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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
11 - 12 July 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/f94b9ccb-ea69-4bd4-a341-435561b57d17?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meetings which took place in March and May are still under preparation.

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

1. *Plectranthus amboinicus* extract

The point was postponed.

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

The Commission informed that discussions on the delays of Member States in complying with the deadlines set for product authorisations in Regulation (EC) No 1107/2009 are planned for the workshop "Zonal Authorisation Procedure Improvements and Developments (ZAPID)", which will take place in Braunschweig, Germany on 5-7 December 2023. Member States were invited to provide reasons on the delays of the regulatory deadlines for the approval and authorization procedures by 31 August 2023 to contribute to the planning of the workshop.

In addition, the Commission informed about a document sent by the International Biocontrol Manufacturer Association (IBMA) listing examples of dossiers concerning biopesticides which are facing serious delays. The document was made available on CIRCABC. The Commission invited Member States to examine the reasons of these delays and to follow up discussions with the Working Groups on Biopesticides Working Group and Post Approval Issues.

1. Financial assistance to Member States in the context of PPP and BPR between 2023-2027

   The Commission informed that the evaluation of the applications from six Member States (plant protection products) and ten Member States (biocides) of the call SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA had finished. The signature of the grants is expected in October/November 2023.

One Member State thanked the Commission for these grants but mentioned that they are not enough as in their view the regulatory processes need to be simplified. Two other Member States supported this and flagged that the evaluation of dossiers has progressively become more and more complex, needing more resources. Even the implementation of EU-agreed administrative guidance documents increased the workload of Member States. These Member States suggested to assess the impact on workload and the added value for each new or updated guidance document.

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

The Commission reminded rapporteur Member States that submission of applications (dossiers) after the deadline for application, without a clear reason linked to technological issues (new IUCLID system), should be clearly declared non-admissible.

The Commission also informed that an overview table had been uploaded on CIRCABC, listing active substances which are under assessment under both Regulations (EC) No 1107/2009 and (EU) No 528/2012, and encouraged the respective rapporteur Member States to cooperate in order to gain efficiency and in the spirit of the concept of one-substance-one-assessment.

The Commission gave an update on changes made to the draft non-paper outlining a process for providing access to old studies, invited to comments by 31 August 2023, and indicated it aims to ask the Committee for endorsement at the next meeting in October.

The Commission also informed that following the discussions in the meeting of this Committee in January 2023 on the reallocation request of a rapporteur Member State, the Commission sent a letter to the Competent Authority of Hungary to draw its attention about the obligation to ensure that enough human resources should be made available to comply with the regulatory obligations, and to urgently proceed with the completion of the evaluation of the dossiers for which Hungary has been allocated as rapporteur Member State, in particular tefluthrin and halauxifen-methyl. The letter was made available on CIRCABC.

Furthermore, the Commission informed that it was contacted by an applicant to discuss the follow up to the data gaps identified during the 2020 review of the existing maximum residue levels (MRLs) for the active substance tefluthrin according to Article 12 of Regulation (EC) No 396/2005. Given that for the submission of the required confirmatory data timelines apply, the Commission advised the applicant to submit the necessary data via IUCLID to comply with the legal requirements and the deadlines.

The Commission reminded that Member States should fully and timely fulfil the responsibilities when they act as rapporteur Member State.

3. IUCLID

The Commission reported the discussions with Member States and stakeholders held during the 7th IUCLID Pesticide Steering Network (Parma, June 2023).

Furthermore, the Commission reminded Member States that only the IUCLID format should be used and/or requested for the submission of active substance dossiers.

Finally, the Commission mentioned that the backlog of admissibility checks is reduced, and reminded Member States that there is still a high number of submitted dossiers that still need to be assessed as regards their admissibility.

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

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

1. Flutolanil

The Commission informed that there has been no progress on the evaluation of the EFSA Conclusions and a more general discussions on the decision making of PFAS substances needs to take place before taking a decision on flutolanil (and its metabolites) which belong to this category of substances.

Member States are invited to comment by 21 August 2023.

2. Dimethomorph

The Commission informed that the EFSA Conclusion is available and summarised its findings. The active substance was identified as an endocrine disruptor for humans and wild mammals as well as for non-target organisms. As regards negligible exposure, a narrow margin of manoeuvre to identify safe conditions of use is given. As regards the derogation according to Article 4(7) it appears that none of the representative uses (*Phytophthora* in strawberries, downy mildew in lettuce and grapevine) are fulfilling the criteria to address a serious plant health issue, except for two situations (*Phytophthora* in strawberries in Spain and downy mildew in lettuce in Denmark).

Member States were invited to comment by 31 August 2023 on the EFSA Conclusion and on a potential non-renewal or restricted renewal for uses on strawberry at transplantation in greenhouses.

3. Glyphosate

The Commission services recalled that on 6 July 2023 EFSA transmitted its Conclusion on the peer review of the risk assessment for glyphosate to the European Commission and Member States, as well as to the applicant.

The Commission services expressed their appreciation for the Member States acting jointly as Rapporteur (the AGG), EFSA and all Member State experts involved in the peer review for their thorough and comprehensive work, the huge resources made available, and the dedication shown during the evaluation of the dossier, which had allowed to finalise the EFSA Conclusion without further delay in addition to what had been announced last year.

EFSA provided a summary of the key findings in the EFSA Conclusion on the peer review of the risk assessment for glyphosate and explained that the full Conclusion would be published at the end of July, following a check for removal of confidential information as required under EU legislation. The background documents will be published successively thereafter, also following a check for removal of confidential information.

The Commission services noted that the EFSA Conclusion does not identify any critical areas of concern that would prevent the renewal of the approval of

glyphosate as an active substance for use in plant protection products, provided that certain conditions and risk mitigation measures are set in order to address a number of issues that could not be finalised and other outstanding issues (data gaps), which are the following:

Issues not finalised:

- the assessment of one of the impurities in the EU reference specification, for which a clastogenic potential could not be excluded;
- consumer dietary risk assessment for some crops (carrot, lettuce and wheat) grown in the first year of rotation on a plot where glyphosate was used in the preceding year;
- risk assessment for aquatic plants due to contact exposure via spray drift;

Outstanding issues:

- for one of the co-formulants in the product for representative uses information on the short- and long-term was not available, while data on acute toxicity and genotoxicity for the product (including the co-formulant) did not identify concerns;
- while there is no indication that glyphosate as an active substance has neurotoxic potential, data from the public literature on glyphosate-based formulations and a study with glyphosate-trimesium (which is not approved in the EU) show effects of developmental neurotoxicity;
- the potential risks to biodiversity via indirect effects and trophic interactions, which the experts recognised as being complex and dependent on multiple factors.

Other issues:

- high long-term risk to wild mammals for some representative uses that were identified as a result of a conservative risk assessment due to lack of data for further refinement;
- the potential effects on the microbiome where no definitive conclusions could be drawn due to lack of standardised regulatory guidance and/or established harmonised criteria;
- potential relevance of possible groundwater exposure via bank infiltration and the connectivity of surface water bodies to groundwater aquifers;
- the need for mitigation measures to ensure an acceptable risk to non-target terrestrial plants.

The Commission services explained their analysis of the relevance of the issues listed above and informed that detailed considerations to address them would be included in the draft Renewal Report for glyphosate, which will be provided for comments to the Member States on 13 July and, as legally required by Article 14(1) of Regulation (EU) No 844/2012, to the applicant. Comments should be submitted no later than 27 July 2023.

The Commission services will consider all comments in view of preparing an updated draft Renewal Report and a draft Implementing Regulation, which will be sent to Member States ahead of a special meeting of this Committee that is

tentatively planned for 15 September 2023, subject to confirmation. The vote on the draft Regulation is planned for the meeting of this Committee scheduled for 12-13 October 2023, in view of finalising the decision-making procedure before the expiry of the current approval of glyphosate on 15 December 2023.

The Commission services further informed that they had not yet finalised reflections on the appropriate length of a renewed approval, while noting that the substance had now been assessed two times within a rather short period of time, each time necessitating a high amount of resources while coming to similar results. The Commission services invited Member States to also share their views on this matter when providing comments on the draft renewal report by 27 July 2023.

Two Member States inquired if the impurity present in the reference specification can be excluded or if it needs to be monitored. The Commission services explained that changes in the manufacturing process that will eliminate the impurity might be possible. As the impurity will be considered toxicology relevant and its content will be limited to levels that are considered safe in the renewed approval, methods for detection and quantification will have to be presented by the applicant.

Another Member State noted that no firm conclusion was drawn by EFSA on the risks to biodiversity based on the available data. It considered that a guidance document on this issue needs to be developed and suggested to set a confirmatory data requirement in the renewed approval to further assess the issue once guidance would become available. The same Member State announced that it will send comments to request that harmonised conditions and restrictions will be set for all Member States, including for conducting comparative assessments in order to reduce the overall use of glyphosate. It also suggested that limits to the maximum amount of glyphosate that can be applied per hectare should be considered, in particular taking into account the uses where a risk to wild mammals was identified. The Commission services explained that imposing mandatory comparative risk assessment in the case of glyphosate might not be compatible with Article 50(2) of Regulation (EC) No 1107/2009, which entitles Member States to conduct voluntary comparative assessments prior to granting product authorisations. Member States are also empowered to set maximum application rates in product authorisations. The Commission services also noted that the risk to mammals was identified only for some, but not all, representative uses and was based on the results of a conservative first tier assessment - therefore there is a possibility for applicants for product authorisation to provide further data to be evaluated by Member States to verify whether the uses concerned are safe.

A Member State expressed concerns that requests for access to documents might force them to disclose the whole file on glyphosate. The Commission services reminded that granting such access needs be done in full compliance with the applicable legislation, especially protection of personal and where applicable commercial data, and considering that the decision-making process is still ongoing. EFSA recalled that it would publish the Conclusion and its background documents in full as soon as practically possible so that they will be accessible for everyone.

Another Member State asked if information for the general public will be provided in a format that is comprehensible by non-experts. EFSA and the Commission services noted that they had made available on their respective websites information specifically addressed to non-experts which is regularly updated.

- Basic substances

There was no news to report.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval

1. (3E)-dec-3-en-2-one

The Commission recalled the comments from Member States including the Rapporteur Member State, who agree on the need to close the data gap on the metabolism of (3E)-dec-3-en-2-one. The applicant was informed about the opportunity to submit additional studies to close the data gap, as it is a new active substance. The Commission informed that the applicant aims to provide this information in view of a potential approval of the active substance.

- Renewal of approval

2. Aluminium silicate calcined

The Commission informed that the discussions on this active substance depend on the finalisation of the mandate to EFSA concerning a weight of evidence approach for active substances of natural origin (see point A.09).

3. Sulphur

The Commission reminded that the discussion about the identified areas of concern (high risk for non-target arthropods and soil macroorganisms) is similar to the ones of other similar substances (naturally occurring and/or essential elements) for which a mandate to EFSA concerning a weight of evidence approach for active substances of natural origin is intended (see point A.09). Exchange of views are also currently ongoing with the Rapporteur Member State and EFSA to clarify some technical points.

One Member State sent comments about the possibility of setting confirmatory information (for the risk for soil macro-organisms) and to assess at authorization level the issues identified for non-target arthropods. Another Member State proposed risk mitigation measures. One Member State agreed with the view of the Commission of broadening the discussion of this active to include other naturally occurring substances and/or essential elements.

Member States were invited to send further comments by 31 August 2023.

4. Metrafenone

The Commission highlighted the main findings of the EFSA Conclusion and informed that the review report is in preparation and intended to be made available to Member Stats after this meeting. Member States were invited to comment on the EFSA Conclusions and the upcoming draft review report by the 31 August 2023.

5. Trinexapac

The Commission recalled that the EFSA Conclusion was first made available in March 2018 and that a draft Renewal Report proposing renewal of approval was prepared and discussed with this Committee in 2018. The Commission reminded that, since the EFSA Conclusion was finalised before 10 November 2018 and a decision on the new scientific endocrine disrupting criteria was not possible on the basis of the available information at that time, Article 14(1) of

Regulation (EU) No 844/2012 applied and accordingly, after discussions at this Committee, the Commission mandated EFSA to finalise the assessment.

On 8 June 2023, EFSA made available the updated Conclusion in which it confirmed that trinexapac-ethyl does not meet the criteria to be considered as an endocrine disruptor.

The Commission informed that the draft Renewal Report had been updated to reflect the updated EFSA Conclusion. Member States were invited to comment on the updated Renewal Report by 31 August 2023.

6. Hydrolised proteins

The Commission summarised the findings of the EFSA Conclusion and explained the reasoning presented in the Review Report.

One Member State informed about the request of an applicant for a hydrolysed protein active substance of different origin and based on wheat proteins. The Member State asked for guidance on how to proceed with such situation.

Member States were invited to comment by 31 August 2023.

- Basic substances

7. Caffeine

The Commission gave a short update on the status of the application. Two Member States commented on the additional information submitted by the applicant to support the application for an approval of caffeine as basic substance. One Member State indicated that the submitted literature is not complete and unacceptable effects on the environment cannot be excluded based on the provided information. Another Member State also noted that the new information still does not allow for an assessment of effects on non-target organisms. Furthermore, in the area of human toxicology assessment, the open points on the exposure assessment that were mentioned earlier in the EFSA report are still not addressed. Consequently, both commenting Member States are of the opinion that based on the provided information, it will be difficult to conclude that the approval criteria as a basic substance are met.

The Commission also briefly summarized the comments received from EFSA. EFSA observed that the efficacy of the intended uses is not confirmed. Appropriate non-dietary exposure assessment is not provided. The concern and uncertainties related to the consumer risk assessment of caffeine used as a plant protection product are not addressed. The appropriate environmental exposure assessments were not available in the applicant's updated application. Nevertheless, the available FOCUS groundwater calculations are sufficient to indicate that the parametric drinking water limit of 0.1µg/L, that would be applicable to caffeine if approved as an active (basic) substance, would be significantly exceeded for the use pattern requested in the application. The significant surface water exposure will occur from the uses being requested. As regards ecotoxicology, a low risk to non-target organisms might be concluded only for the use under permanent greenhouses, with the exception of aquatic organisms, since exposure via drainage cannot be excluded.

Member States were invited to comment and inform on their positions concerning a potential non-approval or approval of caffeine as basic substance.

A.06 Confirmatory Information:

1. Flutianil (amended Review Report to endorse)

   The Committee endorsed the amended review report which considered the comment from one Member State.

   One Member State indicated that it was not in position to endorse the amended review report based on concerns regarding groundwater, expressed at the time the renewal of this active substance was voted.

2. Pendimethalin

   The Commission noted the comments of two Member States which expressed preference that the highest bioconcentration factor (BCF) value is used for regulatory purposes when experimental data from more than one species are available, and explained that a draft mandate to EFSA to organise a peer review on confirmatory data concerning pendimethalin is under preparation.

A.07 Guidance Documents, in particular:

The Commission recalled that for the January meeting of this Committee one Member State had submitted a proposal for a method to assess effects on biodiversity, which his made available on CIRCA BC together with other relevant on biodiversity reports1, and on which Member States were invited to comment. The Commission indicated that it had received additional comments suggesting that biodiversity issues should be considered at the same time as the update of the guidance document on terrestrial ecotoxicology / non target arthropods.

1. Prioritisation of Guidance Documents process (to endorse)

   The Committee endorsed the document which outlines a process to update the prioritisation list.

   The Commission indicated that the one-pager document which intends to outline criteria to Member States which would like to proactively be involved in the preparation of draft guidance documents is still in preparation together with EFSA.

2. Data requirements and list of agreed test methods (Part A - chemicals) – Revised versions of Communications 2013/C 95/01 and 2013/C 95/02 (to endorse)

   The Committee endorsed the draft revised Communications 283/2013- Part A and 284/2013- Part A and the Commission indicated that it would proceed now with their adoption.
   The Commission also mentioned that the underlying rationale-document, a summary of comments from Member States and stakeholders, as well as an

[1] Nationale Akademie der Wissenschaften Leopoldina, acatech – Deutsche Akademie der Technikwissenschaften, Union der deutschen Akademien der Wissenschaften (2020): Biodiversität und Management von Agrarlandschaften – Umfassendes Handeln ist jetzt wichtig.
KEMI PM2/21 Methods for assessing the effects of plant protection products on biodiversity.
KEMI PM 7/21 Resilience of biodiversity to plant protection product use – the modifying influence of landscape and interventions
Alix, Bylemans, Dauber, Dohmen, Knauer, Maltby, Mayer, Pepiette, Smith, 2022. Optimising agricultural food production and biodiversity in European landscapes. Report of an online-Workshop. Tünen Report 98.

additional comment from one Member States are available on CIRCA BC, and presented the revised version of the new database on guidelines and supporting documents, which will be consulted soon with Member States to verify the content before making it publicly available.
The Commission also informed that some 'quick fixes' to the data requirements identified during the revision of the Communications may be considered in the framework of the amendment of the data requirements which are needed following the EFSA Guidance Document on the risk assessment of plant protection products on bees and on birds and mammals.

3. Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012, Rev 11 (guidance on basic substances) (to endorse)

   The Committee endorsed the amended Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012, revision 11.

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

   The Commission presented a revised version of the document which had considered the comments received from Member States. The Commission reiterated that it considers this document as an important step forward in order to implement in a more harmonised way the Point 1.5. of the Introduction of the Annexes of the current Data Requirements and that the document is expected to contribute to the Farm to Fork targets by offering a possibility of more targeted risk assessment for scenarios where it is expected a priori that there will be low environmental effects such us biological active substances or applications with low environmental exposure (e.g., precision application techniques).
   The Commission also emphasized the added value of the case studies that were provided during the consultation of an earlier version together with comments to the document. However, the Commission considers that the inclusion of these case studies in the document would be misleading as they have not been peer reviewed and that its value would be limited because all risk assessments need to be done on a case- by-case basis. Further developments of the case studies may be possible with increasing experience.
   Member States were invited to send by 31 August 2023 their position in view of endorsing the document.

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

   The Commission shared a comment from one Member State, from an NGO and from an applicant organisation.
   The Commission explained that it is needed to ensure that the Regulations on the data requirements and on the uniform principles are aligned with a revised guidance document before that guidance document can be endorsed, and summarised which changes to these regulations on could be envisaged. Member States were invited to send their views on what changes are considered necessary by 31 August 2023.

One Member State underlined the importance of protecting bees and welcomes the revised Bee Guidance Document which it considers a major improvement. This Member State conders a swift implementation important but fears a negative impact on delays for the risk assessments due to the significant higher complexity. It furthermore expressed concern regarding the need of carrying out field studies with solitary bees for substances of natural origin.

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

   This point was postponed.

7. EFSA Guidance Risk assessment for Birds and Mammals

   The Commission shared a comment from two Member States and gave further replies to comments sent in for the previous meeting.
   The Commission explained that it is needed to ensure that the Regulations on the data requirements and on the uniform principles are aligned with a revised guidance document before that guidance document can be endorsed, and summarised which changes to these regulations on could be envisaged. Member States were invited to send their views on what changes are considered necessary by 31 August 2023.
   One Member State indicated being in favour of a fast implementation of the revised Birds and Mammals Guidance Document and therefore considers no change necessary to the Regulations on the data requirements and uniform principles.

8. 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 reminded Member States that a final commenting round on the draft document was held by the agencies in early June, allowing Member State authorities for pesticides and biocides to provide final comments on the advanced pre-final draft of the guidance, in particular in view of allowing for a smooth implementation afterwards. Comments were received from several Member States and were being considered by EFSA and ECHA, in view of finalising the Guidance Document in the coming weeks.
   The Commission underlined that as for other guidance documents prepared by the agencies, once the document is published, discussions on implementation would be initiated with the Member States.
   It was also recalled that there are several active substances that have confirmatory information requirements concerning the impact of water treatment processes, that would be triggered by the new guidance. The Commission explained that it would carry out an exercise to identify the relevant cases in view of work planning.
   One Member State asked whether there would be a need to amend the data requirements once the guidance was adopted and agreed – the Commission indicated that it would reflect on that.

9. Explanatory notes on data requirements on micro-organisms

   The Commission recalled that these Explanatory Notes, drafted by the EU Biopesticide Working Group, aim to provide guidance to improve and harmonize the understanding of the new data requirements on micro-organisms, for both applicants and risk assessors. The Commission highlighted that a stakeholders' consultation was just concluded, and that work is ongoing to finalise document. Member States were invited to comment on the latest draft by 31 August 2023.

10. FOCUS surface water scenarios (ongoing mandate EFSA)

    EFSA presented the results from work related to the mandate to repair the FOCUS surface water scenarios and associated guidance and calculation tools, which consist of introducing into all the FOCUS surface water scenarios (both runoff and drainage) a 20-year assessment period instead of the existing 16 to 18 month assessment period. EFSA indicted the need of a risk manager consultation, and the Commission indicated to reflect how to best organise this.

11. Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides (for info)

    The Commission explained that the Statement was available and that it put forward several aspects relevant for risk managers. Member States were asked to provide any views of comments by 31 August 2023.

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

1. Article 44(4)

   The Commission informed about the notification received since the last meeting of this Committee concerning an amendment of the instructions for use of four market authorisations of PPP containing aluminium phosphide and magnesium phosphide, due to unacceptable risk for skippers and transporters. The background documents substantiating the decisions were uploaded to CIRCABC.

   Following the notifications received in the meeting of March 2023 on three withdrawn authorisations of cyazofamid based plant protection products, due to risk of leaching of metabolites DMS and DMSA to groundwater, the Commission informed that it requested advice from EFSA. Following a bilateral discussion, it was agreed to emphasise the importance of the pre-submission meetings, where rapporteur Member States shall request a justification to the applicants on the labelling of the molecules' strategy in order to be able to the most likely break-down routes.

2. Article 36(3)

   The Commission informed about the notification received since the last meeting of this Committee concerning a rejection of authorisation under the zonal system. The decisions were not challenged at national level.

3. Article 53

   See point A.18

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 a draft mandate to EFSA is in preparation as discussed during the previous meetings of this Committee. Accordingly, the decision-making process on the four active substances which will be considered as pilot cases in this mandate (aluminium silicate calcinated, rape seed oil, pelargonic acid and sulphur) will be on hold until EFSA had finalised the work on the mandate.

2. New dRR (draft Registration Report) templates (to endorse)

   The Commission informed that the draft Registration Report (dRR) templates concerning micro-organisms had been revised to reflect the new data requirements on micro-organisms which entered into force in November 2022. The templates have been commented by relevant working groups (Post-Approval Issues, Biopesticides), this Committee, and stakeholders. In addition, the Commission informed that the guidance document SANCO 6895/2009 is under revision to reflect the changes applied to the above-mentioned templates.

   Member States were invited to comment on the amendment of the dRR templates and the draft amended document SANCO 6895/2009 by 31 August 2023.

A.10 Safeners and Synergists.

The Commission informed about the progress on the draft Commission Regulation. After incorporating Member State comments, the Commission is intending to proceed with the administrative steps in view of the preparation of the draft for public consultation (feedback mechanism) and vote in this Committee.

A.11 Updates, clarifications & questions on specific active substances:

1. Sodium hydrogen carbonate

   Following discussions at the previous meetings of this Committee, the Commission informed of a letter to the authorisation holder of the low-risk active substance sodium hydrogen carbonate which is in preparation.

2. Common metabolites of pyrethroids

   The Commission informed that internal reflection is ongoing, and a proposal for the next steps is expected for the next meeting of this Committee.

3. Common metabolite TFA

   There was no news to report.

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

   The Commission informed that a draft mandate was under discussion with EFSA. One member State had sent favourable comments as regards such a mandate.

5. Prosulfocarb

   The Commission informed that the RMS indicated that it would include the studies submitted under Article 56 of Regulation (EC) No 1107/2009 in the revised renewal report and amend the risk assessment if necessary.

The point on residues detected in non-treated crops was further discussed. In this regard, the Commission reiterated its request to Member States to send national risk mitigation measures in place for the active substance prosulfocarb to the Commission, if not sent yet, by 31 August 2023 (eight Member States had already shared the mitigation measures in place and these were made available via CIRCABC). Two MS had included in their feedback views on how the issue of residues could be addressed during the renewal procedure. The Commission informed it intends to share an overview of the mitigation measure in place in the Standing Committee once the feedback received is complete. This overview will also be forwarded to the Post Approval Issues (PAI) working group for further discussion.

The co-RMS indicated it will liaise with the RMS and will consider the comments received. Another Member State informed of the reassessment of its national authorisations following up on a national court case. It will inform the Commission as soon as the amended authorisations are available.

6. Dimoxystrobin

The Commission informed that a mandate has been sent to EFSA requesting to issue a conclusion on the peer review of dimoxystrobin following application of renewal of approval and confirmatory data identified during the MRL review. This conclusion should contain all the results of the peer review process available so far on the application for renewal of approval, including the assessment of the application for MRL for different oil seeds, and for the MRL application addressing the confirmatory data identified during the MRL review under Article 12 of Regulation (EC) No 396/2005. The deadline for EFSA is 30 September 2023.

A.12 Article 21:

1. Pirimicarb

The Commission provided a brief update since the previous meeting. Two Member States had indicated to wait until the Conclusion on the peer-review for the renewal was available before making a final decision. Another Member State had asked why an approach taken for other substances (e.g., S-metolachlor) had not been followed – the Commission explained that in this case there were still indications of a safe use and that the Conclusion on the peer review was expected in the near term, indicating that waiting for this outcome would ensure a decision based on all available information.

2. Flupyradifurone

The Commission indicated that it intends to request EFSA to provide scientific and technical assistance to deliver a statement on the information submitted by the authorisation holder taking into consideration the assessment of the Rapporteur Member State (RMS) Greece. The authorisation holder has also submitted their comments on the assessment. The draft mandate under Article 21(2) is under discussion with EFSA.

A.13 General issues for information / discussion:

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

a) New cases

The Commission explained the comments received from two Member States about the new entry K-PAK. A discussion took place as regards the mode of action: immobilisation (trapping) was considered out of scope, while suffocation (invasive) was considered in the scope. Member States were invited to comment by 31 August 2023 about the alignment of conclusions regarding K-PAK (new), STYX and SILTAC (existing entries) in function of their mode of action (immobilization or suffocation).

b) Physical barriers

One Member State announced that it will propose a slight amendment to the draft decision scheme to be integrated in the scope document rev.74. The Commission invited Member States to comment on this revised draft decision scheme on physical barriers.

2. Basic substances – general issues and survey

The Commission informed that 24 Member States responded to the survey on basic substances and thanked for those replies. The Commission reiterated that the input from all Member States is very important to obtain a complete picture on all aspects of basic substances, and to understand how Member States interpret certain elements mentioned in the regulation. The Commission will proceed to analysis of the responses and inform the Committee in due time.

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

The Commission informed that Italy and Finland offered to be lead countries for submitting to OECD draft test guidelines regarding chronic and acute oral toxicity testing of solitary bees respectively.

The Commission intends to share a first version of the workplan for the development of test methods for pollinators in the next meeting of this Committee. A comment from one Member State regarding field testing was uploaded to CIRCABC.

4. ECI 'Save Cruelty Free Cosmetics

The Commission informed that its Communication on this ECI will be published before the 25 of July (https://europa.eu/citizens-initiative/sites/default/files/2023-07/C_2023_5041_EN.pdf)

5. PFAS

Commission informed that comments were received from two Member States and that some stakeholders also made requests on the topic of PFAS. In addition, the Commission informed that a letter has been sent to EFSA, asking EFSA to state in their Conclusions if the chemical structure of an active substance (and/or its metabolites) fulfils the definition as PFAS or not according to the definition in the REACH restriction proposal.

6. Semiochemicals

The Commission referred to the suggestion submitted by one Member State some time ago, referring to scientific work carried out by experts regarding semiochemicals and wondering if an extension of the group of Straight Chain Lepidopteran Pheromones (SCLP) to other semiochemicals would be feasible in order to speed up the access to the market of such active substances. It was also

compiled from scientific literature and reviewed by these experts, that some SCLP are also efficient against insects other than Lepidoptera.

Since the compilation of the scientific information provided by the Member State offers a solid basis, the Commission suggests amending the Guidance Document on Semiochemical Active Substances and Plant Protection Products (SANTE/12815/2014-rev. 5.2, May 2016) in order to accelerate the possibilities for potential applications of new active substances or for plant protection product authorisations, where relevant. The Commission suggested to add three Annexes to the guidance document, listing information on semiochemicals which are structurally related to different extent to SCLP.

Member States were invited to comment by 16 August 2023 on these proposed Annexes and the draft revised guidance document.

7. Innovative pesticide application techniques

   The Commission informed about a recent report published on the performance of Close Transfer Systems (CTS-evaluation.pdf (croplifeeurope.eu)) which is made available to EFSA already, and on the activities carried out by the EU Task Force on Precision Application Techniques where Member States may get involved.

   The Commission also explained in detail the work carried out by OECD regarding application of pesticides by drones (e.g., deriving drift curves, residue trials, best management practices document) as well as the intended integration of the collected data and information in existing guidance documents.

8. Update on Chemicals Strategy implementation

   The Commission reminded Member States that new criteria for harmonised classification became applicable, and that they need to be considered when preparing the respective CLP dossiers aligned with the regulatory procedures under Regulation (EC) No 1107/2009. EFSA had updated the respective CLP/PPP templates (see point A.17.1) and Member States are invited to comment on them by 31 August 2023.

   In addition, the Commission indicated that an update of Annex II of Regulation (EC) No 1107/2009 may be needed in due time and that additional draft Regulations underpinning the one substance one assessment action are in preparation.

A.14 Amendment Regulation 547/2011.

The Commission informed about the outcome of the discussions on the draft shared with this Committee at previous meetings, which took place via an ad-hoc technical meeting with experts on 14 June 2023. The Commission explained that it is revising the draft based on the comments received for further discussions at this Committee.

A.15 Coformulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574

   The Commission informed that several letters had been received from stakeholders and made available on CIRCA BC. One Member State submitted their internal guideline on evaluation of alternatives to co-formulants, on non-significant formulation changes and on polymers and UVCBs as this relates to the discussion on co-formulants.

The Commission reminded that some notifications from Member States were already received in order to amend Annex III including new unacceptable coformulants and invited other Member States to notify other cases in order to proceed with the amendment of Annex III.

2. On-going actions

The Commission informed that there is a new website available on the Assessment of Plant Protection Products (PPPs) (europa.eu), and presented an outline on potential next steps following the two workshops held in May and June 2023, which imply inter alia further discussions at the PAI WG and potential new mandates to EFSA to improve the transparency of the evaluation of the representative product in the substance dossier.

Member States were invited to comment on these potential next steps by 31 August 2023.

A.16 Report from working groups, in particular:

1. Working Group on Biopesticides

The Commission informed about the last meeting of the WG on Biopesticides, where semiochemicals, consortia of micro-organisms, testing methodologies for micro-organisms, explanatory notes for new data requirements, dRR templates update, IUCLID, and guidance on virus were discussed.

2. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009, in particular:

   i. Compendium of conditions of use to reduce exposure and risk from plant protection products

The Commission presented a draft document "Compendium of conditions of use to reduce exposure and risk from plant protection products" and summarised its content and objectives as well as the regulatory context that supports this document. The document lists conditions of use for plant protection products that can reduce human and environmental exposure – and consequently potential risks - while ensuring a safe use (for instance personal protective equipment, specific spraying technologies (including precision application techniques), time restrictions for the applications, indoor uses and other land use measures as buffer zones), and includes qualitative and/or quantitative information on the reduction of exposure of these conditions.

Member States were invited to comment on the draft document by 31 August 2023. The Commission informed that stakeholders would be consulted in parallel.

3. Working Group on comparative assessment

The Commission informed that after the meeting that took place on 16 May 2023, where a proposal to amend Annex IV of Regulation (EC) No 1107/2009 was presented, fifteen Member States provided comments. Also, some stakeholders submitted its views on the proposal, which have been made available on CIRCABC.

The Commission indicated that it is currently addressing the comments received and intends to amend the existing Guidance Document on Comparative Assessment, to align it with the amended Annex.

4. Working Group Post Approval Issues

   The Commission informed about the last meeting of the Post Approval Issues (PAI) Working Group, held on 14 and 15 June 2023. The main points debated were: the elaboration of a repository of agreements reached, the possibility to use a harmonised template for letters of access, the next steps to amend the Guidance Document on new active substance data post-(renewal of) approval and the Guidance Document on equivalence assessment of SCLP, data protection questions, the amendment or withdrawal of the authorisations to withdraw unacceptable co-formulants as soon as possible but no later than 24 March 2023, exchange of views on initiatives to collect information and identify actions on new application techniques, exchange of views on practices as regards authorising plant protection products for organic farming, the continuity of the chair and co-chair of the group.

5. Working Group on Negligible Exposure

   The Commission explained that no further meeting had been held since the last meeting of this Committee and that re-drafting was ongoing, with the next meeting being intended for the end of September.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

   EFSA provided an update on the on-going peer reviews of active substances and the on-going mandates. EFSA indicated that two general experts' meetings (on physicochemical properties and microorganisms), as well as the next Pesticide Steering Network meeting, are planned for October 2023.

   EFSA also explained that it had updated the harmonised CLP/PPP template, which now takes into consideration the new CLP criteria, and invited for comments of Member States by 31 August 2023 (see also point A.13.8). EFSA informed about the launch of two grants to which Member States and, if relevant, other institutions may apply (environmental risk assessment methodologies for plant protection products of low concern and framework partnership agreement to advance the environmental risk assessment of plant protection products).

   EFSA also gave an update on the progress made by the MUST-B/EFSA working group (WG) on the establishment of environmental scenarios for ApisRAM, a honeybee colony model under development by EFSA and Aarhus University for future use in pesticides risk assessment. In particular, the definition and selection of those scenarios was explained, were a "risk matrix" combining a set of landscapes with various degrees of ecological quality (i.e., 9 baseline scenarios going from low, medium to high quality) to which exposure modification factors are applied (i.e. 4 case scenarios going from no impact to small/large/irreversible impact) is defined.

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

   There was no news to report.

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

   There was no news to report.

4. Minor Use Facility (MUCF)

   The Commission informed about the last meeting of the Minor Uses Coordination Facility (MUCF) Steering Group, held on 30 June 2023 in Paris. The Steering Group discussed about: the approval of the draft report of the last Steering group meeting, the Annual Report and Financial Report for 2022, the draft Work Programme 2024 and the Budget proposal for 2024, the activity update on the first MUCF work months in 2023 and an overview of funding contributions received from 2018 to 2023, the timing for the next Annual General Meeting (AGM) in Autumn 2023 and the next MUCF Steering Group meeting, the approval of the revised "MUCF invited Guests and Travel and Subsistence expenses procedures" document and the draft Terms of Reference for the new MUCF Residues Expert Group (ReEG). During the horizontal expert group (HEG) meetings, it is being discussed having a simplified draft Registration Report template, as an Addendum of the Explanatory Note on Minor Uses.

5. OECD, FAO and EPPO activities

   There was no news to report.

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

The Commission informed that it has no news as regards the analysis of the wider ramifications of the ruling on C-162/21 and as regards other on-going cases.

The Commission invited Member States to inform the Committee in case of court cases in national courts, which might be of wider interest.

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

1. possible impact on authorisations

There was no news to report.

A.20 Scientific publications and information submitted by stakeholders:

The Commission referred to three letters of NGOs received for the purpose of the meeting of this Committee, which are made available on CIRCABC.

A.21 Date of next meeting(s):

The Commission confirmed that the next meeting of this Committee will be in September (ad-hoc meeting on glyphosate), most likely virtual and the date subject to confirmation, while the next regular meeting of this Committee would be in person on 12-13 October 2023.

A.22 AoB:

The Commission informed that the work related to the mandate to EFSA regarding acetamiprid is progressing, in particular for re-evaluating the toxicological properties of this active substance and its metabolites and the residue definitions, as well as to perform a targeted review of maximum residue levels (MRLs). Meanwhile additional information and studies that might affect the outcome were received from Nisso Chemical Europe and PAN Europe and will be considered by EFSA.

One Member State expressed concerns that MRLs for acetamiprid are routinely exceeded in some products.

The Commission informed of the public hearing at the ENVI Committee of the European Parliament on "How to make sure that pesticide manufacturers disclose results of toxicity studies". Questions for the sanctions and penalties imposed for violations of plant protections products legislation are expected to be raised. As this is an exclusive prerogative of the Member States, they were invited to verify if provisions for such exist in their national legislation and if, when and for what such sanctions and penalties have been imposed.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance fat distillation residues 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 review report PLAN/2023/637 RR).

(PLAN/2023/637)

The Commission summarised the draft documents and the recent comments received by three Member States: one Member State expressed it support for the renewal, whereas the two others were reluctant to support the renewal due to the relevant impurity nickel, as the measured levels of nickel in all 5 representative batches were (slightly) above the maximum content of 0.1 g/kg. The Commission recalled that this limit was expressively set in review report as well as in the draft Regulation.

Vote taken: Favourable opinion.

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 Cydia pomonella granulovirus (CpGV) 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 Review Report PLAN/2023/240 RR).

(PLAN/2023/240)

The Commission presented the draft Implementing Regulation and the draft Review Report together with the comments received from two Member States. A technical error was noted in the Annex and a correct version was uploaded on CIRCABC before the vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 as regards the allocation to Member States, for the purposes of the renewal procedure, of the evaluation of etoxazole whose approval expires on 31 January 2028.

(PLAN/2023/1102)

The Commission presented the draft Implementing Regulation which allocates the Rapporteur Member State and co-rapporteur Member State for the active substance etoxazole.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, eugenol, fludioxonil, flufenacet, flumetralin, fosthiazate, geraniol, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad, thymol, and tritosulfuron.

(PLAN/2023/1470)

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 31 October, 30 November and 11 of December 2023, respectively. These 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 approval. The extensions are proposed depending on where each active substance stands in the renewal process on the basis of the remaining regulatory steps for which maximum time periods are defined in the legislation. The Commission indicted that this approach gives more predictability to Member States to plan their own resources for handling applications. The Commission reminded about the possibility to rescind the extensions at any time.

One Member State indicated that it does not agree with the extension of quizalofop-P-tefuryl and that, in its opinion, active substances should not be treated equally because of different hazard profiles.

Another Member State pointed to the preliminary conclusions on endocrine disrupting properties of fludioxonil and flufenacet and suggested to grant only one year extension to the substances which are still at Rapporteur Member State level. However, another Member State supported the approach of the Commission, since it has been proven that one year is not enough to complete the assessment and decision making and longer periods is proving more legal certainty and giving competent authorities time to complete eventual authorisation procedures.

The Commission reminded that 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.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance 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 informed that since the previous meeting there have been few developments. After discussions at this Committee, the Rapporteur Member States is currently considering refinements and possibilities to mitigate risks in the area of ecotoxicology issues, and expects to deliver a document containing its findings soon. At the request of the Member States, this document will be shared once available as a starting point for further discussion and decision-making.

Member States were invited to comment by 16 August 2023.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance rape seed oil 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 Review Report PLAN/2022/976 RR).

(PLAN/2022/976)

The Commission informed that the discussions on this active substance depend on the finalization of the mandate to EFSA concerning a weight of evidence approach for active substances of natural origin (see point A.09).

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance pelargonic acid 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 Review Report SANTE/11124/2021).

(SANTE/11122/2021)

The Commission informed that the discussions on this active substance depend on the finalization of the mandate to EFSA concerning a weight of evidence approach for active substances of natural origin (see point A.09).

In addition, the Commission informed that no major changes have been done in the draft Implementing Regulation and the draft Review Report. One Member State submitted comments on the active substance's purity, providing arguments why food grade quality should be expressed with reference to food flavourings legislation. The Commission indicated it prefers to keep the current text specifies purity by referral to the minimal quantity of pelargonic acid present, the maximum quantity of three relevant impurities and being of food grade quality as specified for fatty acids to be used as food additives. It explained that this provides equivalent or higher safety compared with reference to food flavouring specification for pelargonic acid. In addition, it was noted

that during the whole risk assessment process this was the way the purity of the active substance was defined, and no objections were raised to this approach.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance ethephon 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 Review Report PLAN/2023/1087 RR).

(PLAN/2023/1087)

The Commission summarised the comments received on the draft renewal report from the applicants and three Member States. The Commission also explained a comment received from an NGO. The Commission shared a revised renewal report and a draft Regulation and announced that a vote is intended for the meeting in October.

One Member State did not have a final position yet but reminded of its earlier concern regarding the assessment of endocrine disrupting properties.

Member States were invited to comment by 31 August 2023.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance aluminium ammonium sulfate 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 Review Report PLAN/2023/1217 RR).

(PLAN/2023/1217)

The Commission shared a revised renewal report and a draft Regulation and announced that a vote is intended for the next meeting in October.

One Member State did not agree with the proposal for environmental fate and behaviour concerns.

Member States were invited to comment by 21 August 2023.

C.06 Exchange of views 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 concerning the placing of plant protection products on the market (Draft review report SANTE/10746/2018).

(SANTE/10745/2018)

The Commission explained the draft review report supporting the non-approval proposal for the new active substance asulam-sodium and summarised the comments of four Member States received since the last meeting in May: three Member States supported the proposal with some suggestions for amending the texts, while one Member State challenged the conclusions on absence of serious plant health risk. Another Member State concerned by a possible derogation according to Art. 4(7) was invited to confirm its initial position.

Member States were invited to provide comments and initial position on the proposed non-approval by 31 August 2023.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance metiram 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 review report PLAN/2023/1253 RR).

(PLAN/2023/1253)

The Commission reminded that the EFSA conclusion was published on March 2023, and that the applicant comments to the EFSA conclusions were uploaded on CIRCA BC, including concerns expressed by applicant on the methodology used for the calculation on dermal penetration and for the Acute Reference Dose proposed by EFSA. The Commission also indicated that a draft non-renewal report has been sent to applicant and will be uploaded on CIRCABC.

Three Member States had already expressed their position in favour of a non-renewal. One Member State indicated it had no position yet.

Member States were invited to provide comments and initial position on the proposed non-approval by 31 August 2023.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance benthiavalicarb 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 review report PLAN/2023/1017 RR Rev.1).

(PLAN/2023/1017)

The Commission recalled that EFSA Conclusion identified the following critical areas of concern: 1) Carcinogenic potential and in particular the criteria for classification as Category 1B are met (RAC opinion adopted on 18.03.2022), 2) the criteria for endocrine disruption (ED) for humans for the T and EAS modalities are met. Negligible exposure cannot be confirmed and, in general, a wide range of alternative fungicide active substances to benthiavalicarb are available.

The Commission informed Member States that the process for non-renewal was progressing and shared the draft Regulation and an updated version of the draft Renewal Report for comments. The TBT notification is expected to be launched as soon and a vote was foreseen for the meeting in October 2023.

The comments of the applicant mentioning the lack of possible alternatives and that in their view negligible exposure is possible, are made available on CIRCABC. Also comments received from Member States are made available: one Member State referring to the possibility to apply Art. 4 (7) and two Member States supporting a non-renewal and a vote as soon as possible.

During the meeting three Member States supported a non-renewal, and two informed that so far they had no position.

Member States were invited to comment by 31 August 2023.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance clofentezine 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 review report PLAN/2023/1037 RR Rev. 1).

(PLAN/2023/1037)

The Commission informed Member States that the process for non-renewal was progressing and shared the draft Regulation and an updated version of the draft Renewal Report for comments. The TBT notification is expected to be launched as soon and a vote was foreseen for the meeting in October 2023.

The Commission also informed that comments were received from four Member States since the meeting held in May, all expressing support for non-renewal of approval.

One Member State commented that it would prefer a shorter grace period of 6 months. The Commission invited all Member States to provide views on the grace period they would consider appropriate.

Member States were invited to comment by 31 August 2023.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance triflusulfuron-methyl 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 review report PLAN/2023/641/RR).

(PLAN/2022/2157)

Pro memoria – TBT notification (to be) launched

The Commission shared the draft act, its reply to the letter of the applicant on 6 June 2023, an e-mail from a stakeholder and comments received from three Member States. The Commission informed that the TBT notification was expected to be launched soon and that a vote is intended for the meeting of this Committee in October 2023.

Two Member States supported the Commission's proposal. One Member State stated that the reason of existence of other substances cannot be an argument for not using Article 4.7 because of different climate, risk assessment etc. and therefore, disagreed with the Commission's argument in the draft review report. Four Member States expressed the need to better understand the alternatives (chemical and non-chemical) in weed management in case of sugar beet and chicory and how to use Article 40.2 in order to find suitable solution for the farmers before they can take a final position.

The Commission's suggestion to discuss the topic of alternatives and the use of Article 40.2 at the PAI WG meeting in September was welcomed by Member States. The Commission also informed about the Sugar Market Observatory (SMO) and the Civil Dialogue Group on sugar (CDG)[2] where sector related issues can be discussed among different stakeholders. The Commission also shared the list of some national technical institutes specialised in sugar beet.

[2] https://agriculture.ec.europa.eu/data-and-analysis/markets/overviews/market-observatories/sugar_en

Member States were invited to provide comments and/or positions by 31 August 2023.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance S-metolachlor 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 review report PLAN/2022/2157 RR Rev. 3).

(PLAN/2023/641)

Pro memoria – TBT notification (to be) launched

The Commission informed Member States that the process for non-renewal was progressing, that the TBT notification is closing soon, and that a vote was foreseen for the meeting in October 2023. So far comments were received from four Member States, which supported different grace periods. One Member State requested a longer grace period with respect to the one in the current draft.
Member States were invited to provide comments by 31 August 2023, in particular on the grace periods.