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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***
**14 - 15 May 2025**

***CIRCABC Link:*** *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/71b0946c-af96-4748-9a9a-c0d95f2a74ce?p=1*

# SUMMARY REPORT

## A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the last meeting is in preparation.

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

There was no news to discuss.

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

1. MS experiences and practices (updates and survey)

The Commission informed that the final version of the report on the outsourcing of risk assessment at Member State level was made available on CIRCA BC. The report is not to be published but it will be shared with EFSA.

The Commission reminded that even if the threshold to launch public procurement under Directive 2014/24/EU is not met, still the general rules of the Directive apply and the Member States should make sure that any possible conflict of interest is excluded when they outsource the whole or a part of the risk assessment to external bodies, especially to private companies.

The Commission also stated that the table with the applicable fees per Member State is still not complete. Member States are invited to check the table and send their comments without any further delay.

2. Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008 – implications for DAR/RAR prepared in the context of renewal dossiers

The Commission referred to the discussions at previous meetings of this Committee. There was no additional news to discuss.

3. Annual MS report of the authorisations of plant protection products

The Commission informed that it had already received the reports from all but two Member States and that the Pesticide Database had been updated accordingly. Those two Member States were invited to send their information without any further delay.

4. Delays on regulatory processes

The Commission informed that for some dossiers admissibility has not yet been granted by the respective Rapporteur Member States and referred to discussions which took place at the last meeting of the Pesticide Steering Network.

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

- New active substances / Amendment of conditions of approval

There was no news to discuss.

- Renewal of approval

1. Mecoprop-P

   The Commission summarised the comments received from Member States after the last meeting. These Member States could agree with the proposal to restrict the application rate to 200L/ha. Member States were invited to send comments by 30 May 2025.

2. Amidosulfuron

   The Commission recalled that the main concern for the renewal of approval of amidosulfuron is the impurity 1,2 dichloroethane (1,2 DCE). The Commission suggested that the reasons for non-renewal of the substance might not be strong enough to prevent the renewal, and that to non-renew, the content of 1,2 DCE in the technical specification would need to be above 1g/kg as required for carcinogenic substances and as specified in Annex III to Regulation (EC) No 1107/2009, for unintentional impurities. The Commission informed that the applicant proposed to lower the amount of 1,2 DCE in the technical specification of amidosulfuron to 0.7 g/kg. Based on that the Commission is of the opinion that renewal of the approval of amidosulfuron is possible. Member States were invited to comment by 30 May 2025.

3. Pyrimethanil

   There was no news to discuss.

4. Pirimicarb

   The Commission informed about some additional comments received from Member States and called on the remaining Member States to express their views by 30 May 2025.

5. Formetanate

   There was no news to discuss.

6. Fludioxonil

   The Commission explained that seven Member States had sent comments since the last meeting. One Member State noted that in case of non-renewal, the applicant could apply for approval as new active substance. Another Member State suggested that Article 13(4) of Implementing Regulation (EU) 2020/1740 could be used to justify an additional evaluation under Article 4(7) of Regulation (EC) No 11107/2009, despite of the fact that the required information had not been sent within the legal deadline. The Commission explained that the renewal procedure for fludioxonil had been conducted under Implementing Regulation (EU) No 844/2012, where such provision does not exist.

The Commission informed that it had met with the applicant upon their request. The applicant had explained why the information was not submitted in the time window provided and that the information was submitted later acting in good faith as this was one of the first active substances where the new ED criteria applied to already submitted dossiers. In addition, the applicant informed that they already had the necessary data to address the issues that had not been non-finalised.

One Member State noted that fludioxonil and cyprodinil have similar modes of action and applications and if both fungicides were not renewed this would have very serious consequences for plant protection. Another Member State considered that sodium hypochlorite can be used instead of fludioxonil in some cases. One more Member State asked that if a renewal is granted under Article 4(7) whether it would be possible to market seeds in one Member State when they are treated with fludioxonil in another Member State. A Member State stressed that even if evaluation under Article 4(7) was initiated, the Commission should undertake the necessary steps to protect the consumers.

The Member States were invited to comment by 30 May 2025 regarding a potential renewal or non-renewal of fludioxonil, and whether and how the data on the importance of this active substance can be evaluated in compliance with the applicable legislation.

7. Penoxsulam

   No discussion took place.

8. Paraffin oil (CAS 8042-47-5)

   The Commission informed that EFSA indicated it would revise its Conclusion regarding the unfinalized issues on the acute risk assessment for bees and the off-field NTA risk assessment to follow a harmonised approach with the other on-going paraffin oil assessments. The Commission also shared a comment from a Member State.

   Member States were invited to comment by 6 June 2025.

9. Phosphine

   The Commission explained that human biomonitoring studies presented by the applicant showed that cessation of use of phosphine was associated with a decrease of the frequency of aberrations to values comparable to those observed in the control group and that risk mitigation measures are available and seem effective to protect operators according to the presented studies. In addition, the worst-case scenario for the substance would be a classification as mutagen 2, as an active substance is not to be approved if it is classified as mutagen category 1A or 1B. However, the Rapporteur Member State had submitted a combined Vol1 /CLH -report for phosphides to ECHA that does not propose a genotoxicity classification for the phosphides. Therefore, the Commission is of the opinion that the safe use for phosphine can be demonstrated, so the substance could be renewed.

   Member States were invited to comment by 30 May 2025.

10. Clomazone

    The Commission informed that due to the number of comments from the applicants on EFSA's conclusions, a review of these Conclusions seems necessary. The Commission is currently discussing this with EFSA.

Member States were invited to comment on the applicants' comments by 30 May 2025.

11. Maltodextrin

The Commission presented the EFSA conclusion and indicated that it intends to prepare the documents for a renewal of an approval as a low-risk substance.

Member States were invited to comment by 30 May 2025.

12. Buprofezin

The Commission summarised the EFSA Conclusion. Buprofezin was identified to have endocrine disrupting properties for humans by the T-modality and some issues could not be finalised. The applicant addressed those issues in their comments.

The Commission reminded that all the representative uses of buprofezin are in greenhouses for non-edible crops and that the current approval is also limited to non-edible crops. One Member State commented that the mode of application of plant protection products should also be considered when evaluating if the exposure indoors is negligible.

The Member States were invited to comment by 30 May 2025.

- Basic substances

13. *Quassia amara* L. wood extract

The Commission summarised the comments received from the Member States. One Member State supported the approval of *Quassia amara* L. wood extract as a basic substance because of its use in the food industry and its relatively low risk for many uses. Two Member States would not support the approval because Quassia extract and its component quassin show reproductive toxicity and it is not possible to exclude that such reproductive effects would be mediated by an endocrine mode of action. Moreover, further information is needed to exclude effects on the immune system and on genotoxicity. The appropriate risk assessment for groundwater is missing and low risk to bees and non-target arthropods for all proposed uses cannot be concluded from the available information.

Another Member State thinks that there are too many data gaps relating to the identity of the basic substance, its inherent properties, and the risk assessment for human health to consider *Quassia amara* L. extract as a basic substance meeting the criteria in article 23, regardless of whether the proposed use is field or permanent greenhouses.

Member States were invited to express their position for: 1) non-approval of *Quassia amara* L wood extract as basic substance; 2) approval for all proposed uses; or 3) restricted approval (ornamentals in greenhouse or/and field uses up to BBCH before formation of edible parts of crops).

14. Chitosan and chitosan hydrochloride

The Commission recalled that in March 2022, two Member States requested the Commission to review the approvals of chitosan and chitosan hydrochloride in accordance with Art. 23(6) of Regulation (EC) No 1107/2009. After discussions in this Committee, the Commission mandated EFSA to provide an opinion regarding the approved use(s) of chitosan and chitosan hydrochloride as basic substances. In

February 2025, the EFSA Panel on Plant Protection Products and their Residues (PPPR Panel) adopted a Statement.

Overall, the PPR Panel concluded that the toxicological properties can be extrapolated between chitosan and chitosan hydrochloride and that no toxicological concerns were identified. The estimated levels of chitosan and chitosan hydrochloride in the environment following application in accordance with their approved uses as basic substances would be within the same range, or below, the expected natural background exposure levels and that further consideration in relation to the safety to non-target organisms was not necessary. Thus, the criteria referred to in Art 23 are still satisfied for both chitosan and chitosan hydrochloride and there is no need to withdraw or amend the conditions of approval of these approvals as basic substances. The Review Reports for both substances would be amended to reflect the results of this re-evaluation.

Member States were invited to comment by 6 June 2025.

**A.05 Draft Review/Renewal Reports for discussion:**

- New active substances / Amendment of conditions of approval

1. Clove oil

   The Commission updated about its intention to mandate EFSA with a request to extend the representative uses for the renewal of approval of clove oil with the representative uses for the request to amend the approval conditions (preharvest uses as a nematicide on tomatoes and cucumbers in greenhouses) and to deliver a conclusion regarding the renewal of approval on all these representative uses.

2. Bixlozone

   The Commission informed that the draft Review Report will be shared soon.

- Renewal of approval

3. Pelargonic acid

   The Commission explained that EFSA had updated its Conclusions on pelargonic acid as an outcome of the mandate to further elaborate on the in-field risks to non-target arthropods from the representative use of product MON74134. Considering the update and the comments received from the applicants, the Commission believes that this use can be used to support the renewal of pelargonic acid as a low-risk active substance. One Member State supported this view. Member States were invited to comment by 30 May 2025.

4. Sulfur

   The Commission explained that the applicants do not agree with the EFSA conclusions in particular on the two critical areas of concern of high in-field risk to non-target arthropods other than bees and of high risk to soil macro-organisms.

   The applicants challenged the conclusions because the high in-field risk was derived from a study on *Trichogramma* spp. which is not a standard regulatory test species according to the ESCORT 2 guidance and is not adequate for testing sulfur (e.g. due to volatility of sulfur, repellence towards this species). The applicants proposed to consider the results obtained on the standard non-target arthropods, *Aphidius rhopalosiphi* and *Typhlodromus pyri* where the risks are considered acceptable for

the representative uses of the two representative formulations (Sulfur 80% WG and Sulphur DP), as well for the ground-dwelling arthropods, e.g. *Poecillus cupreus* where the risk is considered acceptable for the representative uses of Sulfur 80% WG.

The Commission asked Member States for their opinion about the second critical area of concern which is linked to the rejection of studies for which only interim reports for earthworm and collembola field studies with the two representative formulations were available in the dossier. The applicant stated that the respective final reports contain no changes in content in materials and methods, results or conclusions with respect to the interim reports.

Member States were invited to comment on the argumentations of the applicants by 6 June 2025 and if a renewal of the approval would be possible.

5. Aluminium silicate calcinated

   There was no news to discuss.

6. Fenoxaprop-P-ethyl

   The Commission explained that EFSA concluded that this substance meets the criteria for endocrine disruption for human health for the A-modality. A discussion on the possibilities for negligible exposure is not possible as the representative uses are all outdoor boom spray applications. It was confirmed by the Rapporteur Member State that no derogations under Article 4(7) was submitted by the applicant during the submission of the application.

   The Commission informed about the comments received from the applicant, an NGO and one Member State on this substance.

   Member States were invited to comment by 30 May 2025.

7. Milbemectin

   The Commission reminded that uncertainties related to the chronic risk assessment for aquatic organisms for uses in open field could be addressed by setting risk mitigation measures to reduce the exposure of the aquatic environment and of the bees and pollinators. In addition, confirmatory information would be requested. The Commission summarised the comments received from Member States and the applicant on the updated Renewal Report.

   Member States were invited to comment by 30 May 2025 in view of a possible vote in the next meeting of the Committee.

8. Triclopyr

   The Commission explained the comments made by Member States after the last meeting. One Member State expressed its preliminary support for a non-renewal based on the critical areas of concern identified for mammals and NTAs. They also said that for the use of spot applications, it has not been demonstrated that there is no risk to the environment. Member States were invited to comment by 30 May 2025.

9. Bensulfuron-methyl

   The Commission explained that the applicant has replied to the request for clarification. The letter and additional information can be found on CIRCABC.

Also, one Member State sent in a technical comment. Member States were invited to comment by 6 June 2025.

10. Spinosad

    The Commission informed that comments were received from four Member States and based on these comments, the Renewal Report was updated. Member States were invited to comment by 30 May 2025.

11. Cyprodinil

    The Commission recalled that the EFSA Conclusion on cyprodinil identified three critical areas of concern and issues that could not be finalised. Three Member States had indicated that they do not see a way to renew the approval in the light of risk assessment findings. Member States were invited to comment by 30 May 2025 on whether the approval of cyprodinil could be renewed or not.

12. Daminozide

    The Commission recalled that the EFSA Conclusion identified one (easy to resolve) critical area of concern related to the maximum level of an impurity and some issues that could not be finalised. The representative uses of daminozide are for non-edible crops in greenhouses and on the field, but it seemed that only indoor uses could serve as a basis for renewal. Currently, the approval is limited to non-edible crops. Only two Member States had sent comments and the response from EFSA on the applicant's comments was only received just before the meeting. Member States were invited to send comments by 30 May 2025.

13. Gibberellic acid (GA3)

    The Commission presented a draft Renewal Report to renew the substance as low risk and a comment from a Member State. Member States were invited to comment by 6 June 2025.

14. Gibberellins (GA4/7)

    The Commission explained that it would share a draft Renewal Report as soon as possible and shared a comment from a Member State. Member States were invited to comment by 6 June 2025.

15. Pyraclostrobin

    The Commission summarised the conclusions of EFSA presented in March, reminding that no critical area of concern is identified, and the active substance is neither ED nor falling under any cut-off criterion.

    The minutes of the PAFF meeting in March 2025 were wrongly pointing to metabolites fulfilling PFAS definition. This statement should be disregarded as the substance does not contain F-moeity.

    There are few open points related to metabolites 500M07, BF 500-15, 500M58, BF 500-6, BF 500-7. Member States were asked to comment by 30 May 2025.

- Basic substances

16. Sodium hypochlorite

    The Commission informed that it has received comments from three Member States. Two of them confirmed that they can support the approval of a solution of sodium hypochlorite of less than 1%. One Member State expressed that it would

not support an approval because it is a substance of concern and operators would be in direct contact with the substance.

The Commission reminded that the Minor Uses Coordination Facility (MUCF) stated that "There is a crucial need for a permanent solution for seed treatment with sodium hypochlorite in Europe. All European countries would benefit from the approval of Sodium hypochlorite as a basic substance. Currently there are emergency authorisation authorised, but they should only remain a temporary solution. The MUCF, the Commodity Expert Group (CEG) Seeds & Mushrooms, along with Euroseeds, advocate that sodium hypochlorite is approved as a basic substance."

The Commission announced that during the next meeting, a tour de table will be held to get an idea of the positions of the Member States. Member States were invited to comment by 30 May 2025.

**A.06 Confirmatory Information:**

1. Pendimethalin

The Commission informed that EFSA was finalising the mandate for an expert discussion on the confirmatory information on pendimethalin. Simultaneously, the evaluation of the renewal application for this active substance by the RMS is on-going. The Member States were invited to consider how to align both on-going regulatory procedures to avoid contradictions, delays, and to have a legally-sound final decision. The RMS informed that it was preparing a dossier for harmonised classification (CHL dossier) of pendimethalin with respect to its PBT properties that will be submitted to ECHA for evaluation.

2. Etoxazole

The Commission informed that EFSA issued its Conclusion on the peer review of etoxazole after the confirmatory information assessment on endocrine disrupting properties. Member States were invited to comment by 6 June 2025.

**A.07 Guidance Documents, in particular:**

1. Memorandum accompanying the compendium of conditions of use to reduce exposure and risk from plant protection products & national (draft) lists on pesticide application equipment or techniques

The Commission reminded that the Compendium is a living document and that it is the intention to list the tools and methods, and to simplify and harmonise where feasible. The is considering setting up a group of experts from the Member States to discuss these issues, starting with drift measurements. Member States were also invited to nominate an expert by 6 June 2025.

Member States were invited to send by 6 June 2025 the list of drift reduction tools/conditions of use and recommended as conditions of authorisation. In addition, Member States were asked to send justifications for the performance values, especially when the performance values exceed those recommended in the EFSA guidelines, and to provide the tests methods used to establish the performance values, e.g. ISO/CEN or national standard protocols, in order to initiate the discussions.

2. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment

The Commission informed that work remained ongoing, and that further news would likely be available for the next meeting of this Committee.

3. Technical guidance on the assessment of negligible exposure to an active substance, safener or synergist in a plant protection product under realistic conditions of use

The Commission informed that the comments submitted by stakeholders were being analysed and that once ready a revised draft would be shared with the Working Group for further discussion.

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

See agenda points C. 01- C. 03.

5. FOCUS surface water scenarios – follow up

The Commission explained that it asked some technical clarifications to EFSA as regards consequences for the aquatic risk assessment from the outcome of the mandate 'repair action' of the FOCUS surface water scenarios, in view of organising the next steps.

The Commission also explained that the FOCUS-Models were developed at the beginning of the 90's, and therefore there is an urgent need to make them compatible with modern IT-programming languages to ensure the continuous availability of these models for environmental risk assessments of active substances and plant protection products on the medium and long term. The Commission is currently exploring options for such IT-programming updates that would not focus on content but programming language, in cooperation with EFSA.

6. Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides

There was no news to discuss.

7. Update of Guidance Document for the regulatory decision making of viruses under Regulation (EC) No 1107/2009

The Commission informed that work is ongoing to amend SANCO/0253/2008 and SANCO/12823/2012 to align these documents with the data requirements of active substances which are micro-organisms which latest update is applicable as from 21 November 2022 (Regulation (EU) No 283/2013).

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

The Commission reiterated that notifications under articles 44(4) and 36(3) should be made via ESFC – which is already used for notifications under Article 53. This will ensure better access to the notifications and easier searchability in the future. In addition, notifications would only be discussed if specifically requested by Member States or the Commission, to ensure that discussion is initiated only when needed.

1. Article 44(4)

The Commission informed that there were two notifications concerning withdrawal of authorisations for two products containing acetamiprid, due to the risk to aquatic organisms which could not be appropriately mitigated.

2. Article 36(3)

The Commission informed that ten notifications had been received since the last meeting of this Committee.

3. Article 53

No discussion on detailed emergency authorisations took place.

**A.09 Microorganism and low risk Active Substances:**

1. New DAR/RAR (Draft Assessment Report / Renewal Assessment Report) template ( **to endorse** )

The Commission informed that the endorsement of these draft DAR/RAR templates is postponed as they are under preparation by some Member States, and as they would need to undergo consultation before being endorsed.

**A.10 Updates, clarifications & questions on specific substances:**

1. Trifluoroacetic acid (TFA)

   The Commission recalled that a second mandate on TFA was under preparation, concerning the formation in soil and leaching into groundwater.

   The Commission informed that one Member State had requested an update from other Member States on actions at national level related to PFAS and/or TFA, and if any Member States were reviewing authorisations. Member States were invited to provide updates in writing.

   One Member State mentioned that based on a study performed on TFA in groundwater, several plant protection products authorised in their jurisdiction were being reviewed and that applicants had been asked to provide comments. Another Member State also indicated that it is reviewing products containing flonicamid.

   Finally, it was noted that an update on activities related to PFAS and TFA in water is intended at the next meeting of this Committee.

2. Talc

   There was no news to discuss.

3. Ozone

   The Commission summarised the state of play as regards the application for an approval of ozone as basic substance. The elements mentioned were the updated application submitted by the applicant, the adopted opinion of RAC proposing harmonised classification of ozone, and an approval of ozone generated from oxygen as an active substance for use in biocidal products.

   Four Member States submitted comments. Three of them support the update of the technical report on ozone as a basic substance. One Member State, based on the current RAC opinion, finds that ozone does not fulfil the requirements in Article 23, and as such there is no need to update the technical report because ozone cannot be approved as a basic substance.

   The Commission informed of a meeting with the applicant and presented the information submitted by the applicant that is related to the current uses of ozone and ozonated water in the agricultural and non-agricultural contexts and included considerations related to the need for risk mitigation measures in uses included in the application for approval as a basic substance.

Member States were invited to comment by 6 June 2025.

4. Dimethenamid-P

The Commission explained the latest developments concerning the reservations expressed by one Member State about the genotoxicity potential of two metabolites M49 and M52 of the active substance Dimethenamid-P. The challenging Member State sent a note which will be further complemented. The applicant confirmed that these metabolites were not found in any metabolism study and were only identified in a lysimeter study. The applicant however followed-up the suggestions discussed last year in the ad hoc experts group set up by the Rapporteur Member State: in order to evaluate the genotoxic properties of these two highly unstable metabolites, additional data was generated with an analogous sub-structure showing negative results in the *in vitro* genotoxicity studies (AMES, HPRT, MNT) that could be used for the read-across to M49 and M52.

The Commission suggested to the initial Rapporteur Member State to consider this new data (2023) carried out with the surrogate compound during the assessment of one of the ongoing requests for authorisation or renewal of authorisation and integrate it in an amended RAR addendum.

## A.11 Article 21:

1. Flupyradifurone

There was no news to report.

2. Tea tree oil

The Commission explained that it sent a letter launching an Article 21 procedure triggered by a RAC opinion concluding a classification as reprotoxic 1B and that the applicant was invited by 6 June 2025 to send information on negligible exposure, or the derogation as set out in Article 4.7.

3. Acetamiprid

The Commission informed that it was intending to ask EFSA to evaluate the feasibility and sufficiency of the testing plan provided by the approval holder to evaluate the developmental neurotoxicity and the endocrine disrupting properties of acetamiprid and the associated deadlines for conducting the proposed studies.

## A.12 General issues for information / discussion:

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

a) Scope document rev.77

The Commission explained that a new daft version of the Scope document (rev.77) was posted on CIRCA BC with several new cases:

- Plastic sheets impregnated with the active substance 1-MCP in order to be gradually released inside the fruit packages. While the requesting Member State recommended to consider the impregnated plastics as a plant protection product as well, the Commission reminded that such ‘treated article’ is not covered by the Regulation and therefore would point to a situation where the plastic foil could be considered as a carrier, not as a plant protection product.

- Product AFIK claimed to be a physical barrier between the insects and the plants to be protected. Similarly to other cases of physical barriers: as long as the claimed effects is avoiding the contact between the crop and the pest, the product should not be considered as a plant protection product, in Commission's view. One Member State objected this conclusion arguing that if the product is killing the pest, it should be considered as a plant protection product.

b) SILTAC, K-PAK, STYX

The Commission explained the latest information received for the cases SILTAC, K-PAK and STYX, based on polyethoxylated siloxanes where the mode of action was explained during previous meeting: increasing the wettability of hydrophobic surfaces including the pests (insects) feeding on plants, which then "die as a result of disruption of physiological processes". This was interpreted as being invasive, putting the three products in the scope of the Regulation.

The K-PAK producer sent information concerning the status of K-PAK in different geographies, reaffirming that K-PAK is not a plant protection product.

The SILTAC producer sent a presentation to support the claimed physical mode of action and the non-invasive effects, resulting in a three-dimensional network which forms around the targeted pests and immobilizes them with a glue-like action. It discussed the product selectivity (only smaller insects would be affected) and the absence of PBT classified compounds in SILTAC (contrary to what was suspected at the last discussion in December). The available test results are more comprehensive than for K-PAK (an MSDS was provided) and STYX (nothing provided).

The Commission mentioned that a law firm acting on behalf of another company than the SILTAC producer denounces this situation of illegal placing/maintenance of a non-authorized plant protection product such as SILTAC on the market and is envisaging legal actions against Member States maintaining the product on the market.

Member States were urged by the Commission to provide their final position as regards the status of those products, as well as their reactions towards procedures to bring the products back on track.

c) Seaweed extract and other plant hormones (overlap with plant biostimulants)

The Commission reminded that the mode of action of seaweed is associated with its high auxin content. In case a product containing auxins is not claimed as plant protection product, the question examined was how it can be claimed as a plant biostimulant considering that its mode of action is not associated with a plant nutrition process.

The Commission recalled that it proposed to segregate the products containing phytohormones either as a plant growth regulator (Regulation (EC) No 1107/2009) or as a plant biostimulant (Regulation (EU) 2019/1009) considering that if the product claims to improve plant root growth it is considered as a plant biostimulant as it will stimulate the plant nutrition due to the stimulated development of the root system; while for effects on all other parts of the plant, by convention this will be considered as a plant growth regulator, hence a plant protection product.

One Member State argued that, if such auxin-rich product would be applied to the foliar part of the plants most likely the plant as well as the roots will be stimulated

to grow. It underlined that some plant hormones (e.g. indolylbutyric acid and gibberellic acid) are approved pesticide active substances, but many other substances are not, even though they fall within the same category as plant growth regulators. For instance, it was reminded that indolbutyric acid is currently approved as a pesticide active substance with the representative use: "Root growth stimulation of cuttings of herbaceous and wooden ornamental plants".

The Commission invited Member States to comment by 6 June 2025. In case the two functions (plant growth regulator and plant biostimulant) it was recalled that the product shall be authorised as plant protection product.

d) CEN standard EN 17700-4 on agronomical traits triggered by plant biostimulant

The Commission explained that the CEN standard EN 17700-4 was drafted with a view to explain further which functionalities and effects are observed after the application of a plant biostimulant on plant physiology. Some examples referred in the draft standard as agronomical traits seem to overlap with the scope of the plant protection product Regulation.

The Commission presented a non-paper including a table analysing the possible overlaps (in particular with the plant growth regulators) that those examples might be generating between the two regulatory frameworks.

Member States were invited to comment on the 'non-paper' available on CIRCA BC by 6 June 2025.

2. Basic substances – general issues

The Commission explained that after internal reflection on different options that could lead to more harmonisation of making basic substances available on the market in EU Member States, it seems that the most appropriate way to introduce the meaningful changes to the current rules would be via amending Article 23 of the Regulation (EC) No 1107/2009. The Commission intends to propose targeted amendments as part of the simplification package announced by the Communication Vision for Agriculture and Food. Member States were invited to submit comments.

3. PFAS

See also point A 10.01.

The Commission informed that the applicant for the renewal of approval of penthiopyrad announced that it was no longer supporting the renewal, therefore, the extension of approval previously granted will be rescinded.

The Commission explained that, in the margins of the ongoing discussion at RAC and SEAC of the upcoming REACH restriction for PFAS substances, stakeholders were pointing to the possible ban of fluorinated-HDPE containers which are highly used in the plant protection products sector (as they protect the content from UV).

The Annex XV preparing the REACH restriction is currently mentioning that for the category 'Other packaging applications', there is sufficiently strong evidence of the availability of technically and economically feasible alternatives for packaging uses of f-HDPE (fluorinated high-density polyethylene).

4. Cut flowers

Postponed.

5. “New” impurities found in plant protection products

   Postponed.

6. Nano-forms of active substances used in plant protection products (update)

   The Commission summarised the reactions received from several Member States about the current situation as regards applications for nano-forms of active substances which were posted on CIRCA-BC:

   - One comment pointed to EFSA’s work and to a new report from the NAMs4NANO project proposing a system for promoting New Approach Methodologies (NAMs) to assess the potential food safety risks of nanoparticles.
   - Another Member State is of the opinion that any “horizontal definition” mentioned in the non-paper distributed in December does not apply to plant protection active substances or products, if this definition/ recommendation is not given in the plant protection regulation. A reference was made to the EFSA “Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health” (EFSA 2021) which applies in principle to plant protection products as well but not if there is no such definition in the scope.

   Two other Member States confirmed that no nano-forms of plant protection products are submitted for approval. Member States were invited to keep the Commission informed of any such applications.

7. Azoles fungicides and resistance in Aspergillus spp.

   The Commission summarised the comments received from two Member States since the last meeting. One Member State suggested a follow up mandate to EFSA to develop a method to assess the potential for cross-resistance with antifungals used in human medicine. A second Member State called for the same as well as other points, including some beyond the discussion on azoles and *Aspergillus* spp.

   The Commission invited other Member States to provide their views and suggestions by 30 May 2025.

8. Copper compounds (residues)

   The Commission explained that EFSA elaborated a draft guidance document to help applicants and authorities to perform the consumer risk assessment of copper under different regulatory procedures. The draft document is including a case study testing the proposed approach and a document highlighting in red the concentration data used in the case study and the PRIMo model 3.1. file used in the case study. All documents have been posted on CIRCA BC and are subject to comments by Member States by 6 June 2025.

   The Committee was also informed about a letter of the Copper Task Force regarding copper levels in processed cereal-based foods for infants and young children, that was discussed in the Residue Section of this Committee.

9. Specific Protection Goals for non-target arthropods, in-soil organisms, non-target plants and indirect effects on biodiversity via trophic interactions.

   The Commission informed about the info session in which EFSA presented its strategy to define Specific Protection Goals for non-target arthropods, in-soil

organisms, non-target plants and indirect effects on biodiversity via trophic interactions. The corresponding document will be published by EFSA on its website.

EFSA and the Commission are revising the internal deadlines for the ongoing mandates on terrestrial ecotoxicology which will be published as an updated outline. The Commission informed that several public consultations and info sessions are foreseen in this outline.

EFSA will now start to work on the lines of evidence as described in the strategy document and the next info session on the setting of specific protection goals is foreseen for the first quarter of 2026.

**A.13 Co-formulants and assessment of formulations:**

The Commission updated about ongoing actions: 1) revision of Commission Regulation (EU) No 284/2013 on data requirements (point C.02) where the request for data on full composition has been strengthened; 2) the creation of an EU list of co-formulants in plant protection products (PPPs) where Member States will be asked soon to complete a list with co-formulants in their countries and 3) the on-going discussion on a proposal on how to move forward with the drafting of a guidance document on the assessment of PPPs including co-formulants where 11 countries and EFSA commented on and 4) a discussion with EFSA and JRC on the technical advancement on synergism in mixtures. Discussions will continue in the next PAI meeting.

**A.14 Implementation of Commission Implementing Regulation (EU) 2023/564 (electronic record keeping):**

The Commission informed that three Member States had send comments since the last meeting, but none had made suggestions on to how to postpone the application of Implementing Regulation (EU) 2023/564 with two years without affecting other legal processes. The Commission also informed that it is still reflecting internally whether a postponement would affect other legislation and in particular the new Regulation on statistics on agricultural input and output (SAIO), which links the introduction of the electronic record-keeping with the data collection on plant protection product use. The Commission recalled that it had adopted Implementing Regulation (EU) 2023/564 in the context of the SAIO Regulation, in response to the calls from the co-legislators.

The Commission also provided clarifications on the provisions of Implementing Regulation (EU) 2023/564 in response to the written contribution from a Member State. A Member State was worried that the application date of Implementing Regulation (EU) 2023/564 is getting closer and there could be no time to adopt measures for postponement. Another Member State inquired on whether it would receive a reply to their contribution sent after the previous meeting.

The Commission repeated its invitation to those Member States that had not yet done so to submit the information on their progress to implement the electronic record-keeping and the experienced difficulties by 30 May 2025. Member States were also invited to send their views on how a postponement of the application of Implementing Regulation (EU) 2023/564 could be done without affecting those Member States who prefer the current date and without affecting the application of the SAIO Regulation and in particular its Article 4(5)(b), read in conjunction with Article 14(2).

**A.15 Report from Working Groups, in particular:**

1. Working Group Post Approval Issues (PAI)

The Commission informed that two Member States sent comments on the latest Template of the Annex to Form C drafted by France and Germany. The Commission shared the comments and the response of France to one Member State. Some of those comments were taken on board and the revised version was uploaded to CIRCA BC. The Committee endorsed the template.

2. Working Group on Biopesticides

The Commission informed that the next meeting is planned for 16-17 June 2025.

**A.16 News and updates, in particular from:**

1. European Food Safety Authority (EFSA)

EFSA informed about progress in the peer review of the risk assessment of active substances, informed about the Pesticide Steering Network meetings, and a project for a support office for pesticide risk assessment (SOPRA), and upcoming publications.

2. Sustainable Use Directive (Directive 2009/128/EC)

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 Committee was debriefed about the recent meeting of the OECD Working Party Pesticides (WPP). In particular, an endorsement of the first consensus document on a micro-organism species (*Beauveria bassiana*). In addition, work will be initiated on (1) Community of Practice – Digital Labels, (2) Guidance document on problem formulation for the assessment of microbial pesticides, and (3) Global Forum data requirements.

Member States are invited to comment by 30 May 2025 on the first draft of the guidance document on Minimum Manufacturing Requirements of Pesticides.

6. Update on Horizon Europe Research projects

There was no news to discuss.

**A.17 Court cases, requests for internal review, Ombudsman cases:**

There was no news to discuss.

**A.18 Exchange of information from the Pesticide Residues section of the Committee, in particular:**

There was no news to discuss.

**A.19 Scientific publications and information submitted by stakeholders:**

The Commission referred to one letter received from Crop Life Europe and two letters received from Pesticide Action Network.

**A.20 Date of next meeting(s):**

The Commission confirmed that the next meeting of this Committee would take place as a hybrid meeting on 9 and 10 July 2025.

**A.21 AoB.**

The Commission thanked those Member States who send input to the potential targeted amendments to Regulation (EC) No 1107/2009 and invited those who still would be interested to contribute soon.

The Commission debriefed the Member States about the COPH meeting which took place 13 and 14 May 2025, in which the reduction of available plant protection products to control quarantine pests by Member States, who need to develop contingency plans, was discussed.

One Member State asked about the implementation of Article 40(2), in particular if there is any restriction as regards the kind of authority which could trigger a mutual recognition via this Article. The Commission suggested to discuss this at the PAI WG.

Another Member State mentioned that the syndrome 'basses richesses' (SBR) is an emerging sugar beet disease. The disease has been observed for the first time in Eastern France but has now spread to other sugar beet growing areas in Germany and Switzerland, but other countries might be infected as well. The planthopper *Pentastiridius leporinus* has been identified as the main transmitting vector of the following pathogens: y-3 proteobacterium (*Candidatus Arsenophonus phytopathogenicus*) and *Stolbur phytoplasma* (*Candidatus Phytoplasma solani*). The Member State would appreciate feedback from the other Member States by 6 June 2025 on whether or not SBR is already present in their territory and if they have granted emergency authorisations against the vector or have effective plant protection products available on the market. Even though the disease or the vector is not present yet, a negative response would help to draw a map and follow the future spreading.

The Commission informed about the concerns of CropLife Europe on the implementation of the revised Birds and Mammals Guidance document which was endorsed in October 2024. One Member State informed that this point has been discussed in a workshop on ecotoxicology of the central zone. The outcome of that discussion will be tabled on the agenda of the Interzonal Steering Committee of June 2025. The outcome of the discussion in the interzonal Committee will be reported in the July meeting of this Committee. The comment from CropLife Europe regarding the version control of the EFSA calculator tool will be forwarded directly to EFSA.

One Member State asked for the planning as regards adjuvants and stressed that they have currently questions of applicants on the issue.

One Member State thanked for the presential meeting and suggested Commission to organise more presential meetings, as travelling is restricted more and more by Member States if there is the possibility to join virtually.

## Section B Draft(s) presented for an opinion

### B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) repealing Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

(PLAN/2022/1649)

The Commission referred to the informative session for Member States that took place on 30 April 2025 to present the final draft and how the comments received after the meeting of this Committee in March had been addressed. The Commission explained that two stakeholders sent letters with some comments on the draft.

The Commission summarised the last comments received from Member States after the informative session and explained the final modifications made to the draft to address those comments.

Member States were asked for their positions: 17 Member States indicated preliminary support, while 5 Member States indicated they would abstain and 4 Member States would be against, because of the hazard bee pictogram, the preference for an end date for implementing the new labelling requirements, and the need of further discussion and clarification on the draft. One Member State had no position (2 %).

The vote was postponed, and Member States were invited to comment by 30 May 2025.

**Vote postponed**.

### 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 quinolin-8-ol as a candidate for substitution 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 Renewal Report PLAN/2024/1247 RR)

(PLAN/2024/1247 rev3)

The Commission presented the draft Implementing Regulation and the draft Renewal Report that addressed the comments received from the Member States. Comments were made by the Member States regarding the approval conditions, the definition of permanent greenhouse, the used calculations, genotoxicity issues and that the active substance is not sold in the Member State. Several Member States that could not support the decision did however express that this was not related to the negligible exposure principle as such.

Spain made the following protocol declaration:

"*Spain supports the proposal of approval of the active substance quinoline-8-ol as candidate of substitution. Nevertheless, some uncertainties remain and have to be clarified through confirmatory data. However, Spain is in favour of promoting these innovative precision technologies*."

**Vote taken:** Favourable opinion.

**B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance Lysate of *Willaertia magna* as a low risk substance 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 Renewal Report PLAN/2025/349 RR)**

(PLAN/2025/349)

The Commission presented the draft Implementing Regulation and the draft Renewal Report that addressed the comments received from the Member States.

**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 Regulation (EU) amending Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, 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**

(PLAN/2023/1937)

Discussed together with C.02 and C.03.

**C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, 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**

(PLAN/2023/1936)

Discussed together with C.01 and C.03.

**C.03 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products**

(PLAN/2023/1934)

The Commission informed that it is finalising the interservice consultations. The Commission reminded that after the interservice consultations, the public consultations via the Feedback Mechanism and the TBT notification will be launched in parallel. The Commission will share the drafts send for the public consultation with the Committee via CIRCA BC. The final texts will then be presented for opinion to the Member States and then subject to scrutiny by the European Parliament and the Council.

**C.04 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing further co-formulants which are not accepted for inclusion in plant protection products**

(PLAN/2024/1813)

The Commission informed on the comments received from one Member State and CropLife Europe.

The commenting Member State proposed correction of some of the CAS numbers and would support a transitional period of five years.

CropLife Europe (CLE) mentioned that a transition period of five years to provide sufficient time for likely reformulation and re-registration, technical comments as regards CAS numbers and naming, the format of the co-formulant reports on the Commission website, and the listing of impurities and some of the substances listed.

Member States were invited to comment by 30 May 2025.

**C.05 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) 2024/1487 as regards the adoption of the work programme for the gradual review of safeners and synergists**

(PLAN/2025/426)

The Commission informed that the Rapporteur Member States for the gradual review of existing safeners and synergists have been appointed and that the draft Commission Regulation (EU) amending Regulation (EU) 2024/1487 will now be prepared for opinion of the Committee at its next meeting in July.

Few Member States flagged the presence in the list of a substance that is also an active ingredient and asked the Commission on the admissibility of this substance. The Commission indicated it will reflect on the way forward.

**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 flutolanil, 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 Renewal Report PLAN/2024/2353 RR)**

(PLAN/2024/2353)

The Commission presented the draft Implementing Regulation and the draft Renewal Report. Some Member States reminded the Commission of the importance of the active substance for the potato industry.

Member States were invited to comment and express their positions by 30 May 2025.

**C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk 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 Renewal Report PLAN/2022/976 RR)**

(PLAN/2022/976)

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

One Member States inquired whether the use in greenhouses should be considered as a specific risk mitigation measure (RMM). The Commission explained that this is a horizontal issue and requires more careful consideration. Another Member State noted that granting the low-risk status to an active substance should not be linked to specific

RMM, because when individual plant protection products are authorised, this evaluation is done in every case and there is duplication of work. The Commission explained that such a change will require an amendment of Regulation (EC) No 1107/2009 through the co-legislative procedure. A third Member State expressed concerns that if an active substance was approved as low-risk, but most of its uses were not low-risk this might create a false impression of safety.

The Member States were invited to comment by 30 March 2025.