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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*
20 - 21 March 2024

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SUMMARY REPORT

A.01 Summary Report of previous meetings.

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

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

There was no news to discuss.

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

1. format of dossier submission (IUCLID)

The Commission informed about the upcoming release of an updated version of IUCLID in April and invited to monitor the ECHA and EFSA website for further information.

In addition, the Commission referred to possible procedures for applications to change the approval status from normal to low risk. The Commission restated that, considering the absence of a legal provision in Regulation (EC) No 1107/2009 allowing the change of status of an already approved active substance, further reflections are needed. The Commission summarised the replies received so far from Member States, and invited the remaining Member States to comment on the option for "early renewal" or to suggest alternative solutions.

Finally, the Commission referred to a letter received from a third party with states that some plant protection product authorisations would be in contradiction with IPM principles because the plant protection product uses could be considered as preventive treatments as they take place before the disease is visible. Member States reacted by providing examples of plant protection products applied before disease is present, before weeds emerge from soil. Member States were invited to comment on the claims made in the letter by 11 April 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. Tritosulfuron

   The Commission summarised that in the EFSA Conclusion there are no areas of concern but several data gaps, and that trifluoroacetic acid (TFA) is one of the main metabolites and it has been recently self-classified as reproductive category 2. In addition, a classification intention has been submitted by Germany according to the Register of Intention published by ECHA. Thus, TFA has to be considered as a relevant metabolite; for groundwater the levels predicted by the risk assessment are above the threshold of 0.1 g/l is. In addition, EFSA confirmed that this substance fulfils the definition of PFAS.

   Member States were invited to comment by 11 April 2024.

2. Mecoprop-P

   The Commission recalled that an updated EFSA conclusion was published on 7 December 2023 and that one area of concern is highlighted for the non-dietary exposure of residents (mammalian toxicity). Two Member States are in agreement with the use of 200 l/ha thus leading to an acceptable risk.

   Member States were invited to comment by 11 April 2024.

3. Dichlorprop-P

   The Commission informed that it received the EFSA Conclusion on 15 February 2024, that is updated with the assessment on the endocrine disrupting (ED) properties of dichlorprop-P following a Commission's mandate sent in January 2019 after discussions in this Committee on the basis of a draft renewal report. EFSA confirmed in this updated Conclusion that dichlorprop-P does not have ED properties.

   In addition, the applicant had applied for an amendment of the conditions of approval to the already approved dichlorprop-P, to clarify that the ester form can approved in addition to the acid. This assessment is still on-going.

   For efficiency, the Commission suggests aligning the regulatory decision making for both the renewal and the amendment of conditions of approval. The Rapporteur Member State of the amended conditions of approval application supported this. Member States were invited to comment by 11 April 2024.

Basic substances

There was no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

New active substances / Amendment of conditions of approval

1. Pydiflumetofen

   The Commission recalled that EFSA published its Conclusion on pydiflumetofen on 11 October 2019. Following discussions, this Committee

considered that the assessment conducted for the persistence of the substance is not fully suitable for volatile substances like pydiflumetofen. Furthermore, EFSA had identified certain data gaps including the assessment of endocrine disrupting (ED) properties as the new scientific criteria to identify ED properties had become applicable in November 2018 (and after the submission of the application which was declared admissible on 28 April 2016). Consequently, the Committee found it necessary to consider additional data on persistence and to address the data gaps identified by EFSA in its Conclusion. EFSA received from the Commission a mandate to organise a peer review and update its above-mentioned Conclusion of pydiflumetofen for all the areas where the Rapporteur Member State has updated the DAR, considering in particular the physicochemical properties of the active substance. The Conclusion was updated and republished on 28 February 2024.

The Commission recalled that this new active substance is not a PFAS, but it has a harmonised classification as reproductive category 2 and carcinogenicity category 2, and a persistence from high to very high. Thus, an approval would only be possible as a Candidate for Substitution.

Member States were invited to comment by 11 April 2024.

Renewal of approval

2. Milbemectin

The Commission summarised the findings of the EFSA Conclusion. The outcome of the risk assessment did not identify any critical areas of concern.

3. Pelargonic acid

The Commission informed that it has received comments from Member States. One of them considers that low-risk status cannot be granted as specific measures are required to mitigate the identified risks. Two other Member States informed that they had authorised products containing pelargonic acid for professional use, but most of them have irritant properties. The Commission reiterated that a low-risk status of an active substance is necessary, but not a sufficient condition for the products containing it to be authorised as low-risk. It also informed about a letter from the applicants where they again argued in favour of such status being granted to pelargonic acid.

The Commission informed that it discussed with EFSA whether a weight of evidence approach to the risk-assessment for non-target arthropods could be applied to the product MON 74134 as it had been done for other groups of non-target invertebrates and whether a mandate to EFSA is needed.

Member States were invited to comment by 19 April 2024 on the risks to non-target arthropods, to inform if they had authorised any low-risk products containing pelargonic acid and/or products for the use in home gardens and allotments, and if risks for non-target arthropods had been identified during the authorisations and how they had been mitigated.

4. Rape seed oil

The Commission informed that it is still reflecting on potential low-risk renewal, and is currently examining if the risk assessment for the lower extreme of the ranges in the GAP were performed or not, in particular for to non-target

arthropods and bees. The Commission started discussions with EFSA on this topic.

Member States were invited to comment by 11 April 2024.

5. Flutolanil

The Commission explained that the pending residues definition, the unfinalized consumer exposure, and the presence of TFA in rotation crops are likely to impede a renewal of the approval of this active substance. The Commission reminded that this active substance is falling under the definition of PFAS.

Member States were invited to comment by 11 April 2024.

6. Folpet

The Commission presented the draft review report and indicated that one field use appears to have acceptable risks. Member States were invited to comment by 11 April 2024.

7. Sulfur

The Commission reiterated that the areas of concern identified by EFSA (non-target arthropods and soil organisms) still remain and that, therefore, a non-renewal is likely unless Member States suggest risk mitigation measures.

The Commission informed that a meeting with Sulfur Task Force and Sulfur Working Group took place on 15 January 2024 and that information from the applicant was uploaded on CIRCA BC.

Member States were invited to comment by 11 April 2024.

8. Aluminium silicate calcinated (kaolin calcinated)

The Commission thanked Member States who replied to the questions posed in the last meeting on the possible way forward. Three Member States supported the renewal as non-low risk active substance, (due to the risks identified for non-target arthropods and issues with the impurities TiO2 and SiO2), no Member State supported a renewal as low-risk active substance, and two Member States favoured a mandate to EFSA for a weight of evidence approach.

One Member State recalled the low suitability of standard ecotoxicity testing according to OECD guidelines of substances with a physical mode-of-action. Another Member State pointed out that there are also kaolin products regulated under the new Fertiliser Regulation based on a different assessment. The Commission informed that the applicant referred to these circumstances in the documents uploaded on CIRCA BC for information.

Member States were invited to comment by 11 April 2024.

9. Metribuzin

The Commission informed that it has received comments from two Member States. One of them provided arguments how critical areas of concern can be addressed. The other one requested to proceed efficiently and to agree on short grace periods.

The Commission explained that it would wait for the updated EFSA Conclusion, which was expected in short time, before proceeding.

Member States were invited to comment by 19 April 2024, in particular on the applicability of Article 4(7) of Regulation (EC) No 1107/2009.

Basic substances

10. Caffeine

The Commission informed that two Member States sent comments stating that the peer review of an additional data sent by the applicant is not needed because the available information provides already enough clarity for a non-approval of caffeine as a basic substance. Altogether, during the last meetings twenty-one Member States expressed their opinion.

The Commission summarised that the majority of the Member States supported the non-approval of caffeine and that it will now proceed for a non-approval of caffeine as basic substance. Member States were invited to comments by 19 April 2024.

11. *Onobrychis viciifolia* var. Perly (sainfoin) dried pellets

The Commission informed that the application concerns pellets that are made from the aerial parts from *Onobrychis viciifolia* (sainfoin) and are used as a nematicide in grapevines to be incorporated into the soil. The pellets have a predominant use as animal feed and as a fertiliser. The Commission indicated that an approval of *Onobrychis viciifolia* (sainfoin) dried pellets as a basic substance is possible.

Member States were invited to comment by 11 April 2024.

12. Eggshell powder

The Commission informed that eggshell powder is available on the EU market as an inorganic fertiliser and a soil improver. The preparation to be used as a plant protection product is a dustable powder containing 100% eggshell powder which is industrially manufactured. The eggshell powder is to be used as a fungifuge on grapevine.

The Commission proposed a non-approval of eggshell powder as a basic substance due to issues regarding the identity of the substance, its unclear content of lead, and possible allergenicity problems. Additionally, the main ingredient, CaCO3, is an approved active substance. Two Member States had sent comments, referring to the same reasons.

Member States were invited to comment by 11 April 2024.

13. Grape seed extract

The Commission informed that grape seed extract is available on the EU market as food supplement and as feed additive. It is to be used as a fungicide on grapevines, apple trees, lettuce and potatoes, via field and greenhouse applications. For consistency with previous applications and transparency, the Commission will refer to *Vitis vinifera* L. seed extract (grape seed extract) for the approval as a basic substance.

One Member State sent in comments saying that an overall low environmental risk cannot be concluded by EFSA. Further to this, there are *in vitro* studies suggesting inhibitory effects on aromatase activity. This Member State is therefore hesitant to an approval as a basic substance.

Member States were invited to comment by 11 April 2024.

14. *Allium fistulosum*

The Commission informed that it would propose the approval of *Allium fistulosum* as basic substance based on the EFSA Technical Report and comments received so far from the Member States. Since the last meeting, one Member State sent comments that were considered in the drafting of the Review Report.

The Review Report will be circulated to the Member States in the next days and Member States were invited to comment by 11 April 2024.

A.06 Confirmatory Information:

1. Aqueous extract from the germinated seeds of sweet *Lupinus albus*

The Commission summarised the comments received from the rapporteur Member State and one supporting Member State on the acceptability of the data on the quinolizidine alkaloids content. One Member State proposed to request the data at product level.

Therefore, and considering that the assessment of the data package revealed no issues, the Commission indicated that a revised Review Report will be submitted for endorsement in the forthcoming meeting of this Committee.

Member States were invited to comment by 11 April 2024.

2. Pendimethalin

The Commission informed it had prepared a draft mandate to EFSA to evaluate received confirmatory information. In addition, ECHA has advanced its work on a guidance on the application of the recently amended CLP criteria including PBT classification, which provides some clarity about how bioconcentration factors (BCF) should be determined when data from more than one species is available. As this was a particularly important question in the evaluation of the confirmatory information on pendimethalin, the Commission will ask EFSA to consider the on-going work on the guidance when conducting evaluation, the confirmatory information.

3. Pinoxaden

The Commission informed that on 24 January 2024, EFSA published a technical report with the outcome of the risk assessment for pinoxaden confirmatory data, and that it intended to mandate EFSA to organise an expert consultation regarding the relevance of the metabolites M3, M11, M52, M54, M55 and M56 and the corresponding groundwater risk assessment.

The Commission furthermore shared comments from the applicant on the EFSA technical report.

A.07 Guidance Documents, in particular:

The Commission informed that the database on Guidelines and supporting documents on Active Substances and Plant Protection Products is published on the SANTE website**.** The Guidelines on Active Substances and Plant Protection Products - European Commission (europa.eu) website will be discontinued as of 1 July 2024. The Commission asked the Member States to keep reporting on any incorrect information

via the database. The Commission mandates EFSA to provide the history versions of the guidance documents in the database.

1. Joint CLP/PPP templates (to endorse)

   The Committee endorsed the updated joint CLP/PPP templates.

2. Compendium of conditions of use to reduce exposure and risk from plant protection products (to endorse) & memorandum accompanying the compendium

   The Commission informed that six Member States sent comments on the compendium document whereas two Member States were commenting on the memorandum accompanying it. The latest editorial amendments were supported apart for the procedural aspects for which four Member States raised a possible extra burden for risk assessors of the rapporteur Member State; one Member State stressed the need of involving EFSA as regards the levels of exposure and to incorporate agreed exposure values into risk assessment models.

   The Commission informed that as after the endorsement of the compendium it intends to mandate EFSA.

   An amendment of chapter 4.1 was proposed in the version submitted for endorsement. Three out of the four arguing Member States kept their reservation but in a spirit of compromise would agree to the endorsement as the compendium represent an important first step. The Committee endorsed the Guidance Document.

   The Netherlands made the following protocol declaration:

   We consider it important that the assessment framework for plant protection products reflects the development of innovative techniques to reduce use and exposure. We acknowledge that the compendium can contribute to the uptake of such techniques. However, we are concerned with the feasibility of the proposal to include new innovative techniques and conditions of use in the dossier for substance approval and product authorisation. While some innovative techniques and conditions of use can currently be feasibly included in the risk assessment, it is acknowledged that for others the (reduction of) exposure cannot yet be reliably estimated with current assessment methodology. Moreover, the evaluation of the exposure reduction performance is not substance or product specific and thus including this in the active substance or product approval and authorisation process as proposed in the compendium is not particularly efficient and may lead to different outcomes based on different data sets for the same techniques, which is undesirable. Furthermore, it will further exacerbate the issues of the challenges MS face to meet the legal timelines. For reasons of feasibility and efficiency the NL cannot endorse the current version. The Ctgb reserves the possibility to not accept applications and/or conditions of use that include innovative techniques and conditions of use for which a proper risk assessment is not considered feasible.

3. Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water (to endorse)

The Commission summarised the comments received since the last meeting and explained that only one Member State had indicated that it could not support the endorsement of the guidance, because the proposed methodology (area: assessment of metabolites) is neither sufficiently tested nor practicable and there was no pilot phase, the additional workload in the procedures (authorisation and approval of active substances as well as authorisation procedures, lack of harmonisation with the implementation for biocides, the fact that knowledge from literature and practical results from drinking water treatment plants should be considered with higher weight , and the need of positive controls in the experimental procedures for more reliability. In addition, a monitoring of the use of the GD should be implemented.

The Commission recalled the thorough process for development of the guidance by EFSA and ECHA, including a public consultation and consideration of comments from Member States, and explained that alignment on implementation also for biocides was being sought to the maximum extent possible. The Commission also explained that there was time for applicants and Member States to familiarise themselves with the guidance since it would not apply to applications until 1 April 2026. The Commission mentioned that the possibility for EFSA and ECHA to provide some training for Member States could also be explored (given the call from a Member State in January).

All other Member States agreed to endorse the guidance, with a date of applicability of 1 April 2026. The Commission informed that it would contact applicants for active substances where confirmatory information requirements are triggered to confirm the deadline for submitting this information.

4. Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances in accordance with article 77 of Regulation (EC) No 1107/2009 REV 1 (to endorse)

The Commission explained that this revised version of the Guidance Document introduces only editorial changes such as: inclusion of the Appendix I of the "Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Regulation (EC) No 1107/2009", and alignment of some definitions with those included in the amendment of Regulation (EU) No 283/2013 (which were drafted after this Guidance Document was endorsed). The Committee endorsed the Guidance Document.

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

The Commission thanked Member States for the comments submitted and explained that a further revision of the draft is in preparation.

The Commission explained that many comments were seeking clarification to the guidance. It was noted that several Member States had also expressed disagreement with the Commission's view on the scope of the judgement in case C-162/21.

One Member States had requested an official interpretation of the Commission of the ECJ Judgement. The Commission stressed that the updated guidance reflects the Commission's position. Moreover, the Commission's view is also noted in the summary records of the meetings of this Committee which took

place in December 2023 and January 2024. Furthermore, the Commission reiterated that only the ECJ can give binding interpretations of EU law.

Member States which did not yet comment were invited to do so by 5 April 2024.

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 updated on the state of the work carried out by the Working Group and the planned next steps. The draft guidance prepared by the Working Group would be shared with Member States for feedback. Then comments would be considered by the Working Group and a revised version prepared. Once ready, a consultation of stakeholders would be carried out.

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

See point A 14.

8. EFSA Guidance Risk assessment for Birds and Mammals

The Commission shared a cover note for the endorsement of the revised Guidance Document as well as comments from Member States and CropLife Europe on the revised Guidance Document. Member States were invited to Member States were requested to provide suggestions, in particular on the implementation schedule for authorisations of plant protection products.

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 (on-going 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 about the ongoing discussion with EFSA on a mandate to revise the EFSA guidance on open literature review in the context of the Regulation (EC) No 1107/2009 and the EFSA guidance on application of systematic review methodology to food and feed safety assessments to support decision making.

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

1. Article 44(4)

   The Commission informed that one notification was received since the last meeting of this Committee; the revocation of the authorisation of a metamitron based plant protection product because the composition of the product placed on the market repeatedly and significantly differs from the composition contained in the authorisation. The authorisation holder did not submit any comprehensible explanations for the deviations and did not cooperate during the hearing procedure.

2. Article 36(3)

   No notifications were received.

3. Article 53

   There was no news to discuss (see also point A.07.5)

A.09 Microorganism and low risk Active Substances, in particular:

The Commission informed that new dates and locations on the BTSF "Risk Assessment on Micro-Organisms" were confirmed by the contractor until the end of the program in Q1 2025. The Commission invited Member States to contact their BTSF National Contact Point to enrol experts in these trainings.

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

1. Sodium hydrogen carbonate

   The Commission informed of a pending request for mutual recognition in Germany for an outdoor use of sodium hydrogen carbonate as a low-risk active substance in vines. In addition, the discussion on the dual approval of this substance is still on hold pending the ongoing court case.

2. Common metabolites 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid and 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid (formed by bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr and pydiflumetofen)

   The Commission informed that it is still discussing with EFSA on a mandate and that two additional substances have been added to the list of common metabolites.

3. Common metabolites of pyrethroids

   The Commission informed that the study on one of the metabolites that is needed for the assessment of the common pyrethroid metabolites is expected to be submitted by applicants in the upcoming weeks via the renewal procedures of two active substances (tau-fluvalinate, lambda-cyhalothrin).

4. Zeta-cypermethrin

   See point A.19

5. Dimethenamid-P

   The Commission informed about the revised assessment report prepared by the rapporteur Member State about data concerning this active substance submitted post approval concerning (1) (Q)SAR-calculations for two metabolites where it

concluded that the metabolites are highly likely not genotoxic and (2) maximum acceptable groundwater concentrations leading to an amended RAR compared to EFSA conclusions.

The Post-Approval Issue (PAI) Working Group discussed outcome of the assessment and one Member State was still reflecting on the conclusions regarding non-genotoxicity of the two groundwater metabolites. The rapporteur Member State announced that a bilateral meeting will be organised with this Member State to discuss and clarify.

The Commission reminded that, if one Member State would consider that there are still concerns, a procedure according to Article 21 would need to be considered.

6. Trifluoroacetic acid (TFA)

The Commission recalled the key events following the notification on TFA made under Article 56 in January 2021. The TFA Task Force had provided an update at the end of February and recalled that Germany had expressed its intention to submit a proposal for harmonised classification and labelling to ECHA, with a submission foreseen by 31 May 2024 based on information in ECHA's Registry of Intentions. The applicant under REACH had proposed self-classification for TFA as toxic for reproduction category 2. Furthermore, the Commission informed that one applicant had also sent a letter, calling for a harmonised approach to the assessment of TFA

The Commission explained that it was reflecting on the possibility to launch a review of the existing toxicological data in view of confirming toxicological reference values. Other possible actions enabling a more comprehensive assessment of exposure to TFA from use of plant protection products was being considered but such a task would take considerable time due to the need to collect and evaluate data and that TFA also comes from other anthropogenic sources.

The Commission invited Member States to provide any information that may be useful for possible activities, e.g., monitoring data, and for any views on their preferred actions and way forward.

One Member State stated that future work must not delay decisions on individual active substances (where TFA is relevant as a metabolite).

7. Classification of mixed sodium nitro compounds

The Rapporteur Member State for Sodium, p-nitrophenolate Sodium, o-nitrophenolate Sodium, and 5-nitroguaiacolate shared its concern concerning the status of a mixture of sodium nitro compounds as a technical concentrate containing the three individual substances. EFSA recommended that this technical concentrate shall be described in Volume 4 of each renewal of approval for each individual active substance. The rationale behind is linked to the fact that ATONIK MUP is resulting from an actual mixing of the three active substances which are manufactured individually in a ratio 1:2:3 or by adding the individual substances to a manufactured mixture of ortho and para nitrophenol.

The rapporteur Member State indicated that a combined RAR for the three active substances has been drafted including a proposal for classification for the technical concentrate and not a classification proposal for the individual

substances because they can only be used as a mixture. It is noted that many studies provided in the dossier were only performed with the mixture. Should there be an obligation to propose a classification for individual substances a lot of new studies would have to be performed to complete the data package which is going against the principle of reducing unnecessary animal testing.

Member States were invited to comment by 19 April 2024. The Commission indicted it intends to ask ECHA RAC colleagues about the possibility to propose a harmonized classification for mixtures like in this case.

A.11 Article 21:

1. Flupyradifurone

The Commission informed that the mandate to EFSA under Article 21 (2) is under finalisation.

The Commission also informed that the day before the meeting it had received additional information from the applicant on the risk assessment of flupyradifurone seed treatments uses. Member States were invited to comment on this by 19 April 2024.

2. Cyazofamid

The Commission informed that EFSA and eight Member States commented on the study strategy provided by the applicant to examine the two metabolites (DMS and DMSA). As previously agreed, an Article 21 procedure will be initiated.

A.12 General issues for information / discussion:

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

a New cases: seaweed extract – plant growth regulator vs. plant biostimulant

The Commission explained that one Member State commented on the non-paper prepared to distinguish between plant growth regulators (Regulation (EC) No 1107/2009) and plant biostimulants (Fertilising Products Regulation): in its view, if the composition and mode of action of seaweed extract varies greatly due to the individual bioactive substances contained and the different cultivation and processing conditions as stated by the European Biostimulants Industry Council (EBIC), a generalised categorisation and evaluation of these actives may not be possible. The Commission invited Member States to comment by 19 April 2024.

The Commission also referred to:

- treated nets containing an insect repellent, which aim to be placed ‘around’ the crops to be protected. They constitute a physical barrier between the crop and the pest affecting it and, in case they were not treated nets, they should be excluded from the scope of the Regulation. However, in order to increase their breathability and avoid the development of mold, they may be treated with an insect repellent in order to be able to widen the meshes. This repellent solution is pre-marketing (industrial application method) and is not directly sprayed on the crops. The Commission suggests considering these kind as nets analogous to “retrievable dispensers” of a plant protection

product, where semiochemical active substance or the product containing it is diffused without any direct contact with the crops. The product treating the nets shall therefore be considered a plant protection product and is falling under the scope of the regulation.

- SILTAC, where the producer had informed it does not agree on the change of status which is, in its views, not falling in the scope of plant protection product regulation because the mode of action is via immobilization due to the three-dimensional structure of the trisiloxane molecule that - due to its size - cannot penetrate the insects and cause physiological disruptions, affecting the pests in purely physical way. Another argument of the company is that SILTAC has no effect at egg stage which indicates that the product is not a wetting agent, destroying hydrophobic surfaces of the pests. Compared to other trisiloxanes, SILTAC contains a co-formulant which creates the tridimensional structure. Several Member States considered that this category of substances shall be falling in the scope of the Regulation in a consistent way.
- Disinfectants, where one Member State came back on the agreed interpretation and decision tree organizing the scoping of disinfectant between biocides or plant protection products Regulation with several situations: (1) cleaning and disinfection before the growing season of machines and tools, etc. for handling potatoes as well as rooms (which are not necessarily empty), boxes and the like for storing seed potatoes at the company; (2) Cleaning and disinfection of machines, tools, containers, boxes, etc., which have been used in outside areas, before handling potatoes with a disinfection product with a documented effect against plant pathogenic viruses and microorganisms, including plant pathogenic bacteria; (3) Cases where premises and machines etc. must be emptied of potatoes every year, and then cleaned and disinfected before intake of new potatoes; (4) Disinfection of empty greenhouses or storage rooms for plants, where the aim may be to both remove biofilm/algae to increase light pass through as well as prevent plant pathogens.

Member States were invited to comment on these cases by 11 April 2024.

b. Physical barriers: concerned entries in Scope Document and potential follow-up

The Commission presented a draft document indicating which entries of the scope document would be affected by the decision tree proposed to distinguish products falling in or outside the scope due to their physical mode of action, including the physical barriers.

This document also outlined some procedural aspects to ensure smooth transition, should the product status be modified based on this new interpretation of the scope. A stepwise approach was proposed.

Member States were invited to comment by 19 April 2024.

2. Basic substances – general issues and survey

The Commission informed that a meeting on basic substances will be held on 28 May 2024 online. Seventeen Member States have already appointed experts. The Commission invited the remaining Member States to appoint experts too.

3. Work plan for the development of test methods focusing on wild pollinators

The Commission informed that no comments were received on revision 1 of the workplan and that it intends to share this version on its website after redaction of personal data. The Commission reminded that this workplan is a living document and any suggestion for amendments can be send to the Commission at any moment.

4. PFAS

The Commission informed that recently the US EPA removed some PFAS from their list of co-formulants and that such substances are not yet in Annex III of Regulation (EC) No 1107/2009.

A.13 Amendments to Regulation (EU) No 547/2011.

The Commission thanked for the comments to the revised draft and reacted to the main aspects, e.g., the colour scheme and the labelling of products for seed treatment.

During the meeting, Member States asked about the compatibility of Article 66 (2) with the proposal for a colour scheme and of Article 49 (4) with the proposal for including sentences for the use or sowing of treated seeds in the labels. Some Member States explained their national regulatory tools to convey the risk mitigation measures to the user in the packages of treated seeds. Several Member States explained their suggestions for the colour scheme, e.g., to include emergency authorisations.

Member States were invited to comment by the 5 April 2024 on a draft sentence to allow volume reduction when a product is applied by precision application techniques.

A.14 Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013.

The Commission thanked for the comments to the draft regulations, which were currently being addressed. the revised drafts will also include a few additional changes with respect for the data requirements for micro-organisms as regards classification and labelling.

The Commission summarised the next procedural steps, in particular the TBT notification, public consultation, and scrutiny by European Parliament and Council.

A.15 Co-formulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574

The Commission informed that eleven notifications were received so far from Member States, one overlapping and one as formaldehyde releasers and that on the basis of these notifications, it intends to prepare an amendment to Annex III to Regulation (EC) No 1107/2009.

The Commission also informed that in the Biopesticide Working Group eight Member States had submitted their national list of coformulants used in plant protection products which contain microorganisms as active substance. Furthermore, the Commission clarified how Member States could notify co-formulants which should be listed in Annex III of Regulation (EC) No 1107/2009 as unacceptable impurities.

2. On-going actions

The Commission invited the Committee and the members of PAI Working Group to comment on the draft outlines for a guidance on the safety assessment of coformulants/plant protection products by 8 April 2024.

The Commission invited Member States to indicate by 5 April 2024 databases to be presented at the information day on coformulants (first half of June 2024).

A.16 Report from Working Groups, in particular:

The Commission informed about the last meeting of the Post Approval Issues (PAI) Working Group, held on 7 and 8 March 2024. The main points debated were: data protection questions, the establishment of a group of Member States to amend the Guidance Document on new active substance post-(renewal of) approval (as one of the main outcomes of the ZAPID workshop), technical equivalence issues, particularly on blends of SCLP (Straight Chains of Lepidopteran Pheromones), discussions on the applicability of Guidance Documents (such as soil photo transformation products in ground water), the applicability of amended review reports, the applicability of new classification when the RAC opinion is available, and the importance for experts to keep track of the different revisions of guidance documents as regards their applicability at the moment the applications were submitted.

1. Working Group on Biopesticides

The Commission informed about the main points of discussion at the last meeting of the Biopesticides Working Group that took place the 14 March 2024, and which covered a debriefing from the OECD meetings, an update from EFSA including the creation of a group of experts to support the peer review of microbial active substances, Member States practices on labelling micro-organisms, and the progress on two studies outsourced by the Commission on background levels and group reviews of microbial species approved in EU for plant protection uses.

2. Working Group on comparative assessment

There was no news to discuss.

3. Working Group on Negligible Exposure

See Point A 07.06 above

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

There was no news to discuss.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA informed about progress in the peer review of the risk assessment of active substances and the on-going mandates, and informed about the planning of the upcoming expert meetings for the peer reviews and the update of the EFSA administrative guidance on pesticides.

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

The Commission informed that it agreed on 21 February 2024 to inform the European Parliament and Council of its intention to withdraw by 31 March 2024 the Sustainable Use of Plant Protection Products Regulation (SUR) proposal, tabled in 2022. In the meantime, the SUD remains in force and Member States continue to implement their National Action Plans. In addition, all users of pesticides must comply with the conditions and risk mitigation measures established in the individual authorisations for the placing on the market and use of plant protection products under Regulation (EC) No 1107/2009. Reducing the risk and use of the most hazardous pesticides remains a key objective of the Commission's work on food safety.

The Commission recalled the Strategic Dialogue on the Future of Agriculture. On 28 February 2024 a letter was sent by the Chair of the Strategic Dialogue to a range of stakeholders inviting them to send inputs. An online survey addressed to European farmers was launched, which is also open to other applicants to CAP support. The next months will be an opportunity for the Commission to engage with stakeholders in this forum: https://agriculture.ec.europa.eu/consultations/farmers-consultation-simplification_en.

3. Health and Food Audits and Analysis (SANTE, Directorate F)

The Commission informed that the published work programme for 2024 includes five audits on the authorisation, marketing and use of PPPs. The audit to Romania took place in February/March and Bulgaria is scheduled for 5 to 19 March. The remaining three audits take place in April (Germany), May/June (Finland) and November (Spain).

4. Minor Use Facility (MUCF)

There was no news to discuss.

5. OECD, FAO and EPPO activities

a) OECD Working Party on Pesticides, seminar on Problem Formulation, Expert Group on Biopesticides

The Commission reported about the OECD meetings that took place from 26 to 29 February 2024, among others in the ONIP (OECD Network on Illegal Trade of Pesticides), the Seminar on Problem Formulation, the Expert Group on Biopesticides and Working Party on Pesticides.

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

The Commission informed about a petition to the EP on sulfuryl fluoride (1034/2023). which asks for a general ban of all uses and is not limited to plant protection products only and encouraged Member States to avoid further delays in the risk assessment of this kind of active substances.

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

1. possible impact on authorisations

   The Commission informed that at the meeting on the Section Residues of this Committee on 1st and 2nd February 2024, MRLs were lowered for deltamethrin, metalaxyl, thiabendazole, trifloxystrobin, dithianon, 1,4-dimetahlynaphthalene, and flupyradifurone.

2. zeta-cypermetrin (TRV to endorse)

   The Committee endorsed updated toxicological reference values (TRV) for zeta-cypermethrin. One Member States indicted to endorse them only for control but not for import tolerances.

   In addition, the TRV for carbendazim were confirmed and the Committee endorsed this.

A.20 Scientific publications and information submitted by stakeholders.

The Commission informed that letters from People for the Ethical Treatment of Animals (PETA), 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.21 Date of next meeting(s).

The Commission informed that the next meeting is scheduled to take place in presence the 22 and 23 of May, subject to confirmation.

A.22 AoB.

The following additional points were discussed.

The Commission informed that an amended Review Report for metiram will be proposed for endorsement at the next meeting of this Committee, to correct a typo. The draft amended report is available to Member States on CIRCA BC.

The Commission informed that in the context of the application according to Article 7 to amend the conditions of approval of metalaxyl-M to increase the level of CGA226048 and to remove the restriction concerning the sowing of seeds, the EFSA Conclusion from October 2023 confirmed that a new level of 10 g/kg can be set for CGA226048. Although for the aspect of the sowing of seeds, a mandate to EFSA to further review certain issues and to update the risk assessment is on-going, the Commission suggests to act without delay on the limit for the impurity and to amend the conditions of approval in this regard to facilitate the product authorisation processes. Therefore, the Commission intends to vote at the next meeting in May. Draft documents were made available, and Member States were invited to send in comments by 11 April 2024.

The Commission informed about a case raised by one Member State regarding the control of impurities in plant protection products originating not only from the active substance and how to calculate the total content of the impurity in the plant protection products. Diverging comments were received by four Member States.

One Member State informed about a monitoring project on residues in cut flowers.

One Member State informed about a funding possibility to provide assistance with the review of the current risk assessment methodology for non-target plants. The Commission informed that it is currently drafting a mandate to EFSA that will include a request for review of the risk assessment methodology for non-target plants.

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)

The Commission summarised the draft restricted renewal and requested the preliminary positions of the Member States.

Twelve Member States expressed the intention to support the Commission proposal although recognising the importance of the active substance for the EU growers. Seven Member States expressed the intention to vote against the proposal because of the importance of the active substance in Integrated Pest Management (IPM), resistance management, and precision agriculture, and requested to further explore scientific or regulatory options to keep some field uses. Three Member States indicted they would abstain for similar reasons. Five Member States had no position set.

Vote Postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance dimethomorph, 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/2023/2347 RR)

The Commission informed that the TBT consultation was concluded and that no reactions were received from third countries, and that some stakeholders had raised concerns (growers of hop and vines, as well as NGOs). Two Member States would have preferred shorter grace periods. One Member States informed that long grace periods are needed, also in the context of MRL setting, due to the long storage period of up to four years of hops, which is crucial for beer production.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance mepanipyrim, 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 SANTE/11620/2017)

The Commission reiterated that it proposed not to renew the approval of mepanipyrim because it meets the criteria for endocrine disruptors for humans and wild mammals for

the EAS-modalities. Additionally, negligible exposure could not be demonstrated and the conditions for the application of the derogation in Article 4 (7) were not fulfilled. Furthermore, a high long-term risk for wild mammals via dietary exposure was identified and several issues could not be finalised. The TBT procedure has been finalised and no comments were received.

One Member State would have preferred a shorter grace but confirmed that it would support the proposal as it is.

Vote taken: Favourable opinion.

B.04 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 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, dithianon, dodine, fluometuron, hexythiazox, isoxaben, lime sulphur, orange oil, prosulfuron, quinmerac, sintofen, sodium silver thiosulfate, tau-fluvalinate, tebufenozide, tembotrione and zinc phosphide

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 31 July and 31 August 2024 according to Article 17 of Regulation (EC) No 1107/2009. The Commission reiterated that the extensions proposed are calculated on the basis of where each active substance currently stands in the assessment and regulatory process.

One Member State indicated it does not support the proposal because the extension periods for azadirachtin, bupirimate, dithianon, hexythiazox, isoxaben, lime sulphur, orange oil, quinmerac, sodium silver thiosulfate, tau-fluvalinate, tebufenozide, tembotrione and zinc phosphide were too long. The Commission explained that these active substances are all currently under assessment by the respective rapporteur Member States, including the commenting Member State, and invited all Member States to provide information on the indicative dates by which they intend to submit the respective renewal assessment reports to EFSA.

Another Member State indicated non-support to the extension granted to candidates for substitution, such as fluometuron and prosulfuron.

A third Member State indicated its support and requested additional time to submit the revised renewal assessment report as it already foresees a delay in the assessment.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the approval period of the active substances dodemorph, lauric acid, methyl octanoate, methyl decanoate, oleic acid and *Trichoderma atroviride* (formerly *T. harzianum*) strain IMI 206040

The Commission presented this draft Implementing Regulation, to retract the extensions granted to the approval periods of seven active substances, setting the expiry dates to a date closer to the original date of expiration. The Commission added fatty acids C8-C10 methyl esters. The retractions proposed were justified because applications for renewal were not submitted or dossiers already submitted were withdrawn.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 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)

The Commission explained the amendments made to the drafts.

One Member State reiterated its comment, delivered in December 2023, concerning a relevant impurity.

Member States were invited to comment by 11 April 2024.

C.02 Exchange of views 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)

Pro memoria – TBT notification (to be) launched

C.03 Exchange of views 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)

Pro memoria – TBT notification (to be) launched