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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
4 - 5 December 2024

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SUMMARY REPORT

A.01 Summary Report of previous meetings:

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

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

1. Ginger extract – withdrawal of an application for an approval as basic substance

The Commission informed that the application for Ginger extract was withdrawn.

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

1. MS experiences and practices (updates and survey)

The Commission explained that it needed some follow up to the answers of the Member States' survey on the outsourcing of risk assessment and that the results of the survey are expected to be presented during the next meeting.

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 informed that following the Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008, the Regulation (EU) 2024/2865 has been published on the OJ on 20.11.2024. This new Regulation incorporates the new hazard classes into the broader regulatory and operational framework of the CLP Regulation, addressing practical implementation, labelling, and compliance mechanisms. Annex II of Regulation (EC) No 1107/2009 will need to be updated in due time.

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

- New active substances / Amendment of conditions of approval

  1. Bixlozone

  The discussion was postponed.

- Renewal of approval

  2. Mecoprop-P

The Commission informed that during a meeting in October, the applicant explained that the use of 200 L/ha is realistic and leads to a safe use and that the previous assessments using models available at the time of submission showed an acceptable use GAP with the use of 200 L/ha. Several Member States expressed the same position in the past. Member States were invited to send comments by 17 January 2025, on the acceptability of the use of 200 L/ha.

3. Triclopyr

The Commission explained that it had a meeting with the applicant regarding the issues raised in the EFSA Conclusion. They focused on the spot treatments as a specific representative use, and they would also send additional comments.

The Commission also informed that besides the two critical areas of concern on risks to mammals and non-target organisms, there are also still several issues that could not be finalised.

Member States were invited to send comments by 17 January 2025.

4. Amidosulfuron

There was no news to discuss.

5. Bensulfuron-methyl

The Commission presented the main elements from the EFSA conclusion. The most important point is that, based on the available estimates for the representative uses in spring cereals, there is the potential for groundwater exposure by bensulfuron-methyl as well as several metabolites above the parametric drinking water limit of 0.1µg/L in all FOCUS scenarios. This led to a critical area of concern. Additionally, EFSA could not conclude that at least one of the representative uses of rice will not result in the legal parametric drinking water limit being exceeded. Several issues that could not be finalised were also concluded by EFSA, all related to the groundwater, surface water and drinking water.

The Commission explained that the applicant claims that no account has been taken of the Covid conditions that were valid at the time of submission of their dossier. The Commission explained that all the relevant studies were only recently finalised, so well after Covid.

Member States were invited to send comments by 17 January 2025.

6. Pyrimethanil

The Commission summarised the comments received from two Member States on the toxicological, fate and residues sections of the EFSA Conclusion.

The Commission informed about a meeting with the applicant to discuss the potential implications when setting Maximum Residue Levels (MRLs) due to the new toxicological reference values (TRVs) proposed in the EFSA Conclusion. These values are lower than the ones set for the current approval. The applicant also explained that the new TRVs imply that for the renewal of authorisations, significant experimental work will be needed before the authorisations can be renewed. A position paper from the applicant was made available to Member States.

7. Pirimicarb

The Commission summarised the main findings in the EFSA Conclusion, noting that for edible crops and field uses there are several risks identified. For the use on ornamental plants in greenhouses, some concerns were identified.

Member States were invited to consider the outcome of the risk assessment and the possibility and feasibility to set specific conditions and restrictions. Member States were invited to send comments by 6 January 2025.

8. Fludioxonil

The Commission presented the EFSA Conclusion and explained that the substance meets the criteria for endocrine disruptor to humans and non-target organisms by the EAS modality. Also, other important issues were identified. Comments from the applicant on the EFSA Conclusion and a reply from EFSA have been provided.

The Commission reminded that the applicant did not submit data to demonstrate negligible exposure nor on the importance of fludioxonil under Article 4(7) of Regulation (EC) No 1107/2009 within the statutory deadlines despite being explicitly informed about that possibility. Later it submitted data claiming that the exposure of humans and the environment to fludioxonil was negligible under realistic conditions of use, for uses as a fungicide in ornamentals in permanent (high technology) greenhouses, i.e. a non-representative use. Also, data on the importance of fludioxonil was submitted to rapporteur Member State. The applicant had asked the Commission to initiate an evaluation under the provisions of Article 4(7) of that data. Many stakeholders had sent letters to support such an evaluation. The Commission explained that, while it fully appreciated the importance of fludioxonil, for legal reasons a priori it cannot initiate such an evaluation. Therefore, the Commission indicated that a renewal of approval seems unlikely.

Nine Member States reacted during the meeting and indicated that fludioxonil was a very important fungicidal active substance and in many cases, they had no alternatives. They stressed that the possibility to apply Article 4(7) should be seriously considered.

Member States were invited to comment by 17 January 2025 on their views regarding a potential renewal and if and how the data on the importance of this active substance should be considered.

9. Penoxsulam

The Commission informed about the main elements of the EFSA Conclusion. This substance is a PFAS and has 7 relevant metabolites some being PFAS. Data gaps were identified for further toxicological assessment of metabolites, some occurring in groundwater above 0.1 µg/L. Currently, no information is reported in the Conclusion about TFA as a metabolite. The applicants' comments on the EFSA Conclusion were made available

Member States were invited to comment by 17 January 2025.

10. Gibberellic acid (GA3)

The Commission informed about the main elements of the EFSA Conclusion and shared the comments of the applicants. Member States were invited to comment by 17 January 2025.

11. Gibberellins (GA4/7)

The Commission informed about the main elements of the EFSA Conclusion and shared the comments of the applicants. Member States were invited to comment by 17 January 2025.

12. Paraffin oil

The Commission shared the comments received from two Member States (one supporting and one disapproving a renewal), and provided its reflections on the open, non-finalised issues such as the consumer risk assessment, the off-field non-target arthropods assessment and the risk assessment to bees. The Commission is considering mandating EFSA on some of those points to finalise the risk assessment. Member States were invited to comment by 17 January 2024.

- Basic substances:

  There was no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval

  1. Pydiflumetofen

  The Commission informed that a mandate has been sent to EFSA in order to peer-review the 28-day inhalation study submitted as a supportive study by the applicant, but which was considered relevant by the Rapporteur Member State, to revise the AOEL and the classification as STOT. The mandate should be completed by the end of March 2025.

  2. Clove oil

  The Commission informed of a meeting with the applicant and a letter sent by them after that meeting. In that letter, the applicant refers to the renewal of approval file of clove oil, as regards the critical areas of concern identified by EFSA in order to lift the proposed restriction. The Commission furthermore shared comments received from three Member States indicating no support for lifting the approval restriction.

  The Commission considers sending a mandate to EFSA with a request to extend the representative uses for the renewal of approval with the preharvest uses as a nematicide on tomatoes and cucumbers in greenhouses.

  3. 1-methylcyclopropene

  The Commission presented an addendum to the renewal report for the active substance 1-MCP, proposing to amend its conditions of approval to expand its use from post-harvest to pre-harvest applications. The risk assessment for environmental and ecological impacts was updated by the Rapporteur Member State and peer-reviewed by EFSA. EFSA's conclusions indicated no significant risks from 1-MCP itself, though two groundwater scenarios exceeded risk limits, and the presence of a potentially relevant metabolite, methallyl alcohol, could not be excluded.

  However, methallyl alcohol was not detected in significant amounts in soil mineralization studies but appeared in hydrolysis studies under stress conditions, which may have influenced the results. The Commission considers the formation of

this metabolite in real-world conditions to be minimal but suggested to request confirmatory data to clarify its formation and, if relevant, toxicological relevance and potential risks to soil and aquatic organisms. Member States were invited to comment by January 17 2025.

4. Elemental iron

The Commission invited Members States to comment on the draft renewal report by 6 January 2025.

- Renewal of approval

5. Pelargonic acid

The Commission informed that a mandate to EFSA to further elaborate on the in-field risks to non-target arthropods from the representative use of MON74134 had been sent.

One Member State informed that it had received a letter from an applicant on how salts of pelargonic acid, formed upon formulation of the plant protection products, should be treated from a regulatory point of view. The Commission explained that it was aware of the issue and considered it a horizontal one, not specifically linked to this active substance and that it will reflect.

6. Rape seed oil

The Commission informed that it is discussing a follow up mandate with EFSA.

7. Sulfur

The Commission informed about the comments received from four Member States. One Member State had suggested to consider recolonization of non-target arthropods (according to the provisions of the MAGPIE project). The Commission asked the Rapporteur for its view on this and will then consider mandating EFSA. Member States were invited to comment on these considerations by 17 January 2025.

8. Aluminium silicate calcinated

The Commission informed that it is discussing a follow up mandate with EFSA.

9. Lenacil

The Commission informed that the draft of the renewal report was sent to the applicant for the comments. The draft renewal report proposes to renew the approval and withdraw the status as candidate for substitution.

The Commission also informed that one Member State sent comments related to one of the metabolites which has to be regarded as relevant based on the classification of lenacil (carcinogenic 2). The Commission agreed that it is important to avoid the presence of this metabolite in groundwater, but that safe scenarios were identified, and that Member States can address this issue, if necessary, while authorising plant protection products.

The Commission invited Members States to comment on the draft renewal report by 6 January 2025.

10. Fenoxaprop-P-ethyl

The Commission summarised the main findings of the EFSA Conclusion, noting the multiple issues not finalised and the critical area of concern that fenoxaprop-p-ethyl meets the criteria for endocrine disruption for human health for the A-modality. The Commission shared the comments of the applicants on the EFSA conclusion.

Member States were invited to comment on the EFSA conclusion and the comments from the applicants by 17 January 2025.

11. 8-hydroxyquinoline (quinolin-8-ol)

The Commission explained that it had received comments from 6 Member States. Some Member States requested additions to the Review Report or amendments.

The Commission stressed once more that, if Member States would agree to renew quinolin-8-ol under the proposed conditions, it would remain a candidate for substitution. Member States will therefore only authorise if there are no alternatives and not be obliged to mutually recognise authorisations, i.e. they would have full control over whether to authorise plant protection products containing quinolin-8-ol on their territory or not.

The Commission also mentioned that there are plant protection products containing this substance authorised in 12 Member States. Even though the substance or the system may not be used in their country, there are still farmers that need the substance, and it can be part of a wider toolbox of solutions.

All Member States were asked for their positions on the current draft: 18 were in favour of the proposed restricted renewal of approval, 3 against, 6 abstained or were not present.

Member States were invited to send any further comments by 6 January 2025.

12. Milbemectin

The Commission explained that after the October meeting of this Committee, it received more comments from the applicant highlighting the importance of the substance to achieve adequate resistance management, since in their view, milbemectin has a unique mode of action. The applicant provided an overview of the remaining mode of actions that would be available for crops grown outdoors for which milbemectin is currently used if the restriction of greenhouse is adopted.

The Commission summarised the comments received from 17 Member States on the available alternatives to control the pests of the current crops for which milbemectin is authorised and on the potential kind of restrictions for the renewal of approval. Ten Member States confirmed the importance of the substance as acaricide for outdoor uses - some of them explained that outdoor uses are authorised in their countries with risk mitigation measures for aquatic organisms and bees. One Member State explained that it would support a restriction to greenhouses.

Member States were invited to comment on the potential restrictions by 10 January 2024.

- Basic substances:

  There was no news to discuss.

A.06 Confirmatory Information:

1. Difenoconazole

   The Commission explained that it is agreed that, although a new uncertainty factor of 1.3 was proposed for refining the dietary and no-dietary risk assessment in the absence of toxicological data on individual isomers for all plant crops, no concerns were identified. Furthermore, Regulation (EU) 2024/2612 establishing new maximum residue levels for difenoconazole in or on certain products, is applicable since 28 October 2024.

   The Commission informed that three Member States indicated support to the suggestions presented in the October meeting: to consider the confirmatory data on the possible impact of the variable isomer ratio and the preferential degradation/conversion of the mixture of isomers on the consumer risk assessment as superseded by the current on-going renewal procedure.

   One Member State mentioned the difficulties faced with this substance to reach a common approach in the framework of the zonal assessment for difenoconazole based plant protection products. This Member State asked the Commission to formalise the conclusion of this confirmatory data e.g. in the report of this meeting.

2. Thifensulfuron-methyl

   During the last meeting of this Committee, the Commission explained its intention to send a mandate to EFSA to organise an expert consultation on three issues:

   - 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;
   - to derive an ADI value for the metabolite IN-L9223, in view of finalising the consumer risk assessment of plant protection products.

   Two Member States sent comments in support of the Commission proposal. Therefore, the Commission will send this mandate to EFSA.

3. Submission of confirmatory information related to the Guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

   The Commission recalled that CropLife Europe had indicated that for some cases more time is needed to develop and submit confirmatory information on the impact of water treatment processes on residues in drinking water, in order to fulfil the demands of the endorsed guidance.

   The Commission explained that EFSA confirmed that the deadline given to approval holders to submit the information by 20 March 2026 may not be feasible in many cases depending on the complexity and scale of the data to be generated. Two Member States sent comments with similar arguments.

   The Commission remarked that the legal obligation to submit the confirmatory information remains. It will therefore prepare a letter to inform applicants on how to proceed in cases where they will not be able to submit all necessary information in line with the Guidance Document by 20 March 2026.

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 informed it is negotiating a mandate with EFSA related to the OPEX guidance update, notably as regards the integration of the closed transfer systems into this guidance.

   The Commission reminded Member States to send information to complement the compendium with the techniques available at national level, as agreed in the Memorandum accompanying the Compendium.

   The Commission also reminded the conditions set in the renewal of approval of captan that clearly refer to uses with pesticide application equipment that increases the precision and accuracy of the application maintaining the application rate on the target crop surfaces and – at the same time – indirectly reducing the applied plant protection product per hectare, and encouraged discussion among Member States to share guidance or procedures developed to implement these conditions.

   The Commission invited Member States to share national experiences on risk mitigation measures able to meet the requirements of the captan Implementing Regulation and to send information that would add to the knowledge on closed transfer systems. Member States were invited to comment by 6 January 2025.

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

   The Commission informed that internal discussions remained ongoing and that a further update is expected at the next meeting.

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 a stakeholder consultation on the draft guidance prepared by the Working Group would be initiated shortly.

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

   See points C.02 - C.03.

5. FOCUS surface water scenarios – follow up

   There was no news to discuss.

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.

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

The Commission informed on the development of a new functionality in the E-Submission Food Chain (ESFC) Platform, currently in use for the submission of emergency authorisations, that would allow Member States to also encode notifications under Articles 36 and 44. This aims to facilitate communication among Member States

and Commission, and work is in progress. The new notifications forms are very simple, and a testing phase is deemed not necessary. The date by which these notifications need to be encoded in ESFC will be indicated in future meetings of this Committee.

1. Article 44(4)

   There were no notifications received.

2. Article 36(3)

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

3. Article 53

   One Member State had suggested that, in case third parties are challenging the emergency use authorisations delivered by one particular Member State, this Member State should be asked to check the reliability of the allegations as preparation of any further discussion at this Committee. Member States were invited to comment on this suggestion by 17 January 2025.

A.09 Microorganism and low risk Active Substances:

The Commission reminded that during the last meeting of this Committee, Member States were asked to provide information on whether they had dedicated teams or procedures for assessing new biological active substances. They were also asked to comment on a proposal made by one of the Rapporteur Member States of new biological active substances on how to improve the current timings in assessing such substances. The Commission summarised the comments received and invited the remaining Member States to provide comment by 17 January 2025.

Three Member States highlighted that dedicated teams for biological active substances may not necessarily lead to reduce their time to access to market, as their internal organisations differ.

A Member State underlined that in its country biological pesticides are still not widely used by farmers, hence accelerating access to the market of these products alone would not have a significant impact.

The Commission reminded that on innovative substances (e.g., peptides, bacteriophages, iRNA) work is ongoing, together with EFSA, to foster knowledge exchange among Member States (e.g., workshops).

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

1. Sodium hydrogen carbonate (updated renewal report)

   The Commission shared a comment from a Member State as well as a letter from a law firm asking to withdraw the approval of sodium hydrogen carbonate as a basic substance.

   The Commission presented a draft revised review report which excludes the use of sodium hydrogen carbonate as a basic substance in grapevine for the Member States Austria and Germany, where a plant protection product based on the low-risk active

substance sodium hydrogen carbonate is available on the market for use in grapevine ('Natrisan').

One Member State asked if the table with uses in Appendix II of the review report of sodium hydrogen carbonate as a basic substance can be extended. The Commission confirmed this would be in line with the proposed revised review report for this substance. One Member State indicated supporting extending the uses.

Another Member State expressed their concerns because prices for 'Natrisan' are determined by the applicant. That Member State would prefer a different solution.

One Member State indicated support and pointed to a national voluntary system for recording the use of basic substances. Another Member State indicated that it will be interesting to see if the use in grapevine will be recorded or not.

One Member State considered the need to revise Article 23 of Regulation (EU) No 1107/2009. The Commission referred for this to the general discussion on basic substances under agenda point A 12.2.

Member States were invited to send comments on the draft revised review report by 17 January 2025.

2. Copper compounds (updated renewal report to endorse)

The Member States endorsed the amended renewal report which now aligns the whole group of copper compounds, namely copper hydroxide, copper oxychloride, Bordeaux mixture, tribasic copper sulphate and copper oxide, the specification including 8 impurities and their related maximum contents.

One Member State reminded about its declaration made during the last amendment of the renewal report concerning the need to mandate EFSA to review the AOEL for copper compounds. As this was not part of the conclusions supporting the amendment of the ADI endorsed in January 2024, the Commission suggested to cover this via the ongoing renewal process.

Regarding the consequences for the status of copper compounds as candidate for substitution of the amended CLP persistency criterion set by Commission Delegated Regulation (EU) 2023/707, the Commission encouraged the rapporteur Member State to urgently proceed with a proposal to amend the harmonised classification, as this would be the basis to further regulatory action.

3. Trifluoroacetic acid (TFA)

The Commission informed that the EFSA WG set up to work on the mandate on toxicological reference values of TFA has started its work and that some further general comments were submitted by Member States since October.

Member States were also informed about a report on sources of TFA in groundwater in Denmark. Importantly, the report highlighted the role of precipitation in the contamination of groundwater with TFA, as well as the role of pesticides.

The Commission noted that the vast majority (25) of approved PFAS active substances are currently under renewal, with conclusions being available already as of today for 3 substances. Several other dossiers are in an advanced stage of peer review. However, for other dossiers the assessment is still at RMS level and delayed. Therefore, the Commission urged the respective Rapporteur Member

States to ensure that the assessments are finalised without further delay, so that the peer review can begin.

The Commission also responded to the call from some Member States to consider a prioritisation of the assessment of TFA formation, in view of being able to decide on active substances more rapidly. A full assessment of toxicology and residues is needed for certain MRL processes – therefore, truncating assessments, in particular limiting to environmental parts only, would lead to the need for ad hoc processes, creating an unpredictable situation and a higher workload.

Finally, the Commission informed that further internal discussions on PFAS and TFA remains ongoing.

4. Talc

   Point postponed.

5. Ozone

   There was no news to discuss.

6. Dimethenamid-P

   There was no news to discuss. The Member State who indicated challenging the outcome of the zonal assessment still needs to reflect on how to proceed formally.

A.11 Article 21:

The Commission informed that on 29 November 2024 the applicant sent to Rapporteur Member State the additional data to assess the endocrine disrupting properties for thiabendazole.

1. Flupyradifurone

   The Commission informed the mandate to EFSA for an assessment under Article 21(2) to evaluate the information submitted by the applicant on the effect on bees is expected to be sent out soon.

2. Tea tree oil

   The Commission informed that the letter to the applicant launching the Article 21 procedure was sent, inviting to provide comments as well as information on negligible exposure and Article 4.7 of Regulation (EC) No 1107/2009.

   The Commission confirmed that it was not aware of the re-opening of the assessment by ECHA of the current proposal for classification.

3. Acetamiprid

   The Commission informed that it had launched a review of the approval of acetamiprid under the provision of Article 21 of Regulation (EC) No 1107/2009 that would evaluate the developmental neurotoxicity and its endocrine disrupting properties. As a first step, a letter had been sent to the approval holder with a request to provide a testing plan for those properties. That plan, together with the associated deadlines for conducting the studies, will be evaluated by EFSA and the rapporteur Member State. The final list of studies that should be provided will be sent to the approval holder.

   One Member State informed that some retailers on its territory had refused to accept products that do not comply with the newly voted MRLs that are not yet into force.

It asked, supported by another Member State, the Commission to ensure that old values of TRVs and MRLs are displayed together with the new ones. The Commission referred the discussion to the Residues section of this Committee.

A.12 General issues for information / discussion:

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

   a) Scope document rev.76

   The Commission briefly presented the comments received from two Member States about some of the last entries (Vegetal Glue and Seaweed extract) and about entries concerned by the last amendment of the scope document concerning physical barriers.

   b) SILTAC, K-PAK, STYX

   The latest reactions from 5 Member States as well as the reactions from the applicants were explained by the Commission. Two Member States informed that the products were placed on the market not as plant protection products but rather as adjuvants. One delegate suggested asking for the compliance of the product with the safety standards imposed by the Food Law for any chemical applied in the food chain. The Commission informed that the classification of several polymerised siloxanes was pointing to the PBT classification. Member States discussed how to solve this change in interpretation maintaining the availability of the product, which seems to be quite used in certain Member States. Member States were invited to comment on the suggestions made during the discussion by 6th January.

   c) Cold Atmospheric Plasma

   The Commission informed about the recent additional explanations provided by the applicant and confirmed that a device generating active substances as such is not falling under the scope. The scope document will be further clarified with a clearer delimitation based on the following principle: if a substance/molecule is applied to plants/crops in order to protect them from pathogenic organisms, the substance/molecule/application is to be regarded as falling in the scope of the Regulation (EC) No 1107/2009.

2. Basic substances – general issues

   The Commission informed that it is working on the development of options that could lead to more harmonisation of the making basic substances available on the market in EU Member States, which will be further discussed with Member States once available.

3. PFAS

   No news to discuss.

4. Cut flowers

   The Commission informed about a case reported in the media in one Member State. The concerned Member State gave additional explanations about this case.

5. “New” impurities found in plant protection products

   One Member State requested clarification on how products, containing small amounts of impurities which are not part of the reference specification (but known to be hazardous), should be handled. This is mostly relevant when there are different

manufacturing sources, even if in case of evidence of technical equivalence. The Commission suggested discussing this issue in the Post Approval Issues Working Group.

6. Update on mandate on the development of protocols for the assessment of emergency authorisations

   The Commission recalled that in December 2022, it had mandated EFSA to develop fit-for-purpose protocols to assess the justifications for emergency authorisations. The first of these protocols, for insecticides and acaricides, is expected in May 2025. In this context, a workshop was held in Madrid last October to collect experiences and expectations from Member States. This workshop was organised by the EFSA contractor for this mandate. Nine Member States attended the workshop as well as a representative from EFSA and the Commission. The report of this workshop will be published on the EFSA website.

   The Commission announced that a second workshop will be held in Athens on 17-18 February 2025 to discuss the first proposal of the evaluation scheme. This workshop will also be organised by the EFSA contractor for this mandate. Both risk assessors as risk managers from Member States will be invited.

   One Member State underlined the importance of resistance management for these protocols and referred for this to an EPPO discussion on this subject.

   Another Member State asked if also Member States not attending the workshop will be able to comment on the protocol. EFSA confirmed this will be possible.

7. Nano-forms of active substances used in plant protection products

   The Commission summarised the information available concerning the applications of nano-technologies in the sector of plant protection products. Some examples reported in a recent research project and in a study funded by ECHA were justifying the need to reflect quickly on a definition and the identification of nano-forms of active substances and/or co-formulants.

   EFSA pointed to its activities dedicated to the topic: Nanotechnology | EFSA.

   Member States were invited to confirm by 17 January 2025 if there are no ongoing applications for approval of a nano-form of active substances.

A.13 Co-formulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574

   The Commission informed that a new draft Regulation amending Annex III was uploaded on CIRCABC, including an updated Annex III list of unacceptable substances that included the notifications received from Member States and EFSA. The current draft list contains the previous Annex III entries (1-144, kept exactly as they were published in the Regulation (EU) 383/2021), plus the 145-163 new entries. Member States were invited to comment by 17 January 2025.

2. On-going actions

   The Commission informed about its reflections following the comments of the Member States on the draft guidance document presented in the June Workshop. The Commission intends several actions to clarify and improve the assessment of plant protection products and co-formulants, including: the revision of the list of unacceptable co-formulants; the revision of the data requirements to ensure that the

full composition of the products is reported by the applicants; updating the draft guidance document keeping consistency with the one-substance-one assessment approach and avoiding multiplication of work.

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

The Commission recalled that it had invited Member States to submit information on their activities to prepare for the implementation of Regulation (EU) 2023/564, that should enter into force from 1 January 2026 as well as the progress that they had made and the difficulties they had experienced and their cause.

Eleven Member States submitted information that showed that, despite of some difficulties, the preparations for digitalisation of record-keeping were on track. The Commission informed that so far none of the difficulties reported would justify postponement of the entry into force date.

The Commission noted that digitalisation was expected to reduce the burden to all professional users, including the farmers. Entry into force as planned would allow to gain experience with electronic record-keeping and to identify and resolve unavoidable problems. The Commission stressed that the data on the use of plant protection products in Europe was very important for several processes. It would also reassure the public that the European agriculture produced safe products of the highest quality. Currently, that data is very hard to obtain and use, despite of being required under other legislation (statistics, drinking water, etc.). The Commission also provided clarifications on the provisions of Implementing Regulation (EU) 2023/564.

One Member State reiterated its request, made at the Agriculture and Fisheries Council held on 23 September 2024, to postpone for two years the entry into force of Implementing Regulation (EU) 2023/564. The Member State also regretted that the Commission had not presented a proposal for this despite of the support by 17 Member States and the opposition of only one. The Commission acknowledged the request and informed that it had replied to the concerned government explaining its current position. That letter had been made available to the Standing Committee.

The request for postponement was supported further by twelve Member States, which cited difficulties with setting up of the electronic record-keeping systems, the need to increase the awareness and to provide training to the professional users. Two of those Member States questioned the scope of data that should be recorded. Another one expressed doubt whether recording the use of plant protection products by the professional users served functions useful enough to justify the extra burden. Five Member States noted that they already worked actively on the implementation and remained flexible to a possible postponement. Some of them noted that any additional time could help their preparations. One Member State recalled that it had opposed the postponement at the Agriculture and Fisheries Council.

The Commission reiterated its invitation to those Member States that had not yet done so to submit the requested information by 17 January 2025.

A.15 Implementation of Regulation (EU) 2024/1487 (safeners and synergists):

The Commission recalled the notification process under Article 3 of Regulation (EU) 2024/1487, noting that two EDTA forms have been notified so far, with a deadline for notifications set for 19 December 2024. Updates were also provided on the steps to amend Annex I of the Regulation, including the consultation procedure.

The Commission clarified the roles of safeners, synergists, and co-formulants in plant protection products. Safeners reduce plant phytotoxicity by influencing plant metabolism, while synergists enhance active substances' efficacy by modulating pest metabolism. In contrast, co-formulants improve efficacy through physico-chemical properties without affecting metabolic processes. The example of rapeseed oil – brought up by CLE - was deemed potentially unsuitable, as it is already approved as an active substance and may not fit the work program based on further information.

The Commission also reminded that applicants are responsible for notifying substances suspected to act as safeners or synergists, with clarification possible before or after dossier submission. Synergists, like piperonyl butoxide, are distinguished from co-formulants by their demonstrated metabolic mode of action.

The Commission also referred to the potential burden of a double dossier submission - under REACH Regulation and Regulation (EC) No 1107/2009 (PPPR). Beside the on-going discussions on potentially amending some provisions of the REACH Regulation, the Commission mentioned that the use of IUCLID as submission tool for both REACH and PPPR would facilitate the process, and that the few involved substances in the work program for safeners and synergists is not expected to pose a big burden for applicants should a double submission still be needed.

A.16 Report from Working Groups, in particular:

1. Working Group Post Approval Issues (PAI)

   The Commission provided a short update of the last meeting held on 27 and 28 November 2024. The next meeting is planned for 5 and 6 March 2025.

2. Working Group on Biopesticides

   The Commission informed that the minutes of the September meeting of this Working Group were made available to the Committee.

A.17 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 an on-going survey to Member States on the peer review process of pesticides.

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 Commission reminded about the invitation to the OECD week of meetings from 25-28 February 2025, with a special focus on the Seminar (1,5 days) concerning the emerging issues in the risk assessment of biopesticides (peptides, Bt, semiochemicals). The Commission also informed on the Drones Working

Group (study on operators' exposure) and the collaborative project on digital labelling.

6. Update on Horizon Europe Research projects / Research and Innovation Day (February 2025)

   The Commission informed about the planned Research and Innovation Days, which will take place on the 11-12 February 2025 aiming at regulators and researchers as audience. The Member States were invited to forward send the "save the date message" to researchers in their countries.

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

The Commission informed that since the last meeting of this Committee in received three new requests for internal review (IR): IR/2024/285142 (alleged omission to take measures to end approval of active substance fluopyram), IR/2024/789284 (alleged omission of the Commission to adopt a non-renewal regulation concerning the active substances flufenacet), and IR/2024/655828 (renewal of approval of the active substance captan).

In addition, two court cases were initiated: Case T-576/24 (Bündnis für eine enkeltaugliche Landwirtschaft e. V. seek annulment of the decision of the European Commission on the request for internal review of the extension of fluopyram (IR/2024/047990)), and Case T-578/24 (Deutsche Umwelthilfe e.V. and AURELIA Foundation seek annulment of the rejection of their request for internal review of the renewal of glyphosates' approval (Implementing Regulation (EU) 2023/2660)).

The Commission also informed that the Court ruled in Case T-104/23 dismissing PAN Europe's action to annul the Commissions' refusal to grant access to preparatory documents on cypermethrin's approval renewal. The judgment upheld the Commission's decision.

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

The Commission informed that at the last meeting of the Residue Section of this Committee that took place on 25 and 26 November 2024, no measures were voted which would impact the authorisation of plant protection products by Member States.

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed about letters received from CropLife Europe and PAN Europe, which address several points on the agenda of this Committee meeting.

A.21 Rules of Procedure of the PAFF Committee:
- based on the Standard Rules of Procedure[1], and the basic Comitology Regulation (EU) No 182/2011[2]

The Commission informed that draft rules of Procedure for this Committee (all its sections) are made available. They formalise the procedures in place so far. Member States were invited to comment by the end of 2024.

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1 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:206:0011:0013:EN:PDF

2 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0182&qid=1730898633391

A.22 Date of next meeting(s):

The Commission informed that the next meeting of this Committee is intended for the 11 and 12 of March 2025, subject to confirmation.

A.23 AoB:

The Commission announced that a call for two positions for national experts is open and that a two-day Research and Innovation webinar is organised on 11-12 February 2025.

The Commission referred to previous discussions on the detection on treated seeds contaminated with neonicotinoids. Member States involved in the confirmed that they check further the details for further discussion at this Committee.

One Member State suggested to consider the technical expertise of EPPO as regards resistance management, in particular in the context of determining the need of certain active substance modes of action when implementing the provisions of Regulation (EC) No 1107/2009.

Another Member State commented on the mandate recently sent to EFSA to review the terrestrial environment guidance. The Commission reminded that two mandates were sent to EFSA in parallel, one to update a Guidance Document and another mandate to develop methods to assess indirect effects on biodiversity.

A third Member State reminded that the updated version of SANCO 10473/2003 draft (version 6) is still available for review and open for your comments.

Different issues with the enforcement of Regulation (EC) No 1107/2009, in particular the measures against illegal plant protection products at national level were discussed. Some Member States expressed the views that coordination at EU level is necessary, similar to the enforcement working group which was cancelled. The Commission will reflect on possible actions in order to help the Member States coordinate their enforcement actions.

Section B <u>Draft(s) presented for an opinion</u>

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 rev 2)

The Commission presented the draft Implementing Regulation and the draft Renewal Report. One Member State indicated that it could not support the proposal because the conditions of approval were not met.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance mepiquat chloride 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/2024/1843 RR)

(PLAN/2024/1843)

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

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 *Pythium oligandrum* B301 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/2024/2432 RR)

(PLAN/2024/2432)

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.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low risk active substance *Betabaculovirus phoperculellae* 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/2024/2073 RR)

(PLAN/2024/2073)

The Commission presented the draft Implementing Regulation and the draft Renewal Report. Most of the comments on the Review Report received from the applicant and Member States were addressed. The draft Review Report and the draft legal act address the taxonomical change occurred during the risk assessment period (i.e., from *Phthorimaea operculella* granulovirus to *Betabaculovirus phoperculellae*).

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Bacillus subtilis* strain RTI477 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 Review Report PLAN/2024/2050 RR)

(PLAN/2024/2050)

The Commission presented the draft Implementing Regulation and the draft Renewal Report that addressed all comments expressed by Member States after the October meeting. One Member State indicated it would not support the proposal (in particular

the low-risk aspect due to the uncertainties regarding the two metabolites of potential concern).

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Bacillus velezensis* strain RTI301 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 Review Report PLAN/2024/2192 RR)

(PLAN/2024/2192)

The Commission presented the draft Implementing Regulation and the draft Renewal Report that addressed all comments expressed by Member States after the October meeting. One Member State indicated it would not support the proposal (in particular the low-risk aspect due to the uncertainties regarding the two metabolites of potential concern).

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 conditions of approval of the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* (Draft Review Report SANTE/11962/2020 Rev. 2)

(PLAN/2024/2075)

The Commission presented the draft Implementing Regulation and the draft Renewal Report. Following the assessment of the confirmatory data required by the approval of this active substance, the approval conditions needed to be amended as regards the specification of the technical material as commercially manufactured and the provisional specification was replaced setting a maximum level of lupanine as a marker compound.

Vote taken: Favourable opinion.

B.08 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), *Bacillus amyloliquefaciens* subsp. *plantarum* D747, benalaxyl-M, cyprodinil, dichlorprop-P, formetanate, fosetyl, halosulfuron – methyl, imazamox, milbemectin, phenmedipham, pirimicarb, *Pseudomonas* sp. strain DSMZ 13134, pyrimethanil, pyriofenone, pyroxsulam, spinosad, sulphur, *Trichoderma harzianum* Rifai strains T-22 and ITEM 908, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T-25 and TV-1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, triticonazole and ziram

(PLAN/2024/2331)

The Commission indicated that the approval periods of the twenty-eight substances included in the draft proposal, expire between 31 January and 30 April 2025. Because it will not be possible to adopt decisions on their renewal or non-renewal before the expiry of the current approval, Article 17 of Regulation (EC) No 1107/2009 obliges the Commission to extend the approval period of the substances concerned. 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.

One Member State indicated its non-support to the extension of cyprodinil. Another Member State indicated its non-support due to the presence of halosulfuron-methyl in the Commission's proposal, as it has been classified as toxic for reproduction category 1B.

Another Member State expressed its reservations due to the presence of the active substances cyprodinil and halosulfuron-methyl in the draft proposal, but nevertheless would support the Commission on these extensions.

The Commission reminded that the risk assessment deadline for cyprodinil is planned by EFSA by 20 December 2024. Once the EFSA conclusion will be available, discussions will be initiated at this Committee. EFSA explained that time is still needed for the completion of the assessment under Article 4(7) for the active substance halosulfuron-methyl, and therefore the extension proposed is justified.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

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 Member States on the control of the labels, the role of competent authorities when checking the physical and the digital labels and on the transitional periods for the implementation of the regulation. Three Member States suggested to establish stronger labelling requirements for the products containing basic substances to ensure a proper control. One of them suggested that the update of the labelling regulation should include provisions covering basic substances.

The Commission explained that the public consultation on the draft regulation via the feedback mechanism and the consultation via TBT are intended to be launched early in 2025. After that, the Commission would revise the draft to consider the last comments from Member States and stakeholders.

The Commission informed that it had already received a joint letter from the stakeholders CropLife Europe - ECCA – Euroseeds, as well as written input from IBMA, in which they provided comments on different aspects of the regulation. Commission invited the stakeholder to submit these comments via the public consultation.

C.02 Exchange of views of the Committee on a draft Commission Regulation 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)

See point C.04.

C.03 Exchange of views of the Committee on a draft Commission Regulation 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)

See point C.04.

C.04 Exchange of views of the Committee on a draft Commission Regulation 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)

This point was discussed together with C.02 and C.03.

The Commission informed about the progress since the last meeting, in particular explaining that the final comments from the Member States had been considered. The Commission explained that the main change is the inclusion of new requirements for developmental neurotoxicity (DNT) to strengthen the assessment. The proposal also allows for the use of the DNT *in vitro* battery (DNT-IVB) in combination with an assessment of other data. This is a step to allow the use of new assessment methodologies (NAMs) in risk assessment. It was noted that EFSA and international partner continue working on the development of the use of NAMs and on building a framework for the assessment of DNT.

The Commission explained that after the inter-service consultation on the three draft Regulations, the public consultation via the Feedback Mechanism and TBT notifications will be launched in parallel. The final texts will then be presented for opinion of Member States and then subject to scrutiny by the European Parliament and Council.

C.05 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 amended draft Implementing Regulation 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 before 1 April 2025. Member States were invited to comment by 17 January 2025.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2015/408 as regards the deletion of gamma-cyhalothrin, ipconazole and oxamyl from the list of active substances to be considered as candidates for substitution

(PLAN/2024/2005)

The Commission presented the amended draft Implementing Regulation to update the list of candidates for substitution by deleting from the Annex to Regulation (EU) 2015/408, those active substances that were no longer approved or whose approval would expire before 1 April 2025. Member States were invited to comment by 17 January 2025.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance flufenacet, 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/2024/2430 RR)

(PLAN/2024/2430)

The Commission presented the draft Implementing Regulation and the draft Renewal Report for the non-renewal of flufenacet based primarily on the identified endocrine disrupting properties of the substance and the high potential for contamination of groundwater above statutory limits with its metabolite trifluoroacetic acid (TFA). The drafts consider the comments submitted by the applicant and Member States. Two Member States requested that the provisions of the act and the text of the Renewal Report were harmonised.

The Commission asked Member States for their preliminary positions. 25 Member States expressed their preliminary positions while the other two Member States had no position yet.

Member States were invited to comments by 16 December 2024.

C.08 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 concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2024/2353 RR)

(PLAN/2024/2353)

The Commission explained that flutolanil, where representative uses as a fungicide used on seed potatoes and flowers were submitted, was falling under the definition of PFAS and may potentially form TFA, a substance where recently a dossier with a proposal to classify it as toxic for reproduction Category 1B was submitted to ECHA.

The consumer risk assessment for flutolanil remains incomplete due to several data gaps. The applicant sent comments end of November 2024.

The Commission asked Member States for their preliminary positions and 12 Member States expressed their preliminary support to the Commission’s proposal of a non-renewal, 13 Member States had no position and indicated the importance of the active substance or pointed out the toxicological uncertainty of TFA due to the still ongoing regulatory process. Two Member States indicated no support.

Member States were invited to send comments and positions by 6 January 2025.