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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*
12 - 13 October 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/758b4b88-591e-4be5-ace6-76d25a2ba5b7?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meeting of 22 September was published, while the one of the meeting in July was still in preparation.

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

1. *Plectranthus amboinicus* extract

The Commission informed that an application for an approval of an extract of Plectranthus amboinicus as basic substance was received via IUCLID end of May 2023. The substance has insecticidal properties, and it is meant to be used as fumigant in dispensers in greenhouses on tomato against the silverleaf whitefly.

The application is at admissibility stage and the Commission is waiting for the reply of the applicant.

2. *Camellia oleifera* seed extract

The Commission informed that an application for an approval of an extract of *Camellia oleifera* seeds as basic substance was received via IUCLID in July 2023. The substance is to be used as a molluscicide to control *Pomacea maculate* (golden apple snail) on common rice.

The application is at admissibility stage and the Commission is waiting for the reply of the applicant.

3. Fenugreek seeds

The Commission informed that an application for an approval of the powder of the seeds of fenugreek (*Trigonella foenum graecum*) as basic substance was received via IUCLID in June 2023. Fenugreek was previously approved as an active substance until 31/10/2020. The substance is to be used as a fungicide on vineyards, vegetables and fruit, under field and greenhouse conditions.

The application is at admissibility stage and the Commission is waiting for the reply of the applicant.

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

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

   - approach on access to old studies (to endorse)

   The Commission informed that comments on the draft non-paper had been received from several Member States and from stakeholder and were being analysed. Final changes were being made to the non-paper in view of an endorsement by the Committee at its next meeting in December. Member States were already invited to apply the principles in the paper and to report on any specific issues or difficult cases that arise and require discussion.

2. Information on delays / information collection for ZAPID workshop

   The Commission presented the latest status of preparations for the ZAPID workshop. The Commission asked those Member States and third countries, which have not yet nominated participants to send the nominations within the next few days. The Commission informed about travel arrangements and accommodation and the intended support to Member State delegates.

   As part of the preparation for the ZAPID workshop, the Commission shared the comments received from 3 Member States on the reasons for the delays of the approval and authorisation procedures and a summary of those comments. The Commission invited other Member States to provide further input by 6 November 2023.

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

- New active substances / Amendment of conditions of approval

  There was no news to discuss.

- Renewal of approval

  1. Flutolanil

  The Commission summarised the findings of the EFSA Conclusion and informed that this active substance complies with the definition of PFAS which was followed in the REACH draft restriction proposal. Member States were invited to comment by 10 November 2023.

  2. Milbemectin

  The Commission summarised the findings of the EFSA Conclusion and the comments from the applicant. Member States were invited to comment by 10 November 2023.

  3. Metconazole

  The Commission presented the outcome of the EFSA Conclusion and shared the comments of the applicant. Member States were invited to comment by 6 November 2023.

  4. Triclopyr

  The Commission informed that the publication of this conclusion, and consequently a draft renewal report from the Commission, is on hold as the Rapporteur Member State is checking if all lawfully submitted data was assessed. The Rapporteur

Member State indicated to check this by the end of October. The Commission shared the comments from the applicant on CIRCABC.

5. Tritosulfuron

The Commission summarised the findings of the EFSA Conclusion and the applicant comments. The Commission also informed that this active substance complies with the definition of PFAS which was followed in the REACH draft restriction proposal, and that one of the main metabolites is TFA (trifluoroacetic acid) for which an Art. 56 notification under Regulation (EC) No 1107/2009 was submitted and further regulatory actions are on-going by submitting additional data related to the REACH registration of TFA.

Member States were invited to comment by 10 November 2023.

6. Folpet

The Commission summarised the findings of the EFSA Conclusion and highlighted that many concerns related to this substance are like those of captan, which has a similar chemical structure and is currently under discussion at this Committee for a potential renewal of approval.

Member States were invited to comment by 10 November 2023.

- Basic substances

There was no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval

There was no news to discuss.

- Renewal of approval

1. Metrafenone

The Commission briefly presented the active substance which has no critical area of concern but there were issues not finalised such as a provisional consumer risk assessment.

Member States were invited to provide comments by 27 October 2023.

2. Trinexapac

The Commission informed about comments received from Member States on Revision 3 of the draft Renewal Report. The main point raised was the need to ensure that the reference specification is finalised as part of the renewal process.

The Commission explained that it had further examined the file and updated the draft Renewal Report to include a reference to the specification in the Volume 4 of the Renewal Assessment Report (RAR) containing levels of impurities that are considered acceptable, therefore addressing the critical areas of concern in the EFSA Conclusion and the comments from the Member States.

Member States were invited to comments on the revised version of the draft Renewal Report by 27 October 2023.

3. Hydrolised proteins

The Commission informed that one Member State provided comments on the draft renewal report and about comments from the applicant.

Member States were invited to comment by 27 October 2023.

4. Mepanipyrim

The Commission presented the updated draft Review Report and recalled that in May 2017, an EFSA conclusion on mepanipyrim was made available. Based on this conclusion, a Review Report was prepared proposing a restricted renewal of approval. In line with Article 14(1) of Regulation (EU) No 844/2012, after discussion in this Committee, the Commission mandated EFSA to further examine the endocrine disrupting (ED) properties of mepanipyrim in line with the new ED criteria applicable since November 2018.

On 18 July 2023, EFSA made available its updated Conclusion on the peer review of the pesticide risk assessment of mepanipyrim, concluding that the mepanipyrim is considered to meet the criteria for endocrine disruptors for humans and wild mammals as non-target organisms for the EAS-modalities. Also, a high long-term risk was identified for wild mammals exposed to mepanipyrim via dietary exposure, for all representative uses, as well as several issues that could not be finalised.

Negligible exposure could not be demonstrated for mepanipyrim because residues above the default value of 0.01 mg/kg are expected to occur. Since the applicant did not submit an Article 4(7) derogation assessment of Regulation (EC) No 1107/2009 and, consequently, no assessment was possible by EFSA, the Commission considers that it cannot be concluded that the conditions for the application of the derogation in Article 4(7) are fulfilled.

Based on these elements, the Commission proposes not to renew the approval of mepanipyrim. Member States were invited to comment by 10 November 2023.

5. Urea

The Commission briefly presented the active substance and the draft review report. Although there was no critical area of concern, an issue that could not be finalized remained: due to the lack of GLP 5-batch analysis, data compliance of the technical urea with the proposed levels of impurities such as biuret, formaldehyde, or lead, could not be concluded. Consequently, the Commission introduced a condition in the draft renewal report. Member States were invited to comment by 27 October 2023.

6. Metribuzin

The Commission informed that the EFSA Conclusion had identified several critical areas of concern that would preclude the renewal of approval. EFSA has also evaluated the necessity of this active substance as herbicide to control a serious danger to plant health which cannot be contained by other available means.

Member States were invited to comment by 27 October 2023 on the Conclusion, whether the approval of metribuzin can renewed or not, and on whether Article 4(7) could be applied.

The Commission also informed that on 25 October 2023 it would meet the applicants upon their request.

7. Dimethomorph

The Commission informed about the comments received from five Member States, overall supporting a non-renewal of the approval considering the many issues of concern identified in the EFSA Conclusion. The Commission briefly presented the information provided by the applicant (outside the allowed period for supplementing the dossier) concerning the additional genotoxicity studies provided by the applicant to address the residue definition for ruminants and the risk for consumers (linked to the metabolite morpholine).

Member States were invited to comment on this additional information and on the draft renewal report by 10 November 2023.

- Basic substances

8. Caffeine

The Commission informed that since the last meeting, three Member States submitted comments. The other Member States were invited to send comments by 10 November 2023.

9. Magnesium hydroxide

The Commission informed that the Review Report as well as 2 documents with comments from the applicant are available on CIRCABC. Magnesium hydroxide is proposed to be used as a fungicide on several crops in the field.

EFSA proposed in the Technical Report that the specifications for magnesium hydroxide for approval as a basic substance should be set according to the ones that are set for the food additive E528 under Regulation (EC) No 1333/2008. It would therefore appropriate that the name of this basic substance is magnesium hydroxide E 528.

No harmonized classification for any hazard was recommended by ECHA so far. EFSA concluded that no problems are expected as regards residues, under realistic conditions of use. The environmental exposure assessment was also considered acceptable by EFSA. A low risk was concluded for birds and mammals, aquatic organisms, earthworms and other soil micro- and macro-organisms and biological methods of sewage treatment. The substance is expected to have a low ecotoxicological profile towards non-target arthropods (including bees) and magnesium is naturally occurring in the environment, therefore EFSA concluded that magnesium hydroxide E528 can be considered as having a low risk to bees and non-target arthropods other than bees.

Based on all these elements, the Commission proposed to approve magnesium hydroxide E528 as a basic substance.

Member States were invited to comment by 27 October 2023.

A.06 Confirmatory Information:

1. Pendimethalin

The Commission informed that ECHA has started work on a Guidance on the application of the recently amended CLP criteria in the part concerning PBT classification and a draft has been made available. This guidance provides some clarity about how bioconcentration factors (BCF) should be determined when data from more

than one species is available. As this was a particularly important question in the evaluation of the confirmatory information on pendimethalin, this guidance is expected to be helpful to resolve the issue. The Commission intends to send a mandate to EFSA to evaluate the information available, taking into account the ongoing work on the Guidance.

A.07 Guidance Documents, in particular:

1. Explanatory notes on data requirements on micro-organisms (to endorse)

The Commission presented the last draft version of the Explanatory Notes, and recalled that this document provides guidance to harmonize the understanding of the new data requirements on micro-organisms. The Commission highlighted that, for those contents on which discussion is still ongoing (e.g., on how labelling microbial plant protection products as regards their sensitizing potential), it was considered appropriate to make a reference to the ongoing discussions (e.g., the possible amendment of Regulation (EU) No 547/2011).

The following protocol declaration was made by Germany:

The distributed version of the explanatory notes on data requirements on microorganisms for voting in the SCoPAFF October 2023 did not reflect the agreed version from the last WGBP meeting in September 2023.

Germany is of the opinion, that both precautionary sentences are necessary since there is clear scientific evidence, that products containing microorganisms could have sensitizing effects.

In general, labelling with H317and H334 is not possible as the provisions of the GHS system cannot be used for microorganisms. In order to achieve alignment with the GHS system, the wording of the second precautionary sentence was based on the label for skin sensitization.

This is in contrast to the European Commission's argument stating that the second phrase will not fully align with the CLP regulation, as the CLP regulation does not apply for microorganisms.

2. Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO 6895/2009) (draft amendment to endorse)

The Commission presented the new version of the guidance document SANCO 6895/2009, which reflects the changes applied to the draft Registration Report (dRR) templates discussed under the agenda point A.07.03. The Committee endorsed this updated version of SANCO 6895/2009.

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

The Commission presented the new versions of the draft Registration Report (dRR) templates concerning micro-organisms, which 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, and Biopesticides) and in this Committee. Stakeholders were also consulted.

The Committee endorsed this updated version of the dRR.

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

The Commission informed that due to the comments received from Member States and a last-minute discussion with one Member State, the document is still under revision and that no updated draft version was provided for the meeting.

The Commission explained the concerns raised by this one Member State as regards the outcome of the pre-submission meetings when using this document and the impact on the peer review process. The Commission informed that it has been clarified in the draft document that the pre-submission meetings usually take place three years before the submission of the complete dossier and are not legally binding. At that stage, the information provided by the applicants in the template might be limited to decide on the exclusion or not of certain studies. Further data can be always requested by the Rapporteur Member State (RMS), the co- RMS and/or EFSA during the peer-review process.

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.

The Commission informed that a revised version of the document will be distributed after the meeting together with a table with all the written comments received from Member States.

Member States were invited to send their final comments and positions as regards endorsing the document by 10 November 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. 13.

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

There was no news to report.

7. EFSA Guidance Risk assessment for Birds and Mammals

See point A. 13.

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 informed that it was reflecting on the next steps in terms of implementation of this guidance document, in particular considering the need to amend the data requirements and uniform principles. Member States were informed about a position paper submitted by CropLife Europe in which concerns about the required experimental studies and the timeline for implementation were identified. On the other hand, the Commission informed Member States that it had received a message of support for the guidance from the water industry.

Member States were reminded that there are a significant number of active substances for which a request to submit confirmatory information was set to provide information on the impacts of water treatment processes on residues in drinking water, once guidance was in place.

Member States were invited to comments on the implementation of the guidance by 10 November 2023.

9. FOCUS surface water scenarios (on-going mandate EFSA)

There was no news to report.

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

There was no news to report.

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

The Commission explained that four Member States made comments on the draft revised version (rev.8) of the guidance document circulated at the meeting of this Committee in July. The suggestions were taken on board as far as the definition of the three new groups of semiochemicals.

One Member State informed that encapsulated semiochemicals would apparently be excluded from the organic farming scheme. The Commission will verify this interpretation internally.

Member States were invited to comment by 27 October 2023.

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

The Commission informed that it would share a revised version of the guidance document as soon as it is available to start discussions.

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

1. Article 44(4)

The Commission informed that it had received six notifications since the last meeting of this Committee. The notifications concerned the withdrawal of five plant protection products (PPP) due to the presence of unacceptable co-formulants in the formulations and the withdrawal of cyazofamid based PPP due to the risk of leaching of metabolites to groundwater.

2. Article 36(3)

The Commission informed about the twelve notifications received, four of which concerned rejections of mutual recognition applications and only one decision was appealed at national court but finally dismissed. The eight remaining notifications are the result of the rejection of authorisation following the zonal system. Also in this case, only one decision was appealed at national court and finally dismissed.

3. Article 53

There was no news to report.

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

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

The Commission recalled that on 23 March 2023 the approvals of eight *Bacillus thuringiensis* strains (Bt) were renewed. They included a condition which is based on a precautionary minimum time period that shall elapse between the application of a plant protection product containing these active substances and the harvesting of edible crops meant for fresh consumption. This condition applies if residue data reported by the EFSA conclusion showed a Bt density above the level of 10^5 CFU/g. In addition, the Implementing Regulations call for the generation of more data regarding the decline of Bt concentration after application as well as storage stability data. Currently, the Commission is collecting information on projects on the generation of data regarding possible toxigenicity of Bt and/or *Bacillus cereus sensu lato*. The Commission invited Member States to provide information in case of awareness on relevant ongoing projects on Bt or Bc sensu lato.

The Commission informed that it launched two studies which will facilitate access to the market of micro-organisms. The first one is a "Literature review on the occurrence and population levels in soil of micro-organism species used in plant protection" (works started 1 September 2023), the second one is a "Review of biology and ecology of micro-organism species used in plant protection" (work will start in the following weeks).

The Commission also informed that it had in depth and complex exchanges of views as with EFSA as regards the possibility to further evaluate the risk assessment of four active substances of natural origin (sulphur, pelargonic acid, rape seed oil and kaolin), and in particular the possibility to submit a mandate for their further evaluation taking into account their specific features as natural substances.

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

1. Sodium hydrogen carbonate

The Commission informed that the discussion on the dual approval of this substance, both as a regular active substance and as a basic substance, will be continued until there is clarity on the marketing of this substance as a regular active substance. The Commission informed that for this reason a letter was sent to the authorisation holder in Austria but so far, no reply was received.

2. Common metabolites of pyrethroids

The Commission shared the draft Review Reports of cypermethrin and lambda-cyhalothrin that are amended following the EFSA Opinion issued in September 2022 and the EFSA Statement issued in April 2023 as a result of a mandate from the Commission on the assessment of the common pyrethroid metabolites.

The Commission invited Member States to comment on the amended draft Review Reports by 27 October 2023.

3. 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 is currently under discussion with EFSA.

4. Prosulfocarb

The Commission presented the feedback received since the last meeting from 4 more Member States on the risk mitigation measures currently in place for prosulfocarb. The Commission summarised all feedback received in one table which was shared on CIRCABC and recommended to look up details, if necessary, in the individual submissions. The Commission informed that this overview will also be shared in the Post Approval Issues Working Group.

One Member State informed of a recent change to a national authorisation. This will be notified via article 44 of Regulation (EC) No 1107/2009. Another Member State received an article 56 notification and will verify if the study submitted was already mentioned in the earlier notifications under article 56. Both points will be discussed in the next meetings of this Committee.

5. Dimoxystrobin

The Commission informed that in response to a Commission's mandate EFSA has finalised a Conclusion. It is based on an almost complete analysis and only the evaluation of endocrine disruptive properties by the EAS-modality for organisms different from mammals could not be finalised due to lack of data.

Dimoxystrobin is no longer approved, but the Conclusion is necessary to facilitate further work on the substance, in particular on MRLs. On its basis, a draft update of the Renewal Report on dimoxystrobin has been prepared, presented to the Committee, and sent to the applicant for comments.

Member States were invited to comment by 27 October 2023 on the draft update. Endorsement of the updated Renewal Report is planned for the next meeting of this Committee.

6. Acetamiprid

The Commission informed that it had submitted a mandate for extension and revision of the mandate to EFSA for scientific and technical assistance on toxicological properties and maximum residue levels of acetamiprid and its metabolites and a request for additional analysis. The extension was necessary because new relevant information was received by the authorisation holder and a civil society group that should be taken into account. As part of the mandate, if EFSA identifies risk for consumers for one or more of the existing MRLs, it will recommend new MRLs that ensure safety of consumers, where possible, and advise risk managers on alternative options. The outcome of the mandate should be finalised by 31 March 2024.

7. Fat distillation residues – (<u>amended renewal report to endorse</u>)

The Commission explained that an error in the Renewal Report (Rev1), as voted in the July Committee, was corrected (the sentence "*Fat distillation residues are listed in Annex I of Regulation (EC) No 396/2005."* was deleted at the end in the first paragraph on page 4).

The Committee endorsed the amended Renewal Report.

One Member State reiterated that it would not endorse the amended report as it had not supported the renewal of this active substance for the same reasons as declared before (i.e., there are 60 % unknown impurities in the compound, and the known, relevant impurity nickel is not according to the specification in the representative products).

In addition, the Commission informed about a corrigendum requested for the Implementing Regulation (EU) 2023/1755 of 11 September 2023 renewing the approval of the low-risk active substance fat distillation residues correcting the typo in the entry number from 44 to 46 to avoid double entries.

A.11 Article 21:

1. Acibenzolar-S-methyl

The Commission reminded that for acibenzolar-S-methyl an Article 21 procedure was launched, and that the applicant was invited to submit the required studies by 31 July 2025 to allow the assessment of the endocrine disrupting properties.

During a meeting with the Commission on 24 July 2023, the applicant informed that for acibenzolar a provisional self-classification as toxic for reproduction category 1B would be initiated. Subsequent to this decision, the applicant informed the Commission on 8 September 2023 that they reconsidered the generation of such further data and that they intend to stop further investigation on the endocrine disrupting potential, being therefore no longer able to fulfil the requested deadline.

The Commission is reflecting on how to proceed with the withdrawal of the approval of this active substance. Member States were invited to provide comments by 10 November 2023.

A.12 General issues for information / discussion:

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

a) New cases

There were no new cases to discuss.

b) Physical barriers

The Commission briefly explained the amendments on rev. 74 of the scope guidance document concerning the decision tree proposed by one Member State, as well as the proposed alignment of interpretation between SILTAC, K-PAK and STIX entries. One Member State mentioned that one of these products was concerned by a national court case. The Commission underlined that the new decision tree as proposed could have consequences for several entries (highlighted in yellow in the draft rev. 74).

The Commission invited Member States to comment by 10 November 2023 on the draft version of the guidance, e.g., the decision tree and its consequences for existing entries to be re-interpreted, and to provide some suggestions to ensure a smooth transition for the entries where there will be changes in the interpretation.

2. Basic substances – general issues and survey

The Commission thanked Member States for their responses to the survey and informed that the analysis of the received information is ongoing.

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

The Commission presented a first draft of the work plan for the development of test methods focusing on wild pollinators and explained that the workplan, once finalised, will be a living document which will be updated at regular intervals.

Member States were invited to comment on this first draft workplan by 10 November 2023.

4. PFAS

The Commission informed that a letter was sent to EFSA asking to reflect in their EFSA Conclusions whether the active substance assesses would fall under the definition of PFAS, as defined in the REACH restriction proposal. One Member State supported this approach.

The Commission also informed that the public consultation for the proposed restriction under REACH is now closed and that ECHA received more than 5600 comments by 4400 organisations, companies, and individuals.

A.13 Amendments Regulations (EU) No 547/2011, 546/2011, 283/2013 and 284/2013:

As regards the amendment to Regulation (EU) No 547/2011, the Commission explained the changes made in the draft proposal after the ad-hoc technical meeting with experts from Member States which took place on 14 of June 2023. These changes concern the order of the annexes, the hazard sentence and pictogram for bees, the requirements for digital labelling, and the colour scheme for plant protection products. The Commission thanked those Member States who had provided comments for their useful contributions to the revised draft.

One Member State asked about the use of the colour scheme for emergency authorisations. Two Member States remarked the importance of providing coherence between the colour scheme for the labels and the categorisation of active substances and weightings applied for the indicators to calculate the reduction targets on the Sustainable Use Regulation proposal. Another Member State thanked the Commission because of the added value perceived in the updated colour scheme.

Member States were invited to comment on the revised draft regulation by 10 November 2023.

As regards the amendments to Regulations (EU) No 546/2011, 283/2013 and 284/2013, the Commission explained that all three proposals will be presented as a package at the next meeting of this Committee. Besides the necessary amendments to be able to endorse the revised Guidance Documents on bees as well as on birds and mammals, changes will also be incorporated regarding the data requirements for the assessment of endocrine disrupting properties (alignment only, no change in content) as well as changes needed to endorse the guidance document on the impact of water treatment on residues in drinking water.

The Commission made the Member States aware of comments uploaded under agenda A.20 of the NGO PAN Europe and from the applicant association CropLife Europe.

One Member State asked when it will be possible to endorse the revised Bee Guidance Document. The Commission explained that this will only be possible after the adoption of the necessary changes to these implementing regulations, which will be subjected to a 3 month scrutiny of the European Parliament and the Council. Due to the upcoming elections, this is expected not to take place before October 2024.

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

1. Implementation of Regulation (EU) 2023/574

The Commission informed that a question was raised by one Member State about a preservative that is not approved under the Biocidal Products Regulation (BPR). It seems that this substance was listed as a known biocidal substance in the past, but was not supported in the biocidal working program, and therefore it is currently not approved as a biocide. The question is whether this preservative should be listed in Annex III.

The Commission recalled that this substance was never supported under the BPR, so that it was never assessed under this regulation, thus not fulfilling the respective criterion for being listed in Annex III. The Commission indicated that it is still reflecting how to proceed and invited Member States to comment on this topic by 10 November 2023.

2. Ongoing actions

The Commission shared the comments received from Member States on its proposal concerning the next steps after the two workshops which took place earlier this year (May and June 2023) and informed the Committee about the discussion with the members of the Post Approval Issues Working Group in September.

The three activities proposed (1. EU database of co-formulants, 2. guidance how to assess PPPs and co-formulants, 3. how to communicate (improvements)) received strong support from the Member States. The Commission detailed some steps forward on those 3 activities, and invited Member States to provide comments, in particular on the summary of requirements for the EU database of co-formulants, by 6 November 2023.

Further discussions will continue at the upcoming PSN meeting on 24 October 2023, at the meetings of the PAI WG and the Working Group on phys-chem, as well as at the ZAPID workshop in December, and upcoming meetings of this Committee.

A.15 Data requirements and work programme for the EU approval of safeners and synergists:

The Commission informed that the draft Commission Regulation defining data requirements and the work programme concerning these substances was under Inter Service Consultation (CIS) and that it would then be subjected to public consultation (feedback mechanism) and SPS/TBT notification. A vote in this Committee is intended for beginning of 2024, which would then be continued by scrutiny of the European Parliament and the Council.

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

The Commission informed that the last Biopesticides Working Group meeting was held on 20 September. Among other things, the points that were discussed were about the lack of tests for sensitizing potential of micro-organisms, explanatory notes, draft Registration Reports templates, labelling of microbial plant protection products, and initiatives on semiochemicals. The following meeting will take place on 14 and 15 November 2023.

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 informed about the comments received from 6 Member States and 4 stakeholder organisations. The Commission will analyse the comments and an updated version of the document will be presented at the next meeting.

Member States that did not yet provide comments on the draft document were invited to do so by 10 November 2023.

3. Working Group on comparative assessment (no news)

There was no news to report.

4. Working Group Post Approval Issues

The Commission informed about the last meeting of the Post Approval Issues Working Group, held on 13 and 14 September 2023. The main points debated were: the availability of plant protection products (PPP) in general (linked to the discussion of alternatives to triflusulfuron) and the need to increase the availability of biopesticides in particular, by means of legal tools such as the implementation of Article 40(2); the assessment at PPP level of information not assessed at EU level, in particular when it comes to toxicological or ecotoxicological relevance of metabolites; the follow-up of the assessment of the co-formulants' workshop and the need for compilation of the existing so-called mini-products; one Member State informed that in their monitoring they are finding exceedances of impurities but it's difficult to determine if they are attributable to the active substance or to the co-formulants within the formulation sharing the same relevant impurity.

The Commission reminded the additional workload expected once the water treatment guidance document will be endorsed in the Committee, as around 20 dossiers pending this confirmatory data will need to submit the information. The group also debated about the performance of the assessment of the equivalence of SCLP, in particular the blends; and measures taken at PPP level by some Member States on prosulfocarb based PPP.

The next meeting is planned for the 29 and 30 November 2023.

5. Working Group on Negligible Exposure

The Committee was informed that the last meeting of the Working Group was held on 29 September 2023 in which the Commission presented a revised document with a significant change in approach – aiming to provide risk managers with a critical analysis of key elements to inform decision-making as regards the situations where negligible exposure is ***not*** given, rather than providing a definitive outcome on whether exposure is negligible. This was considered appropriate given that significant challenges in developing specific thresholds for non-dietary exposure to humans and since the determination of whether approval criteria are fulfilled ultimately lies with risk managers.

In addition, no specific section on the environment is proposed as it is expected that most substances that are endocrine disruptors for non-target organisms (NTOs) would also be endocrine disruptors in humans and therefore as a first step negligible exposure should be concluded for humans in such cases. A case-by-case approach for the

expected very limited number of cases for NTOs was considered more proportionate, as agreeing on a guidance for none or very limited cases does not seem proportionate in terms of workload.

The Working group was invited to provide comments by 6 November after which it would be decided whether to launch further consultations with Member States (via the Pesticide Steering Network) and stakeholders (via the Advisory Group) or if further working group meetings are needed.

It was recalled that following those consultation, the guidance would then be brought to this Committee for further discussion in view of endorsement.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA informed about the progress on the peer review of active substances and on-going mandates, general experts' meetings on physical-chemical properties and microorganisms, and informed about the upcoming Pesticide Steering Network meeting. In addition, an updated template for CLP/PPP aligned dossiers was made available in view of endorsement.

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

There was no news to discuss.

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

There was no news to discuss.

4. Minor Use Facility (MUCF)

There was no news to discuss.

5. OECD, FAO and EPPO activities

The Commission briefly informed about the ongoing field tests carried out in 2 Member States by the OECD Industry Task Force with drones to complement the data on exposure modelling e.g., regarding drift.

The Commission updated about the activities regarding illegal and counterfeited pesticides and about the latest finding of the operation Silver Axe VIII coordinated by Europol.

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

The Commission informed that as regards court case T-77/20 (non-renewal of chlorpyrifos-methyl), the General Court confirmed that the action for annulment must be dismissed in entirety. The Commission also informed that since March it received requests for internal review.

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

1. possible impact on authorisations

The Commission informed that at the meeting of the Pesticide Residues section of this Committee which took place on 18-19 September 2023, measures on the following active substances were taken with possible impact on authorisations:

Oxamyl	MRLs were lowered.
Desmedipham	MRLs were lowered.
Etridiazole	MRLs were lowered.
Flurtamone	MRLs were lowered.
Difenacoum	MRLs were lowered.
Profoxydim	MRLs were lowered.
Potassium permanganate	MRLs were lowered.
Indoxacarb	MRLs were lowered.
Diethofencarb	MRLs were lowered.
Fenoxycarb	MRLs were lowered.
Flutriafol	MRLs were lowered.
Pencycuron	MRLs were lowered.
(Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate	MRLs were lowered.
Acrinathrin	MRLs were lowered.
Azimsulfuron	MRLs were lowered.
Famoxadone	MRLs were lowered.
Prochloraz	MRLs were lowered.
Sodium hypochlorite	MRLs were lowered.
Haloxyfop	MRLs were lowered.
Thiacloprid	MRLs were lowered.

A.20 Scientific publications and information submitted by stakeholders:

The Commission referred to two letters of NGOs and one of a professional applicant association, 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 informed that the next meeting will be hybrid on the 11 and 12 December 2023, subject to confirmation, and that the planning for the meetings of this Committee in 2024 is 30-31 January, 20-21 March, 22-23 May, 10-11 July, 2-3 October, and 4-5 December.

A.22 AoB:

The Commission informed that the revised Communications listing the study protocols and guidance documents relevant for the Implementing Regulations (EU) No 283/2013 and 284/2013 – Part A have been published: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2023:344:TOC. In addition, and as soon as possible, the Commission will contact Member States and stakeholders to check the draft database of the guidance documents, test methods and supporting documents in order to make it publicly available in the beginning of 2024.

Two Member Sates asked for an update on the cyazofamid Article 44(4) notifications: The Commission informed that since the last meeting of this Committee, another Member State informed the Commission on the withdrawal of cyazofamid based plant protection products in their territory due to risk of leaching of metabolites DMS and DMSA to groundwater. The recent renewal of cyazofamid did not identify DMS as a metabolite of cyazofamid and concluded on the non-relevance of DMSA. However, some Member States would be in a position to support a revision of the renewal of cyazofamid under Article 21. While other Member States consider that it is difficult to demonstrate the origin of these ubiquitous metabolites, as the sources are diffuse and may respond to precedence from other activities, such as outdoor paints and wood preservatives.

The Commission invited Member States to express their preferred way forward as regards the approval of cyazofamid, by 10 November 2023. If Member States consider that these common metabolites should be subject to a further investigation as has been done for others such as triazoles, TFA or pyrethroids, Member States can gather information and send it to the Commission. If on the contrary, Member States consider that these metabolites need to be further investigated as relevant for cyazofamid, Member States can request a review of the approval of cyazofamid on the basis of Article 21.

Section B **Draft(s) presented for an opinion**

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance 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 presented the draft documents. One Member suggested some changes in the draft Annex which were not implemented after discussion, and two Member States indicated that they have concerns related to human health in particular for the powder formulation.

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 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 presented the draft documents. One Member stated that the assessment for endocrine disrupting properties was not fully finalised.

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 active substance glyphosate 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/2023/1497 RR).

(PLAN/2023/1497)

The Commission informed that several Member States had submitted comments on the draft Renewal Report and draft Implementing Regulation that were made available after the meeting of the Committee on 22 September 2023. All these comments had been made available to the other Member States.

The Commission also drew the attention to letters received from stakeholders, which had been made available prior to the meeting and about statements published by EFSA and ECHA in response to criticism from NGOs, which had been published on the Commission's dedicated glyphosate webpage. In the statements the agencies concluded that the points and findings in the letter and report by the NGOs do not have any impact on the overall conclusions adopted by EFSA and ECHA.

The Commission also mentioned that on the day before the meeting it had met 4 NGOs who had handed over a petition signed by 2.5 million citizens since 2017 from all over the world, including third countries, calling for a ban of glyphosate.

The Commission presented the updated draft Renewal Report section by section, explaining the changes made to address the comments received to the previous version

of the draft Report, as well as some small editorial changes and corrections. The Commission also explained why certain comments from Member States had not been taken up. Member States were invited to comment on each section.

The Commission explained that to accommodate a proposal of one Member State it had proposed to set maximum annual application rates at the highest values where no unacceptable risk for small herbivorous mammals was concluded, while allowing Member States to set higher rates for specific plant protection products (PPPs), if additional data is submitted and their risk assessment at national and/or zonal level indicates that no unacceptable risks is identified. This Member State insisted that absolute maximum rates should be set, and if higher levels are found to be safe for certain uses, the limit in the approval regulation should be raised. The Commission explained that the EFSA Conclusion does not give any justification for such absolute limits because the relevant risk assessment had not considered possible refinements. Several Member States strongly opposed setting of any maximum application rates as deviating from the usual practice, having little added value with respect to safety, while expecting to cause implementation difficulties at national and zonal level. They stated that while they could support the current proposal as a compromise and with reluctance, they could not accept any further changes, and this should not set any precedent. One Member State expressed preference that either no maximum application rates or absolute ones are set to ensure legal certainty. Despite this preference, they could support the Commission proposal. Another Member State found the proposal compatible with current practises at national level.

The Commission explained that it had not modified the proposal as requested by one Member State to require mandatory comparative assessment and refusal of authorisations when non-chemical alternatives are available. In its view the EFSA Conclusion did not provide grounds to overrule Article 50(2) of Regulation (EC) No 1107/2009 according to which Member States may conduct comparative assessments for products that contain active substances that are not candidates for substitution but are not obliged to do so. The Member State who had made the proposal noted that both this and their proposal for maximum application rates aim to harmonise the processes across the Member States and support the ambition to reduce the use of chemical pesticides in Europe. In addition, they believed that the existing legal framework allows such measure to be adopted. Several Member States who took the floor opposed the proposal and no other Member State supported it. The Commission recalled that it (and all Member States) supports the reduction of the use and risk of pesticides. However, the tools to achieve this are set specifically in other legal frameworks such as the Sustainable Use Directive and reminded that it had proposed to reinforce these tools in its proposal for a Sustainable Use Regulation currently under discussion.

After finalising the discussion on the draft renewal report, the draft Implementing Regulation and its Annexes were discussed. The Commission explained some editorial and typographic changes (in line with changes made in the draft Renewal Report) that were supported by Member States.

The Commission explained again the reasoning for its proposal for a renewal period of 10 years as set out in recital 30 of the draft Regulation. It noted that most Member States who sent comments supported 15 years as the appropriate renewal period, while one had requested a shorter period. That Member State reiterated its request for a shorter period considering the existing uncertainties, however, without proposing any specific length. No other Member State supported an approval period shorter than 10 years.

Several Member States recalled their proposal for a longer renewal period but stated that the proposal of Commission is acceptable. One Member State expressed that it could not accept less than 10 years.

The Commission and several Member States taking the floor expressed their appreciation for the enormous work and efforts of the Rapporteur Member States, EFSA and ECHA, and Commission.

The Commission proceeded to vote during the meeting. The Member States voting against or abstaining invoked the precautionary principle, political reasons, public opinion, and/or absence of agreement at national level.

Vote taken: No opinion.

The Commission informed that it would refer the draft Regulation to the Appeal Committee that would take part in the first half of November 2023 in accordance with the comitology rules.

The following protocol declarations were made:

Croatia:

"Considering that application restrictions are necessary, and taking into account the precautionary principle, and the negative attitude of part of the public regarding the use of glyphosate, as well as the Commission's strategy from "Farm to fork", as part of the European Green Plan, which emphasizes the need to move to a fair, healthy and ecologically acceptable food system without the use of synthetic chemical products for plant protection Croatia will not support the proposal of the Commission."

Denmark:

"Denmark support banning the desiccation of crops before harvest and that the member states must introduce buffer zones where glyphosate may not be sprayed along streams and nature areas of either 5 or 10 m, depending on the dosage of glyphosate on the fields.

Denmark welcomes the change in the proposal about use on sealed and very permeable areas where the Member States should pay particular attention to these areas.

Denmark would have liked a ban of concentrated products containing glyphosate to non-professionals, but find it covered by the Member States possibilities to non-approval of this use.

With this remarks Denmark can support a renewed approval period of a maximum of 10 years."

France:

La France prend acte des améliorations apportées par la Commission européenne à son projet de règlement renouvelant l'approbation du glyphosate, notamment l'interdiction d'utilisation pour la dessiccation en vue de la récolte et l'obligation pour les demandeurs de soumettre des données confirmatives en ce qui concerne les effets indirects sur la biodiversité via la chaine trophique.

La France invite la Commission à mandater sans délai l'EFSA pour élaborer le document guide qui permettra d'évaluer ces données confirmatives.

Cependant, la France considère que le glyphosate est une substance dont l'utilisation doit être réduite à l'échelle européenne et limitée aux utilisations pour lesquelles il n'existe pas d'alternatives. Le règlement d'approbation devrait traduire cet objectif et contribuer à la trajectoire de réduction européenne. En l'état, ce règlement renvoie aux États membres la mise en œuvre éventuelle de mesures de réduction de l'utilisation, alors qu'une approche portée par la Commission permettrait de renforcer la cohérence du marché intérieur et d'éviter de possibles distorsions de concurrence.

De plus, la France avait demandé à ce que la durée de l'approbation soit beaucoup plus courte que les 10 ans proposés compte tenu des incertitudes soulignées par les scientifiques.

Pour ces raisons, la France ne peut pas soutenir la proposition de règlement de la Commission européenne et s'abstient.

La France invite la Commission à modifier sa proposition pour répondre aux préoccupations de la France et de nombreux Européens, en restant ouverte à des échanges en ce sens.

Unofficial translation

France notes the improvements made by the European Commission to its draft regulation for renewal of the approval of glyphosate, notably the ban on use for desiccation for harvest and the obligation for applicants to submit confirmatory data with regard to indirect effects on biodiversity via the trophic chain.

France invites the Commission to mandate the EFSA without delay to develop the guide document which will make it possible to evaluate this confirmatory data.

However, France considers that glyphosate is a substance whose use must be reduced on a European level and limited to uses for which there are no alternatives. The regulation for approval should reflect this objective and contribute to the European path towards reduction. As it stands, this regulation refers to the Member States the possible implementation of the measures to reduce the use, whereas an approach led by the Commission would make it possible to strengthen the coherence of the internal market and avoid possible distortions of competition.

In addition, France had requested that the duration of approval be much shorter than the 10 years proposed given the uncertainties highlighted by scientists.

For these reasons, France cannot support the regulation proposed by the European Commission and is abstaining.

France invites the Commission to modify its proposal to respond to the concerns of France and many Europeans, while remaining open to discussions in this direction.

<u>Germany</u>:

" Glyphosat ist mit Abstand das meist eingesetzte Totalherbizid. Glyphosat wirkt systemisch, d.h. aufgenommen über die Blätter gelangt es in alle Bestandteile der Pflanze und führt zum Absterben der Pflanze.*

** Seit 2017 sollen die Mitgliedstaaten bei ihren nationalen Zulassungsentscheidungen über glyphosathaltige Pflanzenschutzmittel die Auswirkungen auf die Biodiversität einbeziehen und gegebenenfalls Anwendungsbedingungen zur Risikobegrenzung festlegen.*

** In Deutschland haben wir bereits national auf dem Verordnungsweg bestimmte Anwendungen von glyphosathaltigen Herbiziden verboten/beschränkt.*

** Allerdings fehlen auch über 10 Jahre nach Inkrafttreten der VO (EG) Nr. 1107/2009 weiterhin eine anerkannte harmonisierte Bewertungsanleitung und konkrete Anforderungen an ein Risikomanagement, um die indirekten Auswirkungen auf die Biodiversität und insbesondere die Effekte auf Nahrungsnetze in den Zulassungsverfahren einheitlich bewerten und regulieren zu können.*

** Auch die EFSA hat festgestellt, dass insoweit mangels verfügbarer Informationen keine eindeutigen Schlussfolgerungen gezogen werden können und mögliche negative Effekte nicht ausgeschlossen werden können.*

** Deutschland fordert weiterhin, dass der EFSA ein Mandat zur Verwendung der von Deutschland bereits vorgestellten Interimsmethode zur Bewertung der Biodiversität erteilt wird.*

** Deutschland wird deswegen der erneuten Genehmigung des Wirkstoffs Glyphosat nicht zustimmen, sondern sich enthalten."*

Unofficial translation

Glyphosate is by far the most commonly used total herbicide. Glyphosate has a systemic effect, i.e. when absorbed through the leaves it gets into all parts of the plant and causes the death of the plants.

Since 2017, Member States have been required to take into account the effects on biodiversity in their national authorization decisions for plant protection products containing glyphosate and, if necessary, establish conditions of use to limit the risk.

In Germany we have already banned/restricted certain uses of herbicides containing glyphosate through national regulations.

However, even more than 10 years after Regulation (EC) No 1107/2009 came into force, there are still no recognized harmonized assessment guidelines and specific requirements for risk management to assess uniformly for regulatory purposes during the approval procedures the indirect effects on biodiversity and in particular the effects on food webs.

The EFSA has also determined that, due to a lack of available information, no clear conclusions can be drawn, and possible negative effects cannot be ruled out.

Germany continues to demand that EFSA is mandated to use the interim method for assessing biodiversity that already exist in Germany.

Germany therefore does not agree with the renewal of approval of the active substance glyphosate, but will rather abstain.

<u>Italy</u>:

"L'Italia apprezza il grosso sforzo collettivo profuso dagli Stati membri, dall'EFSA, dall'ECHA e dalla Commissione per finalizzare una nuova valutazione del glyphosate, avvenuta a pochi anni di distanza dalla precedente e con l'esame di un notevolissimo numero di dati.

Tuttavia, in relazione ad alcuni punti di ulteriore approfondimento evidenziati dal parere dell'EFSA ed emersi nella discussione finalizzata all'adozione del regolamento di rinnovo l'Italia ritiene opportuno sottolineare che sia auspicabile:

- *che l'utilizzo della sostanza attiva non sia autorizzato in fase di pre-raccolta*
- *l'avvio, a livello comunitario, di ulteriori studi integrativi finalizzati alla raccolta di dati atti a colmare le lacune conoscitive al fine di tutelare la biodiversità e le diverse matrici ambientali;*
- *il completamento, senza indebito ritardo, della valutazione dei dossier relativi all'approvazione o al rinnovo dell'approvazione di sostanze attive potenzialmente alternative al gliphosate."*

Unofficial translation

Italy appreciates the great collective effort made by Member States, EFSA, ECHA and the Commission to finalize a new evaluation of glyphosate, which took place a few years after the previous one and involved the examination of a very considerable amount of data.

However, regarding some issues for further investigation as highlighted by the EFSA opinion and which emerged in the discussions to adopt the renewal regulation, Italy deems it appropriate to underline that it is desirable:

- that the use of the active substance is not authorized in the pre-harvest phase.
- to launch, at community level, of further integrative studies for collection of data to fill data gaps in order to protect biodiversity and the various environmental matrices;
- to complete, without undue delay, of the evaluation of the dossiers relating to the approval or renewal of the approval of active substances that are potential alternatives to glyphosate.

<u>Latvia</u>:

"Latvia supports the Commission's Implementation Regulation draft PLAN/2023/1497 with the following reservation:

Considering the evaluation of the EU's scientific and competent authorities EFSA and ECHA and the Commission's proposal, Latvia supports the draft Regulation for renewal of the approval of glyphosate for a shortened period, but at the same time encourage to set at least 30 days interval between the use of glyphosate and harvesting."

<u>The Netherlands</u>:

"First of all, The Netherlands would like to express its appreciation for all the work that has been done by the AGG consortium, EFSA and the Commission on this dossier.

This resulted in a comprehensive risk assessment, where no critical areas of concern were identified by EFSA. The Netherlands acknowledges this outcome.

On the other hand, in the Netherlands there are concerns present in society and amongst several scientists about the effects of glyphosate on biodiversity and about a possible link between the use of glyphosate and Parkinson's disease. Also, on scientific

level, there have been several studies showing associations between the exposure to glyphosate and the development of Parkinson's disease. The concerns about biodiversity and the possible health effects of glyphosate lead to an adopted resolution in the Dutch Parliament to vote against a renewal of glyphosate.

Following these concerns, the Netherlands will initiate a scientific research at our National Institute of Public Health and the Environment (RIVM) on a possible causal link between the use of glyphosate and Parkinson's disease. EFSA will be asked to be involved to ensure the results will be useful to interpret possible risks of the active substance glyphosate.

The Netherlands would like to have an explicit confirmation from the Commission that the approval of glyphosate will be revoked when and if, from this study or from any other scientific information, it can be concluded that glyphosate causes unacceptable risks to humans, animals or the environment; especially in the case of a causal link between glyphosate and Parkinson's disease.

In addition, The Netherlands asks EFSA to give priority to the development of test protocols on neurodegenerative impact of PPP's in order to include such studies in future risk assessments.

The Netherlands also supports the development by EFSA of a risk assessment framework on the indirect effects of PPP's on biodiversity.

Overall, The Netherlands acknowledges both: the outcome of the risk assessment and the concerns from society and the Dutch Parliament on the possible impact of glyphosate on biodiversity and human health. Therefore, The Netherlands will abstain on the current proposal.

<u>Portugal</u>:

"Portugal supports the proposal for renewal of glyphosate as it has been established from the scientific risk assessment that glyphosate meets the approval criteria provided for in article 4 of Regulation (EC) No 1107/2009 as no critical areas of concern were identified during the peer review of the substance.

Although we acknowledge that there are issues that need further consideration including at Member State level when (re)authorizing plant protection products we find that the overly prescriptive approach and setting of redundant conditions that dismiss the role of MS as Risk Managers will mostly contribute to unharmonized approaches from applicants and competent authorities to (re)authorization of glyphosate based plant protection products at zonal and national level, uncoherent decision making and increased administrative workload."

<u>Slovenia</u>:

"The Government of Slovenia advocates banning the use of glyphosate on non-agricultural areas.

Regarding the use of glyphosate for agricultural production purposes, the Government of SI advocates that its use be limited as much as it is possible. Use is permitted only where no suitable alternative methods are available.

Since the Commission's proposal goes in the direction of the position of the Government of Slovenia, Slovenia supports the Commission's proposal. Therefore, Slovenia votes in favour of the Commission proposal."

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance asulam-sodium in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (Draft review report SANTE/10746/2018).

(SANTE/10745/2018)

The Commission informed that the applicant had withdrawn the application and therefore the vote is postponed. An updated draft act will be proposed for vote at the next meeting of this Committee.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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).

(PLAN/2023/1017)

The Commission explained some minor changes to the texts which were introduced since the last meeting and informed that the TBT notification process ended on 18 September 2023 and that no comments were submitted by third countries, nor were any additional letters provided by the applicant or stakeholders since the previous meeting.

The Committee was reminded that comments had been received from one Member State since the meeting held in July 2023, reiterating it wish to shorten the grace period to a maximum of 6 months. After discussion during the meeting it was decided to retain the period of 12 months stated in the draft.

Vote taken: Favourable opinion.

Germany made a protocol declaration:

Germany is in agreement with the presented drafts of the non-renewal regulation and the non-renewal report for the active substance benthiavalicarb.

However, due to the critical concerns identified in the renewal report Germany considers it necessary to apply the shortest possible transitional and grace periods of 3 and 6 months for the active substance benthiavalicarb (comparable to S-Metolachlor).

Furthermore, Germany would appreciate if the European Commission could explain the reasons why longer transitional and grace periods (> 3 + 6 month) were proposed.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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 renewal report PLAN/2023/1037 RR).

(PLAN/2023/1037)

The Commission explained some minor changes to the texts which were introduced since the last meeting and informed that the TBT notification process ended on 13 September 2023 and that no comments were submitted by third countries, nor were any additional letters provided by the applicant or stakeholders since the previous meeting.

The Committee was reminded that comments had been received from one Member State since the meeting held in July 2023, reiterating its wish to shorten the grace period to a maximum of 6 months. After discussion during the meeting it was decided to retain the period of 12 months stated in the draft.

Vote taken: Favourable opinion.

Germany made a protocol declaration:

Germany is in agreement with the presented drafts of the non-renewal regulation and the non-renewal report for the active substance clofentezine.

However, due to the critical concerns identified in the renewal report Germany considers it necessary to apply the shortest possible transitional and grace periods of 3 and 6 months for the active substance clofentezine (comparable to S-Metolachlor).

Furthermore, Germany would appreciate if the European Commission could explain the reasons why longer transitional and grace periods (> 3 + 6 month) were proposed.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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 explained some minor changes to the texts which were introduced since the last meeting and informed that the TBT notification process ended on 18 September 2023 and that no comments were submitted by third countries, nor were any additional letters provided by the applicant or stakeholders since the previous meeting.

The Committee was reminded that comments had been received from one Member State since the meeting held in July 2023, reiterating it wish to shorten the grace period to a maximum of 6 months. After discussion during the meeting it was decided to retain the period of 12 months stated in the draft.

Vote taken: Favourable opinion.

Germany made a protocol declaration:

Germany is in agreement with the presented drafts of the non-renewal regulation and the non-renewal report for the active substance metiram.

However, due to the critical concerns identified in the renewal report Germany considers it necessary to apply the shortest possible transitional and grace periods of 3 and 6 months for the active substance metiram (comparable to S-Metolachlor).

Furthermore, Germany would appreciate if the European Commission could explain the reasons why longer transitional and grace periods (> 3 + 6 month) were proposed.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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/2023/641/RR).

(PLAN/2023/641)

The Commission informed that the TBT notification process ended on 29 September 2023 and that one comment was submitted by third countries to which replies has been sent; no additional letters provided by the applicant or stakeholders since the previous meeting.

The Committee was reminded that comments had been received from one Member State since the meeting held in July 2023, reiterating a previous call to keep the grace period to a maximum of 6 months, and another comment was received requesting a longer grace period (6 +12 month). The Commission welcomed the views of other Member States and after discussion decided to retain the period of 6 months.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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/2022/2157 RR).

The Commission informed that the TBT notification process ended mid-September 2023 and that no comments were submitted by third countries. The Commission shared four additional letters provided by the stakeholders since the previous meeting.

The Committee was reminded that comments had been received from five Member State since the meeting held in July 2023, confirming their opinions and one Member State reiterating a previous call to shorten the grace period to a maximum of 6 months. The Commission welcomed the views of other Member States and after discussion decided to retain the period of 9 months.

Vote taken: Favourable opinion.

Germany made a protocol declaration:

Germany is in agreement with the presented drafts of the non-renewal regulation and the non-renewal report for the active substance triflusulfuron-methyl.

However, due to the critical concerns identified in the renewal report Germany considers it necessary to apply the shortest possible transitional and grace periods of 3 and 6 months for the active substance triflusulfuron-methyl (comparable to S-Metolachlor).

Furthermore, Germany would appreciate if the European Commission could explain the reasons why longer transitional and grace periods (> 3 + 6 month) were proposed.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, 2-Phenylphenol (incl. its salts such as sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, clofentezine, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fluazifop P, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, spiroxamine, sulphur, tetraconazole, tri-allate and triflusulfuron.

(PLAN/2023/1472)

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 31 December 2023. The extensions are necessary because it will not be possible to adopt decisions on the renewal or non-renewal of approval of these active substances before the expiry of their current approvals. The extensions are proposed depending on where each active substance stands in the renewal process based on the remaining regulatory steps, for which maximum time periods are defined in the legislation. The Commission reminded about the possibility to rescind the extensions at any time.

Two Member States indicated that they could not support the draft act because of the presence of 8-hydroxyquinoline as one of the active substances to extend the approval period. In their view the extension calculated for 8-hydroxyquinoline is not justified. One Member State could support the draft act subject to a shorter extension for 8-hydroxyquinoline, given the hazardous properties of the substance and that the derogation of Article 4(7) or the negligible exposure were not fulfilled during the assessment performed by the Rapporteur Member State (RMS). EFSA confirmed that the conclusions will be published by the end of 2023. Therefore, the duration of the extension for the active substance was agreed to be shortened to twelve months.

For clofentezine and triflusulfuron, as a regulatory decision was proposed for vote during this meeting, they were removed from the draft Regulation.

The active substance prohexadione was added to the batch as it also expires by 31 December 2023 and the RMS confirmed that the renewal procedure is still ongoing.

The vote was taken on the amended draft act.

Vote taken: Favourable opinion.

The following protocol declaration was made:

The Netherlands does not agree with the extension of the approval period of difenoconazole because of the risks regarding fungal resistance. Nevertheless, because we are faced with a package of substances, we will vote in favour of the entire package.

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 on the recent results of the harmonised classification process for captan in the framework of the CLP Regulation requirements. According to the draft RAC opinion issued on 14 September 2023, captan was proposed to be classified, among others, as REPRO 2, which makes two of its metabolites becoming relevant. The Commission anticipated the possible need to request confirmatory information to assess the relevance of the two metabolites which are present in every use for all scenario above the limit values. Concerning the development of the decision-making process on captan, the Commission reported that it will mandate EFSA to check the scientific robustness of the data used by the Rapporteur Member State to perform the re-assessment of certain ecotoxicological endpoints related to field uses. Depending on the results of the mandate, the Commission may amend the previous version of the drafts.