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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
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CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/9f03a75c-eaa8-4932-955c-b5b85324a43d?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary reports of the meetings which took place in July and September are published, while the one of the October meeting is still in preparation.

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

1. Potassium stearate

The Commission informed that this application was submitted end of September 2023. The substance has insecticidal properties, and it is meant to be used in fields and greenhouses on arable crops, ornamentals, vegetables and fruit crops.

However, potassium stearate is an approved active substance under Regulation (EC) No 1107/2009, as it is covered by the active substance fatty acids. Plant protection products containing this active substance are authorised in several Member States. Since one of the approval criteria of Article 23 of Regulation (EC) No 1107/2009 is that a basic substance is not placed on the market as a plant protection product, the application cannot be considered admissible. The letter was sent to the applicant on 15 November 2023.

2. *Schinopsis lorentzii*, ext. bisulfited

The Commission informed that this application was submitted end of October 2023. It has fungicidal properties, and it is meant to be used in fields and greenhouses on vegetables, grape vines, and fruit trees.

The application is at admissibility stage. Negative feedback is being prepared, inviting the applicant to submit additional information.

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

1. Renewal process (Regulation (EU) 2020/1740)

– approach on access to old studies (to endorse)

The Commission explained that comments received from Member States and the three industry associations (Crop Life Europe, International Biocontrol Manufacturers Association and European Crop Care Association) had been compiled, reviewed, and responded to, and that a revised version of the non-paper was made available to Member States on 28 November, which considered those comments.

In addition, the Commission explained that two further versions had been made available before the meeting, to address some last-minute comments.

The Commission again recalled that the non-paper is not a legal instrument nor legally binding, rather that it sets out a common understanding of how old studies can be made available for the purposes of renewal of approval applications, if applicants cannot obtain them. It was underlined that the non-paper can be revised in future based on experience gained, if needed, and that it was hoped that applicants would reach agreements so that the need to use the outlined options in the non-paper would not be frequently required.

Several Member States expressed some concerns about the non-paper and the approaches taken, in particular concerns about the resources needed to sanitise documents, the possibility to use third party consultants and on the legality to make studies available. Several Member States asked for some additional time to consider the last-minute changes to the text and two Member States informed that the document was still being considered by their legal teams.

Therefore, the Commission postponed the endorsement and agreed that Member States could provide further comments by 10 January2024, in view of a possible endorsement at the meeting on 30-31 January 2024.

2. Alignment dossiers PPP / CLH (Regulations (EU) No 844/2012 and (EU) 2020/1740)

The Commission reminded the Committee of the obligation to submit a CLH report together with the Renewal Assessment Report, according to the provision of the Regulations (EU) No 844/2012 and (EU) 2020/1740, which is fully applicable since 27 March 2021.

3. Availability of PPP products/ Information on delays / ZAPID workshop debrief

The Commission informed that four out of six grants to support Member States in reducing delays and improving regulatory processes were signed (Latvia, Spain, Estonia, and Slovakia). The remaining 2 grants will be signed soon. The projects start on 1 January 2024 and will run for 60 Months.

Regarding the Workshop on the Zonal Authorisation Procedure – Improvement and Development (ZAPID workshop) and the progress on the assessment of Plant Protection Products, including co-formulants, the Commission informed that since the last meeting of this Committee, the topic was discussed at several occasions: the Pesticide Steering Network meeting on 24 October 2023, the Post Approval Issues (PAI) meeting and the Working Group on phys-chem in November 2023, and finally, the ZAPID workshop in December 2023.

At ZAPID, the topic on assessment of plant protection products was discussed in two break-out groups. Germany presented their relevant databases that contain the data and assessments of Plant Protection Products including co-formulants since the 70'. The participants agreed that there is a need for a database and for guidance at EU level. As for the database, Member States' delegates indicated that they prefer a step by step

approach. The report of the workshop is expected to be available in the beginning of 2024.

4. Possible procedures for applications to change status from normal approval to low risk

The Commission recalled that some applicants expressed interest in changing the status of an active substance, in particular from regular to low risk active substance. The Commission informed that such a change of status of an already approved active substance, in particular from a regular active substances to a low risk active substances, is not foreseen outside the context of a renewal procedure because it is not supported by any provision in Regulation (EC) No 1107/2009).

After recalling the legal framework governing the substantive decisions to be taken in respect of an active substance, the Commission highlighted that the concept of "status" is alien to Regulation (EC) No 1107/2009 and is not assimilable to the concept of "condition". Therefore, as it would not be legally sounded to change the status without any general regulation providing an ad hoc procedure enabling such change, the Commission suggested as possible solutions either the "normal" renewal procedure or an "early" renewal.

Some Member States raised concerns were raised on the allocation of recourses outside the renewal program, usually planned long in advance. Some Member States suggested the possible submission of a new approval under Article 7 of Regulation (EC) No 1107/2009.

Member States were invited to send their comments and suggest alternative solutions by 20 January 2024.

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

- New active substances / Amendment of conditions of approval

1. Metalaxyl-M

The Commission reminded that the EFSA Conclusion had been published on 31 October 2023 and briefly recalled the background to the application for amendments of the conditions of approval. A summary of the findings in the EFSA Conclusion was then given.

The Commission explained that the critical area of concern for the risk to birds and mammals reflects the higher-level outcome but not the detail, at zonal level. However, it appears that a safe use for birds and mammals can be demonstrated for the low application rate on spinach covered by the representative use, at least in the Southern zone, when considering some qualitative aspects and the use of precision drilling.

Given the nature of the critical area of concern and the need to have a firm basis to finalise decision-making, the Commission proposed to send a mandate to EFSA to further examine the issue, with a focus on providing more detail on the outcomes of the assessment.

Member States were invited to reflect and provide comments by 18 December 2023 on:

- the information provided by the applicant on the sowing densities for spinach;

- the use of precision drilling equipment for seeds, including spinach;
- their views and agreement to send a mandate to EFSA.

- Renewal of approval

2. Mecoprop-P

The Commission informed that an updated EFSA Conclusion was published on 27 October 2023. This Conclusion was updated following the request from the Commission to review the risk assessment as regards the non-dietary exposure and the endocrine-disrupting (ED) properties of mecoprop-P in accordance with the new ED criteria. EFSA concluded that Mecoprop-P does not meet the ED criteria neither for humans nor for environment. Using the EFSA calculator, the predicted exposure of residents (sum of all exposure pathways) was below the AOEL except for children entering treated areas (75th percentile) even when applying a buffer strip of 10 m and drift reduction measures during application (critical area of concern). Other non-finalized issues were:

- The consumer risk assessment could not be finalised due to the outstanding data to confidently address the nature and magnitude of residues in plant and animal matrices.
- The long-term risk to birds could not be finalised.

The Commission informed that it received comments from the applicant on the EFSA conclusion and also that EFSA indicated that a slightly amended version of the conclusion will be soon republished.

Member States were invited to comment by 10 January 2024.

- Basic substances

3. *Allium fistulosum*

The Commission recalled that *Allium fistulosum* is a perennial onion placed on the market as food. As a basic substance, it is to be prepared by the operators in the form of a) a dispersible concentrate prepared by mixing dried *Allium fistulosum* plant pieces with water, and b) in a form of a plant rodlet formulation where the fresh *Allium fistulosum* plant is cut into pieces and then mixed with the soil. Both formulations are proposed to be used against the bacteria *Ralstonia solanacearum* for soil treatment before tomato-sowing in the field and in permanent greenhouses.

The EFSA Technical Report was published in November 2023. The applicants were invited to submit comments on this report, but they did not respond. The Commission gave a short summary of the main findings of EFSA's Technical Report.

The preliminary conclusion from the EFSA assessment seems to be that *Allium fistulosum* could be proposed for an approval as basic substance. The issues to consider seem to be the irritant properties and the potential operator exposure and, for the use as spray application the non-finalised assessment as regards the risk to aquatic organisms.

The Commission needs to further reflect on the details of the way forward.

Member States were invited to send by 20 January 2024 their comments to the EFSA Technical Report and positions concerning the approval as basic substance of a plant rodlet formulation and a dispersible concentrate to be applied as spray.

4. Eggshell powder

The Commission informed that the EFSA technical report was published mid November 2023. The intended basic substance eggshell powder is available on the EU market as an inorganic fertiliser and as a soil improver. The preparation to be used is a dustable powder containing 100% eggshell powder which is industrially manufactured, and it should be directly applied without additional steps and preparations. The eggshell powder is to be used in plant protection as a fungifuge on grapevine, applied via a specific duster for agriculture with a powder coating option.

The EFSA technical report mentions that in the framework of the fertiliser use, there have been no reports on immediate or delayed harmful effects on human or animal health and there are no concerns regarding the non-dietary exposure. However, according to the classification provided by companies to ECHA in REACH registrations, this substance has the potential to cause (because of the CaO) serious eye damage, skin irritation and respiratory irritation. Because the application did not mention any investigation of inhalation toxicity and the potential for skin or eye damage, EFSA recommends the use of personal protective equipment (including respiratory protective equipment) for operators.

Based on the proposed specification and the intended use, EFSA could not conclude that the use of eggshell powder is safe for the non-dietary exposure to the impurity lead. Considering the likely high content of lead in the eggshell powder according to the specification provided by the applicant, a neurodevelopmental effect cannot be excluded based on the dietary exposure estimates for consumers. EFSA therefore concludes that risk management considerations are necessary.

Finally, due to the intended last application of eggshell powder at BBCH 89 (when the berries are ripe for harvest) residues of eggshell powder are very likely to be present on the berries. EFSA therefore notes that eggs and products derived thereof require allergen labelling under the EU food law. Risk management consideration is once again required.

Comments from the applicant as well as supporting letters are available on CIRCABC.

One Member State asked whether the application of eggshell powder would affect the fermentation of wine because of the late time of application (BBCH 89).

Member States were invited to send their comments by 10 January 2024.

5. Grape seed extract

The Commission informed that EFSA technical report was published end of October 2023. The intended basic substance grape seed extract is available on EU market as food supplements and feed additive. Grape seed extract is proposed to be used in plant protection as a fungicide on grapevines, apple trees, lettuce, and potatoes, consisting of field and greenhouse applications.

EFSA did not raise any concerns for human and animal health from the proposed uses from dietary as well as non-dietary exposure. Even though no concerns are

present regarding operator exposure during mixing and loading; in the absence of investigation of inhalation toxicity and the potential for skin or eye irritation, EFSA does recommend the use of PPEs.

In general, EFSA concluded on a low risk for non-target organisms. For non-target terrestrial plants, a low risk can only be concluded for uses in permanent greenhouses. A lack of data does also not allow to conclude a low risk for aquatic organisms.

Comments from the applicant as well as supporting letters are available on CIRCABC.

Member States were invited to send their comments by 10 January 2024.

A.05 Draft Review/Renewal Reports for discussion:

- Renewal of approval

1. Metribuzin

The Commission informed that it has met with representatives of the Metribuzin Task Force (MTF) who contested the EFSA Conclusion with respect to the identified critical areas of concern. All documents received by the applicants together with the replies of EFSA and the Rapporteur Member State as well as the summary of the meeting have been made available to the Committee. A letter was received from PAN Europe which calls for the non-renewal of the approval of this active substance.

The Commission also informed that EFSA is preparing an update to the Conclusion that is expected by the end of January 2024.

One Member State requested that in case of non-renewal of the approval a grace period not longer than six months should be granted due to the endocrine disruptive properties of metribuzin. The Commission explained that as usual the period would be set following a discussion at the Committee.

The Member States were invited to comment by 20 January 2024.

2. Metconazole

The Commission presented its proposal to renew metconazole as a candidate for substitution and shared the first draft of the Review Report. The Commission informed that EFSA will soon publish a revised version of the Appendix B of the EFSA Conclusion. This revision, however, does not have a bearing on the outcome of the assessment. Member States were invited to provide positions/comments, by 10 January 2024.

3. Milbemectin

The Commission summarised the findings of the EFSA Conclusion. Member States were invited to comment by 10 January 2024.

- Basic substances

4. Caffeine

The Commission gave a short summary of the process of an evaluation of an application for an approval of caffeine as basic substance. The initial Commission proposal was a non-approval as a basic substance due to multiple data gaps

identified by EFSA which did not allow to conclude that the substance meets the criteria of Article 23. The approval process has been put on hold upon request of an applicant who intended to submit additional information to support their application.

Within the updated application, the applicants submitted the revised application template and more than 60 new documents which are mainly published literature. The applicants also deleted from the GAP table the growth stages when the edible parts of crops are present to reduce consumer exposure. Furthermore, the intended application rates and a total number of applications were reduced in the updated application.

The Commission asked EFSA for feedback on the updated application, and EFSA informed that the new information does not change the conclusions of the already published EFSA Technical Report.

Five Member States submitted their comments on the updated application and on the EFSA's feedback. Generally, all the commenting Member States indicated that it would be difficult for them to conclude that the approval criteria as a basic substance are met. They point out the high application rates, and too many fundamental data gaps such as the non-concluded issue of non-dietary exposure, the environmental exposure which may require risk mitigation measures and a lack of data in the ecotoxicology section. One Member State informed additionally that theophylline, which is a metabolite of caffeine, has a harmonised classification as toxic for reproduction category 1B. The same Member State is of the opinion that an assessment of the risk related to the formation of the metabolite when caffeine is used as a pesticide is therefore needed.

One Member State is of the opinion that the new data should be evaluated in a new procedure of a Pesticide Peer Review. This is due to the concerns identified during the previous assessment and because the applicant submitted a substantial number of new studies, and above all for the sake of transparency.

The Commission identifies the two options for a way forward: a vote on a non-approval proposal based on the available data and EFSA's feedback; or the evaluation of the new data submitted by the applicant in a new peer-review process involving the Member States and EFSA.

As regards the EFSA Technical Report on caffeine. Caffeine is naturally occurring and approved as a food additive. The application concerns pure caffeine powder to be diluted in water and applied as a spray at a concentration higher than a concentration of caffeine in coffee (espresso), and at high application rates of 2 times 9 kg per hectare.

In addition to many data gaps, the Technical Report of EFSA indicates that the available FOCUS groundwater calculations are sufficient to indicate that the parametric drinking water limit of 0.1µg/L, would be significantly exceeded for the uses requested in the application. This limit of 0.1µg/L would be applicable to caffeine if it was to be approved as a "regular" active substance. Significant surface water exposure will also occur. EFSA confirmed that in the applicant's updated application the appropriate environmental exposure assessments were still not available and that the conclusion that the parametric drinking water limit of 0.1µg/L would be significantly exceeded is still valid. Additionally, the non-dietary exposure assessment is still not provided in the updated application. The

argumentation provided by the applicant evokes that the background exposure of the environment to caffeine is higher than the exposure resulting from the use requested in the application. Similarly, the applicants evoke that the voluntary consumption of caffeine in the form of foodstuff goes beyond or is comparable to the level of exposure expected for the operators and consumers as a result of the use as a basic substance.

The Commission stressed that caffeine has been detected in groundwaters and surface waters in Europe and all over the world. The presence of caffeine in European groundwaters results from anthropogenic pollution. The use of caffeine in agriculture would mean its deliberate release in the environment, and it will add to the already existing pollution. As regards the non-dietary exposure, the operator's exposure, even if below the value of an intake of no concern, will be additional to the voluntary caffeine consumption.

The Commission invited the Member States to reflect on the applicability of a sort of a risk envelope approach in this case that would consider the background levels of caffeine pollution or consumption, and to send comments and positions by 20 January 2024. In particular, the Member States were asked whether they support a) a full peer review of the updated application by the Member States and EFSA before the final decision is taken; or b) a non-approval as a basic substance based on the available information that they consider sufficient to conclude that the criteria of Article 23 are not met, without a full peer review of the updated application. Member States were requested to prepare their positions for a "tour de table" in January.

5. Ozone/ ozonated water

The Commission reminded that the evaluation of the application for an approval of ozone as a basic substance has been on hold since January 2022 upon request of the applicants who intended to submit additional information to support their application. The Commission informed that the applicants provided the updated application together with new bibliographic references including some studies. The Commission needs to reflect on the way forward with this updated application.

One Member State expressed interest in making ozone available to farmers for plant protection purposes.

A.06 Guidance Documents, in particular:

1. Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009 (to endorse)

The Commission informed that a revised version of the document together with a table summarising the comments received from Member States were available on CIRCA BC.

The Commission explained the changes made in the document to accommodate these comments, in particular as regards the role of the template of problem formulation in the pre-submission meetings and the peer review process for the approval/renewal of active substances. The Commission clarified in the document that the pre-submission meetings usually take place years before the submission of the dossier and that at that stage, the information provided by the applicants in the template might be limited. Therefore, the information provided for discussion during the pre-submission meeting will not be legally binding. According to the regulation, further data can always be

requested by the Rapporteur Member State (RMS), the co- RMS and EFSA during the admissibility of the application and the peer-review process.

The Commission also remarked in the document that the burden of proof when completing the template always remains on the applicant. The Commission also explained how the template can be included in the IUCLID dossier to be considered in the peer review.

The Commission reiterated that it considers this document as an important step forward to implement in a more harmonised way the Point 1.5. of the Introduction of the Annexes of the current Data Requirement Implementing Regulations.

The Commission explained during the meeting the comments received from one Member State on the relevance of some ecosystem services (ES) for Problem Formulation. Another Member State asked about the use of the concept of ES in the document. The Commission explained that the concept of ES is only used to establish the framework in the document and for communication purposes and does not have an influence on the Risk Assessment. The Commission proposed a bilateral meeting with these Member States to discuss further these comments.

Another Member State provided written comments on the use of the template of Problem Formulation as justification for not providing data on the IUCLID dossier.

Member States were invited to send their final comments and positions as regards endorsing the document by 10 January 2024.

2. Guidance document on semiochemical active substances and plant protection products (SANTE/12815/2014) – draft amendment

The Commission explained that the draft updated version of this guidance document was consulted with stakeholders and the Biopesticides Working Group. Stakeholders suggested some small amendments which were considered. The Post-Approval Issues Working Group suggested amendments for chapter 8 regarding technical equivalence. Member States were invited to comment on the revised draft version by 10 January 2024.

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

The Commission informed about comments received from Member States, advocating for a suitable period (of around 2 years) to implement the guidance. The Commission explained that it was preparing an implementation schedule that would be shared once ready. Member States were invited to send comments and views on the implementation.

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

See point A.12.

5. EFSA Guidance Risk assessment for Birds and Mammals

See point A.12.

A.07 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 the ten notifications received since the last meeting of this Committee: three notifications concerned rejections of mutual recognition applications and seven concerned a rejection of authorisation under the zonal system. None of the decisions were appealed at national courts.

3. Article 53

See point A.16

A.08 Microorganism and low risk Active Substances, in particular:

The Commission informed that new sessions would start soon under the Better Training for Safer Food (BTSF) Programme, focusing on the new data requirements of micro-organisms. The Commission informed that the contractor has preliminarily indicated the following dates: 20-23 Feb 2024, 30 April-3 May 2024, 4-7 June 2024, October 2024, December 2024, March 2025. The Commission stated it will keep the Member States informed once the dates will be officially communicated. Member States were invited to contact their national contact points to appoint experts to the training sessions.

1. Implementation of low risk criteria for active substances of natural origin

The Commission recalled that a change of the status of an active substance once renewed might be legally difficult (see point A.03.4) and that for this reason it is important to take the right decision when renewing the active substances.

Regarding the pelargonic acid the Commission informed that it discussed the results of the risk assessment with respect to non-target organisms with EFSA and further analysed the Conslusion. It was noted that for the uses of pelargonic acid-based plant protection product MON 74134 in home gardens and allotments several issues were considered:

- a low acute and chronic risk for bees was concluded on the basis that (i) pelargonic acid causes extremely rapid and non-selective burn-down of green tissues (as revealed in the semi-field studies) rendering treated plants and flowering weeds unattractive to bees shortly after its application; (ii) the application of the ready-to-use MON 74134 formulation normally is expected to cover olny a part of the overall area. Also, for highly managed lawn and turf where mowing is routinely done the ‘treated crop’ and ‘flowering weeds in the treated crop’ scenarios are not relevant;
- a low risk was concluded for earthworms and other soil macroorganisms based on a qualitative weight-of-evidence approach on the basis of (i) the localised spot application, (ii) the fact that the product has a limited pack size and is a ready-to-use trigger spray; and (iii) the fast degradation of pelargonic acid in soil (half-life of 1.6 days);

Also:

- a low in-field risk was concluded for the uses of NEU 1170 H on paths and open areas with tree growth, woody ornamentals, decorative lawns and turf, and for the uses of VVH–8086/BCP1004D on vineyards and potatoes;
- pelargonic acid is undergoing fast degradation in soil, water and air as well as its volatility from the plant surface.

The Member States were invited to comment by 20 January 2024 on whether the above considerations could be applied with respect to the risks from MON 74134 for non-target arthropods and how this could affect the assessment of those risks.

The Commission presented 3 possible ways forward for the active substance rape seed oil and asked the Member States to indicate which of the 3 possible ways forward they were inclined to support:

a) Renew rape seed oil, as suggested in the proposal presented in December 2022 (standard renewal), before the general discussion to reconsider this proposal was initiated;

b) Renew rape seed oil as a low-risk substance, considering that the issues identified were at Tier 1 level for NTAs and bees and due to the unspecific mode of action, and that a more realistic field application scenario would consider that the fast biodegradability of rape seed oil would lead to only transitory effects and recovery potential of NTAs and bees; or

c) mandate EFSA to reassess rape seed oil asking for a qualitative weight of evidence based environmental risk assessment.

One Member State pointed out that similar use scenarios for similar substances are being considered as basic substance application.

Member States were invited to comment by 10 January 2024.

A.09 Updates, clarifications & questions on specific active substances:

1. Common metabolites of pyrethroids / lambda-cyhalothrin (revised review reports to endorse)

The Commission shared the comments received from two Member States and from the applicants of cypermethrin and lambda-cyhalothrin on the revised draft Review Report. The Committee endorsed the revised Review Report of lambda-cyhalothrin.

The Commission explained that no revision to the Review Report of cypermethrin was deemed to be necessary as the Commission plans to re-open the EFSA mandate on the common pyrethroid metabolites to include the assessment of the metabolite PBAld and to finalise the related residue definition for cypermethrin. The missing study to conclude on the toxicity of PBAld is expected to be submitted soon via a renewal procedure of another active substance.

At a request from a Member State, the Commission clarified that the revision of the Review Report of gamma-cyhalothrin can be expected once the EFSA Conclusion on the on-going review of the renewal of lambda-cyhalothrin becomes available. Gamma-cyhalothrin is one of the isomers of lambda-cyhalothrin, and the renewal will expire in 2025 as no application was submitted.

2. Dimoxystrobin (revised review report to endorse)

The Commission presented a draft update of the Renewal Report on dimoxystrobin. This report reflects the EFSA Conclusion that is based on an almost complete analysis and only the evaluation of endocrine disruptive properties by the EAS-modality for organisms different from mammals could not be finalised due to lack of data. Although dimoxystrobin is no longer approved, this update, in particular setting new Toxicological Reference Values (TRVs) and a residue definition for risk assessment (RD-RA), is necessary to facilitate further work on the substance, specifically on

MRLs. The draft renewal report has undergone only editorial changes compared with the previous version presented to the Committee in October 2023.

The updated Renewal Report on dimoxystrobin (Revision 3) was endorsed by the Standing Committee without objections or further comments.

3. beta-cyfluthrin (revised review report to endorse)

A formal update was necessary to the Review Report of beta-cyfluthrin, i.e., to add the reference to the revised EFSA Conclusion issued in 2020. The Committee endorsed the revised Review Report of beta-cyfluthrin.

4. Copper compounds (updated toxicological reference values to endorse)

The scientific opinion adopted by EFSA on the re-evaluation of the existing health-based guidance values (HBGV) for copper and the exposure assessment from all exposure sources recommended an Acceptable Daily Intake (ADI) of 0.07 mg/kg bw/day and noted that there is no need for an Acute Reference Dose (ARfD). The Commission proposed to add these values to the EU Pesticides Database.

The Commission also reported about a product ("MasterCop") containing a form of copper which was not supported by the approval dossier: a highly soluble form of tetraminecopper sulphate which differs from the five other forms of copper covered by the EU approval dossier. The lower solubility allows slower bioavailability.

As this form of copper is not approved, the Commission recommended that the concerned Member States consider the following:

- the authorisation for placing of products containing this form of copper to be revoked and no further delivered.
- any emergency authorisation(s) for this form of copper should be delivered in line with the ECJ judgement on emergency use authorisations (when risks can be considered as acceptable).

5. Sodium hydrogen carbonate

The Commission informed that the applicant did not reply yet on the letter asking for clarity on the marketing of this substance as a regular active substance. The discussion on the dual approval of this substance is therefore still on hold.

One Member State asked if the competent authority concerned could not provide this information. The Commission informed that according to ESTAT rules this information cannot be disclosed by that Member State, i.e., to avoid that statistical info can be connected to individual companies.

6. Prosulfocarb

The Commission informed that more information had been provided regarding the notification under article 44 of Regulation (EC) No 1107/2009. The Commission invited Member States to look at the notification for their national authorisations, and indicated that Member States can ask to discuss this topic at any time in this Committee, should new information become available.

7. Cyazofamid

The Commission informed that Denmark and Sweden withdrew the authorisations of the products containing cyazofamid based on Danish (DEPA) findings of two metabolites, DMS and DMSA in a field trial. The Commission informed that a meeting

was held at the request of the applicants in November 2023 and shared the comments received from the applicant.

The Commission shared the comments from 5 Member States who are of the opinion that an Article 21 is the appropriate mean to address this issue at EU level. Member States were invited to provide positions/comments by 20 January 2024.

8. *Trichoderma atroviride* strain SC1

This point was postponed.

9. TFA

Member States were informed that the TFA Task Force had provided an update on ongoing work, which was shared on CIRCABC. According to the update provided, the anticipated submission of an updated REACH dossier and the update to the notification under Article 56 of Regulation (EC) No 1107/2009 was foreseen for the first quarter of 2024.

It was also noted that the ECHA Registry of Intentions had been recently updated to indicate the intention for the submission of the CLH dossier by Germany in May 2024.

10. Phenmedipham

The Commission recalled that in the former EFSA conclusion (EFSA, 2018), no Toxicological Reference Values could be set as the genotoxic concern could not be ruled out. Later, in 2019 the ECHA RAC Opinion was published which reported that RAC, in line with the dossier submission, did not consider the available data to raise a significant concern about genotoxicity. If this aspect of genotoxicity, as if the genotoxicity concern could now be ruled out, there would be implications on the issues not finalised set in the former EFSA conclusion and their related data gaps:

- non-dietary exposure risk assessment could not be conducted since reference values could not be established;
- the consumer risk assessment could not be finalised as, due to non-conclusion for genotoxicity, reference values could not be established.

Therefore, it would be possible now to reach a conclusive outcome on genotoxicity (in line with the ECHA RAC Opinion) and, accordingly, to set Toxicological Reference Values s and to perform the dietary and non-dietary risk assessment. In turn, this would trigger the need of updating the current renewal assessment report (RAR) to introduce the necessary revisions (i.e., on genotoxicity assessment alongside the consequent setting of Toxicological Reference Values, non-dietary exposure calculations and dietary exposure calculations).

Once the revised RAR would be available, EFSA would proceed to drafting the conclusions along with a Member States consultation on the draft conclusions. The RMS confirmed its capacity to revise the RAR by the end of February 2024, so to enable proper planning of the onwards steps.

A.10 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
   a) New cases
   b) Physical barriers (short update)

These points were postponed.

2. CHED-N - introduction of notification system for imports of PPPs

The Commission informed that it is working on a draft delegated regulation under Article 45(4) of Regulation (EU) 2017/625 concerning the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union. Plant protection products have been included in the scope of this draft delegated regulation. This means that the Member States may choose whether to oblige the operators to use the CHED-N notification system for PPPs. It is currently discussed whether to include also safeners and synergist in the scope of this delegated regulation.

One Member State asked why the biocidal products were not included in the scope as well. The Commission will check this and inform the Member States during one of the next meetings.

A.11 Amendments to Regulation (EU) No 547/2011:

The Commission thanked those Member States who had provided comments to the revised draft and informed that an overview table was available on CIRCA BC.

The Commission explained that the main comments received from Member States concerned the transitional period, the proposed hazard sentence and pictogram for bees, the requirements for digital labelling, and the colour scheme.

Member States then asked about the responsibility of the authorisation holder as regards the content and the availability of the digital label. Some Member States remarked that additional information could be included on the digital label as long as it follows the authorisation. Many Member States shared their views on a possible risk or hazard-based attribution criterion(a) triggering the pictogram/sentence ("Dangerous/hazardous? to bees") at EU level. Two Member States explained their proposals as regards the modification of the colour scheme.

The Commission explained that it aims to launch the interservice consultation (ISC) of the draft soon, and will distribute a revised draft after the meeting.

Member States were invited to provide comments on the current proposal for the hazard sentence and pictogram for bees and information on their national tools to communicate potential risks to pollinators in their labels by 20 December 2023.

A.12 Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013:

The Commission explained that draft amendments of Regulations (EU) No 546/2011, 283/2013 and 284/2013 will be presented as a package. All three updates will be voted under the regulatory procedure with scrutiny (RPS) and are thus impacted by the 2024 European election recess period from 15 March until 10 July 2024. The Commission furthermore informed that a public consultation will be organised before the proposals will be tabled for a vote in this Committee. After the vote, the proposals will be forwarded to the European Parliament and the Council for scrutiny.

The Commission explained that the endorsement of the Bee Guidance Document is a 2-step procedure with the first step being the updates mentioned in the previous paragraph. The second step, which is the actual endorsement of the Guidance Document itself, can only take place after completion of the first step and is not expected before

the end of October 2024 (i.e., not before 3 months after the end of the election recess period).

The Commission informed that the three drafts are under finalisation and will be shared with the Committee shortly after the meeting. The proposed changes will reflect three new or revised guidance documents (namely bees, birds and mammals and water treatment processes) and a number of other small amendments which are needed in order to align with the recent update of the Commission Communications setting out the list of test methods and guidance documents.

Member States were invited to comment on the three proposals by 20 January 2024.

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

1. Implementation of Regulation (EU) 2023/574

The Commission informed about several aspects related to the implementation of Regulation (EU) 2023/574:

A) Unacceptable coformulants

A notification from one Member State for 4 coformulants to be listed as unacceptable was received by the Commission: 3 of the notified substances are SVHC according to REACH, the 4th is a non-approved biocide. This substance was not supported under the Biocides Regulation and did not enter in the biocide review program. According to other Member States, this does not mean implicitly that the substance is to be considered as non-approved. The Commission reminded that further notifications are welcomed in order to updated Annex III.

B) Template for notification

There is no specific template to be used for notification, Member States can notify by email or letter providing the relevant information.

C) How to approach criterion n.10

Member States should collect data and perform a risk assessment. EFSA will check the risk assessment submitted by Member States.

D) Formaldehyde releasers

According to the summary of the questionnaire sent out among Member States, different positions are taken, and harmonization is needed. The same subject has been also discussed – among others - at the Working Group on phys-chem properties (Parma 22-23.11) and the minutes of this meeting will be circulated when ready.

Member States are invited to send comments by 10 January 2024.

2. Ongoing actions

Please refer to the summary available under point A 03.3.

A.14 Report from Working Groups, in particular:

1. Working Group Post Approval Issues

The Commission informed about the last meeting of the Post Approval Issues Working Group, held on 29 and 30 November 2023. The main points debated were: a clarification of the RMS dealing with confirmatory information; new active substance

data post-approval; MRL review and CLH dossier for the active substance trifloxystrobin; a proposal to update chapter 8 of the Guidance Document on semiochemicals in view of a clarification of equivalences of SCLP approved individually and not as blends; follow-up discussions on dimethenamid-P conclusions of the assessment of new active substance data post-approval; follow-up discussion on the possibilities of a co-formulants' database; the applicability of the new birds and mammals guidance document and the possible transitional measures; how different Member States handle applications for minor uses extensions during "the frozen period" when the AOEL is lowered (even if within the risk envelope for toxicology) as cut-off criterion, or whether only possible changes of ADI and ARfD are considered to refuse these applications; data protection issues; the application of the *Mutatis Mutandis* principle in the context of the Article 59 (1); the control of equivalence assessments of technical materials under Article 38 of Regulation (EC) No 1107/2009 to avoid duplication of work, among others.

A.15 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 workshops organised via outsourced projects in the context of methodologies for non-target arthropods and off-field exposure.

A.16 Court cases, requests for internal review, Ombudsman cases.

The Commission informed briefly about Case T-565/23 (Aurelia Foundation vs European Commission), in which the Aurelia Stiftung seeks annulment of the Commission's decision rejecting their request for internal review of Commission Implementing Regulation (EU) 2022/2364 as regards the extension of the approval period of the active substance glyphosate.

In addition, Case T-94/23 (POLLINIS France vs European Commission), in which POLLINIS France is seeking annulment of the Commission's decision rejecting their request for internal review of Commission Implementing Regulation (EU) 2022/708 as regards– inter alia - the extension of the approval period of the active substance boscalid. Case T-94/23 has been transferred to the same chamber and judge-rapporteur as other Aarhus pesticides cases.

A Member State asked for an update of the interpretation of the Commission on the judgement in case C-162/21. While the analysis of the wider ramifications of the ruling was not yet fully concluded – in particular with regard to substances for which an approval was not renewed, the Commission reiterated that for several points for which inquiries had been received from Member States and stakeholders, there is already internal agreement on the interpretation of the judgment:

- Member States can no longer grant emergency authorisations that would be incompatible with Article 53(1) as interpreted in the judgment in case C-162/21, in particular emergency authorisations for coating of sugar beet seeds for outdoor sowing with neonicotinoid active substances (thiamethoxam, clothianidin and imidacloprid) and emergency authorisations for the sowing of such seeds;

- Member States can no longer grant emergency authorisations also for any other outdoor use of the three neonicotinoids (thiamethoxam, clothianidin and imidacloprid) e.g., foliar spraying and also for any other crop;
- granting of emergency authorisations for any active substance when there is a specific explicit restriction in the approval/non-approval regulation, is not possible anymore, including also for other uses such as foliar spraying. This applies not only to the neonicotinoids but also to other active substances with a restriction in their approval.

The Commission explained that it was working on an update to the existing guidance and would share it once a final interpretation was available.

The Commission informed the Committee of a letter sent to 6 Member States indicating that certain Emergency Authorisations granted after the judgment by these Member States do not comply with the judgement in case C-162/21. The Commission therefore asked to withdraw these authorisations if possible and to not repeat them. Certain Member States also indicated to be surprised by the letters sent out by the Commission while the Commission has so far not confirmed its interpretation on the judgement.

Several Member States indicated that a harmonised interpretation across the EU is needed in order to guarantee an equal level playing field for EU farmers. One Member State expressed its view that the judgement only applies to substances where a restriction to the treatment and the sowing of seeds is included in the approval. Another Member State raised concerns that applicants may withdraw applications for substances during the evaluation or decision-making process to avoid having a negative decision that may preclude the granting of emergency authorisations.

The Commission informed that it received several requests for internal review which concern the following:

- Implementing Regulation (EU) 2023/1757 on the extension of the approval periods of the active substances flufenacet and sulfuryl fluoride;
- Implementing Regulation (EU) 2023/1757 on the extension of the approval periods of the active substances chlorotoluron, flufenacet and prosulfocarb;
- European Commission's reply of 3 October 2023 (Ref. Ares (2023)6685241) to a previous request for internal review of 8 May 2023 concerning Implementing Regulation (EU) 2023/574 laying down detailed rules for the identification of unacceptable co-formulants in plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

A.17 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 of the Pesticide Residues section of this Committee which took place on 20-21 November 2023, measures on the following active substances were taken with possible impact on authorisations:

2,4-DB	MRLs were lowered.
Iodosulfuron-methyl	MRLs were lowered.
Mesotrione	MRLs were lowered.
Pyraflufen-ethyl	MRLs were lowered.

A.18 Scientific publications and information submitted by stakeholders:

The Commission referred to one letter received from an NGO, which was made available to the Committee via CIRCA BC.

A.19 Date of next meeting(s):

The Commission informed that the next meeting of this Committee will take place on 30 and 31 January 2024.

A.20 AoB:

The Commission recalled that in March 2023 eight *Bacillus thuringiensis* (Bt) strains were renewed for approval under the condition for the applicant to submit spore density decline studies on one edible crop within 30 months after the approval.

The Commission informed that a letter was received from the "Bt task force" claiming that a meeting with the RMS and the co-RMS was held, and that the applicants have been requested to submit studies exceeding what is provided for in the Regulations renewing the approval of the eight Bt strains. The Commission reminded Member States to apply a "need to know" approach in compliance with the conditions provided for in the regulations renewing the approval of the eight Bt strains. The Commission invited Member States to comment on the letter from the Bt task force.

The Commission thanked the Member States and EFSA once again for their work and cooperation during the glyphosate renewal process and provided a short update on the state of play.

During the Appeal Committee held on 16 November 2023, the vote of the Committee on the Commission's proposal to renew the approval of glyphosate delivered 'no opinion' (no qualified majority in favour or against).

In accordance with Article 20 of Regulation (EC) No 1107/2009, the European Commission is obliged to adopt an Implementing Regulation on the renewal or non-renewal of an active substance even when no qualified majority, either in favour or against, is reached in the Standing Committee and in the Appeal Committee. As the EFSA Conclusion on glyphosate did not identify critical areas of concern that would prevent a renewal, the Commission adopted the Implementing Regulation (EU) 2023/2660 renewing glyphosate for a 10-year period on 28 November 2023, which was published the day after. The glyphosate webpage has been updated.

The Commission reminded the Member States that following the renewal of approval, the next step is the renewal of the authorisations of plant protection products in accordance with Article 43 of Regulation (EC) No 1107/2009.

The Commission explained that, in the framework of a previous MRL assessment of difenoconazole, an exceedance of the chronic intake was identified when considering the existing MRLs, assuming no change of the isomer ratio. Consequently, Member States and the Commission agreed to ask EFSA to prioritise the MRL review and to not wait for the renewal of the active substance to be completed (as it is usually done for the Article 12 MRLs review). EFSA therefore proceeded with the review of the MRLs, which is currently at an advanced stage. According to a preliminary risk assessment, it is confirmed that a risk for consumers cannot be excluded for some of the existing uses, even without considering the impact of a change of the isomer ratio. The Article 12 review was then put on hold, in order to wait for the outcome of the assessment of the isomer ratio in the peer review of confirmatory data of the active substance. However, the outcome of the peer review of confirmatory data with regard to the isomer ratio observed for the residues, identified the need for an expert consultation prior to conclude. Nevertheless, since according to the assessment of the confirmatory data, EFSA cannot exclude a changed isomer ratio and the need to use appropriate uncertainty factors in the risk assessment for difenoconazole, EFSA would now expect that even more uses/MRLs could not be safe any longer. In view of the above, the Article12 review needs to know as soon as possible which the factors are to be used for taking the isomer ratio into account, in order to finalise the related opinion, and provide sound recommendations on the exceedances identified. Therefore, the Commission informed the Committee on its intention to send a mandate to EFSA to organise an expert consultation to be able to conclude on the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment.

The Commission informed that it is expected to vote on the approval of magnesium hydroxide as basic substances at the next meeting of this Committee, as Member States provided useful comments on the draft review report and the applicant was consulted.

The Commission also informed about the upcoming relevant meetings at OECD and two Member States asked for information on the guidance document SANCO/10473/2003 Rev 5.

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) concerning the non-approval of the active substance asulam-sodium in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (Draft review report SANTE/10746/2018)

SANTE/10745/2018

The Commission presented the draft Implementing Regulation, which was amended with respect to the version presented at the last meeting of this Committee in order to reflect the withdrawal of the application by the applicant.

Vote taken: Favourable opinion.

B.02 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 benzovindiflupyr, bromuconazole, buprofezin, cyflufenamid, fluazinam, fluopyram, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metsulfuron-methyl, phosphane and pyraclostrobin

PLAN/2023/2323

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 31 of January, 29 February, 2 March 2024 and 31 March 2024. The extensions according to Article 17 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 approvals. The Commission explained that the extensions proposed are calculated on the basis of an estimate of the time still needed to complete the renewal procedure. The remaining regulatory steps depend on where each active substance currently stands in the process, and maximum time periods are defined in the legislation. The Commission reminded about the legal possibility to rescind the extensions at any time.

One Member State indicated that longer periods of extensions provide for more predictability and encourage the submission of new PPP applications. However, when decisions on renewal are taken before the granted extension expires, Member States have to face a duplication of work when renewing the PPP recently authorised.

Another Member State indicated that it does not agree with the extension of buprofezin and the long extensions granted to substances that are candidates for substitution.

The RMS for buprofezin updated the Committee on the current status of the assessment after the three-month stop-the-clock and the experts' discussions.

The Commission reminded that, for many substances the risk assessment has not yet been finalised by the respective rapporteur Member States; In case there is enough evidence that the approval criteria are not satisfied, it has already and may continue to ask EFSA to proceed with the peer review on parts the dossier in order to proceed with the respective non-renewals.

Vote taken: Favourable opinion.

The following protocol declarations were made:

Denmark:

Denmark support the extensions, but the re-evaluation of mecoprop-P, flutolanil and buprofezin should be completed as soon as possible. For mecoprop-P, there is a conclusion from EFSA from October 2023 that shows critical areas. The Commission should therefore as soon as possible forward a review report to restrict the use. For flutolanil there is an EFSA conclusion from June 2023, and the Commission should as soon as possible present a review report for vote. Buprofezin is assessed to be endocrine-disrupting in humans, but there is not yet an EFSA conclusion. We therefore emphasize that the assessment should be finalized as soon as possible.

Germany:

The current proposal on the extension of the approval periods for the active substances (PLAN/2023/2323) can be supported by Germany although we have concerns regarding the extension periods for the active substances buprofezin and flutolanil. The

active substance buprofezin was discussed in the PREV expert meeting of June 2023. Finally, it was concluded by the experts that buprofezin fulfils the criteria for classification as an endocrine disruptor (T-modality) and thus also fulfils the cut-off criteria according to Regulation (EC) No 1107/2009, Annex II, No. 3.6.5. In the interests of human health protection, efforts should be made to reach a decision on the active substance buprofezin as soon as possible. An extension of the approval period until December 15, 2025 is not justifiable from the health risk perspective. Therefore, the approval period should be extended until December 15, 2024 at the latest. Due to the high priority, EFSA should be asked to finalize the EFSA Conclusion as soon as possible so that the European Commission can complete the procedure for (non)-renewal of approval within one year. The formal extension of the approval period for the active substance flutolanil for another 1.5 years is not appropriate in view of the identified risk for operators and workers for the use on potatoes. As the final EFSA Conclusion on flutolanil is already available (EFSA Journal 2023;21(6):7997), the approval period should be extended by a maximum of one year. Germany would appreciate if the European Commission could swiftly prepare the review report to decide on the(non)-renewal of approval for the active substance flutolanil.

The Netherlands:

The Netherlands does not agree with the extension of the approval period of bromuconazole because of the risks regarding fungal resistance.

Nevertheless, because we are faced with a package of substances, we vote in favor of the entire package.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

PLAN/2023/2195

The Commission summarised the ongoing procedural steps which are necessary before voting the proposed legal text (i.e., feedback mechanism and Technical Barrier to Trade notification). Furthermore, the Commission informed the participants that one Member State sent comments before the meeting requesting more specific (eco)toxicological data requirements to be added in the Annex of the legal text. Another Member State commented during the meeting on the topic of Maximum Residue Levels and its enforceability.

Finally, the Commission asked the Member States to send their comments by the 10 January 2024 at the latest, in view of a vote in the January meeting of this Committee.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance hydrolysed proteins as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/1723 RR)

PLAN/2023/1723

The Commission summed up the comments received from two Member States after the last meeting of this Committee in October and explained the modifications made to the draft Review Report and the Annex of the draft Regulation.

One Member State mentioned the problems that control authorities are facing when monitoring, with co-formulants containing the same impurities as identified in the active substance. The Member State suggested to clarify in the implementing regulation that such co-formulants would not count during such findings. The Member State was invited to provide more details by 10 January 2024.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance urea as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011) (Draft Renewal Report PLAN/2023/2197 RR)

PLAN/2023/2197

The Commission summarised the comments received from two Member States after the last meeting, which concern the origin and limits of the impurity values as well as the minimum purity of urea.

Member States were invited to comment by 10 January 2024.

C.04 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 comments received from three Member States as well as the applicant after the last meeting of this Committee. Two of them explicitly supported the way forward as proposed by the Commission asking for confirmatory data.

Member States were invited to comment by 10 January 2024.

C.05 Exchange of views 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/2347 RR)

PLAN/2023/2347

The Commission presented the draft regulation and informed that the TBT notification will be launched soon and that the vote is foreseen for the March meeting of this Committee.

Three Member States indicated they would prefer a shorter grace period.

C.06 Exchange of views 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11620/2018)

SANTE/11618/2018

The Commission informed that the TBT notification will be launched soon and that the vote is foreseen for the March meeting of this Committee. Comments on the drafts made available were received from one Member State.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the withdrawal of 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/2650 RR)

PLAN/2023/2650

The Commission recalled that during the evaluation and peer review of the submitted confirmatory information requested for the active substance acibenzolar-S-methyl, the assessment could not be finalised because new criteria to identify endocrine disruption properties became applicable during the evaluation. This is detailed in the statement of the European Food Safety Authority (EFSA). As a consequence, after discussing in this Committee, the applicant had been requested to submit information under Article 21 of Regulation (EC) No 1107/2009 by the end of June 2025.

On 8 September 2023 the applicant informed the Commission that they will not submit the information requested to address Article 21 due to their preliminary self-classification of the substance as toxic for reproduction category 1B (R1B). The applicant also informed the Commission that for that same reason it has opted to stop further production of all plant protection products containing acibenzolar-S-methyl as active substance for the EU countries (post meeting note: on 12 December 2023, the applicant submitted to the Commission a notification for the new classification).

As a consequence of this classification, the substance would not be expected to meet the approval criteria under Regulation (EC) No 1107/2009 as it would meet one of the

cut-off criteria (R1B). As a consequence of the applicant not submitting additional information that would allow to assess the dossier in view of the new classification, the Commission presented a draft withdrawal regulation.

The Commission reminded that existing authorisations of plant protection products will need to be withdrawn. EU Member States must withdraw existing plant protection products containing acibenzolar-S-methyl at the latest 6 months from the date of entry into force. A period of grace in line with Article 46 of Regulation (EC) No 1107/2009 is allowed and shall expire at the latest 12 months from the entry into force (allowing for a final season of use).

Three Member States indicated they would prefer a shorter grace period (3+6), which would be enough to cover the next field campaign.

Member States were invited to comment by 10 January 2024.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance trinexapac, as trinexapac-ethyl, 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/11247/2018)

SANTE/11246/2018

The Commission reminded that a draft Regulation has been made available, that the inter-service consultation was ongoing and that the draft Renewal Report has been modified to consider further comments received from the Rapporteur Member State and to strengthen the provisions.

One Member State had already reacted before the meeting to indicate its agreement with the changes.

Member States were informed that a vote was planned for January 2024.

Final comments were welcomed by 10 January 2024.