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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
22 - 23 May 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/3e6bffb3-a281-492f-ade4-51fc6b8bcba7?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary reports of the meetings in January and March 2024 are in preparation.

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

1. chitosan hydrochloride (extension of use)

The Commission informed about a new application submitted for an extension of use of chitosan hydrochloride as a basic substance. The extension covers *Brassica* arable crops and in particular oilseed rape, to control *Sclerotinia* stem rot (*Sclerotinia sclerotiorum*) with a spray application. The application is at the admissibility stage.

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

The Commission recalled that once a year Member States are required to submit information by active substance on the plant protection products (PPP) they have authorised. This information is made publicly available via the EU Pesticide Database without any further verification.

Some Member States had reported that they had authorised PPP that contain active substances which were no longer approved. The Commission had contacted these Member States for verification and if necessary, correction of the submitted information. Those countries which had not yet replied were asked to do so without delay.

The Commission clarified that only information on the regular PPP authorisations (not on the emergency authorisations or for research and development) should be provided. The Member States should consider when the approved active substances expire and act on the PPP authorisations concerned accordingly. Only information for PPP that are authorised and not on those that are no longer authorised but are still in a grace period(s) should be reported.

One Member State explained that it had received complaints from stakeholders that according to the EU Pesticides Database in some other Member States PPP containing

non-approved active substances were still authorised. As such PPP were no longer available to them, this was perceived as an unfair competitive advantage.

Another Member State asked to clarify the date to which the annual reporting should refer to, as it may change the data.

The Commission stated it will consider clarifying the issues raised in order to harmonise the data as much as possible. Also, the disclaimer in the EU Pesticide Database might be amended to clarify that the data on the authorisations is not checked by the Commission and responsibility of Member States.

1. pending applications for new biopesticides

The Commission informed that a meeting will be organised with the Rapporteur Member States which are currently assessing new active substances which are biological (e.g., micro-organisms, pheromones), to discuss difficulties causing potential delays and possible actions to mitigate them. The Rapporteur Member States were invited to reflect on what these difficulties are, and which actions could resolve them.

2. 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. Emphasis was made in particular for the active substances whose applications were submitted before 10 November 2018 and that are still under assessment by rapporteur Member States. This request was made as a consequence of the reluctancy of some Member States to support the Commission's proposal to extend the approval periods of a batch of substances, highlighting that the extension periods were too long.

The Commission informed it received feedback from eleven Member States, that provided very heterogeneous information on the status of their assessments and engaged on submission dates.

3. MS experiences and practices (updates and survey)

The Commission recalled that it had launched a survey on how the risk assessment is organized at Member State level. So far 22 Member States have replied. The Member States that have not replied yet were invited to do so as soon as possible.

4. Upcoming regulatory processes (safeners and synergists)

The Commission informed that the new safener and synergist legislation (Commission Regulation (EU) 2024/1487) would be published 29 of May and that there are upcoming deadlines, as follows:

- Art 3(1): The Commission publishes the tentative list of substances by 19 July 2024 (list obtained from Member States survey in 2020).
- Art 3(2): By 19 December 2024, any interested party may submit a notification of further substances or preparations potentially used as safeners or synergists in plant protection products authorised for the placing on the market in at least one Member State as of 19 June 2024 (entry into force date).
- Art 3(5): The Commission updates the tentative list by 19 March 2025.
- Art 4(1): Any interested party wishing to apply, in accordance with Article 7 of Regulation (EC) No 1107/2009, for the approval of a safener or synergist included in the list referred to in Article 3(1), may submit a request for inclusion

of that safener or synergist in the work program for gradual review by 19 June 2025.

- Art 6(2): By 19 December 2025, the Commission shall adopt the work program by amending Annex I to this Regulation (Safeners and synergists). (This date triggers the transitional provision for existing authorisations).
- Art 8(1): By 19 June 2028, applicants for the approval of a safener or synergist shall, individually or collectively, submit the application for approval of the safeners or synergists to the rapporteur Member State.
- Art 9(2): The rapporteur Member State shall, within 45 days following the date specified in Article 8(1), inform the applicant, the co-rapporteur Member State, the Commission, and the Authority of the date of receipt of the application and of its admissibility.

The Commission reminded the Member States to inform potential prospective notifiers and applicants to avoid withdrawing (or amending) authorisations of plant protection products containing substances not included in the work program.

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

- New active substances / Amendment of conditions of approval

1. Clove oil

The Commission presented the EFSA conclusion regarding the amendment of approval conditions. Comments from the applicant on this conclusion were shared on CIRCABC.

Member States were invited to comments by 21 June 2024.

- Renewal of approval

2. 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 six Member States supported this. The Commission also informed of a meeting with the applicant.

The Commission intends to mandate EFSA Conclusion for completing the assessment of the lower range of the GAP.

3. Dichlorprop-P

The Commission reiterated its suggestion to align the regulatory decision making for both the renewal and the amendment of conditions of approval, for which the peer review is still on-going. The Committee agreed to this. Therefore, discussion on this active substance will be reinitiated once until EFSA publishes the outcome of the amendment of conditions of approval. Until then, dichlorprop-P will be taken of the agenda.

4. 8-hydroxyquinoline (quinolin-8-ol)

The Commission recalled that the approval of an active substance can only be renewed if a risk assessment demonstrates that the current safety standards for approval are fulfilled by the active substance. Quinolin-8-ol is a candidate for substitution due to its harmonised classification as toxic for reproduction Category

1B. Substances that are classified as R1B can only be approved if it is demonstrated that exposure to humans is negligible.

The EFSA conclusion on the renewal procedure did not identify any risks which are relevant for the restricted representative uses and negligible exposure under these uses seemed demonstrated. Currently all MRLs are set at default.

Two issues could not be finalised due to the lack of harmonised guidance: non-dietary exposure of bystanders and residents and the consumer dietary risk assessment. These issues could be addressed by setting specific conditions and restrictions. Furthermore, confirmatory information for confined rotational crops metabolism data and non-dietary exposure would be asked to increase confidence in the decision making.

The Commission pointed out that, in summary, under these conditions a restricted renewal seems possible, that the expiry date of approval is 31 December 2024, and that it intends to vote in the meeting of this Committee scheduled for October.

On request of Member States, the Commission clarified that it considered the new draft version of the Guidance document on negligible exposure and that it intends to refer to the reference values calculated by EFSA on which no issues for the consumer risk assessment were identified.

Some Member States wondered if a specific closed transfer system would need to be specified and if the representative use scenario is realistic.

The Commission announced it will circulate the draft renewal report for comments by email.

- 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 the rapporteur Member State had accepted to evaluate an additional study (inhalation, 28 days).

- Renewal of approval

  2. Milbemectin

  The Commission reminded that the outcome of the risk assessment is favourable and did not identify any critical areas of concern. Although parts of the risk assessment could not be finalised by EFSA, the Commission considers that they can be addressed by imposing certain conditions. The Commission explained that it had an exchange of information with EFSA to clarify several parts of the Conclusion and invited Member States to consult this information shared on CIRCA BC.

  3. Pelargonic acid

  The Commission informed that it is finalising a mandate to EFSA to perform a quantitative weight of evidence assessment of the risks that the representative use of the plant protection product MON 74134 poses on non-target arthropods.

4. Rape seed oil

The Commission informed that it is still exploring the best way forward together with the rapporteur Member State and EFSA.

The Commission reminded about the importance to finalise the risk assessment also for the lower range of the application of the representative uses provided in the dossiers, and not only to focus on the worst-case scenarios (upper end of the range). A better understanding of the lower end of the ranges is needed to determine if the active substance qualifies as a low-risk or not, or if there is a safe use or not. The Commission stated that having such complete assessments avoid delays and stalemate with regulatory decision making on active substance at this Committee, as it is the case for rape seed oil.

EFSA added, that sometimes the applicants do not provide the calculations for the lower dosage uses, even if asked. The Commission invited EFSA to document such cases.

Member States were invited to comment by 7 June 2024.

5. Flutolanil

The Commission explained that it is still examining the details, however one of the metabolites of this active substance is TFA, so that a renewal for this active substance seemed unlikely.

6. Sulfur

The Commission reiterated is invitation to consider whether and which possible risk mitigation measures could be applied in order to manage the two areas of concern for soil organisms and non-target arthropods, in order to consider if a renewal of approval would be possible. Member States were invited to comment by 7 June 2024.

7. Aluminium silicate calcinated

The Commission informed that it is still reflecting and discussing with EFSA on some open issues. Member States were invited to comment by 7 June 2024.

8. Tritosulfuron

The Commission informed that the applicant withdrew the application and that the corresponding non-renewal documents are in preparation, with the intention of a possible vote in the next meeting of this Committee.

9. Metribuzin

The Commission informed that EFSA had published the update on its Conclusion. The changes made are not substantive and three critical areas of concern related to endocrine disruption properties, exposure to bystanders and residents and risks for bees have been identified. Those concerns preclude the renewal of approval of metribuzin. The exemptions provided by Article 4(7) of Regulation (EC) No 1107/2009 cannot be applied as no serious danger to plant health which cannot be contained by other available means was identified.

Most Member States which had submitted comments considered that renewal was not possible. Accordingly, a Report for a non-renewal was prepared. Member States were invited to comment by 7 June 2024.

- Basic substances

1. Caffeine

The Commission explained that, since most of the Member States supported the non-approval of caffeine, it amended the Review Report that was provided to the applicant, who does not agree with the proposal for non-approval.

The applicant submitted additional information concerning a method to prepare the substance for use as granules, the consumer exposure, the operator exposure, and the toxicity to non-target organisms. There were no new arguments provided. The Commission recalled that the applicant had revised the application several times, including the request to put the dossier on hold for one year to provide more data.

Member States were invited to comment by 21 June 2024.

2. *Allium fistulosum*

The Commission summarised the comments of the applicant and the Member States on the draft Review Report to approve *Allium fistulosum*, processed, as a basic substance.

One Member State is of the opinion that no safe use has been demonstrated for the use as soil treatment spray. The Commission indicated that for the spray uses in the greenhouse only negligible exposure can be expected, via drainage. Furthermore, EFSA indicated that the potential exposure to bioactive molecules in *Allium fistulosum* from the intended uses would be lower than the exposure to the equivalent bioactive molecules in garlic from the approved representative uses of garlic extract. The EFSA Technical Report did not exclude the exposure of surface water, however, it also did not identify any specific concerns for aquatic organisms. Based on a weight of evidence, considering the nature of the substance, and that it is expected to be non-persistent in the environment, the Commission proposed an approval as a basic substance for all the uses requested.

The second commenting Member State supported the approval of *Allium fistulosum* as a basic substance and suggested including the methods for reducing the exposure of operators to irritant components, such as wearing tight fitting eye protections while handling large amounts of *Allium fistulosum*. The Commission reminded that the draft Review Report indicates already that the users should consider using commonly available methods to reduce exposure to irritating components during the preparation and use of the substance, assuming that users are aware of the general properties of onion plants which are available to the general public as food.

The applicant also provided comments in which they specified the missing details concerning the preparation of the substance for use. The Review Report was amended accordingly.

Member States were invited to comment by 21 June 2024.

3. Eggshell powder

The Commission presented its proposal of a non-approval of eggshell powder as a basic substance, due to issues regarding the identity of the substance, the unclear content of lead in the powder and due to possible allergenicity problems.

Three Member States had sent comments supporting a non-approval.

The applicant had sent comments on the draft Review Report where they do not agree with the Commissions proposed reasoning.

Member States were invited to comment by 7 June 2024.

4. Grape seed extract

The Commission explained that the applicant had requested to add the liquid form of the grape seed extract to the approval. The applicant said that it is merely the previous phase in the extraction process (before the powder) and should not present any additional problems.

The Commission checked with EFSA whether this would indeed not cause any additional issues. EFSA however could not confirm this and questioned whether the material in the liquid form would have the same quality as the dried material. During the drying process some of the volatile substances present in a solution might evaporate, depending on the process conditions and the nature of the substances. The drying process might also influence the viability/presence of possible microbial contaminants. Obviously, these elements have an effect on all other sections of the risk assessment. The applicant did not provide any additional information in this regard.

The Commission explained that it would therefore not accept this additional liquid form without more information provided by the applicant and proceed on the basis of the powder form.

One Member State had sent in comments supporting the approval as a basic substance.

Member States were invited to comment by 7 June 2024.

A.06 Confirmatory Information:

1. Aqueous extract from germinated seeds of sweet *Lupinus albus* (amended report to endorse)

The Commission explained that the confirmatory information required from the applicant had been submitted. The draft amended Review Report made available for endorsement included the necessary changes to confirm the technical specification of the active substance as manufactured (based on commercial scale production) and in particular, the maximum content of the quinolizidine alkaloids (QA). The draft amended Review Report was endorsed by the Standing Committee.

The Commission informed that, as a next step, the approval Regulation needs to be amended as regards the content of total quinolizidine alkaloids .

2. Pendimethalin

The Commission informed that the mandate to EFSA for a peer review of the confirmatory information is in preparation.

A.07 Guidance Documents, in particular:

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

The Commission summarised the comments received on the draft cover page for the endorsement of the revised Birds and Mammals guidance document. There are diverging views with two Member States and one EFTA country in favour of the

possibility to use all or parts of the revised guidance document earlier for the authorisations of plant protection products. Two Member States asked for an earlier application of only the timeweighted average factor while one Member State agreed to the implementation scheme as proposed by the Commission.

The Commission made the Member States aware of a contribution from Croplife in which they express concerns about the timeweighted average factor, the benchmark dose approach and field studies.

Given that the benchmark dose approach might affect the setting of endpoints and to ensure the full guidance document can be applied with regard to the use of the timeweighted average factor, the Commission proposed to implement the revised Guidance Document first for active substance approvals, as of 1 June 2025 with an option for applicants to start using it earlier, and for plant protection products only if the active substance was already assessed according to the revised Guidance Document.

Two Member States expressed a preference for implementing the guidance document simultaneously for the approval of active substances and the authorisation of plant protection products. Three Member States suggested to discuss its implementation in the Post Approval Interest (PAI) Working Group. One Member State indicated agreeing with the implementation scheme as proposed by the Commission given the complexity of the document. The Commission indicated that it would reflect and suggested to discuss this point also at the next PAI WG meeting.

Member States were invited to comment by 7 June 2024 on the implementation scheme, in particular regarding its use for the authorisation of plant protection products.

2. EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure (for endorsement)

   The Committee endorsed the updated EFSA Administrative guidance.

3. Compendium of conditions of use to reduce exposure and risk from plant protection products (editorial clarifications for endorsement)

   The Commission explained the slight revisions in this updated version that clarifies the last column of the table in the Annex to the Compendium. One Member State indicated that the reaction from industry towards the Compendium endorsed in March is positive but misunderstood as if the performance values mentioned in the table would be already fully validated. The revised Compendium was endorsed by the Committee with the exception of the same three Member States that already abstained from endorsing during the last meeting of this Committee.

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

   The Commission explained that two Member States had commented on the draft memorandum presented in March. They stated that the determination and validation of exposure reduction performance should occur independently from the risk assessment of active substances and products. Harmonisation of testing methodologies for measuring drift, in particular, and exposure reduction performance in general was identified as a pre-requisite. They also suggested to define the criteria to consider the values validated and to update exposure models. They also called for a check of the availability and affordability of the techniques to be assessed.

The Commission explained its first ideas on how to complement the compendium, for instance via a mandate to EFSA to review data supporting the exposure reduction performance values. Member States were invited to comment by 21 June 2024.

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

   The Commission thanked Member States for providing constructive comments to the document, adding clarifications, and strengthening the harmonisation of the justification of emergency authorisations, and then recalled that some Member States expressed disagreement with the view expressed on the scope of the judgement in case C-162/21.

   Member States were invited to comment by 7 June 2024.

   The Commission informed that Member States should have a position on the draft at the next meeting of this Committee, in view of its potential endorsement.

6. 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 comments from Member States on the draft guidance were being analysed and calling on other Member States to provide comments by 7 June.
   - The Committee was informed that a meeting of the Working Group would be scheduled to address the more complex comments.

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

   The Commission informed that this new guidance is available and that it intends to endorse it at the next meeting of the Residue Section of this Committee (September 2024).

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

   See agenda point A. 13.

9. 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.

10. FOCUS surface water scenarios (ongoing mandate EFSA)

    There was no news to discuss.

11. 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.

12. Updates of EFSA guidance on Application of systematic review methodology to food and feed safety assessments to support decision making and the EFSA guidance on open literature review in the context of the Regulation (EC) No 1107/2009

The Commission informed that mandate to update this guidance document is under discussion with EFSA. One Member State asked for a centralised process to review literature.

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 about a high-level meeting with the Romanian Ministry of Agriculture and the Romanian National Phytosanitary Authority to discuss the granting of emergency authorisations by Romania in August and November 2023 for plant protection products containing neonicotinoid active substances. The Commission will set up a meeting between experts from Romania and neighbouring countries to share information about alternatives.

One Member State informed that foliar application costs up to ten times more than seed treatments.

A.09 Microorganism and low risk Active Substances:

The Commission informed

- that a new study was published by ANSES (Fichant et al., 2024) to investigate the enteropathogenic potential in non-animal models of strains of *Bacillus cereus*, including *Bacillus thuringiensis*. The authors concluded that results ranged from no effects to observed effects. Due to the uncertainty of the results, the Commission highlighted the importance of having further scientific data and informed that it is considering the possibility to mandate EFSA to eventually generate more primary data.
- that the applicant had communicated a proposal to the RMS and the co-RMS for a protocol to generate the confirmatory information requested for the eight *B. thuringiensis* strains renewed in March 2023.
- on the Single Market Enforcement Task Force (SMET) aiming at facilitating access to the market of biological active substances and biological plant protection products. SMET is focusing on identifying bottlenecks and suggesting solutions to Member States. Meetings will be held with the relevant Member States delegations, and the Commission invited delegates to communicate with their counterpart involved in SMET.

The Commission also informed about a letter addressed to an applicant wishing to apply for a change of the status of its recently renewed active substance to a low-risk substance. In the letter the Commission confirmed that Regulation (EC) No 1107/2009 does not provide for such ad hoc procedure enabling such change, and therefore, the low-risk status of an active substance can only be granted in the context of an approval or a renewal procedure.

The Commission gave an overview of the replies received by some Member States.

One Member State stressed the practical consequences if renewals would be initiated earlier; they would affect workload, interfere with timelines of ongoing dossiers, disorganise the work program. Member States were invited to comment by 21 June 2024.

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

1. Metiram (amended report to endorse)

The Committee endorsed an amended report which corrected a typo mistake.

2. Acetamiprid (amended report)

The Commission informed that EFSA had published a Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites. The main findings are:

- Acetamiprid causes molecular and cellular effects that might lead to an adverse outcome at organism level, and therefore might present a developmental neurotoxicity (DNT) concern. This was concluded using an adverse outcome pathway (AOP)-informed integrated approach to testing and assessment (IATA). The assessment performed was more conservative than the one presented in the previous opinion of the EFSA PPP Panel. At the same time there are major uncertainties in the body of evidence for the DNT properties and further data is needed to clarify them. In the light of the above, the Statement proposes to apply an additional uncertainty factor to lower the ADI and ARfD.
- The metabolite IM-2-1 is considered unlikely to be genotoxic and it is not expected to have a different toxicological profile compared to the parent.
- It is proposed to include metabolite IM-2-1 in the residue definition of risk assessment (RD-RA) for leafy and fruit crops.
- Using the newly proposed toxicological reference values (TRVs) and residue definition, EFSA performed calculations of the consumer exposure in terms of percentage of the ARfD for different commodities and for many food commodities there are exceedances.

The discussions on the maximum residues levels (MRLs) will take place at the Standing Committee on Plants, Animals, Food and Feed - Section "Phytopharmaceuticals-Pesticide residues". However, in order to set appropriate MRLs, the updated TRVs and RD-RA should be endorsed at the next meeting of this Committee. Therefore, a draft amended Renewal Report was presented.

Additionally, the Commission explained that in the light of the current EFSA Statement and the previous EFSA PPP Opinion, any future re-evaluation of the approval of acetamiprid will require generation of new experimental data, including DNT animal studies.

The authorisation holder had submitted written comments that were made available to the Committee.

One Member State informed that they still had a national prohibition of use of acetamiprid, and they had submitted written comments on the EFSA Statement, and that there was an urgent need to amend the applicable MRLs values. Considering that

the approval of acetamiprid will only expire in 2033, they thought that it would be inappropriate to wait for the renewal process to address the uncertainties of its toxicological and ecotoxicological properties.

Member States were invited to comment by 7 June 2024.

3. Sodium hydrogen carbonate

The Commission informed that the related court case is still on-going.

4. Common metabolites of pyrethroids

The Commission informed that in order to finalise the assessment of the common metabolites of pyrethroids, the aneugenicity study for the metabolite, PBAld is expected to be delivered by the applicants for the renewal assessment of lambda-cyhalothrin and tau-fluvalinate. The respective Rapporteur Member States will confirm when the study will be available.

5. Dimethenamid-P

The Commission recalled this case study discussed at the PAI WG, and reported about the specific meeting among the zonal RMS for authorisation of products and another Member State which does not agree with its assessment to discuss the genotoxic potential of the Dimethenamid-P metabolites M49, M52, M53 and M59. The two Member States could not agree on metabolites M49 and M52. Whereas one considered that M49 and M52 are unlikely to be genotoxic and indicated that it will continue the renewal procedures for the plant protection products and will assess the new requests for authorisation, the other Member State argued that available (Q)SAR prediction results triggered positive genotoxicity alerts.

The challenging Member State was invited to send more details before the upcoming meeting.

6. Trifluoroacetic acid (TFA)

The Commission provided an overview of the comments received from Member States since the meeting in March. Of particular note was that one Member State, based on existing knowledge, considers that the findings of TFA in groundwater are not related to the use of plant protections products (PPPs) whereas two others considered that the elevated findings of TFA in groundwater are (at least partly) related to use of PPPs.

Several Member States flagged the need to assess TFA exposure as part of the assessment of active substances in a harmonised way. The Commission agreed that this was of high importance, but also recalled that TFA originates from multiple sources, and is also found in rainwater. The Commission reiterated that it is drafting a mandate to EFSA to review the toxicological reference values for TFA.

The Commission reminded Member States that in case of pre-submission meetings with applicants for active substances that may lead to the formation of TFA (in soil or as a residue, in particular in rotational crops), the possibility for formation of TFA in soil and as a residue needs to be considered.

The Commission also noted that TFA should be considered as a relevant metabolite in groundwater since the applicant has self-classified TFA under REACH as toxic for reproduction category 2 (R2). In addition, Germany intends to submit a dossier for harmonised classification and labelling to ECHA proposing classification as toxic for

reproduction category 1B (R1B). It was noted by the Commission as well as one Member State that this would have impacts on decisions.

One Member State noted that there should be harmonisation also during the assessment of PPPs at Member State level.

7. Thifensulfuron-methyl

The Commission recalled that one Member State had raised this point during the last meeting of this Committee. The thifensulfuron-methyl metabolite IN-L9223 was assessed as not relevant and as tolerable in concentrations up to 0.75 µg /L during the renewal of approval of the active substance in 2016. However, during the renewal of approval of thifensulfuron-methyl based plant protection products, it has been highlighted (in the central zone) that the available data was not sufficient to derive an appropriate ADI for the metabolite. As a result, no refined consumer risk assessment could be carried out in accordance with Step 5 of Guideline SANCO/221/2000 (rev.11, 21 October 2021).

A data gap was also identified in the EFSA Conclusion for thifensulfuron-methyl (EFSA Journal 2015;13(7):4201) but was neither addressed in the Renewal Report 2016 nor in Regulation (EU) 2016/1424.

There seems to be a major disagreement among Member States in the assessment of this metabolite.

In an attempt to clarify the situation, the Commission requested the zonal rapporteur Member States from the Northern, Central or Southern zone, that carried out an assessment of thifensulfuron-methyl based PPP, to share by 21 June 2024 their experience on the data used to derive an ADI, and perform a refined risk assessment at product level.

8. SDHI fungicides

France informed about two reports from ANSES on SDHI active substances. In one of these reports, the lowering of 11 toxicological reference values (TRVs) is proposed as well as some recommendations regarding the human toxicology assessment including consumer exposure. The Commission suggested to have a more detailed presentation in the upcoming meeting of this Committee.

The Commission also reminded that for all TRVs questioned in the ANSES report, a renewal of approval is currently ongoing, or the substances are no longer approved:

- The approval of carboxin, isopyrazam and penfuflen expired or was withdrawn.
- The renewal procedures for cyflumetofen, benzovindiflupyr, isofetamid, fluopyram and penthiopyrad are ongoing, and the Commission reminded the respective Rapporteur Member States to minimise the delays, if any.

The Commission invited Member States to comment by 21 June 2024.

9. Copper compounds: nanoparticles

The Commission informed about a letter sent by a French researcher who argues about the possible risk entailed by nanoparticles of copper formed by a reaction between Cu2+ from copper pesticides and plant phenols, observed in studies by blending copper sulphate with several plant extracts. A link was evoked by this researcher with the development of Alzheimer’s disease.

The Commission informed that EFSA examined the study and concluded that there is no convincing evidence of the nanoparticles formation, nor their stability and persistence in significant concentrations during further plant growth, so as to be present at the harvest, thus a causal link with the disease is very premature.

10. Talc

The Commission informed that talc - approved as basic substance since 2018 - had been proposed for harmonised classification as Carcinogen 2 and STOT RE1 (target organ: lungs). There is no RAC opinion adopted yet and the CLH process is not finalised.

The Member States were invited to provide comments or suggestions regarding regulatory actions on the approval as basic substance.

A.11 Article 21:

1. Flupyradifurone

The Commission informed that details on the mandate to EFSA are still under discussion.

One Member States had commented on the additional information from the authorisation holder on the risk assessment of flupyradifurone seed treatment uses and it does not consider that this information should be included in the ongoing review.

2. Cyazofamid

The Commission informed that the Article 21 was launched via a letter to the applicant requesting submission of data by 20 March 2026.

A.12 General issues for information / discussion:

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

The Commission informed about the reaction of one Member State towards a question raised by another Member State concerning the decision tree supporting the differentiation for disinfectants between plant protection or biocides legislation. It was concluded from the discussion that, in practice, a biocidal disinfectant product will be effective against plant pathogens. Therefore, obliging an operator to obtain the double authorisation is not bringing any added value, except if the operator specifically claims an efficacy against a specific plant pathogen, then, there is no formal obstacle to apply for authorisation under the plant protection product Regulation.

1. New cases: seaweed extract – plant growth regulator vs. plant biostimulant (update)

   Seaweed extract: the additional comment from one Member State concerning the expected effects of the seaweed extract due to the presence of phytohormones or complex carbohydrate compounds were transmitted to DG GROW for a discussion with their experts on fertilisers/plant biostimulants.

   Combustion gases: the new technique to control voles, consisting of a mechanical injection of combustion gases (and accessorily fuel fumes as well) was considered out of the scope. The Member States were invited to comment in particular as regards animal welfare.

Member States were invited to comment by 21 June 2024.

2. Physical barriers: follow-up and new cases (e.g. UV protectant, Natural vegetal glue)

The Commission explained the two new cases, UV protectant and natural vegetal glue related to the new decision scheme regarding physical barriers and proposed to consider both cases as out of the scope.

The "Non-paper" prepared by the Commission analysing the consequences of the decision tree regarding 'physical barriers' was commented on by one Member State. Member States were invited to comment by 21 June 2024.

2. Basic substances – general issues

The Commission recalled that a meeting with Member States to discuss basic substances is planned for the 28 May. The meeting will focus on the placing on the market of basic substances. A total of 24 Member States nominated their experts for the meeting. The Member States who did not yet nominate their experts were invited to do so by 7 June 2024.

3. PFAS

The Commission reminded that the first PFAS substance (tritosulfuron) was proposed for a non-renewal due to its metabolite TFA produced at levels above the regulatory threshold. The Commission updated on the ongoing general actions on PFAS and on the RAC and SEAC procedure at ECHA.

4. Cut flowers

The Commission summarised information from two projects done in two Member States. One project was about potted flowers and seeds sold for ornamentals. The other one on residues of pesticides in imported cut flowers. Member States were invited to comment by 7 June 2024, in particular about the possibility to set maximum residues for cut flowers.

5. IPM principles

The Commission summarised the comments from Member States concerning the compatibility of using plant protection products in prevention of emergence of diseases or pests: all indicating the compatibility of preventive treatments for a successful control of many pathogens with IPM principles, in particular when the relevant decision support systems or any existing warning/forecast tools are confirming the risks under the particular pedo-climatic circumstances.

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

The Commission explained it has considered all comments received and consulted EFSA on some of comments. Feedback from EFSA is awaited. The Commission informed that also some changes regarding the requirements for micro-organisms will be included in the next drafts.

Member States were invited to send additional comments on the three drafts, in particular those who did not comment yet.

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

1. Implementation of Regulation (EU) 2023/574

The Commission informed on the notifications for substance to be added to the list of unacceptable co-formulants, submitted by three Member States, and invited Member States to comment on the suggested template submitted by one Member State.

2. Ongoing actions

The Commission provided an update on the ongoing actions, i.e., the developments of common databases and the guidance document. In particular, the Commission shared the comments of the Member States on the draft outlines for the guidance on the safety assessment of plant protection products / co-formulants and informed about the workshop with Member States, the European Commission, EFSA and ECHA that would take place on the 20 June. Member States were invited to nominate participants by 7 June 2024.

A.15 Report from Working Groups, in particular:

1. Working Group on Biopesticides

There was no news to discuss.

2. Working Group on comparative assessment

The Commission informed about the last meeting that took place the 29 April, focusing on a draft amendment of Annex IV of Regulation (EC) No 1107/2009 and following discussions initiated in May 2023. The next meeting is scheduled for 28 June.

The Commission informed that it would attend as observer in the 54th meeting of the EPPO Working Party on Plant Protection Products – 2024-05-28/30 - Antalya (Türkiye).

3. Working Group on Negligible Exposure

There was no news to discuss.

4. 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 ongoing mandates, and informed about the planning of the upcoming expert meetings for the peer reviews.

EFSA and the Commission invited Member States to nominate a risk manager by 7 June 2024, to attend a workshop for the revision of the terrestrial ecotoxicology guidance document. This workshop is jointly organised with EFSA and will be held in Brussels from 8 to 9 October 2024.

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)

A representative of the MUCF gave an overview of the results and ongoing work of the activities of the MUCF. In particular, as future challenges for minor uses they raised the decline in the number of approved active substances in the EU and of investment in new active substances, which is expected to lead to an increase in phytosanitary gaps for minor uses.

5. Agri-environmental Statistics (AES) Working Group, Pesticide Statistics

The Commission informed about the meeting of the AES Working Group, Pesticides Statistics that took place on 22-23 April 2024, including about the forthcoming calls for grants for PPP use data collection under the provisions of the Statistics on Agricultural Input and Output (SAIO) Regulation.

The Commission recalled that one of the most important sources of data on pesticides were the records of use of plant protection products by professional users under the provisions of article 67 of Regulation (EC) No 1107/2009. The competent authorities of Member States were invited, when preparing for the implementation of Implementing Regulation (EU) 2023/564 to establish close cooperation with their national counterparts in the field of agro-environmental statistics to ensure that the data collected would be used in the best and most efficient way.

6. OECD, FAO and EPPO activities

    1. OECD Working Party on Pesticides, seminar on Problem Formulation, Expert Group on Biopesticides

The Commission informed about the OECD Task Force on drones and referred to the draft Best Management Practices document which could be useful to organise the conditions of use for operators in case they are using drones for the application of pesticides. Upon suggestion from one Member State, the Commission invited to share the respective practical approaches regarding the authorisation of plant protection products for aerial spraying with drones.

The Commission signalled that the minutes of the OECD meetings held in February 2024 were made available to Member States for information.

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

The Commission informed that on 25 April 2024 the European Court of Justice (ECJ) published the preliminary rulings concerning C- 308/22 (PAN Europe v. Ctgb) and C-309/22 / C-310/22 (PAN Europe v. Ctgb).

The Commission also informed that there is a new court case launched against the decision of the European Commission to refuse the Arhus request for review of Commission Implementing Regulation (EU) 2023/1446 concerning the extension of the approval of the active substance tebuconazole: T-201/24.

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

1. possible impact on authorisations

The Commission informed that at the last meeting of the Residues section of this Committee that took place on 22 and 23 April 2024, MRLs were lowered for

phosphonic acid and its salts expressed as phosphonic acid(R), napropamide, pyridaben and tebufenpyrad.

2. carbendazim (TRV to endorse)

The Committee endorsed the new toxicological reference values for carbendazim (ADI 0.02 mg/kg bw/day, ARfD 0.02 mg/kg bw).

A.19 Scientific publications and information submitted by stakeholders:

The Commission informed that letters from Pesticide Action Network (PAN Europe) and Crop Life Europe (CLE) were received for this meeting of the Committee, and made available via CIRCA BC.

A.20 Date of next meeting(s):

The Commission informed that a virtual additional meeting of this Committee is planned for 28 June (date to be confirmed) and that the next regular meeting is scheduled for the 10 and 11 July 2024.

A.21 AoB.

The Commission informed that the data to be submitted by the applicant of thiabendazole in the context of the launched procedure under Article 21 of Regulation (EC) No 1107/2009, are expected to be submitted by the second quarter of 2025.

One Member State indicated that they had some poisoning events linked to ziram, and was wondering if this was also the case for other Member States, who were invited to submit information by 21 June 2024.

One Member State wondered about the use of Multiple application factors (MAF) in the risk assessment for non-target plants (NTPs), and another Member State informed about the initiation of a project on NTPs inviting interested Member States to join. The Commission indicated that a mandate to EFSA is in preparation which would cover these aspects, and invited Member States to comment by 21 June 2024.

One Member State informed about a workshop planned for September 2024 on Pesticide Fate and Effects on Environment in Northern Zone, and invited other Member States to attend.

One Member State informed about a report on European hedgehogs (Erinaceus europaeus), where a range of pesticides and biocides and other xenobiotics were detected. Whether or not these levels carry a health risk for the hedgehogs remains unclear. The findings included both approved and prohibited pesticides.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12270/2020)

(SANTE/12268/2020)

The Commission summarised the technical and procedural steps that lead to the presented renewal restricted to indoor uses (Greenhouses) and asked each Member State for its position. Only twelve Member States (representing less than 35 % of the population) supported the draft. Fifteen Member States indicated no support because they considered captan is crucial for field uses due to its importance in IPM and resistance management, because safe uses can be expected using precision agriculture, and because there are no alternatives.

The Commission indicated that - subject to confirmation - an ad-hoc meeting of this Committee is planned for the 28 June 2024 to further discuss.

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance metconazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/2697 RR)

(PLAN/2023/2697)

The Commission presented the documents.

Vote taken: Favourable opinion.

The Netherlands made the following protocol declaration:

The Netherlands believes there is evidence for the potential link between the occurrence of azole-resistant A. fumigatus in the environment and the spread of azole-resistant Aspergillus in infected patients.

A report of the EU Agencies and the Joint Research Centre (JRC) on azole resistance is expected to be published and will provide the current state of knowledge on all available scientific evidence including the identification of measures that could be implemented.

The Netherlands asks the Commission to give priority to any necessary measures needed on the approval of metconazole that lead from this report.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance acibenzolar-S-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) 2016/389 (Draft Renewal Report PLAN/2023/2650 RR)

(PLAN/2023/2650)

The Commission presented the documents. Three Member States would have preferred shorter grace period (3+6 months) but agreed to support the proposal as it is originally formulated. One Member State asked if MRLs would be aligned to the default values and the timing for this action. The Commission confirmed that discussions will be initiated in the Residue Section of this Committee.

Vote taken: Favourable opinion.

Spain made the following protocol declaration:

Taking into account the decision of the notifier to stablish a preliminary self-classification of the substance as toxic for ***reproduction category 1B*** *and considering the relevance of this information for the human health, Spain considers that the period for withdrawing the authorisations, and the grace periods, should be as short as possible. From our point of view, it should be* ***no more than 3 months to withdraw authorisations and 6 months for the grace period.***

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) 2020/617 and No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M (Draft Addendum to the Review Report PLAN/2024/792 RR)

(PLAN/2024/792)

The Commission informed that the Regulation and the Review Report were amended as regards the conditions of approval for the maximum level of impurity CGA226048 in the technical material as manufactured, and that it also included the request for confirmatory information regarding the water treatment processes, because the guidance is now in place.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance *Onobrychis viciifolia* (sainfoin) dried pellets 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/2024/790 RR Rev1)

(PLAN/2024/790)

The Commission presented the documents and explained some changes to the Review Report. Four Member States expressed their non-agreement to the proposal for approval because there are still issues that they consider were not sufficiently addressed as regards dermal exposure and inhalation. Additionally, the approved fertilizer use is approved for amounts up to 3000 kg/ha and lower that the uses proposed here (up to 10000 kg/ha). They consider that the effects on the environment are therefore unknown and there are not enough data on soil animals. According to these Member States, the criteria for approval as a basic substance are therefore not met.

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 2019/150 as regards allocation to Member States for the purposes of the renewal procedure of deltamethrin

(PLAN/2024/1012)

The Commission explained that, after the UK left the EU, deltamethrin had only a rapporteur Member State allocated for the renewal under Regulation (EC) No 1107/2009. In addition, an assessment is on-going under the biocidal products Regulation.

Taking into consideration these ongoing renewal risk assessments of deltamethrin, in particular the timelines for the submission of the information on endocrine disrupting properties requested by EFSA (from 28 August 2023 until 2 March 2026) and ECHA (from 11 September 2023 until no later than 1 November 2026), it was considered appropriate to align these assessments, in view of providing coherence and contributing to the implementation of the one substance-one assessment approach.

For these reasons, Sweden – rapporteur under Regulation (EU) No 528/2012 - accepted to act as co-rapporteur Member State for the renewal under the Regulation (EC) No 1107/2009. The proposed draft act is implementing this.

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 extension of the approval periods of the active substances amisulbrom, s-abscisic acid, thiencarbazone and valifenalate

(PLAN/2024/1032)

The Commission presented this draft Implementing Regulation that extends the approval period of four substances, currently expiring on 30 September 2024. 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.

Vote taken: Favourable opinion.

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EC) 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 informed that the interservice consultation is ongoing, and summarised and reacted to the comments received from Member States, in particular a sentence on volume reduction when using precision application techniques, the hazard sentence and pictogram for bees, the safety sentences for the protection of bystanders and residents and the sentence indicating the expiry date of the products. The Commission also summarised the main format changes included as regards the safety sentences and the description of the bee pictogram and the colour scheme.

During the meeting, other Member States raised concerns about possible challenges to enforce the safety sentences for the use or sowing of treated seeds and the provision on the digital label. Other Member States raised concerns about the inclusion of the

sentence for volume reduction and explained that efficacy for lower doses must be always demonstrated with data and trials.

One Member State 1) remarked that the information in the digital label should be identical to the physical label, 2) asked about the proposed transitional measures and the voluntary application of the Regulation for a specific period, and 3) asked about the link between the parameters used for the non-dietary risk assessment and the terminology used in specific safety sentences.

One Member State explained that the criteria to assign the pictogram should be linked with the outcome of the risk assessment and not with the hazard of the formulation of the specific product. Another Member State asked about the flexibility to adapt the proposed safety sentences to the national situation. Few Member States explained their reasons for not supporting the current proposal for the colour scheme.

The Commission explained that it assessed how many products with different active substances would fulfil the criteria for assigning the bee pictogram based on the formulation endpoints reported in the EFSA Conclusion and that this information is on CIRCABC.

Member States were invited to comment by 7 June 2024.

C.02 Exchange of views 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 summarised the few changes compared to documents presented in the last meeting, concerning the deadlines for the confirmatory information submission.

One Member State sent two comments requesting a change of the maximum value for the impurity dimethoate. This comment could not be taken on board as it was not in line with the EFSA peer review.

Member States were invited to comment by 7 June 2024.

C.03 Exchange of views 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 highlighted the main discussion points concerning the risk assessment of folpet. The chronic risk to bees, although identified in the EFSA conclusion, seems not to be an issue when the pesticide product containing folpet is applied on non-attractive crops. Furthermore, the Commission explained that the issue of the consumer exposure related to the natural presence of one of folpet’s metabolites can be solved by requesting confirmatory information.

Member States were invited to comment by 7 June 2024.