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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
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SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that all summary reports of previous meetings are published.

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

1. Lecithins – extension of use as basic substance

The Commission informed that it received a new application for an extension of use of lecithins as a basic substance. The new application covers the extension of use of lecithins to be applied as a fungicide, by spraying outdoors on grass in gardens, green spaces, and infrastructures, especially on sport fields. The application is under validation.

2. Talc – extension of use as basic substance

The Commission informed about the applicant's request to extend the use of talc as a basic substance on grasslands as a fungifuge. However, the Commission stated that the classification of talc as carcinogen recommended by the RAC (Risk Assessment Committee of the ECHA) and issued 26 September 2024, needs to be considered too. Since talc is also used for other purposes, e.g. cosmetics or food additive, further horizontal reflection is needed.

Member States were invited to comment by 4 November 2024.

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

The Commission informed that one Member State had submitted a note on the implementation of Article 30 of Regulation (EC) No 1107/2009, expressing interest in reactivating this provision possible with limit to biopesticides. However, the Commission clarified that Article 30 had been inapplicable since 14 June 2016, as no extension was granted under Article 30(3) of Regulation (EC) No 1107/2009 before the specified deadline. Thus, retroactively reactivating this provision (ex tunc) was not considered feasible. However, the Commission is currently exploring alternative solutions to address this matter.

1. MS experiences and practices (updates and survey)

The Commission informed that it is still analysing the survey on the risk assessment at Member States. There are some difficulties interpreting the results from the survey due to misunderstandings on some questions, in particular the difference between outsourcing to public and to private entities. Some Member States will be contacted to clarify their answers.

2. PIMS database: information on authorisation of plant protection products (note to be endorsed)

The Standing Committee endorsed the "*Note on the information of the authorisations of plant protection products provided annually by the Member States to the Commission*" (document PAFF-PPL-Oct 2024-Doc.A.03.02, see https://webgate.ec.europa.eu/dyna2/pgd/).

The Commission informed that the Member States will receive an invitation in early 2025 to provide information on the plant protection products authorised by them as of 1 January 2025. Their replies should be in accordance with the endorsed note.

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

- New active substances / Amendment of conditions of approval

1. 1-methylcyclopropene (1-MCP)

The Commission presented the EFSA Conclusions and the applicant's comments. 1-MCP is a gas currently used as a growth regulator only in post-harvest settings and closed environments. The applicant has been seeking approval for its use in pre-harvest applications as well.

The (eco)toxicity of the parent compound does not raise major concerns, except for groundwater exposure limits being exceeded in two out of nine scenarios.

According to the applicant, EFSA's assessment is overly conservative regarding both the parent compound (a gas) and one of its metabolites, methallyl alcohol. The applicant argues that this metabolite is present at levels below the 5% trigger value. They also believe that the DT50 values (up to 1,000 days) assigned to the parent compound and the metabolite are overly conservative, as studies on the parent compound showed a DT50 of just one hour, and the metabolite is known to degrade rapidly through mineralization processes.

Moreover, the applicant claims that methallyl alcohol should be excluded from the risk assessment as a metabolite of no concern, in line with the criteria in the guidance document SANCO221/2000rev.11[1], based on its chemical structure. This guidance defines a metabolite of no concern if it is an organic compound with an aliphatic structure, consisting only of C, H, N, or O atoms, with no 'alerting structures' such as epoxides, nitrosamines, nitriles, or other functional groups of known toxicological concern.

The Commission is inclined to propose approval of the new conditions. No comments were made during the meeting. Member States were invited to comment by 21 October 2024.

[1] https://food.ec.europa.eu/system/files/2021-10/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr-rev11.pdf

- Renewal of approval

2. Mecoprop-P

   The Commission informed about the non-dietary exposure for residents, related to the water volume for the representative use (400 L/ha) and concerning the use of the new EFSA calculator (which was not mandatory at the time of dossier submission in 2014). The Commission reminded that the 200 L/ha water volume (safe use) is also included in the representative uses proposed in the renewal dossier and that the use of mecoprop-P applied in 200 L water/ha (or lower) in cereals is a common practice in some Member States where plant protection products containing this active substance are currently approved.

   The Commission explained that EFSA seems to support the worst case of dermal absorption. Following these updated guidance documents (OPEX and dermal absorption), the highest dermal absorption value of 22 % must be used for covering the highest and lowest volume of water for the representative use under consideration. The proposal to use a lower dermal absorption value would deviate from the guidance document approach.

   Five Member States expressed their agreement on the 200 L water/ha approach for identification of the safe use while one disagreed.

   Member States were invited to comment by 21 October 2024.

3. Paraffin oil

   The Commission informed about the EFSA Conclusion that was published in July 2024 and shared the comments of the applicants. One Member State stressed the importance to specify the CAS number (CAS 8042-47-5, chain lengths C17-C31).

   Member States are invited to comment by 4 November 2024.

4. Triclopyr

   The Commission summarised the EFSA Conclusion of triclopyr. There are critical areas of concern regarding the acute and long-term risk to mammals and the risk to non-target arthropods. Member States were invited to comment by 21 October 2024.

5. Amidosulfuron

   The Commission explained that in the EFSA Conclusion there were no areas of concern, but some data gaps were identified. Furthermore, the Commission informed about one relevant impurity, 1,2-Dichloroethane, and its amount in the batches of the active substance submitted for the assessment was much higher than the level finally accepted in EFSA Conclusion. Member States were invited to comment by 4 November 2024.

6. Flufenacet

   The Commission presented the EFSA Conclusion of flufenacet and explained that a critical area of concern and several serious issues that could not be finalised had been identified. Those would most likely preclude the renewal of the active substance. The applicant had submitted its comments where it challenged the Conclusions. EFSA, the Rapporteur and the Co-Rapporteur Member State had been invited to reply to them. Those replies will be provided to this Committee once they

are received. EFSA informed that it was ready with its reply and the Rapporteur Member State added that it would send a reply in near future.

One Member State inquired if - with respect to the flufenacet metabolites - the same approach as with the tritosulfuron metabolites would be adopted as both active substances are PFAS (per- and polyfluoroalkyl substances). The Commission confirmed that this is likely for consistency, and that intends to finalise the regulatory decision making before the current approval of the active substance expires on 15 June 2025.

Member States were invited to comment, in particular on whether flufenacet could be renewed as an active substance or not, by 21 October 2024.

7. Bensulfuron-methyl

   The Commission presented the EFSA Conclusion. Member States were invited to comment by 4 November 2024.

8. Pyrimethanil

   The Commission presented the EFSA Conclusion and the applicant's comments. Member States were invited to comment by 4 November 2024.

- Basic substances

  There were no points to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval

1. Pydiflumetofen

   The Commission informed that the new submitted 28d-inhalation study and the subsequent Rapporteur Member State (RMS) evaluation have been made available to the Committee. A mandate to EFSA will be soon send to peer review the assessment by the RMS, in particular if the 28-day inhalation toxicity study may have an impact on the AOEL (0.03 mg/kg bw/day instead of 0.1 mg/kg bw/day) and on the proposed classification of pydiflumetofen. In addition, the Commission referred to a few Member States comments (some against the acceptability of such a study, some in favour of the EFSA evaluation). Member States were invited to comment by 21 October 2024.

2. Clove oil

   The Commission informed that EFSA identified several critical areas of concern during the peer review of the risk assessment to change the approval conditions for the active substance clove oil. In addition, the procedure for renewal of approval of this substance is currently ongoing but the representative uses for the renewal of approval do not include preharvest uses in greenhouses.

   Member States were invited to comment on the best way forward regarding the amendment of the approval conditions by 4 November 2024.

3. *Pythium oligandrum B301*

   The Commission informed that the EFSA Conclusion was published in July 2024 and does not identify any critical areas of concern, but some issues were not finalised, which however do not seem precluding the substance from approval. The

Commission presented the draft Review Report and invited the Member States to comment by 21 October 2024.

4. *Phthorimaea operculella* granulovirus (PhopGV)

   The Commission informed that the EFSA Conclusion was published in July 2024, and does neither identify any critical areas of concern nor any issues not finalised, hence the substance is proposed for approval as a low-risk substance. The Commission underlined that along the risk assessment, a taxonomical change occurred, and that the micro-organisms was renamed from *Phthorimaea operculella* granulovirus to *Betabaculovirus phoperculellae*.

   The Commission presented the draft Review Report and invited the Member States to comment by 21 October 2024.

5. *Bacillus subtilis* RTI477

   The Commission presented the draft review report and explained that the EFSA Conclusions identified several data gaps relating to the two metabolites subtilisin and surfactin C. *Bacillus subtilis RTI477* and *Bacillus velezensis* RTI301 (see next point) are sharing similar characteristics, mode of action and pattern and are associated in one single representative plant protection product. The draft Review Report is proposing to consider the available information regarding these metabolites of potential concern by applying the principles of the guidance document on metabolites, consequently the active substances could be approved as low-risk. Member States were invited to comment by 21 October 2024.

6. *Bacillus velezensis* RTI301

   The Commission presented the draft review report and explained that the EFSA Conclusions identified several data gaps relating to the two metabolites subtilisin and surfactin C. *Bacillus subtilis RTI477* and *Bacillus velezensis* RTI301 (see previous point) are sharing similar characteristics, mode of action and pattern and are associated in one single representative plant protection product. The draft Review Report is proposing to consider the available information regarding these metabolites of potential concern by applying the principles of the guidance document on metabolites, consequently the active substances could be approved as low-risk. Member States were invited to comment by 21 October 2024.

- Renewal of approval

7. Pelargonic acid

   The Commission informed that it intended to submit a mandate to EFSA to further elaborate on the in-field risks to non-target arthropods from the representative use of MON74134. Since there are no EU-harmonised risk assessment schemes for home garden uses, as an illustrative risk assessment, EFSA would be asked to consider the approach of the Netherlands as described in the Chapter 7 of the "Evaluation Manual for the Authorisation of Plant protection products according to Regulation (EC) No 1107/2009". The Member State were invited to inform the Commission by 21 October 2024 if they objected this approach.

   One Member State informed the Standing Committee that in 8 out of 81 groundwater samples collected in 2022 pelargonic acid was identified at concentration exceeding the limit value of 0.1 µg/L. The Commission noted that this finding was in-line with the Conclusions from the risk assessment that there

might be problems with groundwater contamination when pelargonic acid was applied on some soils.

8. Rape seed oil

   The Commission informed that a mandate to EFSA about the potential for recolonisation/recovery of populations of invertebrate non-target organisms is about to be finalised. The Commission referred to comments from a Member State, whether greenhouses should be regarded as well as a type of cultivation or only as specific risk mitigation measures. Member States were invited to comment, particularly their view on greenhouses, by 4 November 2024.

9. Flutolanil

   The Commission presented EFSA's Conclusions. While EFSA did not identify any critical areas of concern for flutolanil, the Commission highlighted significant risks associated with the representative use on tulips and irises. These included a high chronic risk to aquatic invertebrates, even with mitigation measures, and a high reproductive risk to mammals. Additionally, a chronic risk to adult bees was noted, both for treated crops and succeeding crops.

   The Commission also emphasized that flutolanil is a PFAS and that its metabolite, trifluoroacetic acid (TFA), has been detected in succeeding crops. The participants were reminded that TFA had been the subject of a notification under Article 56 of Regulation (EC) No 1107/2009. Furthermore, the notifier of the REACH registration dossier on TFA (Regulation (EC) No. 1907/2006) provided additional information. Industry has self-classified TFA as toxic to reproduction (Category 2), and in June 2024, Germany submitted a proposal for harmonized classification and labelling (CLH), suggesting classifying TFA as toxic to reproduction (Category 1B). Due to the presence of TFA as a metabolite in succeeding crops, the lack of data on the (geno)toxicity of other metabolites, and the incomplete information on the metabolic behaviour of flutolanil residues in poultry, EFSA deemed the available data insufficient to complete the consumer risk assessment for its use on potatoes.

   In view of this situation, the Commission indicated that there are concerns about the safety of flutolanil for consumers, operators, and workers in the context of its use on seed potatoes, as well as for non-target species in tulip and iris cultivation. Therefore, it indicates that a non-renewal of approval of flutolanil seems indicated.

   There were no requests for the floor during the meeting. The Commission invited Member States to comment by 21 October 2024.

10. Sulfur

    The Commission recalled that two Member States had reacted positively on the suggestion of reducing the BBCH to find a safe use for sulfur. One Member State opposed such an approach, suggesting considering recolonisation of non-target arthropods in the field. The Rapporteur Member State provided an opinion on the risk for non-target organisms by suggesting the possibility to submit additional data at authorisation level such as field studies.

    In addition, Member States were informed that the applicant sent comments expressing its view that interim study reports provided in the dossier should have been considered in the assessment as they can be considered to reflect their respective final reports. Finally, the Commission informed that a new harmonised

classification for sulfur has been published in the 22nd ATP to be in force from 1 May 2026.

There were no requests for the floor during the meeting. The Commission invited Member States to comment by 21 October 2024.

11. Aluminium silicate calcinated

The Commission informed that a mandate to EFSA will be finalised soon. There were no comments of Member States.

12. 8-hydroxyquinoline (quinolin-8-ol)

The Commission recalled that:

- the representative use of quinolin-8-ol is as a fungicide and bactericide against soil-borne pathogens in tomato in permanent greenhouses, applied by drip irrigation;
- according to the available information in the EU Pesticides Database it is currently authorised in 12 Member States;
- quinolin-8-ol is a candidate for substitution (CfS) due to its harmonised classification as toxic for reproduction Category 1B.
- Substances that are classified as R1B can only be approved if it is demonstrated that the exposure is negligible and therefore the discussion if quinolin-8-ol can be renewed is focussed on whether negligible exposure was demonstrated.

The Commission explained that on the basis of the dossier, a renewal with restrictions seems possible, and highlighted the conditions and restrictions that would be set to ensure exposure is negligible. Following a request from one Member State the Commission informed that it was reflecting on setting confirmatory information on genotoxicity to add further confidence to the overall conclusions of the peer review, given that ECHA's Committee for Risk Assessment (RAC) had not considered quinolin-8-ol to be mutagenic, whereas a data gap for more information on genotoxicity was established during the peer review.

Based on the comments received during the previous meetings and in writing the Commission noted that the discussion was more of a conceptual one, related to negligible exposure, rather than on specific technical aspects. The Commission recognised that the current proposal put forward was the first of its kind.

Member States were reminded about the significant amount of time invested during more than 4 years, to finalise a guidance document on negligible exposure. Although such a guidance document is not yet endorsed, good progress has been made and the case of 8-hydroxyquinoline demonstrates how the current draft can work in practice.

The Commission also stressed that the imposition of the use of closed transfer systems (CTS) to ensure exposure of operators is negligible, is an important step and that CTS were already being used – even compulsory - in some Member States. The Commission underlined that if certain technology is available, it should be implemented and that a wider deployment of such devices would contribute to a better protection of operators in the EU. The Commission intends to prepare a mandate to EFSA to consider this aspect as part of an update to the guidance on non-dietary exposure.

Finally, the Commission reminded Member States that if the approval of quinolin-8-ol is renewed it will remain a CfS. Therefore, mutual recognition will not apply.

The Commission invited Member States who had previously opposed the renewal or had no position yet, to comment. One Member State indicated that it is inclined to support, and that wider discussions on CTS should not impede renewal. Another Member State indicated concerns about not having CTS validated at EU level before a possible renewal of approval. The Commission recalled that the applicant would have to demonstrate compliance of products with the conditions of approval, including the negligible exposure of the operators by the use of CTS in their applications of authorisation of plant protection products.

Member States were invited to comment by 21 October 2024.

13. Mepiquat chloride

    The Commission presented the EFSA Conclusion where no issues had been identified that would preclude the renewal of the approval of active substance. Therefore, it also presented draft Renewal Report. The applicant had submitted its comments on both the Conclusion and the draft report. Member States were invited to comment by 21 October 2024.

14. Lenacil

    The Commission updated the Committee and indicated that a renewal seems possible and that it will finalise the draft renewal report soon.

- Basic substances

  There were no points to discuss.

A.06 Confirmatory Information:

1. Difenoconazole

   The Commission informed that the outcome of the peer review related to the isomeric composition and conversion of difenoconazole, as mandated by the Commission, showed that concerns were not identified. Furthermore, the Article 12 review of the MRL was finalised on 29 August 2024.

   Since the risk assessment deadline for the renewal is set by the end of 2024, Member States were invited to send their views by 21 October 2024 on the possibility to consider the confirmatory data superseded by the on-going renewal procedure.

2. Etoxazole

   The Commission informed about the outcome of the EFSA Technical Report issued in July 2024 and a follow-up mandate for a peer review related to the ED assessment for NTOs other than mammals (deadline of the mandate is Q2 of 2025).

3. Thifensulfuron-methyl

   Considering the outcome of the consultation with Member States, the applicant, and EFSA on confirmatory data for thifensulfuron-methyl, the Commission informed on its intention to send a mandate to EFSA to organise an expert consultation to be able to conclude on the genotoxic potential of the metabolite IN-W8268, to further discuss the available refinements of the risk assessment for aquatic organisms when exposed to thifensulfuron-methyl, and to derive an ADI value for the metabolite IN-

L9223 in view of finalising the consumer risk assessment of plant protection products. Member States were invited to comment by 4 November 2024.

A.07 Guidance Documents, in particular:

1. EFSA Guidance Risk assessment for Birds and Mammals (for endorsement)

   The Commission presented the revised cover page and reminded of comments received from Crop Life Europe. One Member State asked for a clarification regarding the use of the benchmark dose approach at national level for authorisations.

The Committee endorsed the guidance document.

2. 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 presented the comments received from two Member States, as well as the latest works initiated regarding possible mandates to EFSA to complement the compendium. One Member State suggested to further discuss the techniques that could be identified to implement the conditions of use set for the recent case of captan as a pilot case to the compendium.

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

   The Commission informed that internal discussions are ongoing following the discussions with Member States.

4. 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, following a consideration of Member State comments and some further discussions in the Working Group, a final draft is now ready for the consultation of stakeholders. This would be likely launched soon.

   The Commissioned noted that once the stakeholder consultation is completed, an update on the comments received and the next steps to finalising the guidance would be provided.

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

   See point A. 13

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

   The Commission reminded that this guidance published by EFSA in 2017 explains how to perform the exposure assessment of soil organisms to plant protection products and their transformation products. This guidance document is not yet endorsed given that the corresponding risk assessment scheme for in-soil organisms has not been aligned yet.

   The Commission explained that EFSA is now reviewing the guidance document on the risk assessment of soil organisms and suggested to remove the point from the

agenda until the guidance is finalised. Member States were invited to comment on this suggestion by 4 November 2024.

7. FOCUS surface water scenarios (ongoing mandate EFSA)

   The Commission clarified that the mandate is finalised since EFSA delivered the outcome in 2020 and apologised for the typo on the agenda.

   The Commission asked EFSA in 2016 to undertake a 'repair action' of the FOCUS surface water scenarios, the associated guidance and calculation tools. The Commission reminded that the main request was to introduce into all FOCUS surface water scenarios a 20-year assessment period instead of the current 12- or 16-month assessment period.

   The Commission reiterated that in one of the PAFF meetings of 2023 EFSA presented to Member States the outcome of the mandate and indicted the need of a risk manager consultation. The Commission explained that it will schedule a meeting with EFSA during the following weeks to discuss how to organise this consultation and that it will inform Member States about the outcome in the next meeting.

8. 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 (for info)

   The Commission reminded that it had requested EFSA to perform a review of the scientific paper of Gimsing et al. (2019) on the design and conduct of groundwater monitoring studies. The EFSA PPR Panel concluded that the paper provides many recommendations and raises several aspects relevant for risk managers. For instance, the EFSA Panel noted that there is a need to develop an agreed exposure assessment goal because the design and interpretation of monitoring studies depends on this goal. The Commission will reflect on the way forward.

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

1. Article 44(4)

   The Commission informed about one notification received since the last meeting: the revocation of the authorisation of a tefluthrin based plant protection product, since information cast serious doubts concerning the details on the manufacturing site as specified by the applicant in its application for the technical equivalence. The decision was taken in terms of Article 44(3)(b), namely, that false or misleading information supplied concerning the facts on which the authorisation was granted.

2. Article 36(3)

   The Commission informed about twelve notifications received since the last meeting of this Committee: seven notifications concerned rejections of mutual recognition applications and five concerned rejections of authorisations under the zonal system. Six of the decisions were challenged at national courts but the appeals were dismissed.

3. Article 53

   The Commission updated Member States on the dialogue with Romania following the repeated issuing of emergency authorisations for treatment of seeds with neonicotinoids for outdoor sowing. A first meeting was held in June 2024 between

the Commission, Romania, Hungary, and Finland. On 20 September 2024 a second meeting was held between Romania and Bulgaria. The meetings enabled an exchange between efficacy experts on how the different Member States are dealing with certain pests in maize, sunflower and cereals. Information was shared, including on ongoing research projects to look for non-chemical alternatives.

The Commission also stressed that granting emergency authorisations for outdoor use of neonicotinoids (imidacloprid, thiamethoxam and clothianidin) is not possible following the Court judgement and urged Romania to not repeat again.

Finally, the Commission also reiterated the commitment to prevent the use of antimicrobials for crop protection which seems to be well complied except for one Member State which keeps delivering emergency uses authorisation for application of antibiotics in fruit yards. The Commission recalled the renewed commitment concerning antimicrobial resistance made by the EU at the United Nations General Assembly (see point A.16.6 of the agenda).

A.09 Microorganism and low risk Active Substances:

The Commission reminded that in June 2024 a meeting was held with Rapporteur Member States currently assessing new biological active substances to understand which factors are possibly delaying these assessments, and the possible solutions/mitigating actions. The meeting highlighted the need of understanding if dedicated teams or dedicated procedures for biologicals active substances are in place for biological active substances.

The Commission informed that a proposal was made by one of the Rapporteur Member States involved in the meeting on how improving the current timings in assessing such new active substances. Member States were invited to comment on the proposal by 4 November 20024.

On the group review on micro-organisms, the Commission recalled that a study is ongoing to gather peer-reviewed information on biology and ecology of microbial species used in EU in plant protection. The Commission underlined that this study would generate monographies on microbial species, which could eventually support the dossier preparation but also the assessment of new strains by risk assessors. The Commission informed that the EU Biopesticides Working Group has been asked to support on the review of the drafts of these monographies, in view of a later endorsement by the Committee once finalised. Member States were invited to give their teams the necessary time to participate in these review exercise.

On the Single Market Enforcement Task Force (SMET), the Commission reminded that this initiative aims at identifying bottlenecks and suggesting solutions concerning access to market of biological pesticides. The Commission informed that a survey was launched addressing Member States authorities responsible for the single market, to understand the status on the implementation of good practices to facilitate access to market of biological pesticides (e.g., mutual recognition, availability of relevant expertise).

On *Bacillus thuringiensis,* the Commission informed that discussion is ongoing with EFSA on a possible mandate concerning generating new data, and that the ‘Bt task force’ sent a letter to the Commission (shared with the Committee) in which disagreements with the studies of Bonis et al. 2021 and Fichant et al. 2024 were raised.

The Commission informed that a new training session of "risk assessment of micro-organisms" under Better Training for Safer Food (BTSF) was made available (from the 10 to the 13 December 2024 in Malta), and that interested Member States can apply for enrolment by 25 October through their national contact point.

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

1. Sodium hydrogen carbonate

   The Commission informed about the judgement in court Case T-43/23 and a letter received from the applicant of sodium hydrogen carbonate. Member States were invited to send their views regarding the approval of sodium hydrogen carbonate as a basic substance by 4 November 2024.

2. Trifluoroacetic acid (TFA)

   The Commission noted that the discussion on TFA was generating interest at both EU and national level, and that there are significant concerns about the presence of it in the environment, in particular in aquatic environments. It was recalled that the use of plant protection products is one but not the only source of TFA, adding further complexity to the discussion. The Commission informed that:

   - it had sent a mandate on TFA to EFSA in July entitled "Request for a review of the toxicological reference values for trifluoroacetic acid (TFA)". EFSA is requested to review the recommended TRVs (ADI and ARfD) for TFA considering the available studies. EFSA shall consult Member States and the deadline is October 2025.
   - it was reflecting on the need for a possible second mandate to further explore and increase understanding about the routes of exposure – this would allow to consider the work done in Germany and other Member States.
   - since the last meeting in July comments have been sent by NL and DE

   The Commission also recalled that -as discussed in previous meetings- there are sufficient grounds to consider TFA as a relevant metabolite for decision-making and that it will continue to work on that basis for decisions concerning active substances.

   Concerning the suggestion by one Member State about the need to go beyond the regular scheduled renewal processes and to launch reviews of approvals, the Commission noted that internal reflections are on-going and reminded the one substance-one assessment approach.

   The Commission also acknowledged the need for consistency and harmonisation at national level and invited Member States to inform after the meeting about ongoing or planned actions.

   One Member State commented on the complexity of the situation, considering the number of active substances involved, and suggested to compile an overview of active substances that are or may be expected to generate TFA, in order to determine whether certain actions would be appropriate. Finally, the Member State noted that it was currently analysing the situation for groundwater impact but had not yet fully considered residues in crops.

   Another Member State explained that pressure was growing nationally to review authorisations and stressed the need to ensure harmonisation throughout the EU.

That Member State also mentioned that according to an analysis performed, half of all TFA in the environment in its territory would come from two active substances and that according to its experts, all PFAS active substances containing the TFA moiety will generate TFA eventually, therefore all such substances should be considered.

Another Member States mentioned that an EU approach on both PFAS and TFA is needed and called for a roadmap with timelines.

The Commission concluded by explaining that discussion on PFAS and TFA remained ongoing within the Commission and recalled that certain actions on TFA had already been launched and others would continue.

Member States were invited to provide information on ongoing actions at national level related to TFA, any information on plant protection products which are authorised where the groundwater assessment showed levels < 0.1 µg/L and general comments or views on how to manage TFA at EU and Member State level by 4 November 2024.

3. Talc

   The Commission informed about the RAC (Risk assessment Committee of the ECHA) recommendation to classify talc as Carcinogen 1B, H350 and STOT RE 1, H372, issued 26 September 2024. Besides being approved as a basic substance, talc is widely used in cosmetics and as a food additive, and therefore horizontal dimension needs to be carefully considered (see also point A.02.2 extension of the use of talc as a basic substance). Member States were invited to comment by 4 November 20024.

4. Labelling of mixed sodium nitro compounds

   The point was postponed as a meeting between the RAC (Risk assessment Committee of the ECHA) and the Rapporteur Member State could not yet be organised.

5. Dimethenamid-P

   The Commission explained that one Member State keeps challenging the conclusions of the zonal assessment regarding the toxicological relevance of two metabolites of dimethenamid-P, i.e. M656PH049 and M656PH052, also following an ad-hoc experts' consultation organised by the Rapporteur Member State. The latter indicated that it will anyway proceed with the pending authorisations for dimethenamid-P plant protection products.

   The Commission invited the Member State challenging the conclusions to submit the prediction data according to the genotoxic potential prediction software (DEREK) and to consider preparing a sound justification and request to launch an early review according to Article 21, if it considers it necessary.

6. Copper compounds

   The Commission informed about the reactions received from five Member States to the suggestion explained at the last meeting of this Committee in July, to amend the current conditions for approval as regards the persistency criterion which has been amended by the CLP (e.g. amending Regulation (EU) No 2023/707 of 19 December 2022) so that it does not apply to organic substances. This would lift the persistency status of copper compounds, hence their candidate for substitution

status. The reactions received so far pointed all to the fact that Annex II to Regulation (EC) No 1107/2009 should be amended first, to align it with the CLP amendment.

Some Member States indicated that the consequences of this alignment shall be assessed during the renewal of approval. Other Member States questioned about the possible discrepancy that could be created for products containing copper compounds under other regulatory framework, hence calling on the necessary prioritisation of the amendment of Annex II.

The Rapporteur Member State of the renewal of the approval of copper compounds confirmed that the assessment had not yet been started due to difficulties encountered with IUCLID which prevented to declare the dossier admissible.

Furthermore, the Commission informed that during the last renewal of approval of copper compounds, the revised Review Report wrongly referred in its section on identity of relevant impurities to only three impurities (lead, cadmium, and arsenic) except for Tribasic copper sulphate which includes eight relevant impurities (in addition nickel, mercury, cobalt, chromium, antimony). Member States are invited to note that the 8 impurities and their related maximum content apply for the specification of the whole group of copper compounds, namely copper hydroxide, copper oxychloride, Bordeaux mixture, tribasic copper sulphate and copper oxide as follows:

- Lead max. 0.0003 g/g of copper content
- Cadmium max. 0.0001 g/g of copper content
- Arsenic max. 0.0001 g/g of copper content
- Nickel 1 mg/g copper content
- Cobalt 3 mg/g copper content
- Mercury 5 mg/g copper content
- Chromium 100 mg/g copper content
- Antimony 7 mg/g copper content

This should be considered when renewing the authorisation of plant protection products or establishing the equivalence statement for new sources of one of the copper compounds. However, the revision of the specifications by the former Rapporteur Member State shall also be considered in view of the renewal of the approval currently ongoing (see above).

Member States were invited to comment about this alignment of the impurity profiles by the 14 October 2024.

7. Ozone

The Commission summarised the status of the ozone application, that was put on hold in January 2022 on a request of applicants who wanted to submit additional information. In December 2023, the applicants provided the updated application, including several studies. The Commission made the updated application available to the Member States.

Given the availability of the new European evaluations of the safety of ozone generated from oxygen as an active substance for the use in biocidal products of

product-types 2, 4, 5 and 11, based on the opinions of the Biocidal Products Committee, and given the updated application submitted by the applicant in December 2023, the Commission considers requesting EFSA to update the Technical Report on the application for approval of ozone as basic substance. It is also proposed to consider in the updated Technical Report the identification of the substance as "ozone generated from oxygen and directly dissolved in water".

One Member State indicated its support for an approval of ozone and soil disinfectants in general. Another Member State also indicated its support for an approval of ozone and mentioned the need to bear in mind the fact that the substance as applied is not ozone itself but ozonated water with very low ozone concentration.

The Member States were invited to comment by 21 October 2024, indicating whether they agree that the Commission requests EFSA to update the Technical Report.

8. Acetamiprid

The Commission recalled that the 23 and 24 September 2024 a meeting of this Committee was held in parallel with a meeting of the pesticide residues section. During this meeting the Commission endorsed the amended Renewal Report for acetamiprid which included an updated residue definition for risk assessment and updated ADI and ARfD values. The endorsement was done in conjuncture with the vote on the draft Commission Regulation adjusting of MRL values for 38 commodities which resulted in qualified majority support for the proposal.

The Commission also informed that it would launch a review the approval of acetamiprid under the provision of Article 21 of Regulation (EC) No 1007/2009. This review will evaluate the developmental neurotoxicity and endocrine disruption properties of the active substance. The first step will be to submit a letter to the approval holder with a request to provide a list of studies on the above properties that it could submit and a timeline for that submission.

A.11 Article 21:

1. Flupyradifurone

The Commission informed that there was no consensus among the Member States on whether to include in the mandate to EFSA under Article 21(2) the additional information submitted by the applicant in March 2024 on the risk assessment of flupyradifurone seed treatments uses in oil seed rape and sugar beet for honeybees and alfalfa leaf cutting bees.

2. Tea tree oil

The Commission informed Member States about a meeting with the applicant, where the explained that they are performing studies to show that the classification proposed by RAC (as R1B) is not appropriate for humans. The applicant considered that the new data should be evaluated before a review under Article 21 of Regulation (EC) No 1107/2009 is initiated. It was noted that discussions remain ongoing in the CARACAL on whether the RAC opinion should be re-opened to take on board new data. The Commission is reflecting and will come back on this at a later meeting of this Committee.

A.12 General issues for information / discussion:

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

- Scope document rev.76 (update)

  The Commission summarised the comments received from three Member States on the rev.76 of the scope document following the integration of the decision tree about physical means or mode of action. The Commission indicated that these comments will be integrated in a revised version to be discussed at the next meeting of this Committee.

- SILTAC, K-PAK, STYX

  The Commission presented the comments received about the status of the product SILTAC and other related products based on polymerized siloxanes, as well as the argumentations and information provided by the manufacturer of SILTAC which is challenging the fact that it should be considered as a plant protection product. The four commenting Member States unanimously confirmed that:

  - the product aims at killing the target pests,
  - contrary to a physical barrier consisting in a layer or a net which is placed or sprayed on a plant or soil and that the pest organisms are not able to cross or overcome, the detailed characteristics of SILTAC described in the analysis and information provided by the manufacturer point to the formation of a net-like polymer structure on body surfaces of (e.g. motile forms of) herbivorous insects and mites which die from this immobilisation,
  - therefore, the direct application of such a chemical on a pest organism should be considered a plant protection product application.

  Member States were also noting the interest expressed by fruit producers in particular for this kind of products. One Member State circulated during the meeting information concerning a safety assessment carried out for these products.

  Member States were invited to comment by 4 November 2024 on the following questions:

  - Are those products commercialised in your Member States?
  - Based on the information provided by manufacturers, do you consider (all of or some of) them as falling in the scope of the Regulation (EC) No 1107/2009?
  - Reaction towards the safety sheet prepared by one Member State (as provided to the Committee the meeting)
  - In case of confirmation of the status as plant protection products, do Member States see the need for a transition period in view of the submission of the necessary dossier for approval as active substance and the further authorisation as plant protection products? How long should this transition period be?
  - How to regularise the situation?

- Cold Atmospheric Plasma

  The Commission presented the information provided by one person from academia towards the technique consisting in generating chemical intermediates (e.g. reactive nitrogen species (RNS) such as nitric oxide (NO), nitrogen dioxide (NO2) and nitric acid (HNO3), and small amounts of hydrogen peroxide, a reactive oxygen species (ROS) and ozone. As these substances are generated to kill pathogenic microorganisms it was concluded in July 2022 that the Cold Atmospheric Plasma technology falls under the scope of the Regulation (EC) No 1107/2009.

  Member States were invited to confirm by 4 November 2024 whether the in-situ generation of reactive nitrogen species is falling in the scope of Regulation (EC) No 1107/2009 and if so, how to consider the compounds generated versus the cold atmospheric plasma generator.

- Procedural aspects – change of status

  The Commission informed about a request from one Member State to complement the introduction to the scope document on procedural aspects (currently indeed only addressing the 'how to present a new request for interpretation') regarding the amendment in the interpretation whether a product falls or not in the scope (see recent case of SILTAC above).

  Member States were invited to send by 4 November 2024 suggestions to complement this second chapter of the introduction with the following elements:

  - Case 1: products in the scope and authorised turn to be not falling anymore after revision: what would be the proposed phase out period?
  - Case 2: products stated as outside the scope and after reassessment becoming subject to the Regulation (in the scope):
    - How long can the products remain on the market? Under which conditions?
    - How long would the manufacturer have to submit the application for active substance approval and afterwards as plant protection product?

2. Basic substances – general issues

   The Commission made available the report from the meeting on basic substances that was held in May 2024. Internal work is in progress to develop options for more harmonisation as regards basic substances.

   One Member State indicated that the most important issue for the Member States is the possibility of controlling the products containing basic substances on the market. This Member State called Commission to establish stronger labelling requirements for the products containing basic substances. It suggested that the update of labelling regulation should include provisions covering basic substances.

   Another Member State agreed that provisions on labelling of basic substances should be added to the current draft to update the existing labelling regulation even if basic substances are in principle not covered by these provisions which concern only plant protection products.

   The Commission reiterated its intention to continue the discussion on basic substances. Member States were invited to send any general comments on basic substances they might have.

3. PFAS (per- and polyfluoroalkyl substances)

   There was no news to discuss.

4. Cut flowers

   There was no news to discuss.

5. “New” impurities found in plant protection products

   There was no news to discuss.

6. Implementation of Commission Implementing Regulation (EU) 2023/564

   The Commission recalled that requirements for the electronic keeping of the records of professional use under the provisions of Article 67 of Regulation (EC) No 1107/2009 as stipulated in Commission Implementing Regulation (EU) 2023/564. It also recalled that this implementing act had adopted in March 2023 as part of a commitment made during the negotiations Regulation (EU) 2022/2379 on statistics on agricultural input and output (SAIO Regulation) as the European Parliament and the Council of the EU, since it was considered that collection of the necessary data would be very difficult in absence of electronic records of the professional pesticide users.

   The Commission reminded that the provisions of Implementing Regulation (EU) 2023/564 will become applicable from 1 January 2026. Therefore, it was necessary to take a stock of the preparations of the Member States for implementation of this act, in particular:

   - The measures that Member States have taken so far to prepare for the implementation;
   - Any specific difficulties Member States have experienced in the preparation for the implementation and the reasons for them;
   - Any difficulties with interpreting the provisions of the Implementing Regulation that require clarification.

   One Member State stated that some of the data to be recorded under the provisions of Implementing Regulation (EU) 2023/564 are outside of the scope of Article 67 and not necessary for statistical and control purposes. It already had electronic record-keeping system, which would need to be modified inline of the new requirements.

   Another Member State noted that while they were making a progress with the preparation for implementation, a significant difficulty was that the professional use of plant protection products is often done by contractors. Those contactors needed to be trained on the new electronic record-keeping requirements. Also, the farmers often had obligations to report on the pesticide use under other European legislation and this created confusion with the obligation of the contractors to keep the records.

   A third Member State recalled that it had not supported the electronic record-keeping as it increases the burden for the farmers, but they were working on setting such systems. They were experiencing technical difficulties in this process.

   Another Member States was also working on setting up the necessary systems but had problems to organise the data gathering process.

A Member States informed that they already were using electronic record-keeping systems but asked for guidance on the definition of 'professional user' at European level.

A Member States recalled that they had requested at the Agriculture and Fisheries Council held on 23 September 2024 that the Commission postponed the applicability of Implementing Regulation (EU) 2023/564 for two years. That request was supported to one extend or another by 17 Member States and opposed only by one. They requested that the Commission presented a proposal to that effect at the December meeting of the Standing Committee. Its government had submitted a letter to the Commission containing that request and the justification for it.

The Commission stressed that record-keeping obligations under Implementing Regulation (EU) 2023/564 are fully in line with the empowerment and the provisions of the basic act. The relations between the contractors and the farmers were also considered and provisions for exchange of records were available. At the same time, it was not possible with this implementing act to go beyond the provisions of the basic act in areas such as creating a request for users to always submit the records to the competent national authorities, to set up centralised databases, etc.

The Commission stated that electronic record-keeping would reduce the burden for the farmers, although initial setting could pose some challenges for the Member States. It acknowledged that farmers had different reporting obligations under different legislation, but electronic records would make this process easier.

The Commission informed that it participated in the discussions at the Agriculture and Fisheries Council and noted that a postponement of the application of the Implementing Regulation (EU) 2023/564 would make it significantly more difficult for the Member States to collect the data required under SAIO Regulation and might be counterproductive. Regarding the letter from the government mentioned in the discussion, a reply will be prepared.

Regarding the definition of 'professional user' as at it comes from Directive 2009/128/EC, the Commission preferred to discuss possible harmonisation at the bodies set under that directive.

Member States were invited to submit the requested information on their preparations for implementation of Implementing Regulation (EU) 2023/564 by 4 November 2024.

A.13 Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013:

The Commission shared the comments received from Member States on the latest drafts and informed that new versions of the draft Regulations will address these comments. The new version of the drafts will be shared after the meeting and Member States were invited to comment by 4 November 2024.

One Member State asked for a clarification on the timing of the actual endorsement of the revised Bee Guidance Document. The Commission explained that this is only possible after the finalisation of the scrutiny period for these drafts after a positive vote.

The Commission informed about a note from the industry about its appreciation that some draft amendments were clearly pointing to their desired definition of biocontrol,

which was not the purpose in Commission's eyes even if the idea will likely be worked out in future proposals.

A.14 Co-formulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574

   The Commission informed that the draft regulation amending Annex III is currently under preparation. The list of notifications -received from 4 Member States and including also two substances found in the EFSA technical report- has been provided to the Committee. Comments received from Crop Life Europe were also made available to the Committee. The Commission recalled the importance of clarification about the issue of impurities: if a co-formulant containing an unacceptable impurity should be listed or if the impurity as such should be listed. Member States were invited to comment by 21 October 2024.

2. On-going actions

   The Commission shared the Member States comments received so far. It informed about the latest discussions with some Member States related to their comments as well as that the Commission also informed the Post Approval Issues (PAI) Working Group in September. The Commission indicated that it is now reflecting on the comments. The report of the June Workshop has been published on the dedicated website on the assessment of plant protection products.

A.15 Report from Working Groups, in particular:

1. Working Group Post Approval Issues (PAI)

   The Commission informed about the last meeting of the Post Approval Issues (PAI) Working Group, held on 18 and 19 September 2024.

   The main points debated were acceptability of parallel trade permits requests during the renewal of products, types of applications for amendment of authorisations impacted by Regulation (EU) 2023/574, implementation of the recent European Court of Justice preliminary rulings, screening of active substances that have undergone an EU assessment according to the new endocrine disrupting criteria, harmonised implementation of the recently adopted captan restrictions to the relevant authorisations, difficulties faced when performing technical equivalences of substances where EFSA conclusions contain data gaps for the reference specification and relevance of impurities.

   The next meeting is planned for 27 and 28 November 2024.

2. Working Group on Biopesticides

   The Commission informed on the main discussion points held at the last Biopesticides Working Group meeting in September 2024 (e.g., on consortia of micro-organisms, on the group review of micro-organisms and on the guidance document on botanicals).

3. Working Group on comparative assessment

   There was no news to discuss.

4. Working Group on Negligible Exposure

   No specific news – see point A 07.04 for information on the draft guidance document.

5. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009

   There was no news to discuss.

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 and the on-going mandates, and informed about the planning of the upcoming expert meetings for the peer reviews. EFSA also informed about the progress on developing a fit for purpose risk assessment for low-concern active substances.

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

   The Commission informed that a SUD WG meeting is confirmed for 12-13 December 2024.

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

   a) Digital Labelling workshop

   The Commission reported about the workshop co-organised with the OECD about digital labelling for pesticides on 17 September 2024. It appeared that there are opportunities to cooperate and set up a project at OECD level: this could address standardisation of digital data to help both the input to regulators (e.g. in view of the submission of dossiers) and the output of the regulatory process (e.g. for the generation of labels in compliance with conditions of use, for the set-up of searchable online database). The Commission will keep Member States informed of the developments of this OECD project.

   b) Consensus Documents on *Beauveria bassiana* and on *Bacillus amyloliquefaciens*

   The Commission informed about the latest developments of these two consensus documents which are developed in parallel to the group reviews (see point A.09 of the agenda above).

   c) Drones Working Group

   The Commission reported about the latest progress made by the OECD WG on Drones (Unmanned Aerial Vehicles – UAV) and the industry task force. Attention is drawn on two publications which could be of interest to Member States, and which were made available to the Committee for information:

- The final version of the Best Management Practices for Safe and Effective Application of Pesticides Using Unmanned Aerial Spray Systems (UASS).
- The final version of the proposed field study protocol Guidance, i.e., recommendations for Conducting UAV Field Drift Trials.

d) Seminar Biopesticides

The Commission informed about the OECD intention to organise a seminar on "Emerging Risk Assessment Approaches in Biopesticides" with 3 half-days concerning (1) semiochemicals and the calculation methods for background levels, (2) *Bacillus thuringiensis* taxonomic change (linked to the discussion concerning toxigenicity of *B. cereus* vs *Bt* and (3) peptides.

e) UNGA on Antimicrobial Resistance Policy

The Commission informed about the political declaration adopted on 27 September 2024 at the United Nations General Assembly which is revising the policy regarding anti-microbial resistance. This declaration was addressed to Quadripartite organizations (FAO, UNEP, WHO, WOAH) for the follow-up which will consist in a progress report on the implementation of the Political Declaration and the organisation of a conference in 2029.

f) Update on Horizon Europe Research projects

The Commission presented the most recent and relevant EU-funded research and innovation projects relating to plant health and plant protection under Horizon 2020 and Horizon Europe. It announced that an innovation day that is currently under development, that would allow interaction between the regulators and the academic community to increase the respective expectations.

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

The Commission informed about the following new applications submitted before the European Court of Justice**: Case T-467/24 (**Deutsche Umwelthilfe e.V. vs. European Commission against the decision of the European Commission to reject the request for internal review under the Arhus Regulation of Implementing Regulation (EU) 2023/1757 concerning the extension of the active substances flufenacet and sulfuryl fluoride) and **Case T-399-24**: (*Collectif des maires antipesticides, Comité de Recherche et d'information indépendante sur le Génie Génétique and Association Agir pour l'Environnement* requesting the annulment of the Commission's decision rejecting the applicant's Aarhus request for an internal review regarding Regulation (EU) 2023/2660 renewing the approval of the active substance glyphosate and of the Regulation (EU) 2023/2660 itself).

The Commission also informed about the following Ombudsman complaints: **Case 177/2023/VB** where the Ombudsman concluded that there is no maladministration in the decision by the European Commission to rely on a standard adopted by the European and Mediterranean Plant Protection Organization (EPPO), and **Case 728/2024/VB** a complaint of PAN Europe on the ZAPID workshop in Braunschweig, December 2023 that the Commission is currently addressing.

The Commission also informed that it received a new Aarhus request for internal review (IRR 2024 **/643077)** from two German NGOs concerning the extension of the approval of the active substance pendimethalin (Commission Implementing Regulation (EU) 2024/2221).

A.18 Exchange of information from the Pesticide Residues section of the Committee:

The Commission informed that at the last meeting of the Residue Section of this Committee MRLs were lowered for fenbuconazole, penconazole, zoxamide and acetamiprid.

A.19 Scientific publications and information submitted by stakeholders:

The Commission informed about documents submitted by CropLife Europe that provide detailed technical views on aspects related to non-relevant metabolites in view of the Commission proposal for a Directive modifying the Water Framework, Groundwater and Environmental Quality Standard Directives. Member States were reminded about the need to ensure discussions are joined up at national level in advance of the on-going Co-Decision trilogues.

CropLife Europe also indicated that more time to develop and submit confirmatory information on the impact of water treatment processes on residues in drinking water is needed, in order to fulfil the demands of the endorsed guidance. Views of Member States on the points raised were invited by 4 November.

The Commission also informed about a letter received from PAN Europe, which address several points on the agenda of this Committee meeting.

A.20 Date of next meeting(s):

The Commission indicated that the next meeting would be in person on 4 and 5 December 2024.

A.21 AoB:

Reporting under Official Control Regulation (OCR): The Commission reminded the Member States that since 2020 the reporting under Article 68 has not longer to be done under this Article of Regulation (EC) No 1107/2009, but it had been included in the annual reports under Article 113(1) of the OCR, and that the Member States representatives should contact their country single body for that purpose. Reporting has to be done via a dedicated e-tool available to the Member States (AROC).

The Commission explained that a Member State informed that *treated seeds contaminated with imidacloprid and thiacloprid* were detected in its territory. The concentrations of these active substance detected on the treated seeds was of very low level (0,02%), the source of contamination was not clear, but it seemed that the seeds were treated in two other EU-Member States.

The Commission reminded that both substances were not approved in the EU which means that the treatment of seeds with plant protection products containing these substances was not possible in any Member State. Furthermore, according to the interpretation of the Commission, the use of seeds treated with plant protection products containing non-approved active substances is also not possible.

For imidacloprid there was no possibility to have emergency authorisations under Article 53 for outdoor uses either as there was explicit prohibition in the non-approval regulation and as according to the judgment of the European Court of Justice in the court case C-162/21, the Member States could not derogate to a restriction set in an implementing regulation. For thiacloprid there were no emergency authorisations

issued for 2024, neither for treatment, nor for sowing of treated seeds. Same for indoor uses of imidacloprid. In addition, the seeds treated under emergency authorisations did not benefit from the free movement of seeds under Article 49.

As to the concentration level, more information would be necessary to clarify the situation. It could be cross-contamination during the seed treatment or cross-contamination during the plant protection products manufacturing process. The Commission reminded also that treatment of seeds for the export outside EU under emergency authorisations was not possible as explained in the emergency authorisations guidance document.

The Member State where the contaminated seeds were detected indicated that they would contact the two Member States where the seeds had been treated to provide them further details. The Member States involved were invited to inform the Committee during the next meeting for the follow up.

The Commission informed about the Commission *roadmap on non-animal testing* and other developments on test methods and validation.

The Commission reminded Member States about the need to ensure that *lists of tests and studies*, as supplied by the Rapporteur Member State following an assessment of an active substance and then subsequently published in the EU Pesticides Database, are correctly sanitised. Member States were asked to double check lists that they had already sent to the Commission and, if necessary, send updated lists.

The Commission informed that a request has been sent to applicant to confirm the deadline for submitting the additional studies for *thiabendazole*, which were requested under Article 21.

The Commission also reminded Member States about the importance to register in the on-line tool AGM for being reimbursed for the meetings participated in person. One Member State informed about the upcoming High Level Meeting of Member States' Competent Authorities.

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) approving the basic substance *Vitis vinifera* L. seed extract (grape seed extract) 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/2024/800 RR)

(PLAN/2024/800)

Vote postponed.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of 1,3,7-trimethyl xanthine (caffeine) 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/10846 /2021)

(SANTE/2021/10844)

The Commission presented the draft Implementing Regulation and the draft Review Report for the non-approval of 1,3,7-trimethyl xanthine (caffeine) as a basic substance.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance *Allium fistulosum*, processed, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2024/798 RR)

(PLAN/2024/798)

The Commission presented the draft Implementing Regulation and the draft Review Report. One Member State indicated it would not support the proposal because sprayed field applications are included in the list of intended uses (GAP table) and in their opinion a safe use has not been demonstrated for aquatic organisms for this type of application. Another Member State supported the proposal but indicated that it would have preferred that a sentence is included in the Review Report that states that operators should wear tight fitting eye protection.

The Commission clarified that the Review Report indicates that the users should consider using commonly available methods to reduce exposure to irritating components during the preparation and use of the substance. It is assumed that there is no need to provide very precise details on the specific risk mitigation measures, because the users are aware of the properties of onion plants which are available to the general public as foodstuff and therefore will be able to choose the necessary precautions that are most suitable to their situation.

Vote taken: Favourable opinion.

B.04 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 metribuzin, 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/2024/1249 RR)

(PLAN/2024/1249)

The Commission presented the draft Implementing Regulation and the draft Renewal Report. Two Member States stated that they would have preferred shorter periods but they would support the Commission's proposal. One Member States noted that it could accept shorter periods.

Vote taken: Favourable opinion.

The following protocol declaration was made by the Netherlands:

The Netherlands are in favor of the proposal for the non-renewal of the substance, but we would prefer a shorter grace period (3+6 months instead of 6+12 months).

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance tritosulfuron, 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/2024/1025 RR)

(PLAN/2024/1025)

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

Vote taken: Favourable opinion.

The following protocol declarations were made:

The following protocol declaration was made by Spain:

Spain supports the Commission proposal for the non-renewal of the active substance Tritosulfuron, however ES is in the opinion that the grace period should be shortened to 3+6 because cut-off criteria are met,

The following protocol declaration was made by Sweden:

Sweden is of the opinion that the ongoing classification process at ECHA should be mentioned in the review report on tritosulfuron, alternatively, what type of effects that triggered the Article 56 notification. The fact that both the parent compound and TFA fall within the PFAS definition should also be included. Both these issues would be of broad interest, but as a minimum the latter should be included in the renewal report. Further to this, in light of withdrawals and the possibility to allow for emergency authorisations for non-approved substances, transparency is of importance.

B.06 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 8-hydroxyquinoline, aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, fluroxypyr, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain Fe 9901, tefluthrin and terbuthylazine.

(PLAN/2024/1841)

The Commission indicated that the approval periods of the thirteen substances included in the draft proposal, expire on 31 December 2024. In this situation, Article 17 of Regulation (EC) No 1107/2009 obliges the Commission to extend the approval period of the substances concerned because it will not be possible to adopt decisions on their renewal or non-renewal before the expiry of the current approval. The length of the extension periods is calculated ad-hoc for each active substance, and it depends on the regulatory steps still needed to be completed in the respective renewal procedures according to the legal timelines.

Three Member States indicated non-support to the extension granted to 8-hydroxyquinoline. The Commission reminded that the substance is currently being discussed at this Committee since 23 May 2024, deliberations are expected to continue and TBT consultation will still need to be carried out before the Committee could vote, therefore the one-year extension is necessary to complete the regulatory procedure.

Another Member State indicated it support the draft but requested the Commission to take a decision as soon as possible for the active substances 8-hydroxyquinoline and terbuthylazine.

Vote taken: Favourable opinion.

B.07 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 periods of the active substances fenpyrazamine and flumetralin

(PLAN/2024/1842)

The Commission informed that this draft Implementing Regulation intends to retract the extensions granted to the approval periods of the two active substances, setting the expiry dates to a close date of 15 January 2025 while giving time to Member States to withdraw the relevant existing authorisations in their territories.

The Commission explained that the retractions proposed are justified because the respective applicants confirmed that they no longer support the applications for the renewal of the approvals.

The Commission informed that it provided a letter from an applicant to the Committee complaining on the retraction proposed. However, Article 17 of Regulation (EC) No 1107/2009 doesn't take the commercial and business decisions into consideration, and therefore it is not possible to justify anymore the extensions granted.

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 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 summarised the comments received from nine Member States on the previous draft which were mainly on the implementation of the digital label, the bee pictogram, the transitional measures, and the wording use for some of the phrases that communicate risk mitigation measures. The Commission explained that a public consultation via feedback mechanism will be launched soon. After that, the Commission would revise the draft to consider last comments from Member States and stakeholders.

During the meeting, the Commission reacted to the main comments sent by Member States. Several Member states explained that at national level, their competent authorities do not approve the final commercial labels of the products and that this is done by the official control bodies. These Member States shared their views on the resources needed in the future to check additional information on the digital labels.

The Commission explained that one Member State requested a meeting to discuss different points on the current proposal in particular on the pictogram, the sentences for

treated seeds, the sensitisation sentence and the sentences related to the protection of human health. This Member State was invited to send concrete proposals on the draft.

The Commission also informed about some views of a stakeholders expressed in several letters received, in which they express

1. the need for clarity on the entry into force and transitional measures for digital labels
2. concerns on the colour scheme since some stakeholders believe that it may discourage the use of biocontrol products and generate confusion with existing labelling regulator requirements, while others found the colour scheme as too favourable to biocontrol products
3. alternatives to the bee pictogram, comments on the sentences proposed for the use of treated seeds, and comments on the sensitisation sentence for micro-organisms.

The Commission also informed about an online workshop from the Agriguide project (https://www.agriguide.eu/) including digital labels for Member States on 18 October 2024.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance milbemectin 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/2018/4326 RR)

(PLAN/2018/4326)

The Commission explained that after the July Committee, it received comments from five Member States on the renewal report.

The Commission also explained that the applicant requested a meeting to discuss the proposed restricted renewal. In this meeting, the applicant explained that a restriction to greenhouses would be disproportionate and claimed that there are safe open field uses authorised in different Member States. The applicant underlined the importance of the substance for some crops like hops for which in some Member States, according to their information, there are no alternatives on the market. In addition, the applicant remarked that two studies were presented in the dossier for the aquatic risk assessment and disregarded during the peer review (an indoor microcosm study and a study to assess the toxicity of the substance towards *Chironomus riparius*). The applicant claimed that the microcosm study was disregarded without considering all the uses presented in the GAP for renewal, i.e. the study covers the GAP of 2 applications (with an interval of application of 10 days) while the peer review did not accept the study arguing that it did not cover 3 applications and neither shorter interval between two applications.

The Commission explained that these studies were discussed during a teleconference in the peer review of 2018 and a data gap was set. The applicant did not have time during the one month stop the clock to provide the study and the chronic risk assessment could not be finalised.

The applicant also explained that according to their view, the chronic risk assessment conducted for Daphnia by EFSA for illustrative purposes is protective enough and

claimed that in 2018 they conducted a new *Chironomus riparius* study (following the OECD 218 Guideline) as requested by EFSA in the data gap set.

The Commission summarised again the different studies submitted by the applicant in the dossier and the ones that were considered (or not) for the aquatic risk assessment during the peer review, and invited Member States to comment on this considering in particular the potential kind of restrictions for the renewal of approval.

Several Member States reacted during the meeting and suggested that other regulatory solutions could be explored to renew the approval also covering the possibility for field uses, such us the request of confirmatory information or the review of the new study by EFSA if requested by the Commission. Some Member States expressed the importance of the substance for outdoor strawberry cultivation and hops and claimed that milbemectin is one of the last acaricides for field uses available in the European market.

Member States were invited to comment by 21 October 2024.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*

(PLAN/2024/2075)

The Commission informed that following the assessment of the confirmatory data required for this active substance, its approval conditions have to be amended to remove the indication that the specification of the technical material as commercially manufactured is provisional and to set the level of lupanine as a marker compound for the relevant impurities quinolizidine alkaloids at a maximum of 0.035g/kg.

The Commission reminded that the amended review report was endorsed by the Standing Committee on Plants, Animals, Food and Feed on 23 May 2024. Member States were invited to comment by 21 October 2024.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council

(PLAN/2024/2004)

The Commission presented the draft Implementing Regulation which intended to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 by deleting those active substances from the Annex to Regulation (EU) No 540/2011, the approval of which had expired or would expire in near future. Member States were invited to comment by 21 October 2024.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2015/408 to update the list of candidates for substitution

(PLAN/2024/2005)

The Commission presented the draft Implementing Regulation which intended to update the list of candidates for substitution by deleting from the Annex to Regulation

(EU) No 2015/408, those active substances that were no longer approved or whose approval would expire in near future. Member States were invited to comment by 21 October 2024.