## **EUROPEAN COMMISSION**



Health and Food Safety Directorate General

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## Standing Committee on Plants, Animals, Food and Feed Section *Phytopharmaceuticals - Legislation* 30 - 31 January 2024

**CIRCABC Link:** <a href="https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/f05affdd-9749-437a-9ddf-fa7520b1f3da?p=1">https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/f05affdd-9749-437a-9ddf-fa7520b1f3da?p=1</a>

#### **SUMMARY REPORT**

## **A.01** Summary Report of previous meetings:

The Commission informed that the summary reports of the October and December are 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:

The Commission informed that six Member States (Lithuania, Austria, Latvia, Spain, Estonia and Slovakia) signed grants under SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA-PESTICIDES, published on Funding & tenders (europa.eu).

- 1. Renewal process (Regulation (EU) 2020/1740)
  - approach on access to old studies (to endorse)

The Commission summarised the comments received by Member States since the last meeting of this Committee and presented the final version of the non-paper. The Commission underlined that:

- The non-paper is not legally binding, nor does it bind Member States to follow the options laid down therein.
- The options outlined in the non-paper are possible best practices, but do not preclude other options.
- The objective is to provide Member States with possible solutions to a problem that may happen occasionally (so far, there have been very few cases). It is in the interest of all parties (and in the interest of maximum transparency) to find a way to ensure all studies are submitted in renewal applications.
- The non-paper can be reviewed in the future, based on experience gained by Member States.

The Committee endorsed the non-paper, however, two Member States were not able to do so. One Member State noted concerns about possible resource implications

for Member States and another had concerns about the legal basis for Member States to perform confidentiality checks of old studies. Another Member States did not object to the endorsement but questioned the utility of the non-paper, in particular in the context of challenges of decisions by applicants. The Commission informed that the non-paper would be published on the SANTE website.

#### 2. Risk assessment

The Commission informed of its intention to launch a survey to Member States as regards whether and under which conditions they outsource a part of the risk assessment of dossiers.

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

The Commission restated that, in light of the absence of a provision allowing the change of status of an already approved active substance, further reflections on possible solutions are needed.

The Commission gave an overview of the replies received from three Member States and invited Member States to provide further comments or suggestions.

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

• New active substances / Amendment of conditions of approval

## 1. Metalaxyl-M

The Commission explained that following the request for Member State feedback on the suggestion to send a mandate to EFSA to further examine the risks, Member States had confirmed that there is a wide range of sowing densities for spinach – from less than 1 million to 12 million seeds per hectare, and that precision drilling is a method often used for sowing of spinach seeds. These details are important consider in an updated assessment.

The Commission also indicated that further consideration of the regulatory provisions related to sowing of seeds, in case of a difference in outcome between zones was needed in view of future decision-making, and that it intended to mandate EFSA to update the assessment.

#### 2. Isoflucypram

The Commission informed that additional testing on neurotoxicological development will be made available by the applicant to the Rapporteur Member State by 2025 at the latest.

#### Renewal of approval

#### 3. Tritosulfuron

The discussion was postponed.

## 4. Folpet

The discussion was postponed.

#### 5. Mecoprop-P

The discussion was postponed.

#### 6. Sulfur

The discussion was postponed.

#### • Basic substances

#### 7. Allium fistulosum

The Commission summarised the comments that were submitted by the Member States. Three Member States indicated they would support an approval of *Allium fistulosum* as a basic substance. However, two of them mentioned potential concerns for operators because some constituents in *Allium fistulosum* are notified as regards human health classification and labelling for acute toxicity at high doses, or local skin and eye irritation.

The content of these substances in the extract was not available in the application and there is no harmonised human health classification for *Allium fistulosum* or its constituents. The EFSA's recommendation for personal protective equipment for operators when handling the product containing *Allium fistulosum* is supported, in particular goggles.

Another Member State expected that the amount handled by an amateur user would be comparable to cooking and that the use of gloves is therefore not required. For professionals, a much higher amount is handled, and gloves should be required.

Additionally, one Member State indicated that for the intended field uses, direct exposure of surface water bodies can be excluded for plant rodlet application but not for spray applications. For the intended uses with spray application in the field and greenhouses where soil is exposed, it is not possible to conclude on a low risk. They mentioned the example of the active substance garlic extract for which the spray application in the field was not approved.

The Commission invited the Member States to provide comments and positions on the potential approval of *Allium fistulosum* as a basic substance in a formulation as plant rodlets and as a dispersible concentrate by 25 February 2024.

#### 8. Capsicum oleoresin

There was no news to discuss.

#### A.05 Draft Review/Renewal Reports for discussion:

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

#### 1. Metribuzin

The Commission informed that it has received comments from four Member States supporting a non-renewal of approval of metribuzin. The Commission also informed that an update of the EFSA Conclusion is in preparation and that a draft Renewal Report will be prepared once this is available.

The Commission invited Member States to comment by 25 February 2024, in particular whether the approval of metribuzin can be renewed or not and whether Article 4(7) of Regulation (EC) No 1107/2009 would be applicable.

#### 2. Milbemectin

The Commission summarised the findings of the EFSA Conclusion. Member States were invited to indicate by the 18 February 2024 if they would support a renewal of approval.

#### 3. Pelargonic acid

The Commission informed that it has received comments from two Member States. One of them reiterated its views already expressed during the Committee meeting in July 2023 on how the minimal purity of the active substance should be expressed. The Commission explained again why it maintained its position.

The Commission also informed that it had asked EFSA whether a qualitative weight of evidence approach to the risk-assessment for non-target arthropods could be applicable, as it had been for other groups of non-target invertebrates.

#### 4. Rape seed oil

The Commission informed that since the last meeting of this Committee 2 Member States had indicated support for a renewal as a non-low risk active substance, 1 Member State support a renewal as low risk active substance restricted to indoor uses, and 2 Member States indicated that a further mandate to EFSA would be helpful for a weight of evidence based environmental risk assessment.

One Member State asked if the design of the OECD 214 test guideline, targeted for chemicals, is appropriate for substances with a mechanical mode of action like rape seed oil. Another Member State inquired about the low-risk status of this substance when it is used as a safener and synergist.

Member States were invited to comment by 18 February 2024.

#### 5. Flutolanil

The discussion was postponed.

## 6. Aluminium silicate calcinated

The Commission informed it is still reflecting whether there are conditions given for a renewal as low risk active substance, taking into account that there are issues identified only at Tier 1 level for NTAs and bees due to the unspecific, mechanical mode of action. Member States were invited to comment as regards the possibility to renew as low risk active substance by 18 February 2024.

#### Basic substances

#### 7. Caffeine

The Commission summarized the comments that were submitted by two Member States which support the non-approval of caffeine as a basic substance. One of them because there are still too many data gaps for both toxicology and ecotoxicological points. The updated application does not seem to address the issues that EFSA raised in the technical report of 2021 and, therefore, a peer review of the new information would not be of much value. That Member State indicated that, in principle, they are not against caffeine as a basic substance, but they think that the current application does not sufficiently demonstrate that the intended uses are of no concern for human health and the environment. The second commenting Member State provided a summary of the main concerns identified and indicated that a new full peer review of the updated application would not allow concluding that the basic substance criteria are met.

All Member States were asked for their positions: 9 supported a full peer review of the new information submitted by the applicant, 10s indicated that a peer review is not needed because, based on the available information, there is already enough clarity that caffeine should not be approved as a basic substance, and 8 did not express their opinion.

Seven Member States took floor during the discussion. Two of them clarified that in principle they support a non-approval of caffeine as basic substance as they do not see any other option given the data available, however for procedural reasons they support the peer-review. Five other Member States indicated that there is no other way forward than a non-approval. One Member State mentioned that the peer review could clarify some outstanding issues but would not change the overall outcome of the assessment which leads to a non-approval, therefore they support to proceed on the basis of the current EFSA outcome. One Member State explained that they generally support approvals of basic substances but in the case of caffeine there were too many issues identified during the assessment. They also suggested that it would be more useful if EFSA dedicates it's time to other dossiers that are more promising. One Member State emphasized the difference among caffeine, coffee, and coffee grounds, as well as the toxicity of caffeine and known cases of health problems in cattle fed with caffeine-contaminated feed.

The Member States who did not express their position were invited to communicate it by 25 February.

#### 8. Ozone/ ozonated water

There was no news to discuss.

#### 9. Onobrychis viciifolia var. Perly (sainfoin) dried pellets

The Commission summarized the findings of the EFSA Technical Report as well as the comments received from the applicant. The Commission also reported that the applicant did not reply to many of the Member States and EFSA's questions, and they did not provide the requested information on several topics.

Member States were invited to express their thoughts on whether or not to approve this substance as a basic substance.

#### 10. Sunflower oil

There was no news to discuss.

#### 11. Eggshell powder

The Commission summarized the findings of the EFSA Technical Report as well as the comments received from one Member State on this Report. The Member State referred to the newest document where the production of the eggshell powder is described. They also explained the calculations of the composition commonly used for fertilisers. This is why they question whether the eggshell powder really contains calcium oxide (CaO) or whether it only contains calcium carbonate (CaCO3). This question has been forwarded by the Commission to the applicant.

The same Member State also wondered whether the late time of the application (BBCH 89) of the eggshell powder could influence the fermentation process of wine. This question has also been posed to the applicant.

The applicant replied that the basic substance is the same as the approved fertiliser which has a composition of 51% of CaO. They confirmed that the treatment does not impact the wine making process and that the substance is intended as

preventative treatment well before harvest and to facilitate and help the formation of the berries.

Member States were invited to comment by 18 February 2024.

## 12. Grape seed extract

The Commission summarized the findings of the EFSA Technical Report. Two Member States had sent comments on the peer review process and on the EFSA Technical report.

Member States were invited to comment by 18 February 2024.

## **A.06** Confirmatory Information:

#### 1. Difenoconazole

The Commission informed that in December 2023 EFSA finalised the Technical Report on difenoconazole confirmatory data. In particular, in the residues section, divergent views were expressed by EFSA, the Rapporteur Member State, other Member States and the applicant on the degradation of diastereoisomers in aged residues. EFSA recommended to further discuss the point in a peer review expert meeting.

Additionally, in the framework of an MRL assessment, EFSA identified an exceedance of the consumer chronic intake when considering the existing MRLs. Consequently, the Standing Committee on residues agreed to prioritise the review of the existing MRLs for difenoconazole according to Article 12 of Regulation (EC) No 396/2005. Therefore, the Commission informed that it had mandated EFSA to organise the necessary expert meeting to complete the assessment for difenoconazole with regard to the consumer risk assessment, in order to allow the prompt finalisation of the prioritised MRL review. The other sections for which this confirmatory data is relevant, will be superseded by the currently ongoing renewal procedure.

## 2. Aqueous extract from the germinated seeds of sweet Lupinus albus

The Commission informed that in December 2023, EFSA finalised the Technical Report on aqueous extract from the germinated seeds of sweet *Lupinus albus* confirmatory data. EFSA agreed with the proposals of a maximum content of the relevant impurities quinolizidine alkaloids (QA) and 0.035 g/kg for lupanine as a marker. Overall, the proposed reference specification is considered acceptable from a (eco)toxicological point of view. However, the studies submitted were not conducted under GLP. These studies were considered acceptable by the RMS, however EFSA is of the opinion that the batch analysis should be performed under GLP.

Member States were invited to comment by 25 February on the Technical Report and, in particular, on the acceptability of the non-GLP studies provided.

#### 3. Pendimethalin

There was no news to discuss.

#### A.07 Guidance Documents, in particular:

The Commission informed that the new database listing guidance documents is available and that the pesticide website will soon contain a link to it. The current static

website will stay available until the end of July 2024. Some further updates of the database (e.g., addition of supporting documents, history versions of the guidance documents) are foreseen. The Commission asked the Member States to keep reporting on any incorrect information via the database.

The Commission also informed that a mandate to EFSA is in preparation to revise the EFSA guidance on open literature review in the context of the Regulation (EU) No 1107/2009 and the EFSA guidance on Application of systematic review methodology to food and feed safety assessments to support decision making.

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

The Commission informed that comments were received from two Member States on the version of the document shared for the previous meeting, which supported the endorsement of the document. One Member State suggested to include this document in future guidance for specific groups of biopesticides and incorporate future experience on applying it. The other Member State explained that criteria for a harmonized implementation of the document are needed.

The Commission explained that EFSA had initiated a project to develop risk assessment guidance for pesticides of potential low concern, where several Member States are involved. This Guidance Document as well as the case studies that were provided as part of its consultation process will be considered in this EFSA project.

The Commission explained that a bilateral meeting with one Member State took place earlier in 2024 to better understand its concerns on the draft document, in particular as regards the reference to Ecosystem Services (ES). During the meeting, the Commission understood that this Member State supports the idea of having a guidance that provides a method to justify that certain data are not essential for the environmental risk assessment if scientifically justified, as this would allow to accelerate the approval of low risk substances. This Member States also agreed that the concept of ES has advantages for communicating with the public. The Commission had reiterated that this is the aim of referring to ES in the draft document, where the concept of ES is used as a conceptual bridge to link the concepts of hazard, exposure and the current data requirements, while not having a direct influence on the risk assessment as such.

The Commission understood that the concern of this Member State is that the current protection goals would be put under discussion. The Commission reiterated that discussions on protection goals are not in the scope of the document. Protection goals set in the legislation apply fully when applying the provisions of point 1.5 of the introduction of the Annexes of the data requirements and of the problem formulation proposed in the draft document under discussion.

After this meeting, the Commission made a few additions to the document with the purpose of further clarifying the issues raised, as well as minor modifications as regards the inclusion of the document in IUCLID and a rephrasing of some titles to reflect better the regulatory provisions. This revised version of the document was uploaded on CIRCA BC for endorsement.

The Commission explained that the day before the current meeting, the Member State referred above indicated that despite the bilateral meeting and the changes in the document, it was not in a position to endorse the document.

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 Requirements and that it has been discussed for about one year at this Committee after being consulted intensively with Member States, EFSA, and stakeholders. Additionally, 23 case studies were provided which ensured practicability of the document.

Another Member State proposed to proceed with the endorsement of the document since it had been discussed for more than a year and no further changes were expected in the text. This Member State also remarked that there is a need to start using the document.

The Commission asked if any Member States would oppose to this suggestion to proceed with the endorsement. All Member States (with the exception of the one that had sent the last comments) agreed with the endorsement and the document was endorsed.

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

The Commission explained the latest amendments to the updated guidance document, which address comments from stakeholders, several Member States, and EFSA. Most of the changes were of editorial nature but a new method of application was also added ("Sprayable matrix").

One Member State suggested to postpone the endorsement to allow a final review. However, as all other Member States supported endorsement and a further delay would also delay the implementation of the document, the Committee endorsed the Guidance Document.

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 that – taking into account the comments already received - it had made available a draft implementation schedule and invited Member States to provide comments by 15 February 2024. The Commission outlined that:

- a period of applicability of 2 years is appropriate for providing time for applicants to do the necessary work and for Member States to be ready for such evaluations.
- the guidance should not be applied to plant protection product assessments until the active substance contained in a particular plant protection product has been assessed in accordance with this guidance.

With regard to confirmatory information that had been set in the approvals of active substances and which are pending the availability of this guidance, the Commission informed that it would contact applicants and Member States once the date of implementation was fixed, to recall their obligations. For this purpose, an overview of the cases was provided. The Commission invited Member States to comment on this overview. In the few cases where an overlap with the renewal process was expected, the Commission noted that it would be more efficient to carry out a single assessment during the renewal.

Two Member States asked whether there would be a test/pilot phase for the guidance. The Commission explained that this was not considered necessary.

One Member States enquired whether there would be training for applicants and Member States. The Commission noted this request and said it would discuss possibilities to provide support with EFSA and ECHA.

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

The Commission informed that the draft document would be shared with the Member States soon to initiate a commenting round.

The Commission informed the Member States that it intends to operationalise the field 'area actually treated' which is designed to collect data on the actual use of plant protection products for which an emergency authorisation was granted. This information would be useful to provide more accurate data on the actual use since it is known that in some cases there is no use despite an authorisation being given, or the use is much lower than anticipated. It was suggested that this information could be useful for refining the Harmonised Risk Indicator 2 in the future.

The Commission also took the opportunity to recall again, as done in December 2023, that it considered:

- Member States can no longer grant emergency authorisations that would be incompatible with Article 53(1) of Regulation (EC) No 1107/2009 as interpreted by the Court 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 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 restriction in the approval/or a restriction in the last regulation for that substance, is not possible anymore. This applies not only to the neonicotinoids but also other active substances with a restriction in their approval.

The Commission informed that it responded to a question from several MEPs (E-003023/2023) on the granting of certain emergency authorisations by some Member States and reminded those Member States who did not yet reply to the letters sent by the Commissioner on granting certain emergency authorisations to do so. The Commission also reminded about the importance of immediate notification of emergency authorisations in the ESFC database.

A number of Member States expressed their concerns about filling in the 'area actually treated' on a mandatory basis, because of the resources needed and difficulties obtaining accurate information, in particular for plant protection products that have a regular authorisation for other uses than the one given under the emergency authorisation. One Member State mentioned the lack of a legal basis for collecting such information. Several Member States pointed towards the

possibility to use data from electronic records, in the future. The Commission agreed to reflect on this.

Several Member States asked for more clarity on the interpretation of the Commission on the judgement in case C-162/21. The Commission stressed that it does not interpret judgements of the Court which are already interpretations of EU law. However, the Commission explained that the view of the Commission would be reflected in the updated guidance, as well as in the reply to the question from the MEPs (see above).

Several Member States commented on the need for further harmonisation when granting emergency authorisations – the Commission referred to the updated guidance to achieve this.

The Commission also presented an overview of the emergency authorisations granted between 1 January 2017 and 30 July 2023.

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

See point A.14.

6. EFSA Guidance Risk assessment for Birds and Mammals

There was no news to discuss.

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

1. Article 44(4)

The Commission informed that, since the last meeting, it had received four notifications on amendments of existing authorisations of prosulfocarb based plant protection products. Adaptations of application rates, the restriction of growth stage applications, the need to use equipment to reduce spray drift and measures to protect bystanders and residents are now included.

2. Article 36(3)

The Commission informed about the six notifications received since the last meeting of this Committee: one notification concerned a rejection of a mutual recognition application and five concerned rejections of authorisations under the zonal system. None of the decisions were challenged at national courts.

3. Article 53

See point A.07.4

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

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

The Commission informed that the second phase of the training "Risk Assessment on Micro-Organism" under the "Better Training for Safer Food" (BTSF) programme has been launched, and that several sessions will be held until 2025. The Commission invited Member States to contact their BTSF National Contact Point to enroll experts.

The Commission summarized the comments received from Member States as regards *Bacillus thuringiensis* (Bt) and the letter that the Bt task force sent to the

Commission in December 2023, which was discussed at the previous meeting of this Committee. The letter raised a concern on the provision of confirmatory data on the 8 Bt species that were approved in March 2023, which, according to the task force, may go beyond to what is required. The Commission called for an approach consistent to what is provided for in the Regulations. One Member State highlighted that the RMSs and the Co-RMS agree to refine the methodology with the applicants and that another meeting with them is intended.

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

## 1. Copper compounds (revised review report to endorse)

The Commission explained that the administrative procedure in case of an amended reference value following an opinion by EFSA would require to amend not only the Pesticides Database accordingly but also the Renewal Report. The Member States unanimously supported the amended Renewal Report, which was therefore endorsed.

One Member State suggested however to review also the AOEL for copper compounds. As this was not part of the conclusions supporting the amendment of the ADI endorsed, the Commission suggested to cover this via the ongoing renewal process.

## 2. Sodium hydrogen carbonate

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

One Member State repeated being in favour to only withdraw uses for those Member States in which there is a national authorisation for sodium hydrogen carbonate as a regular active substance.

Member States were invited to inform the Commission of any request for authorisation for a product containing the active substance sodium hydrogen carbonate, and evidence of availability on the market of the product Natrisan.

#### 3. Cyazofamid

The Commission informed that, following the withdrawal of the authorisations of the products containing cyazofamid in Denmark and Sweden, the applicant - in the light of the launching of an Article 21 procedure - sent the study strategy to examine the 2 metabolites DMS and DMSA in question. The Commission shared the study and a comment from one Member State with the Committee.

Member States were invited to provide positions/comments concerning the way forward, i.e., to launch an Article 21 procedure and on the study strategy proposed by the applicant, by 18 February 2024.

#### 4. Trichoderma atroviride strain SC1

The Commission informed that a Member State received a letter from a company representing the applicant of the plant protection product "Vintec", containing the active substance *Trichoderma atroviride* SC1 as active substance, informing that the active substance is being manufactured in a plant which is different than the one specified in the authorisation and the active substance approval Regulation, and asking for advice on how to proceed.

The Commission referred to Article 44 and Article 45 of Regulation (EC) No 1107/2009, and to the assessment of equivalence of the active substance due to the change of the manufacturing plant.

The Member State which was the rapporteur for the approval of the active substance informed that a contact with the applicant was already established to address this issue.

5. 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 discussion has been postponed as a draft mandate has been sent to EFSA for commenting.

6. Common metabolites of pyrethroids

The Commission informed that there has not been any development because a study on one of the metabolites that is needed to finalise the work on the assessment of the common pyrethroid metabolites is still awaited.

#### **A.11 Article 21:**

1. Flupyradifurone

There was no news to discuss.

#### **A.12** General issues for information / discussion:

- 1. Scope of Regulation (EC) No 1107/2009:
  - a) New cases:
    - a.1. Seaweed extract plant growth regulator vs. plant biostimulant

The Commission explained its interpretation for products containing phytohormones which claim to be either a plant growth regulator (Regulation (EC) No 1107/2009) or a plant biostimulant (Regulation (EU) 2019/1009). Products claiming to improve plant root growth are considered as plant biostimulant, the rationale was explained in a draft document.

Member States were invited to comment by 25 February 2024 and to coordinate with the national colleagues in charge of the Fertilisers Regulations.

- a.2. The Commission asked for the positions of the Member States by 25 February 2024 about plants (not falling under the GMO legislation) that would express insecticidal proteins/peptides/RNAi. The "intended use" is to sow this plant together or within the crop that is meant to be protected from the insect targeted by the peptide/RNAi.
- a.3. Revision 75 of the scope document has been posted on CIRCA BC and is integrating the latest agreed amendments, notably the alignment of conclusions between SILTAC, STYX and K-PAK products based on poly-ethoxylated siloxane. One Member State indicated that these substances were also used as co-formulants and even as synergists.
- a.4. One Member State asked for interpretation on "disinfecting" products used in greenhouses. The Commission referred to the decision tree integrated in the

scope document for these scenarios to distinguish plant protection products from biocides.

## b) Physical barriers

This point was postponed.

#### c) Basic substances vs. fertilisers

The Commission informed that after internal discussions among services, its current interpretation is that a substance authorised as a fertiliser under national rules or under the Fertiliser Regulation (Regulation (EU) 2019/1009) could be approved also as basic substance under Article 23 of Regulation (EC) No 1107/2009. Recital 23 and Article 1 of the Fertiliser Regulation provides that the Fertiliser Regulation does not apply to plant protection products covered by the scope of Regulation (EC) No 1107/2009. Interpreted restrictively, this means that the restriction concerns only plant protection products and not basic substances.

As to the labelling of such basic substances which are also fertilisers, the Commission will suggest to the working group on fertilisers to amend the FAQ to cover this situation, as under the labelling requirements of Annex III to the Fertilisers Regulation the label of an EU fertilising product "shall not make claims by means of statements or visual representations that the EU fertilising product prevents or treats plant diseases or protects plants against harmful organisms".

#### 2. Basic substances – general issues and survey

The Commission made available a report summarising the results of the Member States survey on basic substances that was organised in 2023, where 24 Member States replied.

The survey revealed that there are divergent views, interpretations and practices in the Member States, so there is a clear need for more guidance and harmonisation. It also seems that the questions in the survey were not always clear and future discussion is needed. One of the key issues to address are the modalities for marketing of basic substances.

The Commission explained that it intends to organise a dedicated meeting to share experiences and get a common understanding of the desired direction and of the type of harmonised rules needed. Member States were invited to nominate experts by 25 February 2024 and, those who allow the placing on the market of basic substances, will be invited to present their experiences.

Representatives of 8 Member States took the floor. Several Member States indicated the importance of a discussion on basic substances and the need for a general approach, in particular as regards the placing on the market and labelling of products containing/consisting of basic substances.

Several Member States stressed that Regulation (EC) No 1107/2009 clearly indicates that basic substances should not be placed on the market as plant protection products. One Member State pointed out that if basic substances are to be specifically labelled for their use in plant protection, it may create even more uncertainty in the approvals of basic substances than is currently the case. Another Member State emphasised that allowing basic substances to be placed on the market "as such" for plant protection uses might lead to the situation that they become in fact non-authorised products and illegal plant protection products. The same

Member State indicated that the concern is not the policy but the enforcement. One Member State indicated that the key issue is ensuring a distinction between basic substances and plant protection products - the current legal situation is unclear and results in inconsistencies between the Member States: the same products with the same labels are allowed in some Member States whereas other Member States may penalise their presence on the market.

On the other hand, another Member State warned that products containing/consisting of basic substances are marketed solely by big companies; free access to basic substances should be maintained, otherwise they might become regular plant protection products.

One Member State expressed an opinion that in reality more Member States allow for placing basic substances on the market for plant protection than the survey revealed and that many products containing/consisting of basic substances are specifically manufactured for the purpose of plant protection. This Member State suggested the introduction of some form of notification of products containing/consisting of basic substances so that they can be under a certain level of control.

Another Member State indicated that, while they agree with a strict interpretation of Regulation (EC) No 1107/2009, they also see the benefits of the availability on the market of some formulations and ready to use products containing/consisting of basic substances. They also see a need of supporting the uses of basic substances as products of low risk, compliant with the IPM strategy.

Other points raised included placing on the market of mixtures containing basic substances; stakeholder involvement; practicalities of introducing new rules for basic substances once they are agreed upon.

The Commission indicated that labelling provisions for basic substances are currently not in the scope of the amendment to the labelling Regulation currently under preparation.

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

The Commission shared the comment from one Member State. The Commission explained that the workplan for test protocols only includes those missing test protocols necessary to perform the risk assessment as described in the 2023 revised Bee Guidance Document to ensure researchers are working on protocols that are really needed. The necessity of new testing protocols regarding non-bee pollinators, if any, will only become apparent when EFSA has finalised the review of the risk assessment methodology for non-target arthropods other than bees, for which a mandate is under preparation. The Commission underlined that the workplan is a living document.

Member States were invited to comments on revision 1 of the work plan by 25 February 2024.

#### 4. PFAS

The Commission informed that the public consultation of the REACH restriction on PFAS was not yet finalised and that 5642 comments were received during the consultation.

The Commission also informed about a publication of Pesticide Action Network (PAN) requesting to consider active substances that are PFAS as not acceptable in plant protection products, and about a letter from some MEPs on the same topic.

The Commission recalled the actions taken so far: it had consulted Member States and, so far, no Member State indicated that they had taken specific actions to limit the use of PFAS in plant protection products and biocidal products, it had also mandated EFSA in 2023 to indicate in their conclusions for active substances if they would fulfil the PFAS definition of the REACH restriction proposal. Furthermore, the Commission informed that it made available a letter to PAN on CIRCA BC for the attention of the Member States, and invited them to consider any possible presence of PFAS when assessing authorization applications or when enforcing the implementation of authorizations granted. The Commission also recalled that, as to the possible use of PFAS compounds in plant protection products as co-formulants, i.e., meaning an intentional addition by manufacturers, the Implementing Regulation (EU) 2023/574 for identifying unacceptable co-formulants provides the possibility of proposing the identification of such substances as unacceptable co-formulants at any time.

One Member State suggested to consider the OECD guidance (OECD, 2021; <a href="https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-perandpolyfluoroalkyl-substances.pdf">https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-perandpolyfluoroalkyl-substances.pdf</a>) as regards the PFAS definition.

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

The Commission presented a revised draft, thanked those Member States who had provided comments, and explained how it addressed the comments received.

One Member State explained the reasons to support a hazard sentence for the bees if the criteria based on the toxicity of the formulation is fulfilled and proposed a higher trigger value. Another Member State asked for clarification on sentences related to treated seeds and fumigants. Several Member States shared their preliminary views on the proposal for a colour scheme that would indicate the level of compatibility of the plant protection product with the principles of Integrated Pest Management. One Member State asked whether this Regulation would trigger the relabelling of products that are already on the market.

Member States were invited to comment by 25 February 2024.

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

The Commission explained that it is working on the comments received from Member States on the drafts to amend Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013.

One Member State indicated its intention to still send comments. The Commission therefore invited all Member States to comment by 5 February 2024.

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

1. Implementation of Regulation (EU) 2023/574

The Commission informed that 4 substances had been notified by one Member State to be added to Annex III of Regulation (EC) No 1107/2009: methyl 4-hydroxybenzoate (methyl paraben), Octamethylcyclotetra siloxane (D4); Decamethylcyclopentasiloxane (D5); Dodecamethylcyclohexasiloxane (D6).

One Member State requested the commercial names of the products containing such co-formulants. Another Member State mentioned that it intends to notify an additional substance. Member States were invited to submit additional notifications.

One Member State had suggested to discuss and agree on a format of the notifications which are needed in accordance with Article 3 point 3 in Regulation (EU) 2023/574, a possible template for the co-formulant report, and on the need of harmonisation among Member States regarding formaldehyde releasers. The Commission recalled that discussion during different technical meetings have not resulted in an agreed outcome, and that this could be covered in the upcoming technical guidance for co-formulants.

#### 2. Ongoing actions

The Commission informed that further information is expected to be available at the next meeting of this Committee.

## A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

There was no news to discuss.

2. Working Group on comparative assessment

The Committee was informed that on 26 July 2023, the Commission and EFSA held a bilateral meeting with the French National Commission for deontology and alerts in public health and environmental matters (cnDAspe). On 25 October 2023, a list of recommendations was sent to the Commission to ensure the implementation of a more effective substitution of substances identified as candidates for substitution. Also, as follow-up to the Ombudsman complaint lodged by an NGO (177/2023), on 23 November 2023 the Commission held a bilateral meeting with the Ombudsman.

The Commission intends to organise a meeting of the Working Group on comparative assessment soon, in order to discuss the next steps.

3. Working Group on Negligible Exposure

There was no news to discuss.

- 4. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009, in particular:
  - Compendium of conditions of use to reduce exposure and risk from plant protection products:

The Commission summarised the comments received from 6 Member States and 4 stakeholder organisations, which acknowledged that the draft compendium represents a first step and will trigger the production of data

validating the level of exposure reduction of the techniques listed in the compendium. Other comments referred to:

- o how to express exposure reduction;
- o practices recommended by integrated pest management principles;
- o characterisation of the techniques listed, exposure routes and exposure reduction;
- o compliance of devices/techniques with standards (e.g., CEN/ISO);
- o the need of testing protocols to measure exposure reduction performance;
- affordability of the proposed techniques;
- o distinction between the GAP (driven by efficacy) and risk mitigation measures
- o contribution of the listed techniques to the objectives of the Farm to Fork;
- o precision techniques as not modifying the GAP nor application rates, but limiting the spatial distribution on the crop, and that a reduction of volume applied by surface unit shall made legally possible;
- o procedure to update the compendium.

Member States were invited to comment on the revised version by 25 February 2024.

## A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA provided a planning on the pesticides peer review experts' Teleconferences for January, February and March 2024, an update on the ongoing peer reviews of active substances and on the ongoing mandates.

EFSA also explained that it had updated the harmonised CLP/PPP template, which now takes into consideration the new CLP criteria. Member States had been invited to provide comments in July-August 2023. Overall, a lot of comments were received on the new ED sections raising that the CLH template, as taken over, does not fully match the way the EFSA/ECHA ED guidance is set up and is thus not fit for PPP assessments. A pragmatic approach proposing a compromise solution that could serve the needs for both processes is needed. In line with Member States comments, the existing ED template following the structure of the ECHA/EFSA ED Guidance has been retained, with the addition of the classification-specific elements taken over from the ECHA standalone template, as a pragmatic approach. A final consultation and agreement by ECHA took place in Dec 2023 to January 2024. Minor comments were received from ECHA that did not affect the overall content/structure of the template.

It is intended to endorse the updated templates at the next meeting of this Committee.

2. Sustainable Use Directive (Directive 2009/128/EC) / Proposal Regulation on the sustainable use of plant protection products

The Commission provided a brief update of the ongoing negotiations of the SUR proposal.

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

The Commission provided and overview of the last inspections.

4. Minor Use Facility (MUCF)

There was no news to discuss.

5. OECD, FAO and EPPO activities

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

The Commission reminded the Member States about the coordination meeting planned for 14 February 2024.

The Commission explained the progress made by the OECD working group on drones.

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

The Commission reiterated the information provided in December 2023 on the ECJ judgement in case C-162/21.

The Commission also informed about the following new court cases: Case C-773/23 (Appeal T-77/20) where the European Crop Care Association (ECCA) is challenging a previous judgment regarding the non-renewal of approval of chlorpyrifos-methyl; Case T-1148/23 where Pesticide Action Network Europe (PAN Europe) is seeking for the annulment of a Commission decision that rejected their request for an internal review under the Aarhus Regulation regarding detailed rules for identifying unacceptable coformulants in plant protection products; and Case T-1164/23 where PAN Europe initiated legal proceedings against a Commission decision rejecting their request for an internal review under the Aarhus Regulation concerning the renewal of approval of the active substance abamectin.

The Commission informed that it received several internal review requests concerning the renewal of approval of glyphosate and one concerning the extension of approval of the active substances diflufenican and tri-allate.

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

1. possible impact on authorizations

There was no news to discuss.

## A.20 Scientific publications and information submitted by stakeholder:

The Commission informed that Pesticide Action Network (PAN) Europe and Crop Life Europe (CLE) had submitted letters to the Standing Committee that have been uploaded to CIRCA BC.

#### A.21 Date of next meeting(s):

The Commission confirmed that the next meeting of this Committee will take place on 20 and 21 March 2024.

#### A.22 AoB.

The Commission recalled that the toxicological reference values (TRV) for **spinosad** proposed in the EFSA Conclusion of 2018 were stated in the draft Review Report discussed in this Committee in 2018/2019. At that time, there was no formal endorsement of the Review Report because the Committee decided to mandate EFSA to assess the active substance under the new ED criteria. The ED stop the clock is ongoing. The Review Report will be endorsed once the mandate is finalised. Meanwhile, all actions for residues are progressed on the basis of the TRV which are stated in the draft review report. Member States were invited to indicate if they do not agree with this was forward within 2 weeks.

One Member State requested to add a sentence in the approval conditions of active substances for which maximum levels for relevant impurities are set, stating that the relevant impurities refer to those derived from the active substance and do not refer to another source in a plant protection product i.e., from co-formulants. This request was based on difficulties encountered by control authorities, since in some cases it was not possible to determine whether an active substance present in a plant protection product was compliant if the impurity was also deriving from a co-formulant. The Commission asked for more details on the particular case, indicated the need for careful consideration of the issue given its complexity, and invited Member States to comment.

One Member State suggested to clarify the definition of greenhouses for transparency reasons.

One Member State asked if disinfectant uses should be considered plant protection products or biocidal products. The Commission asked for more details on the concrete case, and suggested the Member State to re-check in light of the recently agreed flowchart to distinguish this kind of cases.

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

B.01 Exchange of views and possible opinion 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 comments received during the feedback mechanism. Eleven contributors commented.

The Commission pointed out that many of those comments were valuable but out of the scope of the proposal; the Commission plans to share them with the relevant Commission's services when relevant.

The Commission summarised the other comments which mainly focused on the delays in presenting the proposal, the absence of provision to set maximum residue levels (MRL), the absence of detailed post approval regulatory steps, the length of the whole approval procedure, the lack of explicit measures to reduce animal testing, the need for a defined mechanism for joint submissions, the alignment to the new PMT/vPvM criteria of the CLP Regulation, the lack of direct reference to combined effects, the use

of "target crops" instead of "target organisms" for safeners and the clarification of data protection and confidentiality aspects.

The Commission reiterated that a number of these comments were out of the scope of Article 25 and 26 of Regulation (EC) No 1107/2009 or were intrinsically covered by Article 1 and Article 4 of Regulation (EC) No 1107/2009 to which the draft Safeners and Synergist Regulation refers to. The comments referring to data protection, animal testing, the use of "target crops" and joint submissions were taken on board and led to an amendment of the draft. The comment on the absence of a provision to set MRLs was raised also during the meeting by one Member State and was discussed.

Successively, the Commission summarised the comments received from Member States. A few Member States kept expressing concerns over the absence of provisions to set MRLs for these substances. The Commission replied that currently there are no provisions to allow the setting of MRLs and that targeted information requirements may be set on a case-by-case basis, depending on the results of the risk assessment.

One Member State expressed concerns over the data-protection-related issues for safeners and synergists. This matter was already discussed during the last Post Authorisation Issues Working Group (PAI) meetings. However, a consensus was not reached. The majority of Member States expressed the view that data protection rules, as applied for active substances, should be followed also for safeners and synergists. This means that data previously used for the registration of plant protection products (PPPs) would adhere to national protection rules and might not be protected in many instances. Only new data pertaining to safeners and synergists may qualify for (new) data protection once a plant protection product registration is granted, typically for a duration of 30 months. The Commission highlighted that, after amending Article 10 of the draft Regulation to specifically address data protection and ensuring that Article 59(3) of Regulation (EC) No 1107/2009 is applicable, data protection will be only granted if a period of data protection has never been granted for a test or study report, or if any previously granted period has not expired. The Commission explained that further amendments would exceed the empowerments of Articles 25 and 26 of Regulation (EC) No 1107/2009. Therefore, resolving this matter would probably imply amending the technical guidance on data protection. Hence, the Commission indicated that it is currently assessing the appropriate course of action.

One Member State commented that the available time for the admissibility check was too short. The Commission pointed out that the workload for each Member State will be low and that the resources for that step can be planned well in advance.

One Member Sate commented on the absence of more specific data requirements. The Commission replied that the data requirements Regulations allows for the Rapporteur Member State to request further data if deemed necessary.

One Member State indicated it would not support the draft because of divergences in the interpretation of the PPP Regulation concerning the composition of PPPs containing safeners or synergists that may be authorised and placed on the market (for example: it should be possible to authorise PPP containing only safeners or synergists instead of safeners or synergists together with an active substance).

Vote taken: Favourable opinion.

*France made the following protocol declaration:* 

France can support the Commission proposal for a regulation 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, considering the need to further harmonize without delay the rules for marketing safeners and synergists. However, the full implementation of these provisions requires the establishment of MRL for safeners and synergists for enforcement purposes.

During the REFIT exercise in 2020 the need to widen the scope of the MRL Regulation to also cover safeners and synergists as well as adjuvants and unacceptable coformulants had already been stressed. It is expected from the Commission to make the relevant proposals for this purpose.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance hydrolysed proteins 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 presented the draft Implementing Regulation.

One Member State indicated not to support the draft due to the missing data to evaluate all sources of the active substance and that, consequently, a safe use would only be achieved if the active substance is used in traps.

Another Member State asked if applicants who intend to apply for amendment of conditions of approval (Article 7) have to wait until the publication of the legal act or if they can start the application process earlier. The Commission indicated that the dossier in IUCLID can be already prepared.

**Vote taken:** Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance urea 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 presented the draft Implementing Regulation.

Two Member State indicated no support because even if urea has a low ecotoxicological effect towards non-target organisms such as bees and arthropods, it has not been demonstrated that there is no attraction of these organisms.

**Vote taken:** Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance 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 explained the changes made to the texts following the inter-service consultation.

One Member State asked for confirmation from the Rapporteur Member State that the rationale provided to address the critical area of concern was acceptable to them. The Rapporteur Member State confirmed that the reasoning was acceptable.

The Commission informed the Member States that the letter sent to the Member States and the Commission in advance of the meeting did not raise any open issues.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance magnesium hydroxide E528 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/2023/2331 RR Rev1)

(PLAN/2023/2331)

The Commission presented the draft Implementing Regulation and explained how the comments received from three Member States were addressed.

One Member State reiterated no support as its comment on potential dermal sensitivity effects of the substance was not sufficiently addressed.

Vote taken: Favourable opinion.

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

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance metconazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/2697 RR)

(PLAN/2023/2697)

The Commission presented the draft Implementing Regulation and the revised Review Report, shared the comments on the Review Report from the applicant and two Member States, and indicated that the vote can be expected in the next meeting of this Committee.

One Member State commented on the ongoing mandate to EFSA on azoles, and the Commission recalled that the report is expected at the end of 2024, and if needed, further actions will be taken.

Member States were invited to comment by 25 February 2024.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12270/2020)

(SANTE/12268/2020)

The Commission recalled that possibilities to refine the risk assessment for certain non-target species for field uses were explored and that the Rapporteur Member State performed such refinement. On 25 July 2023, the Rapporteur Member State communicated to the Commission the refined risk assessment which was shared with this Committee.

The Commission also informed that, on 14 September 2023, the ECHA Risk Assessment Committee (RAC) recommended to classify captan, in addition to the existing categories, also as toxic to reproduction Category 2, STOT RE1 and Aquatic Chronic Category. On 4 December 2023, the Commission asked EFSA for a statement on the Rapporteur Member State's refined risk assessment as well as on the potential impact of the newly proposed RAC classification on the toxicological reference values (TRVs) identified in the EFSA Conclusion (2020).

On 18 January 2024, EFSA sent to the Commission its statement in which it indicated that the new classification had no impact on the toxicological reference values (TRVs). However, the metabolites THPI and THPAM are found at  $> 0.1 \, \mu g/L$  in the majority of the FOCUS groundwater scenarios for all the uses. As a consequence of the new classification of captan, the groundwater metabolites THPI and THPAM became toxicologically relevant since their potential for reproductive toxicity has not been investigated. The Commission explained that since this new classification was proposed after the conclusion of the EFSA peer review on captan, confirmatory information can be set to ensure that further information is provided to address this concern.

Furthermore, in its statement, EFSA considered that the variety of orchard crop characteristics and spraying systems referred to in the scientific publication which was underlying the refined risk assessment cannot be considered as formally agreed for regulatory risk assessment purposes. Consequently, EFSA considered that a low risk to wild mammals, bees and aquatic organisms was not demonstrated for field uses by the refined risk assessments.

The Commission indicated that, as a consequence of the situation, it intends to proceed with the current restricted renewal. The Commission also informed that, according to its knowledge, the applicant indicted to be preparing a dossier under Article 7 of Regulation (EC) No 1107/2009.

One Member State supported the draft implementing act while nine Member States indicated the need to maintain field uses. From these, five Member States stressed that field uses are important (over 95 % of the uses of captan-based PPPs are for field uses)

and that captan is one of the last fungicides left. They inquired about the possibility to still grant emergency authorisations in case of a restricted renewal of approval and indicated that a new dossier submission under Article 7, even if successful, is unlikely to reinstate the field uses in time, as the regulatory procedures take around four to five years and are thus significantly longer than the grace periods. The rapporteur Member State informed that it was not aware of any intention of the applicant regarding a submission of dossier to amend the conditions of approval under Art. 7.

One Member State was disappointed that captan is not maintained for field uses even when uses with precision farming would allow for save uses.

One Member State stressed that there is one safe use, and that full renewal should be granted on this basis.

One Member State stressed that grace periods are only applicable to non-renewals and wondered if other timeframes would apply for restrictions.

The Commission invited Member States to send their comments and positions by 25 February 2024.

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

(PLAN/2023/2347)

<u>Pro memoria – TBT notification (to be) launched</u>

C.04 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11620/2017)

SANTE/11618/2017

Pro memoria – TBT notification (to be) launched

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance acibenzolar-Smethyl, 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) No 2016/389 (Draft Renewal Report PLAN/2023/2650 RR)

(PLAN/2023/2650)

Pro memoria – TBT notification (to be) launched

C.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance metrafenone in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2023/2534 RR)

(PLAN/2023/2534)

The Commission explained that the documents are like those presented in the meeting in October.

Two Member States had commented: one was inclined to support and the other agreed to address the uncertainties of the endocrine disrupting potential for non-target organisms other than mammals with confirmatory information/data.