EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
10 - 11 July 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/aaf17dac-e105-4f96-9788-a4e9d88fd935?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary reports of all previous meetings are published or ready and to be published in the next few days.

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

1. Withdrawal of an application for extension of use of sodium chloride

The Commission informed that in June 2024 the applicants decided to withdraw their application for an extension of use of sodium chloride as basic substance used as an herbicide against water primrose (*Ludwigia peploides, Ludwigia grandiflora*). The assessment of this application will be discontinued without publication of the EFSA Technical Report.

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

The Commission informed that it is receiving increased complaints from applicants related to the refusal of granting mutual recognition authorisations. The Commission informed that it reacts in such cases indicating that mutual recognition is the responsibility of Member States and suggested discussing this topic at the Post Approval Issues (PAI) WG.

1. Expected delivery dates for DAR/RAR

   The Commission recalled that at the last meeting of this Committee, it requested Member States to indicate the expected delivery dates of the draft assessment reports because several stakeholders prevented the Commission on the dilated timelines for placing new active substances on the European market and because some Member States were reluctant to support the Commission's proposal to extend the approval periods under Article 17 while they were delayed on dossiers to be extended were they were Rapporteur Member States. The Commission told that one Member States informed on the difficulties encountered on accessing too old studies.

The Commission also requested feedback on the expected delivery date of tebuconazole, for which the current rapporteur Member State (RMS) took over the assessment from the United Kingdom.

2. MS experiences and practices (updates and survey)

   The Commission informed that the analysis on the survey is ongoing.

   One Member State presented the first results of the grant.

3. PIMS database: information on authorisation of PPPs

   The Commission presented a draft note that clarifies the scope of the information that should be provided for the database concerning authorisation of plant protection products and harmonises the reporting among the Member States. Member States were invited to comment by 30 August 2024.

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

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

  There was no news to discuss.

- **Renewal of approval**

1. Mecoprop-P

   The Commission explained that the area of concern related to exposure of residents may be solved by reducing the application rate to 200 L/ha (lower range included in the GAP) and that several Member States supported this. This solution has been proposed to EFSA and the EFSA comments have been uploaded on CIRCABC. Member States were invited to comment by 30 August 2024.

2. Lenacil

   The Commission explained that there were no areas of concern, however there were some data gaps identified by EFSA. Member States were invited to comment by 30 August 2024.

A.05 Draft Review/Renewal Reports for discussion:

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

1. Pydiflumetofen

   The Commission informed that the Rapporteur Member State finalised the evaluation of an additional study (inhalation, 28 days). In its evaluation, a new lower AOEL was calculated and moreover, based on CLP criteria (Regulation (EC) No 1272/2008), a classification for STOT RE (Category 1, H372 causes damage to organs (lungs) through prolonged or repeated exposure (inhalation route) was proposed. The applicant's comments have been uploaded on CIRCABC. Member States were invited to comment by 30 August 2024.

2. Clove oil

   The Commission shared comments received from two Member States and informed that it intends to check with the Rapporteur Member State for the renewal of approval if the missing data to amend the approval conditions was submitted within the renewal file.

- **Renewal of approval**

3. Milbemectin

   The Commission explained it proposes to renew milbemectin with restrictions due to the uncertainties that EFSA reported in its Conclusion for field uses, derived from a missing chronic toxicity endpoint for Chironomus riparius because which it remains unclear which risk mitigation measures are needed. In addition, a study to confirm that the bone marrow was exposed in the in vivo micronucleus test, an in vitro comparative study and an in vitro phototoxicity study would be requested as confirmatory information.

   The Commission informed that the renewal report was sent to the applicant and summarised the comments received. The applicant asked for a full renewal claiming that there are safe field uses already authorised in different Member States. During the meeting, one Member State asked about the legal definition of permanent greenhouses.

   The Commission requested the preliminary positions of the Member States: eighteen Member States expressed preliminary support, one Member State indicated to vote against and stated that emergency authorisations of milbemectin for open field should be allowed if restricted, and eight Member States had no position yet. Member States were invited to comment by 15 August 2024.

4. Pelargonic acid

   The Commission informed that it continues the discussions with EFSA on a possible mandate for an additional evaluation of the risks that the representative use in home gardens and allotments of the plant protection product MON 74134 poses on non-target arthropods.

   Member States were invited to comment by 15 August 2024 on the above-mentioned risks and to submit information whether they had authorised MON 74134, what risks for non-target organisms had been concluded and how those risks had been mitigated.

5. Rape seed oil

   The Commission informed that the Rapporteur Member State intends to submit additional calculations of the risk for non-target arthropods when exposed to low dosage applications. Member States were invited to comment by 15 August 2024.

6. Flutolanil

   The Commission explained that it is still examining the details, however indicated that one of the metabolites of flutolanil and relevant for rotational crops is trifluoracetic acid (TFA). Since no information on the level of TFA was submitted and the consumer exposure could not be concluded, the renewal for this active substance seems unlikely. Member States were invited to comment by 30 August 2024.

7. Sulfur

   The Commission and some Member States reminded the importance of this substance. Some risk mitigation measures proposed by applicant to demonstrate a safe use for at least the representative use in cereals (i.e. 4 × 8.0 kg a.s./ha with a 7-day interval, BBCH 15-69) are uploaded on CIRCABC. One Member State

requested the possibility of submitting confirmatory information at authorisation stage. Member States were invited to comment by 15 August 2024.

8. Aluminium silicate calcinated

   The Commission informed that it is still reflecting and is considering whether additional calculations of the risk for non-target arthropods when exposed to low dosage applications would be helpful. Member States were invited to comment by 15 August 2024.

9. 8-hydroxyquinoline (quinolin-8-ol)

   The Commission indicated that based on the EFSA Conclusion a renewal of approval of quinolin-8-ol as a candidate for substitution is possible if very strict conditions are fulfilled. Substances that are classified as R1B – like quinoline-8-ol - can only be approved if it is demonstrated that exposure to humans is negligible, which has been demonstrated. The Commission indicated that five Member States had commented since the last meeting.

   The Commission invited Member States to express their positions: fifteen Member States indicated support, while six were not supporting and six had no position yet. Member States were invited to comment by 31 July 2024.

A.06 Confirmatory Information:

1. Pendimethalin

   The Commission informed that it had submitted to EFSA a mandate for a peer review on confirmatory data concerning pendimethalin.

A.07 Guidance Documents, in particular:

The Commission informed that it sent two mandates to EFSA: to update the terrestrial guidance document (non-target arthropods, non-target plants and soil organisms) and to develop methodology to assess indirect effects on biodiversity.

As regards the proposal for multiple application factor (MAF) raised by one of the Member States at the previous meeting of this Committee, the Commission informed about comments received from Member States and reminded that a mandate to EFSA was recently sent to update the Guidance Document on terrestrial ecotoxicology, and that this mandate fully covers these aspects.

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

   The Commission summarised the comments received from four Member States since the last meeting and informed that CropLife resent the comments already shared in May. It also presented a revised cover page for the endorsement of this revised guidance document (GD) which proposes to implement the guidance document simultaneously for active substances and plant protection products after 1 October 2025 and still leaves the possibility for applicants to start using the GD earlier.

   One Member State clarified that its written comments concerned the previous version of the cover page and indicated it could support the latest revision. One Member State expressed concerns regarding the transitional period.

   Member States were invited to comment by 30 August 2024.

2. Memorandum accompanying the compendium of conditions of use to reduce exposure and risk from plant protection products

   The Commission acknowledged the additional comments sent by one Member State concerning the memorandum and explained that a draft mandate to EFSA is in preparation focusing on close transfer system techniques in order to incorporate these into the ongoing revision of the EFSA Exposure Guidance Document guidance document. The Commission is also reflecting on further steps, e.g. possible additional mandates to EFSA.

   Member States were invited to share by 30 August 2024 any national (draft) lists on pesticide application equipment or techniques that they intend to use for the implementation of the restrictions set in the renewal of approval of captan (see B.01).

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

   The Commission recalled that despite the positive reactions on the more technical aspects in the updated draft guidance document, some Member States had expressed disagreement with the Commission's view on the scope of the Judgement of the European Court of Justice "19 January 2023, case C-162/21".

   The Commission explained that it had received some further technical comments from Member States since the last meeting but that the positions of only a few Member States were known. The Commission invited all Member States to express a view or provide further comments –ten Member States indicated that they do not support the updated draft whereas eight indicated support. Those Member States who did not yet have a position were invited to provide their input in writing by 17 July 2024.

   The Commission explained that it would further reflect and discuss internally to determine the next steps.

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 the next meeting of the Working Group would be held on 17 July 2024. The Commission also recalled that once a final draft is available it will organise a stakeholder consultation.

5. Guidance on the assessment of pesticide residues in rotational crops

   There was no news to discuss (leftover from last meeting).

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

   See point A.13.

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

   There was no news to discuss.

8. FOCUS surface water scenarios (ongoing mandate EFSA)

   There was no news to discuss.

9. 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)

   There was no news to discuss.

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

1. Article 44(4)

   No notifications were received.

2. Article 36(3)

   The Commission informed about one notification received since the last meeting: a rejection of a mutual recognition application. The decision was not appealed at national courts.

3. Article 53

   The Commission informed of a meeting between efficacy experts of Romania, Finland, and Hungary to discuss the alternatives to replace the outdoor use of neonicotinoids in Romania, in particular to combat *Tanymecus dilaticollis* in maize and sunflower. The Commission intends to organise a second meeting on this subject with efficacy experts from Romania and Bulgaria.

   The Commission shared two letters from NGOs regarding emergency authorisations in Spain and the Netherlands. One Member State stated that such letters should be shared with appropriate time before the meeting of the Committee with the concerned Member State for better preparation, in particular for verification of the accuracy of the allegations.

A.09 Microorganism and low risk Active Substances:

The Commission informed that a meeting was recently held with EFSA and the Rapporteur Member States that are currently assessing new biological active substances. The aim of the meeting was to identify any blockages for the dossiers, to understand if there are any shared difficulties, or if knowledge and experience exchange across Rapporteur Member States may be helpful. Specific action points were defined and possible follow up actions are under discussion.

The Commission informed on the actions taken under Single Market Enforcement Task Force (SMET) to facilitate access to market of biological pesticides by identifying bottlenecks in the Rapporteur Member States' risk assessment and suggesting actions for improvement. Suggestions were discussed in two meetings with Member States (one at technical level, and one at Member States-directors level), where the participants express their willingness in implementing available tools to facilitate access to the market of biological pesticides. Progresses in Member States will be mapped via a survey.

The Commission also updated on the two studies performed by external contractors on systematic reviews on microbial species approved in the EU as active substances, focusing on their occurrence and population levels in soil, and on their biological and ecological properties, respectively.

The Commission shared the content of a letter sent by the Task Force on *Bacillus* Metabolites reminding the assessment of the 3 main lipopeptides metabolites common

to the *Bacillus* taxon. The need-to-know approach was recalled once again as an important principle for their assessment in line with the guidance document on secondary metabolites.

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

1. Acetamiprid (amended renewal report to be endorsed)

   The Commission recalled that acetamiprid was renewed in 2018 (expiring in 2033) and that EFSA concluded in a statement published 2022 that there was no conclusive evidence of higher hazards compared to previous renewal assessment. However, a statement of EFSA adopted in March 2024 suggested to change the residue definition for risk assessment of leafy and fruit crops and to lower the toxicological reference values (TRV) on the basis of uncertainties related to DNT potential of acetamiprid, with the consequence to adjust (lower) the MRL values for commodities in a next step.

   At the last meeting of this Committee, the Commission presented a draft amended renewal report for endorsement, which includes an updated residue definition for risk assessment and updated ADI and ARfD values, but Member States needed more time to evaluate the document. At that meeting, the Commission also suggested initiating an Article 21 procedure under Regulation (EC) No 1107/2009 that would address the uncertainties on DNT and also confirm the non-dietary TRV. Such an Article 21 review could also cover the assessment under the new endocrine disruptor criteria, which, although from a scientific point of view not urgent, could be anticipated for procedural reasons.

   Based on the comments received from the Member States since the last meeting, the Commission had made further amendments to the draft renewal report to clarify the rationale behind the amendments. The proposed lowering of ADI and ARfD, in the context of high uncertainty related to DNT properties of acetamiprid, is a necessary precautionary measure that will allow subsequent adjustment of MRL values for 38 commodities. The draft act of adjustment of those values was made available for information and the Commission indicated it intends to present it for vote at the next meeting of the Pesticide Residues Section of this Committee (September 2024). In case the draft receives the necessary support and if no objections are raised during the scrutiny procedure by the European Parliament and the Council, the new MRL values would enter into force in May 2025.

   The Commission explained that -considering the potential risks for the human health- it is necessary to act precautionary to protect consumers. If the Commission's suggestion for adjustments of the MRL values, which requires prior endorsement of the updated residue definition for risk assessment and the lower ADI and ARfD values, is not supported by Member States, it might be necessary to propose emergency measures under Article 53 of the General Food Law (Regulation (EC) No 178/2002).

   Some Member States had requested in their comments that (A)AOEL values are also lowered. The Commission explained that any precautionary measure should be also proportional. Lowering of (A)AOEL for acetamiprid would require immediate re-evaluation of all completed and on-going authorisations of plant protection products containing acetamiprid, and would cause lack of harmonisation and legal uncertainty. Therefore, any potential risks from non-dietary exposure to acetamiprid are best addressed with appropriate risk mitigation measures at national

level. Therefore, the Commission considers that lowering of (A)AOEL would be disproportionate and suggests that all TRVs would be evaluated in the course of the proposed Article 21 review, which would allow for consideration of additional data and peer review.

Two Member States stated that they could not endorse the amended renewal report if lower (A)AOEL were not included. Five Member stressed the high importance of acetamiprid and stated that they could not endorse the amended renewal report, because the adjustment of any of the TRVs should follow an Article 21 review that address the uncertainties on the DNT properties of acetamiprid. No Member State opposed the amendment of residue definition for risk assessment of leafy and fruit crops or the initiation of Article 21 review.

The Commission noted that, although renewal reports are not subject to formal vote and to be endorsed, a significant number of Member States representing around half of the EU population were not in a position to accept the amendments of the renewal report on acetamiprid for opposite reasons. Therefore, the endorsement was postponed.

The Commission informed that it would proceed with the preparation of the draft act to adjust the MRL values and intends to present for opinion at the next meeting of the Residue Section of this Committee. It intends to endorse the updated Renewal Report during that meeting.

Member States were invited to comment by 15 August 2024 on the scope of a review of the approval of acetamiprid under Article 21 of Regulation (EC) No 1107/2009.

2. Sodium hydrogen carbonate

   The Commission informed that the General Court considered the application regarding sodium hydrogen carbonate as inadmissible.

3. Common metabolites of pyrethroids

   The Commission informed that the PBAld study on aneugenicity (that is needed to conclude on the residue definition on the common metabolites for the pyrethroid substances) is expected to be available early 2025 during the renewal process of Tau-fluvalinate. Thus, this agenda point is considered closed until renewal process is available.

4. Trifluoroacetic acid (TFA)

   The Commission recalled that, as mentioned in the previous meeting, a mandate to EFSA is under preparation to set toxicological reference values (TRVs) for TFA.

   The Commission informed that Germany had submitted 2 dossiers for harmonised classification and labelling to ECHA, one for TFA and one for TFA salts. It was noted that in accordance with the existing guidance on relevance of metabolites in groundwater, metabolites that qualify for classification as toxic for reproduction or as acute toxicity category 3 (both part of the proposal made by Germany) would be considered relevant. The Commission asked Germany to share the harmonised classification and labelling dossiers with EFSA to facilitate the work on the mandate.

   The Commission also summarised comments from one Member State, which were shared via CIRCABC. In particular, the Member State questioned whether self-

classification or proposals for classification and labelling are a sufficient basis for concluding a metabolite to be relevant and called for further consideration of that point. The Commission noted that regardless of the classification of a metabolite, relevance could also be determined based on unacceptable toxicological properties and that TFA had to be considered based on all pertinent information (including the highly persistent nature of the substance), and in view of the need to ensure protection of groundwater as a particular priority. The Member State also expressed the need for caution to ensure decision-making on substances generating TFA was not premature.

The Commission invited Member States to provide views or comments by 15 August 2024.

5. Thifensulfuron-methyl

The Commission recalled that in previous meetings it had requested feedback from the zonal Rapporteur Member States of the Northern, Central or Southern zones that carried out assessments of plant protection products containing thifensulfuron-methyl, in particular on the data used to derive an ADI for the metabolite IN-L9223. No feedback was received so far.

Since the confirmatory data of the substance has been assessed and the respective outcome of the consultation with Member States, the applicant, and EFSA is already available, the Commission proposed to move this point to the confirmatory data point of the agenda and if necessary, consider an expert consultation to further discuss the risk assessment for aquatic organisms and the relevance of the metabolite IN-L9223.

6. SDHI fungicides

ANSES presented its report on the safety of succinate dehydrogenase inhibitors (SDHI) substances and mentioned its ongoing work to better characterise exposure to these substances.

EFSA agreed to consider the proposed changes to toxicological reference values by ANSES in the ongoing peer review process for the active substances concerned. EFSA furthermore presented its activities contributing to the ANSES recommendations.

7. Talc

The Commission informed that the approved basic substance talc has been recently proposed for harmonised classification as Carcinogenic category 2 and as toxic for lungs by repeated exposure (STOT RE1 (target organ: lungs). The classification, if confirmed, might trigger the revision of an approval as basic substance. The discussion at RAC concerning carcinogenicity is still ongoing, and the CLH process is not finalised.

One Member State submitted comments and considered an approval of talc as a basic substance as no longer appropriate, and suggested that the procedure of the revision of an approval should be initiated as soon as possible.

Member States were invited to comments by 4 September 2024.

8. Labelling of mixed sodium nitro compounds

   The Commission reminded that it contacted ECHA to provide guidance on the best way to proceed for the labelling of the three mixed sodium nitro compounds: sodium p-nitrophenolate, sodium o-nitrophenolate and sodium 5-nitroguaiacolate upon request of the Rapporteur Member State (RMS) for the renewal of their approval.

   As first reference to existing precedents of classification of such mix of compounds ECHA pointed to the terpenoid blend, consisting of p-cymene, d-limonene and alpha-terpinene, for which three separate CLH reports were submitted. Alternatively, ECHA suggested to treat the sodium nitro compounds as a reaction mass of components (i.e. a multi-constituent substance).

   Considering that the individual substances are not expected to reach the market as such but only as a mixture of the three compounds, and that separate CLH reports would imply additional laboratory animal sacrifices that are not in the spirit of the EU legislation, the RMS is proposing to follow the second option proposed by ECHA, meaning one CLH report for the mix of compounds. However, ECHA had a second thought and informed the Commission about their new consideration of the "Substance Identification Guidance" describing how to identify and name a substance. In ECHA's views, the case described with the mixed sodium nitro compounds does not relate to the result of the manufacturing of one individual substance, but the result of the blending of different substances and therefore to a mixture. ECHA said that describing a mixture as a "reaction mass of…" may create confusion, because this is a format specifically used for describing substances. Therefore, ECHA would advise against following this approach.

   ECHA confirmed that it had received other CLH reports for group entries. If the proposed classification for the three substances would be the same maybe one group entry covering the three substances (listed with their individual chemical names and numerical identifiers) could be proposed in one CLH dossier. In this case studies may need to be generated.

   The Commission proposed to organise a bilateral meeting between ECHA and the RMS to clarify the situation.

A.11 Article 21:

1. Flupyradifurone

   The Commission informed the applicant had referred to the additional information submitted 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. They had asked this information to be included in the mandate to EFSA under Article 21 (2) in order to be evaluated as it demonstrates the existence of safe outdoor uses of flupyradifurone.

   Member States were invited to comment by 15 August 2024.

2. Tea tree oil

   The Commission recalled that the approval of tea tree oil as active substance was set to expire on 31 January 2026. The substance has a long-standing history of use in a wide range of cosmetic and human and animal care products. In the context of the renewal process, the Rapporteur Member State submitted a proposal for a

harmonised classification of Toxic for reproduction Category 2. On 30 November 2023, the RAC adopted its Opinion concluding that the substance should be classified as reprotoxic category 1B.

The Commission therefore suggested to launch an Article 21 review procedure to address this issue, while EFSA would continue the peer review process, including initiating an ED stop the clock. Member States were invited to comment by 15 August 2024.

A.12 General issues for information / discussion:

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

   a) Combustion gases to control voles:

   The Commission explained that another Member State supported that the use of engine combustion gases to control voles in fruit yards should fall under Regulation (EC) No 1107/2009 with the gases as active substances, however that this technique should not be permitted for animal welfare reasons.

   b) New Scope document:

   The Commission explained that a new version of the Scope document has been posted on CIRCABC that includes the recent discussion on physical barriers, as well as the latest cases.

   Member States were invited to comment by 30 August 2024, in particular, on the decision to consider the three products based on polyether modified trisiloxane as falling in the scope of the Regulation (EC) No 1107/2009.

2. Basic substances – general issues

   The Commission provided feedback from the meeting on basic substances that took place on 28 May 2024, where 55 participants from 26 Member States, Norway and EFSA participated. The meeting was a kick-off for general discussions about the interpretation of the provisions of the Regulation (EC) No 1107/2009 concerning basic substances. Such a need had been raised by Member States and stakeholders on several occasions.

   The meeting included a presentation of the results of the Member States survey on basic substances conducted in 2023, and presentations of Member States about their implementation and enforcement practices for Article 23 of Regulation (EC) No 1107/2009. Discussions focused on the conditions for placing basic substances on the market.

   The meeting revealed that there are insufficient provisions for the labelling of products containing basic substances and inconsistencies between the conditions of approvals set at the EU-level with the market reality. Several Member States reported problems related to the cross-border trade of basic substances-containing products and the limited use of products containing basic substances in agriculture because of the poorly demonstrated efficacy of basic substances and the fact that the formulation and packaging is not suitable for professional uses.

   The Commission informed that it is reflecting about the next steps and that the report from the meeting will be soon made available.

3. PFAS

   The Commission informed that it received a letter from Pesticide Action Network (PAN) Europe asking to immediately withdraw active substances defined as PFAS and to amend Annex II of the Pesticide Regulation to include cut-off criteria for Persistent, Mobile, and Toxic (PMT), very Persistent and very Mobile (vPvM), Persistent (P) and very Persistent (vP) substances.

   The Commission uploaded on CIRCABC the PFAS national plan for UK and DK.

   Member States were invited to comment by 15 August 2024.

4. Cut flowers

   The Commission informed about comments received from two Member States, one supporting the setting of MRLs for cut flowers and one not.

   One Member State resubmitted a note dated 2017 (uploaded on CIRCABC) requesting:

   - to identify the main exposure parameters for the different categories of actors coming into contact with treated plants;
   - to identify the current provisions and modalities, both in terms of risk assessment and regulation, which contribute to ensuring the protection of people, and to assess the level of protection they provide;
   - to assess the effects on risk levels at the different stages of the production, marketing and consumption chain that may result from the use of certain active substances commonly used in third countries exporting ornamental plants to the European Union and which are not approved at European level;
   - to identify possible shortcomings in the provisions in force and in the measures relating to the different risk analysis components, which would, if necessary, make it possible to strengthen the level of protection.

   Member States were invited to comment by 30 August 2024.

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

The Commission informed that new versions of the draft Regulations are addressing the previous Member States' comments, and additionally include new text concerning active substances of biological and natural origin which still fall under the scope of the data requirements Part A. The new versions of the draft will be shared after the meeting and Member States were invited to comment by 6 September 2024.

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

1. Implementation of Regulation (EU) 2023/574

   The Commission informed that additional notifications were sent by four Member States to add further substances to the Annex III list on unacceptable co-formulants. Furthermore, the Commission informed about a letter from the Pesticide Action Network (PAN) Europe requesting to add the additional substances.

   Member States were invited to comment by 30 August 2024.

2. Ongoing actions

The Commission reported on the Workshop on the guidance document and database for the assessment of plant protection products including co-formulants that took place on 20 June 2024 with the participation of experts from Member States, ECHA and EFSA and DG SANTE.

Member States were invited to comment by 30 August 2024 on a non-paper on sharing data on co-formulants to facilitate the data exchange/sharing among the Member States authorities in short and long-term, and comments on the first draft of the new guidance document on the assessment of plant protection products including co-formulants to launch a wider consultation including stakeholders.

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 12 and 13 June 2024. The main points debated were: seeking for harmonised decisions at product level if the toxicological reference values of acetamiprid are amended and subsequently new MRLs are adopted, GAPs adapted during the on-going renewals of plant protection products and new data generated to address the operator exposure assessment (not only at EU level but also at PPP level); coordinated implementation on what is considered "latest scientific knowledge" following recent European Court of Justice preliminary rulings and communication between concerned Member States to not deviate from zonal Rapporteur Member States' assessments and decisions; generation of residues data to be provided by applicants considering the provisional residue definition; confidential data sharing among Member States when building a common database for the assessment of co-formulants; the necessity of a stakeholder's consultation of the outcome of the Central Zone Ecotox Workshop held in 2022, listing bullet points compiled by the Central Zone Steering Committee, to be added to the existing ecotox manual of the Central Zone.

   The next meeting is planned for the 18 and 19 September 2024.

2. Working Group on Biopesticides

   The Commission informed on the last Biopesticides Working Group meeting held on 10-11 June 2024.

3. Working Group on comparative assessment

   The Commission informed about the last meeting that took place the 28 June 2024, focusing on a draft amendment of Annex IV of Regulation (EC) No 1107/2009. During the meeting, one Member State made a presentation on the implementation of its national decree. It was explained and discussed how to compare risk mitigation measures as proxy and pragmatic solution to find safer alternatives. One Member State expressed its concern on using the same approach for the rest of the Member States, since comparative assessment is a national decision.

   The Commission explained that discussions will continue with a next meeting which will probably take place in September 2024.

4. Working Group on Negligible Exposure

   Covered under point A.07.

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 the new PPR Panel started its mandate (2024 to 2029), and 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 provided and update on the Farm to Fork Pesticide Indicators.

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

   As regards drones and products authorised for application by aerial spraying, the Commission informed that two Member States had commented and that one indicated that it had plant protection products authorised for aerial application in the tree canopy area in forest and in vineyards on steep slopes for application via drones or for aerial spraying by helicopter.

   The Commission referred to the report concerning the project PHYTODRON.

   The Commission informed about two workshops organised by OECD in the autumn, the first one on 17 September about digital/electronic labelling.

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

The Commission summarised the developments concerning the Court cases T-43/23, C-726/22 P, C-316/24 P, T-1148/23, T-1164/23, and T-50/24.

Additionally, the Commission informed that it had carefully assessed all the grounds for a review under the Aarhus Regulation regarding Implementing Regulation (EU) 2023/2660 and concluded that this Regulation does not contravene EU environmental law.

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

There was no news to discuss.

A.19 Scientific publications and information submitted by stakeholders:

The Commission informed that a letter from Pesticide Action Network (PAN) Europe and a letter of Crop Life Europe (CLE) were received and made available via CIRCABC.

A.20 Date of next meeting(s):

The Commission informed that the next meeting of this Committee is planned for 2 and 3 October 2024, subject to confirmation.

A.21 AoB.

One Member State informed that it intends to send a note asking for an EU process to peer review the assessment of the metabolites for Dimethenamid-P.

Another Member State indicated that according to its legal analysis provisional authorisations in accordance with Article 30 of Regulation (EC) No 1107/2009 could be reinstated. The Commission invited Member States to indicate before end of July and as soon as possible if they consider such provisional authorisations as a legally possible.

A third Member Stated wondered how to treat impurities which are not expected but appear in official controls. The detailed discussion on this was postponed.

The Commission informed about the recent discussion with the Task Force of copper compounds producers regarding the recent amendment of the CLP (Regulation (EU) 2023/707 of 19 December 2022) which has revised, among other things, the principles that the PBT assessment shall apply only to organic substances and therefore not for the inorganic salts contained in the active substance copper compounds. The renewal of copper compounds in December 2018 identified them, as candidates for substitution (CfS), based on the outcome of a persistency assessment. Therefore, this new rule may allow to remove the status of copper compounds as CfS. The Commission indicated it is reflecting on the possibility to amend the current approval and invited Member States to comment by 15 August 2024.

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) renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12270/2020)

(SANTE/12268/2020)

The Commission recalled that at the last meeting of this Committee on 24 June 2024, in view of the positions of Member States, it had made available a new draft Implementing Regulation to Member States for a renewal of approval subjected to restrictions. This draft presented in the meeting in June had been slightly amended based on the comments received from Member States since then. The Commission presented the amended documents.

Member States largely welcomed the amended drafts, and several suggestions were made by Member States during the meeting to further clarify the restrictions in order to harmonise their implementation. Suggestions were taken on board in a version amended during the meeting. One Member State indicated it needs time to finalise a list of pesticide application equipment which would fulfil the restrictions. Two Member States

indicated they would do protocol declaration. The vote was taken on the version amended during the meeting.

Vote taken: Favourable opinion.

Denmark made the following protocol declaration:

"Denmark cannot support the proposal because outdoor uses are a part of the proposal. We share the opinion of EFSA, which is also included in the review report. EFSA states that the specific conditions in the scientific study underlying the refined risk assessment cannot be considered as agreed for risk assessment purposes and therefore not considered for a regular exposure assessment at EU level. So, in our opinion safe use has not been demonstrated for outdoor uses. In addition, there is an unacceptable risk of leaching of metabolites, because the new classification of captan implies that the metabolites are relevant."

Austria made the following protocol declaration:

"With respect to the request for confirmatory information to demonstrate that the reduction of exposure through particular application equipment is achieved in practice, we would like to note that for some of the other techniques and pesticide application equipment listed in the "Compendium of conditions of use to reduce exposure and risk from plant protection products" further data to increase confidence in their applicability and efficacy are considered necessary as well. The evaluation of any further data should be performed by a structured and harmonised approach."

B.02 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 Rev1)

(PLAN/2024/800)

The Commission postponed the point as there are few technical checks to be made in the drafts documents made available.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of eggshell powder 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 Renewal Report PLAN/2024/799 RR Rev2)

(PLAN/2024/799)

The Commission presented the draft documents. There were no interventions from Member States.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance metrafenone 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/2023/2534 RR)

(PLAN/2023/2534)

The Commission presented the documents and informed that two Member States already had indicated support for the renewal. One Member State reiterated it considers that the impurity dimethyl sulphate should be set at 0.001g/kg.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance folpet 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/2023/646 RR)

(PLAN/2024/646)

The Commission presented the draft documents. One Member State indicated it has concerns because of residents' exposure if plant protection products (PPP) containing folpet are used in vineyards. The Commission reiterated that this was not a representative use on which the renewal is based, and would be fully assessed by Member States at the renewal of authorisation of plant protection products.

Vote taken: Favourable opinion.

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 acequinocyl, aluminium silicate, captan, emamectin, fatty acids C7 to C20, metrafenone, pendimethalin, plant oils / rape seed oil and triclopyr.

(PLAN/2024/1404)

The Commission presented the draft Implementing Regulation that extends the approval period of active substances, currently expiring on 15 November, 30 November, and 15 December 2024. The draft was amended and the extensions for captan and metrafenone deleted, because regulatory decisions were voted for these active substances during this meeting of the Committee.

The Commission explained that the extensions are necessary because it will not be possible to adopt decisions on the renewal or non-renewal of approval of the active substances before the expiry of the current approval. In such a situation, 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 for each active substance and depends on the regulatory steps still needed to be completed in the respective renewal procedures, according to the legal timelines established in Commission Implementing Regulation (EU) 2020/1740.

One Member State indicated it does not support the proposal because the extension periods granted for candidates for substitution such as emamectin and pendimethalin were too long and proposed an only one-year extension. The Commission explained

that these active substances are currently under assessment by the respective Rapporteur Member States after the public consultation held at EFSA level, and therefore timelines prescribed in the legislation to finalise the renewal procedures would exceed one year. Furthermore, the Commission reminded about the possibility to rescind the extensions at any time.

Another Member State indicated it supports the draft but requested the Commission to take a decision as soon as possible for the active substances with low-risk profile, such as aluminium silicate calcined, pelargonic acid and plant oils/rape seed oil.

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 presented the draft Regulation and thanked the nine Member States that sent comments on the previous draft. The Commission informed about some views of stakeholders expressed during recent meetings, in which they believe that the colour scheme may discourage the use of biocontrol products and generate confusion, while others found the colour scheme as too favourable to biocontrol products. Further, stakeholder were wondering about the implementation of the digital label. The Commission reiterated that a public consultation via feedback mechanism will be launched and that the Commission would revise the draft to consider last comments from Member States and stakeholders.

The Commission asked the preliminary positions of the Member States: sixteen Member States expressed their preliminary intention to support, and eleven Member States had no position yet, indication some redrafting may be required in particular on the provisions on the digital label or the transitional measures.

Member States were invited to comment by 15 August 2024.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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/2022/1649)

The Commission presented the draft Renewal Report and draft Implementing Regulation for non-renewal of metribuzin. Member States were invited to comment by 17 July 2024.

C.03 Exchange of views 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 Renewal Report and draft Implementing Regulation and informed that the TBT consultation was ongoing, and a vote is intended for the next meeting of this Committee. Member States were invited to comment by 30 August 2024.

C.04 Exchange of views 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, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10846/2021)

(SANTE/2021/10844)

The Commission proposed the non-approval of caffeine as basic substance. Since the last meeting, three Member States submitted comments supporting the Commission proposal.

The Commission invited the Member States to indicate their positions and 25 Member States supported the non-approval of caffeine as basic substance. The Commission informed a vote is intended for the next meeting of this Committee. Member States were invited to comment by 4 September 2024.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of *Allium fistulosum,* processed, 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, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2024/798)

(PLAN/2024/798)

The Commission proposed to approve *Allium fistulosum*, processed, as a basic substance. Since the last meeting, two Member States supported the Commission proposal.

One Member State suggested to describe the "methods to reduce the exposure" of operators due to known irritant properties of onion plants (protective glasses during the spray application, and protective gloves during the handling of the substance). Furthermore, given the properties of garlic and onions to cause food allergies in sensitive populations and the cross-reactivity to the genus *Allium*, the same Member State proposed that a warning should be included on the label.

The Commission explained that onions and garlic are not included in the list of allergens covered by EU Regulation ((EU) No 1169/2011) on food labelling. In addition, it is not possible to include labelling requirements in the conditions of an

approval as a basic substance because it would be not possible to enforce such provision.

As regards the detailed recommendations to use protective glasses and gloves, the Commission indicated in the Review Report 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 details on the specific risk mitigation measures, because the users are aware of the properties of onions, which are available to the general public as food.

The Commission informed a vote is intended for the next meeting of this Committee. Member States were invited to comment by 4 September 2024.