. In this context, a list of generic RMM would be helpful.

Based on these comments and bilateral exchange with EFSA, the Commission suggested to mandate EFSA for an expert judgement of the PPR Panel based on weight of evidence for some of the active substance cases currently under discussion at this committee (aluminium silicate calcinated, pelargonic acid and rape seed oil), with respect to the level of expected ecotoxicological effects under field conditions. This mandate would be a pilot case and complement other work already planned by EFSA.

Member States were invited to comment by 12 June 2023.

A.10 Safeners and Synergists:

The Commission shared with the Member States the last draft version of its regulatory proposal on safeners and synergists where Member States comments submitted after previous meeting of this Committee were considered. The Commission informed about the next steps towards the adoption of the act.

Member States were invited to comment by 5 June 2023.

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

1. Sodium hydrogen carbonate

Article 23(1d) of Regulation (EU) No 1107/2009 states that a basic substance should not be placed on the market as a plant protection product (PPP).

The low-risk active substance sodium hydrogen carbonate is authorised in Austria as a PPP; however the local authorities cannot provide indications if this product is actually placed on the market following its authorisation. The Commission indicated its intention to contact the authorisation holder.

One Member State inquired if the discussion on the potential withdrawal of the approval of sodium hydrogen carbonate would be put on hold pending the ongoing court case. The Commission indicated that first clarity on Article 23(1d) is needed.

The Commission furthermore reiterated its invitation to Member States to indicate, by 23 June 2023, the receipt of any applications for authorisation of sodium hydrogen carbonate as a low-risk active substance.

2. Common metabolites of pyrethroids

The Commission reminded that, following the EFSA Scientific Opinion issued in October 2022 on the toxicity of pyrethroid common metabolites, EFSA published its statement on the review of the residue definitions for risk assessment of pyrethroids forming common metabolites on 24 May 2023.

3. Common metabolite TFA

The Commission informed that after an informal request, made at the last meeting of this Committee in March, EFSA had considered the study submitted under REACH in which adverse developmental findings on TFA were identified, to see whether this would impact the existing toxicological reference values (TRVs) for TFA.

EFSA informed that on the basis of its consideration and given the margin of safety that exists, the study submitted under REACH does not impact the TRVs for TFA.

Therefore, the Commission proposed that Member States and EFSA continue to use the agreed endpoints for TFA as part of assessments.

The Commission also noted that TFA is a PFAS and further reflections are needed.

One Member State asked how any new data on TFA, that may be submitted in dossiers for renewal of approval of active substances, would be handled in view of avoiding duplication of work. The Commission indicated it would further reflect on it, also with EFSA, in view of ensuring a pragmatic and manageable approach.

4. Common metabolites 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid and 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid (formed by bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr and pydiflumetofen)

The Commission informed that one Member State had requested to add this point to the agenda.

This Member State is of the opinion that a harmonized toxicological assessment at EU level is required for the groundwater metabolites 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid and 3-(difluoro-methyl)-1-methyl-1H-pyrazole-4-carboxylic acid, which are formed by different active substances (bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr and pydiflumetofen). This Member State suggested to mandate EFSA to perform a harmonized and final evaluation of the toxicological profile of these two metabolites at EU level. At the same time, a harmonized procedure should be established at EU level for the evaluation of common metabolites coming from different active substances and it should be clarified which further data might be required to assess the toxicological relevance of these metabolites.

The Commission informed that applications for renewal were received for Bixafen, Fluxayroxad, Sedaxane, and Benzovinidiflupyr and the risk assessments are on-going, while Pydiflumetofen is not yet on the market and Isopyraxamis is not approved.

Another Member State agreed to the suggestion to mandate to EFSA.

Member States were invited to comment by 12 June.

5. Prosulfocarb

The Commission informed that it advised the Rapporteur Member State of prosulfocarb to include the three studies submitted under Article 56 (fish early life stage toxicity, oral acute toxicity in rats, and a dermal absorption study) in the ongoing renewal procedure and to consider the outcomes in the risk assessment as appropriate in an update of the draft Renewal Assessment Report.

The Commission also informed that EFSA is aware of the possibility of long-range air transport because of the reported incidents of residues found in non-treated crops, and that this would be considered in the risk assessment. The Commission asked the co-rapporteur to ensure this point is addressed in the ongoing peer review, given the reported incidents at national level it its country.

The Commission furthermore underlined that, in case of incidents, adherence of the users to the applicable risk mitigation measures should be verified as soon as possible. The Commission also reminded that Article 67 foresees that uses are recorded and that these records are available to competent authorities.

The Commission intends to make an overview of all risk mitigation measures in place in the EU for this active substance for further discussion in this Committee and the Post Approval Issues (PAI) Working Group.

Member States were invited to provide a list of national risk mitigation measures in place for plant protection products containing prosulfocarb by 23 June 2023.

A.12 Article 21:

1. Acibenzolar-methyl

The Commission informed that an EFSA statement has been published on 20 April 2023 concerning the testing strategy and timelines proposed by the applicant for the assessment of the endocrine disruption properties of acibenzolar-methyl in the context of the review of the approval of the active substance. The proposed deadline is the 2nd quarter of 2025 and has been confirmed to the applicant.

2. Pirimicarb

The Commission provided a brief update following some comments received from Member States since the last meeting and recalled that the renewal process would be concluded in the coming months.

No Member States indicated to oppose awaiting the EFSA Conclusion on the renewal risk assessment before taking action.

Member States which had so far not commented were invited to do so by 23 June 2023.

3. Flupyradifurone

The Commission informed that the Rapporteur Member State submitted its assessment of the additional information on the effects of flupyradifurone on bees, submitted by the authorisation holder in the context of the review under Article 21.

The Commission indicated it intends mandating EFSA in accordance with Article 21(2) to provide scientific and technical assistance and to deliver a statement on the information submitted by the authorisation holder taking into consideration the assessment of the RMS. This will also include a peer review by the Member States.

Member States were invited to send their comments on the information submitted by the authorisation holder to the Commission and the RMS by 12 June 2023.

A.13 General issues for information / discussion:

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

The Commission explained the replies it received since the last meeting from two Member States concerning the use of electric current in combination with magnesium sulphate (desiccant). Both Member States agreed that this case falls outside the scope of Regulation (EC) No 1107/2009, but they drew attention to the possible concern of spraying such a chemical substance in the environment which should be compliant with national legislation. The requesting Member State took good note of this observation.

a) New cases

The Commission informed about two new cases:

The first case concerns the use of bacterial endosymbionts to control aphids under greenhouse conditions, where the release would occur via the aphids carrying the bacterial endosymbionts to infect the "local" aphid population. The Commission wondered if the use of bacteria belonging to the genus *Hamiltonella*, *Wolbachia*, *Regiella*, *Rickettsia*, *Rickettsiella* and *Spiroplasma* with this release mode is falling in the scope of Regulation (EC) No 1107/2009.

The second case concerns a product based on trisiloxane that increases the wettability of hydrophobic surfaces including the pests (aphids and spider mites) feeding on plants, which then "die as a result of disruption of physiological processes". The latter mode of action is normally interpreted as invasive and was considered for similar cases as a plant protection product (see entry 40,100, 178, 222). The Commission proposed to follow the same conclusion here.

Member States were invited to comment on the two new cases by 23 June 2023.

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

The Commission informed about two contradicting messages and a position paper received from industry federations, respectively, representing the biostimulant producers and the biological plant protection products, which are available on CIRCA BC.

c) Physical barriers

The Commission informed that two Member States had commented the decision tree regarding the plant protection practices considered as physical barriers, presented at the last meeting of this Committee, and thanked for the comments which were considered. Two alternative decision trees were proposed by one Member State. Another Member State observed that nets could contain chemicals released in the environment.

Member States were invited to comment on the proposed amendments by 12 June 2023.

2. Basic substances – general issues

The Commission encouraged Member States to complete the basic substances survey, which was send to the Member States beginning of May 2023 in view of compiling current situation in all Member States as well as how they interpret certain elements concerning basic substances. The deadline to complete the survey was prolonged until 9 June 2023 upon request of several Member States.

The Commission also informed on its intention to amend the "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, Rev 10" (guidance on basic substances) in order to ensure a better alignment with the provisions of Article 13 of Regulation (EC) No 1107/2009.

The first paragraph of Section 2.4. of the document SANCO/10363/2012, Rev. 10, on the withdrawal of an application, requires clarification and is proposed to be replaced with "*A withdrawal of an application is possible at all stages of the procedure preceding the moment when the Member States represented in SCoPAFF will have voted on the Commission's proposal for approval (or non-approval) of the substance. The withdrawal of the application interrupts the procedure and a decision by the Commission is only required when the withdrawal occurs after the adoption of the EFSA output*."

Member States were invited to comment on this amendment by 23 June 2023 in view of endorsement of the updated guidance document at the next meeting of this Committee.

3. Potential follow ups on incidents with phosphine products

The Netherlands gave a short update on the incidents in their country and on the public consultation launched on possibilities to minimise the risks connected with the use of loose pill formulations.

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

The Commission informed about the discussion on this workplan at the 49th EU meeting of the National Coordinators for Testing Methods and at the 35th meeting of the OECD Working Party of National Coordinators on the Test Guideline Programme, and that Spain offered to be the lead country to submit a test guideline with regard to chronic toxicity testing of bumblebees to the OECD.

The Commission will now complete the inventory of the test protocols needed with the revised published Bee Guidance Document. From this inventory the workplan will be developed.

Member States were invited to indicate availability to support the development of test protocols for pollinators and the official programme of OECD by 23 June 2023.

5. ECI 'Save Bees and Farmers'

The Commission presented the main points of the Communication regarding the European Citizens' Initiative (ECI) 'Save Bees and Farmers'. This document is available online via https://europa.eu/citizens-initiative/initiatives/details/2019/000016_en

6. ECI 'Save Cruelty Free Cosmetics"

The Commission informed the Committee about this citizens' initiative and that a response will be published latest by 25 July 2025.

7. Phytodrone

The Commission reported about the recent conference organised by OECD regarding the application of pesticides by drones where authorities and stakeholders could exchange their current experiences, expectations and challenges. During the conference, the need to gather more data regarding the differences of drone applications

compared to ground-based spraying equipment as regards exposure assessment (e.g., drift curves, residues) became evident.

8. REACH Restriction PFAS

The Commission updated about the restriction proposal under REACH, currently under the six-month consultation which will close on 25 September 2023. This restriction is not addressed to active substances used in plant protection products (PPPs) - as they are exempted from the REACH Regulation - but contains a non-exhaustive list of PFAS active substances used in PPPs, biocidal products and medicinal products in the Appendix A.3.17. of the Annex A. The same Annex reports that "although the use of PFASs as active substances in PPPs leads to intentional environmental emissions, a rough estimate indicates that PPPs accounts for 2% of the total EU sales of substances that fulfil the PFAS definition. A general restriction of PFASs in PPPs would entail that at least 48 active substances in over 200 products cannot be used anymore. This would have consequences in terms of availability of e.g., fungicides, insecticides and herbicides used in a variety of crops. Limiting the number of different PPPs generally aggravates resistance management".

The Commission informed it will ask EFSA to identify in the EFSA conclusions if an active substance is PFAS or not. A list of active substances which are under current evaluation for their renewal or approval has been uploaded on CIRCA BC, as well as a proposal made by one Member State.

Member States were invited to comment by 12 June.

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

The Commission informed that it received additional comments from four Member States and that for efficiency purposes an on-line technical meeting with Member States will take place 14 June 2023 to discuss these comments and a revised draft.

Member States were invited to provide the name of the experts who will participate in the technical meeting.

A.15 Co-formulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574

The Commission informed that one Member State requested information about how to notify unacceptable coformulants according to the new Implementing Regulation, and that a functional mailbox has been set up for this purpose that can be found on CIRCABC.

In addition, a clarification from another Member State in order to explain the rationale behind their approach in evaluating unacceptable co-formulants has been uploaded on CIRCA BC.

Member States were invited to comment by 12 June.

2. On-going actions and planned workshops

The Commission informed about the workshop on the assessment of plant protection products including co-formulants that took place on 23 May 2023 and shared the presentations and position papers of the six stakeholder organisations which participated.

A dedicated website will be set up: https://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/assessment-plant-protection-products-ppps_en

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

There was no news to report.

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 No 1107/2009

   The Commission summarised and addressed the comments received from four Member States on the 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". Member States were invited to send their position by 12 June 2023 as regards endorsing this document or to send a concrete proposal to implement in the short-term Point 1.5. of the Introduction of the Annexes of Regulations (EU) No 283/2013 and No 248/2013.

   The Commission also informed that a revised draft document "Compendium of conditions of use to reduce exposure and risk from plant protection products" is being discussed with the Working Group. The Commission informed about its participation in several conferences and workshops on drones and precision application techniques and encouraged Member States to get involved in these activities.

3. Working Group on comparative assessment

   The Commission informed about the last meeting that took place remotely on 16 May 2023. The main point of debate was the proposal put forward by the Commission to amend Annex IV of Regulation (EC) No 1107/2009. Experts were invited to send written comments by 15 June 2023.

4. Working Group on Negligible Exposure

   The Commission informed that two further meetings of the Working Group had been held in March and May and that, despite challenging discussions, some progress was made. Member States were informed that the next meeting would likely be in September.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA provided an update on admissibility of IUCLID dossiers, the on-going peer reviews of active substances, and the on-going mandates, and confirmed it will mention in the EFSA Conclusions if a given active substance is also a PFAS. EFSA mentioned that the statement on groundwater monitoring as well as the bee guidance document were published. EFSA explained an internal reorganisation concerning the work on plant protection products and informed that a Working Group on effect models in environmental risk assessments was set up.

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

The Commission thanked Member States for the constructive discussions and good progress made on technical matters in the Council Working Party meetings. The Commission informed that it would reply to Council Decision (EU) 2022/2572 requesting a study complementing the impact assessment of the SUR proposal before the 28 June deadline. Work is at a very advanced stage and will need internal validation within the Commission. The Commission cannot be any more precise on the timing at this stage but thanks Member States for their cooperation in providing additional data to assist with this work.

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

There was no news to report.

4. Minor Use Facility (MUCF)

There was no news to report.

5. OECD, FAO and EPPO activities

The Commission informed that OECD was circulating a survey about the eChemPortal, the Global Portal to Information on Chemical Substances, which aims at facilitating access to information, promotes resource efficiencies, and aims to avoid duplication of work on assessment and subsequently reduce animal testing.

Member States were invited to reply to the survey by 15 June 2023.

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

The Commission informed that it has no news as regards the analysis of the wider ramifications of the ruling on C-162/21 and about the new Case C262/23 on Mancozeb, which is an appeal against the Judgement of the General Court in Case T742/20, where the latter dismissed the applicants' action seeking for the annulment of the "Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of approval of Mancozeb".

The Commission also informed about two new requests for internal review on:

1. "Commission Implementing Regulation (EU) 2023/515 of 8 March 2023 renewing the approval of the active substance abamectin", received on 27 April 2023;
2. "Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 laying down detailed rules for the identification of unacceptable co-formulants in plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council" received on 8 May 2023.

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 Pesticide Residues section of this Committee, which took place on 10-11 May 2023, measures to lower maximum residue levels (MRL) have been voted for pyriproxyfen, denatonium benzoate, diuron, etoxazole, methomyl, teflubenzuron, carbetamide, carboxin, triflumuron, and bifenazate.

2. Toxicological Reference Values (TRV) derived via Regulation (EC) No 396/2005 for fosetyl-Al, potassium phosphonates, and disodium phosphonate (to endorse)

In compliance with Articles 12 and 43 of Regulation (EC) No 396/2005, EFSA jointly assessed the maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates, as these three substances degrade to phosphonic acids. In the framework of that evaluation, EFSA proposed setting the residue definitions for those substances as "phosphonic acid and its salts expressed as phosphonic acid" and suggest the following toxicological reference values (TRVs), which were endorsed in the meeting by the Committee:

Acute Reference Dose (ARfD): not necessary,

Acceptable Daily Intake (ADI): 1 mg/kg bw/day for phosphonic acid.

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed on follow-up information concerning the peer reviewed article Bonis et al. (2021), which identified a possible link between some foodborne outbreaks and the use of *Bacillus thuringiensis* strains in plant protection products. The e-journal PLOS ONE, the same journal publishing the article of Bonis at al. (2021), published an "Expression of Concern" highlighting concerns raised in the interpretation of data presented in the paper of Bonis et al. (2021), in particular as regards the link between the foodborne outbreaks and *Bacillus thuringiensis* as causative agent. It seems that PLOS ONE board members concluded that the data presented and analysed in Bonis et al. (2021) do not appear to be sufficient to support a direct causal relationship between *Bacillus thuringiensis* presence and symptomatology or clinical infection in the analysed foodborne outbreaks.

The Commission informed that discussion will be continued at the Residues section of this Committee.

A.21 Date of next meeting(s):

The Commission informed that the next meeting of 11 and 12 July 2023 is confirmed and will take place as a hybrid meeting.

A.22 AoB.

The Commission reminded Member States that the draft EFSA Conclusion on glyphosate was submitted to them by EFSA for comments on 12 May 2023, and that they can submit comments until 26 May 2023, after which time EFSA will finalise the Conclusion on the peer review.

The Commission invited Member States to be prepared for a detailed discussion on glyphosate at the next meeting of this Committee in July, and explained that given the time limitations to conclude the regulatory decision making - the current expiry of glyphosate is 15 December 2023 - an additional dedicated meeting of this Committee in September will most likely be required.

The Commission also provided an update on on-going council discussions as regards transitional measures to list active substances identified under Regulation (EC) No 1107/2009 as fulfilling some of the hazard criteria directly as classified under the CLP Regulation. Member States experts were invited to liaise at national level with their experts following these discussions, in particular as the negotiations may have

implications for pending dossiers and in view of avoid delays of assessments and/or duplication of work for such dossiers.

One Member State asked to discuss the reduced participation of Member State experts in peer review meetings and wondered how more harmonisation (common approach) could be achieved for active substances which fall both under Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012. On the first point raised, the Commission supported the observation and suggested EFSA to further discuss this at the PSN meeting.

Another Member State informed that it received a request to disclose documents under the Aarhus Regulation concerning the definition of greenhouses, and mentioned the high interest of the topic.

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) 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, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408 (Draft Review Report PLAN/2022/2636 RR).

PLAN/2022/2636

The Commission presented the draft Implementing Regulation and the draft Review Report.

One Member State inquired how the results of the risk assessment of dimoxystrobin would be documented to facilitate the future regulatory work on the substance, including setting of MRLs. The Commission replied that it is considering mandating EFSA to publish a conclusion from the peer review work completed so far.

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 low-risk active substance quartz sand 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/2022/2457 RR)

PLAN/2022/2457

The Commission informed about the comments received since the last Committee in March 2023. One Member State had expressed its concern about crystalline silica (quartz = crystalline silica) and asked to add a sentence regarding impurities in plant protection products. The Commission explained that a reference on the impurity crystalline silica with a particle diameter $\leq$ 10 µm is already given in the Renewal Report, the Implementing Regulation (Recital 14) and the Annex to the Regulation, stating that this impurity should not exceed a level of 0,1% of particles in the technical material.

The second Member State wanted a restriction to "paste application only" if the active substance would be renewed as low risk. The Commission explained that such a kind of restriction would contradict a low-risk status.

Vote taken: Favourable opinion.

Spain made the following protocol declaration:

The hazard of the respirable fraction (≤10 μm) of crystalline silica depends only in particle size (physical property). This property changes by simple treatments, such as grinding, that can be potentially used in the PPP manufacturing/preparation process. Since 100% of the active substance quartz sand is crystalline silica (quartz = crystalline silica, both are the same), the compliance of the specifications for this impurity in the active substance does not guarantee the compliance of these specifications in products due to subsequent processes noted. Consequently, for PPP dusts, the impurity must be controlled, and the following statement should be included in the Review Report and in the specific provisions in Annex of the Regulation renewing the approval: For uses triggering inhalation exposure, the maximum content of respirable crystalline silica (≤10 μm) in the plant protection product (dusts) should not exceed 0.1%.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron – methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, quartz sand, sulcotrione, tebuconazole and urea.

PLAN/2023/997

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 31 August and 30 September 2023. The 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 are proposed depending on where each active substance stands in the renewal process on the basis of the remaining regulatory steps for which maximum time periods are defined in the legislation. The Commission indicated that this approach gives more predictability to Member States to plan their own resources for handling applications. The Commission reminded about the possibility to rescind the extensions at any time.

Two Member States indicated that they could not support the draft act because in their view the extension calculated for halosulfuron-methyl should be shorter, given the hazardous properties of the substance. The Rapporteur Member State of this active substance confirmed that it limited the draft Renewal Assessment Report to the parts of the assessment as regards the fulfilment of the approval criteria as set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009, in accordance with Article 11(4) of Implementing Regulation (EU) No 844/2012. Therefore, the duration of the extension for the active substance was agreed to be shortened to eighteen months.

For quartz sand, as a regulatory decision was proposed for vote during this meeting, it was removed from the draft Regulation.

The vote was taken on the amended act.

Vote taken: Favourable opinion.

The following protocol declarations were made:

- *Denmark votes against the extensions because of aluminium ammonium sulphate. None of the "representative uses" are supported by data and acceptable risk-assessments for all areas. Overall, the lack of data and unresolved risk assessments are substantial and are unlikely to be addressed within a reasonable timeframe."*
- *The active substance Halosulfuron methyl is already classified as Reprotox cat 1B. That is why Spain is not in line to support the extension of the approval period of the substance Halosulfuron methyl. However, as the decision of the extension of the approval period is for 29 active substances, Spain supports the proposal of the EU Commission*
- *The Netherlands does not agree with the extension of the approval period of tebuconazole because of the risks regarding fungal resistance. Nevertheless, because we are faced with a package of substances, we will vote in favour of the entire package.*

B.04 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 substances *Bacillus pumilus* QST 2808 and penflufen.

PLAN/2023/998

The Commission presented this draft Implementing Regulation, setting back the approval period of the active substances *Bacillus pumilus* QST 2808 and penflufen, whose original approval periods were extended by Regulation (EU) 2020/2007 to take into account procedural changes introduced by Regulation (EU) 2020/1740 and became applicable to these active substances. Since no applications for renewal of approval were submitted by the date required in accordance with Article 5 of Regulation (EU) 2020/1740, the current expiry dates will be replaced by the original expiry dates.

The expiry date of the approval period of *Bacillus pumilus* QST 2808 is set back to 31 August 2024.

The expiry date of the approval period of penflufen is set back to 31 January 2024.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

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 refined risk assessment results provided by the Rapporteur Member State. So far, no safe field use could be identified. The Commission asked each Member State whether they support the current draft which restricts uses of captan to greenhouses and, if not, their rationale: 11 Member States indicated support, 8 Member States indicated no support, and 8 Member States indicated that they have no position yet but four of them indicated that the active substance is very important for apple production and/or minor uses.

Many Member States expressed their appreciation for the effort for the further refinements of the risk assessment for captan. Twelve Member States highlighted that the active substance is very important from a socio-economical point of view and that they would like to have the field uses' approval renewed.

From those Member States not supporting or with no position yet, three Member States stated that the restrictions suggested are not realistic in particular because if greenhouses are closed during long periods of time because, between other things, it would also increase the risk of other phytosanitary issues; they also stated that the ecotoxicology issues should and can be solved at Member State level during the authorisation phase because then additional data are available. One Member State suggested to set confirmatory data and another one stressed that the representative field use in the dossier (10 applications per season) is not representing reality anymore, as the products containing captan are alternated with others. Another Member States stressed that there are no risks if the products are applied after flowering.

Two Member States stressed that the new Court ruling may reduce the possibility of granting emergency authorisations in case of restricted renewals. One Member State suggested, supported by other three, that it would be more correct to ban specific uses (i.e. the assessed representative uses which were identified as posing unresolvable risks during the peer review) rather than restricting approvals in a generic way; this because many potential uses are not assessed at EU level during the peer review of the active substance (only one or few representative uses are assessed), and thus many potential uses remain potentially available which have so far not been assessed at EU level but would be fully assessed at Member State level for authorisations and may be safe.

The Commission noted that currently no qualified majority for the current proposal nor for a full renewal proposal seems possible, and that it will reflect.

Member States were invited to comment by 12 June 2023.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Yucca Schidigera* extract 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

This point was postponed.

C.03 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, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/976 RR).

PLAN/2022/976

The Commission suggested to mandate EFSA to clarify based on weight of evidence the level of expected ecotoxicological effects under field conditions in view of the available lower tier studies and fate/behaviour for some naturally occurring active substances (see also point A.09). Member States were invited to comment on this suggestion by 12 June 2023.

In addition, the Commission informed about two comments from Member States received after the last Committee in March 2023. One Member State stated that substances of natural origin cannot automatically be designated as low-risk and on the basis of the current data it would not support a low-risk status of rapeseed. Another Member State added that the recommended risk mitigation measures based on crop free buffer zones to protect aquatic organisms contradict a low-risk status.

C.04 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).

SANTE/11122/2021

The Commission suggested to mandate EFSA to clarify based on weight of evidence the level of expected ecotoxicological effects under field conditions in view of the available lower tier studies and fate/behaviour for some naturally occurring active substances (see also point A.09). Member States were invited to comment on this suggestion by 12 June 2023.

In addition, the Commission presented the updated draft Implementing Regulation and the draft Review Report for the renewal of pelargonic acid together with additional comments received by Member States. The changes made concern the way the active substance's purity is expressed.

The Commission also informed that it had a meeting with the applicants upon their request. The meeting documents together with the clarification of EFSA were uploaded on CIRCABC. Member States were invited to comment by 12 June 2023 on the definition of purity.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance *Cydia pomonella* granulovirus (CpGV) 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/2023/240 RR).

PLAN/2023/240

The Commission presented the draft Implementing Regulation and the updated draft Review Report that proposes a renewal of approval of *Cydia pomonella* granulovirus (CpGV) as low-risk active substance together with the comments on the report received by applicant.

Member States were invited to comment by 12 June 2023.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance triflusulfuron-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 (Draft review report PLAN/2022/2157 RR).

PLAN/2022/2157

The Commission reiterated that it had been discussing the potential application of Article 4.7 both with Member States and internally and that given the hazard of the substances concerned, Article 4.7 must be used very restrictively (see point A.05). The Commission presented the revised Review Report and the draft Implementing Act that reflect this point of view.

The Commission also shared on CIRCA BC the comments from two Member States, from the applicant, and from one stakeholder, and informed about a meeting with the applicant that took place at its request.

Two Member States expressed their support for non-renewal while three Member States reported on the difficulties of their sugar beet growers to find alternatives. The Commission informed about the H2020 project Integrated Weed Management: https://iwmpraise.eu/

Member States were invited to comment and indicate their preliminary positions by 12 June 2023.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance S-metolachlor 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/2023/641/RR).

PLAN/2023/641

The Commission presented the draft documents and informed that a vote is intended for the meeting of this Committee in October. The Commission reminded that the

assessment as regards the potential endocrine disrupting properties was not finalized, but that a confirmation has been sent to the applicant to submit the suitable package of data following the stop-the-clock request EFSA had made during the peer review process.

Several Member States indicated support for the non-renewal but indicated that discussion on the grace period is needed. The Commission also informed that several stakeholders raised their concern as regards a non-renewal as well also some maize producers.

Member States were invited to comment and indicate their preliminary positions by 12 June 2023.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of sodium hypochlorite 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/2021/10408).

SANTE/2021/10406

The Commission asked each Member State whether they support the current draft and, if not, their rationale: 8 Member States were against the proposed approval, 11 Member States would abstain and 8 were in favour.

The main reasons for not being in favour of the draft proposal were the fact that the substance is a substance of concern due to several classifications and therefore does not comply with the definition of a basic substance in Regulation (EC) No 1107/2009; and the fact that the substance is not available on the EU market in the concentration in which it would not be of concern and that the operator would therefore need to wear at least personal protective equipment during the preparation of the product.

The Commission reiterated that this substance is common bleach or “Eau de javel” and that it is approved and allowed to be used in the EU for different purposes, even within households. It is freely available on the EU market and can be bought in concentrations even up the 15% by any user. For these other uses, users are expected to read the label and apply the mentioned precautionary measures such as diluting the substance before use, wearing gloves etc. The Commission also reminded the Member States that the approval as a basic substance would only be allowed for the use in seed treatment and only in concentrations of maximum 1%.

Member States were invited to further explain their positions by 12 June 2023, specifically on whether their position is based purely on the legal point of view that a substance of concern cannot be approved as a basic substance, or because they believe the use of the substance poses a real safety concern as regards the operator.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance fat distillation residues 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 PLAN/2023/637 RR).

PLAN/2023/637

The Commission informed that one Member State commented since the last meeting of this committee, expressing support for the renewal as low-risk if the concentration of the relevant impurity Nickel is limited to 0,01% in the formulated product.

Member States were invited to comment by 12 June 2023.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of hydrogen peroxide silver-stabilised 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/11406/2021).

SANTE/11404/2021

The Commission summarised the procedure for the application of approval of hydrogen peroxide silver-stabilised as a basic substance. In November 2018, the Commission received an application for approval of "hydrogen peroxide stabilised" as basic substance to be used in plant protection as a fungicide and elicitor by spray on field grapevine crops, and as fungicide and elicitor by drip or in a hydroponic bath on the field and in greenhouses on potato, tomato, cucumber and onion. The application was originally treated as an extension of use of the already approved basic substance hydrogen peroxide. However, based on the information submitted by the applicant, it was unclear whether the application should not be regarded as an application for approval of a new substance. As the application was not complete, subsequent revised applications were received in September 2019, December 2019 and August 2020.

The usual evaluation procedure was followed, i.e., the application dossier was distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was invited to address these comments and to complete the application, which was updated in 2021. In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application from EFSA, who submitted to the Commission its technical report on 15 July 2021.

The Commission provided a draft of the Review Report to this Committee and the applicant for comments. Based on EFSA Technical Report, and after discussions at this Committee, it was considered appropriate to include the identity of the declared stabiliser in the name of the substance and to re-define the substance as "silver-stabilised hydrogen peroxide".

The applicant withdrew its application for the approval of silver-stabilised hydrogen peroxide as basic substance by e-mail of 3 April 2023. Due to the withdrawal of the application, the approval procedure was terminated. The Commission made the withdrawal letter available to the Member States on CIRCABC.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of etoxazole which approval expires 31 January 2028.

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The Commission presented the draft Implementing Regulation which defines both the Rapporteur Member State (RMS) and co-rapporteur Member State (co-RMS) for the

purpose of the renewal of the active substance etoxazole, for which the approval period expires on 31 January 2028.

Member States were invited to comment and indicate their preliminary positions by 12 June 2023.