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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

8 - 9 December 2022

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/7c4a51b0-4792-4342-80e8-4d04318e0329?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the Appeal Committee on glyphosate, held on 17 November 2022, was published, while the summary report of the last meeting of this Committee (October 2022) is still under preparation.

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

1. *Quassia amara*

The Commission informed about the confirmation of the admissibility of the application for approval of *Quassia amara* wood as a basic substance. The public consultation on the dossier will be launched soon.

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

The Commission informed that a workshop on zonal authorisation of plant protection products (similar to the one done in Dublin in 2015) is envisaged for the second half of 2023 and asked for volunteer Member States in particular from the Northern Zone, to join the steering committee for the organisation of the workshop.

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

The Commission informed that the launch of the call is scheduled for 18 January 2023, and that Member States would have three months to prepare their applications. The grants are expected to be signed in September/October 2023. Once the call is published, the European Health and Digital Executive Agency (HADEA) will invite the designated entities to submit a proposal and to a workshop to explain details on the grant and the application procedure.

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

The Commission referred to dossiers submitted for the first approval or renewal of approval, in particular as regards:

a) Access to studies by applicants in accordance with Article 6(3) of Regulation (EU) 2020/1740

b) Access to studies by Member States and EFSA under Regulation (EU) No 844/2012 and Regulation (EU) 2020/1740

The Commission recalled that to ensure robust and sound renewal evaluations of active substances, all information on the substance must be taken into account. This includes not only new studies and relevant literature, but also the previous dossiers submitted for the initial approval, previous renewals, or amendments to conditions of approval.

Under Regulation (EU) No 844/2012, this concept already exists (Article 11(3)) but it does not specifically include a provision for applicants to submit the old data in their dossiers.

In order to implement the provisions of the Transparency Regulation (Regulation (EU) 2019/1381) and to ensure that applications for renewal are comprehensive, additional requirements were included in Regulation (EU) 2020/1740, which ensure that applicants submit all information in their renewal applications. As under Regulation (EU) No 844/2012, the Rapporteur Member State is required to take into account old data in its assessment.

Specifically Article 6(3) of Regulation (EU) 2020/1740 states:

'Applicants shall make their best efforts to obtain access to and provide the studies which were part of the approval dossier or subsequent renewal dossiers as required under points (e) and (f) of paragraph 2.

The Member State that acted as rapporteur for the previous approval and/or subsequent renewal dossiers or the Authority shall endeavour to make available such studies where the applicant provides evidence that its attempts to obtain access from the study owner have failed.'

In addition, Article 10 requires that there is public access to the information in the application.

The Commission reported on some challenges encountered when implementing these provisions. In some cases applicants have not been able to gain access to studies despite negotiations with the original data owners. This has led to delays in confirming admissibility by the rapporteur Member States. The Commission was aware that some Member States have been giving access to old studies in cases where best efforts did not result in the applicants securing access themselves, whereas for other Member States this has been problematic.

The Commission informed that it had initiated discussions with EFSA on how to overcome this situation, on the basis of the following:

- In the event that an applicant cannot get access to old studies despite best efforts (the Commission is aware that some harmonisation on that is needed), Article 6(3) of Regulation (EU) 2020/1740 can be used as a basis for Member States to release the old studies to applicants.
- The applicant will then be responsible for uploading these studies in IUCLID as part of the dossier. This implies that the studies will be published and allow for scrutiny during the peer-review, as required under the Transparency Regulation.
- Data protection should not be a barrier for the purpose of use at renewal. The data protection status of the studies would remain valid for authorisation decisions for plant protection products.

- Member States would consult the data owner/original applicant and then assess any claims made.

The Commission noted that this would need to be adapted depending on Member States' feedback and invited Member States to reflect and provide their input, including sharing their experience for cases they have encountered or dealt with already in particular if they are giving access to studies and how they are managing confidentiality issues. In addition, Member State views on 'best efforts' were welcomed in view of finding a harmonised approach.

The Commission underlined the need for Member States and EFSA to have access to all data for their assessments and for the peer review process, including the original dossiers, and highlighted that there were several cases where it was apparent that some Member States and/or EFSA did not have the data on record, for various reasons. The Commission stressed that it wants to find a workable solution that can ensure a smooth and transparent process, avoiding delays in the assessment procedure.

Implementing Regulation (EU) No 844/2012 does not specifically require the applicant to submit the previous data from the first approval, however it does require the Rapporteur Member State to take them into account (Article 11(3) of Regulation (EU) No 844/2012). In case an applicant has access to these old studies they could be asked to submit them. In cases where they do not, the Rapporteur Member State should still ensure that the studies are taken into account in their assessment. In the case of renewal of approval under Regulation (EU) 2020/1740, different provisions apply, as explained above.

In addition, in case the Rapporteur Member State has the opinion that some studies that were relevant at the time of the first approval, are not essential in the framework of the EU renewal of the approval (e.g. residues trials on crops that are not part of the representative uses, for example), they can be briefly described and summarised by the Rapporteur Member State (in line with the original DAR) with a justification on why they were not fully re-evaluated for the renewal.

The Commission also mentioned the particular cases of metalaxyl and oxyfluorfen, where the Commission, EFSA or several Member States have not been able to provide the studies supporting the previous approval processes, and where this is hindering the evaluation by the respective Rapporteur Member State. In view of the continuation of the assessment, the Commission asked all Member States to check their records and share the original dossier with the Rapporteur Member State and/or EFSA, as soon as possible.

The Commission also asked Member States in their role as rapporteur Member States, to identify any other similar cases, in view of ensuring data are shared amongst Member States and EFSA.

3. IUCLID

The Commission summarised the discussions of the 5th Pesticide Steering Network on IUCLID.

4. PPPAMS

The Commission recalled that the existing PPPAMS system will be decommissioned by end of 2022 and the functions for emergency authorisations are being transferred to the E-Submission Food Chain Platform (ESFC). Stakeholders and Member States have

been informed about the upcoming changes and a notice has been added in PPPAMS to ensure users are aware.

The Committee was reminded that Member State users have been invited to test ESFC and provide feedback in view of identifying bugs and/or improvements by 16 December 2022.

The Commission underlined that PPPAMS will no longer be available to submit or process applications from 8 am on 19 December 2022 and that existing data will then be transferred into ESFC which will go live on 3 January 2023. The webpages related to PPPAMS will be updated and the Quick Reference Guides will be replaced.

It was stressed that ESFC will only manage emergency authorisations at this stage. Discussions about using ESFC for other applications types or plans to develop an authorisation database will be resumed in 2023.

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

- New active substances

  1. *Aspergillus flavus* strain MUCL54911

  The Rapporteur Member State informed that the applicant confirmed that new data will be provided to allow to complete the risk assessment.

- Renewal of approval

  2. Clofentezine

  The Commission informed that since internal deliberations remained ongoing.

  3. Benthiavalicarb

  The Commission informed that since internal deliberations remained ongoing. In addition, the Commission mentioned that the applicant requested to stop the publication of the classification proposal of Benthiavalicarb as Carcinogen Cat 1b , as proposed by the Risk Assessment Committee (RAC) at ECHA.

  4. Aluminium silicate calcined

  The Commission summarised the findings of the EFSA Conclusions, in particular the risks identified in the area of ecotoxicology. Member States were requested to share the pros and cons concerning a renewal as a low risk substance in the light of other active substances of natural origin with an unspecific mode of action, which were subject to a risk assessment scheme which may not be fit-for-purpose for such active substances.

  Two Member States indicated that they would be open to a renewal as a low risk active substance, especially in the light of the Sustainable Use Regulation (SUR) negotiations and the Farm to Fork Strategy objectives.

  One Member State suggested to consider a revision of the low risk criteria in Annex II in the light of the discussions today for substances that are of natural origin which do not fulfil the exclusion criteria for a low risk substance of this Annex II, but due to their unspecific mode of action may affect non-target arthropods and bees. Another Member State proposed for active substances that are of a ‘lower risk’ to allow certain specific risk mitigation measures and thus not contradicting a low risk status.

5. *Cydia pomonella* granulovirus (CpGV)

The Commission summarised the EFSA Conclusion and the comments on them received by the applicant. Member States were invited to comment by 9 January 2023.

- Basic substances

  There were no news to discuss.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Asulam-sodium

  The Commission informed that since internal deliberations remained ongoing.

  b) Isoflucypram

  The Commission summarised the EFSA Conclusion, gave an overview about the comments received from three Member States, and informed about a meeting with the applicant early November who submitted a presentation with new information on the active substance which is uploaded on CIRCA BC. The applicant asked to provide more data to close the data gaps identified in the EFSA conclusions. The Rapporteur Member State France agreed to proceed like this and the applicant intends to submit this information by mid 2025. The Committee agreed with this way forward.

  c) Limestone

  The Commission summarised that in 2017 the Rapporteur Member State received an application for approval of limestone and the outcome of the risk assessment, as documented in the EFSA Conclusion, was favourable, did not identify any critical area of concern and stated clearly that limestone and calcium carbonate (CaCO3) are identical.

  Given that an approval for calcium carbonate already exists, the Commission explained that it is appropriate to amend this approval so that it covers also limestone. Commission Implementing Regulation (EU) 2021/1448 will be amended to include limestone in the specification of the active substance calcium carbonate.

  A draft review report was submitted to the Committee and to the applicant. At the day of the discussion at the Committee, there was no reply of the applicant available. Member States were invited to comment by 30 January 2023.

- Renewal of approval

  d) *Bacillus thuringiensis aizawai* strain ABTS-1857

  This point was discussed together with points A.05.e to A.05.k.

  The Commission summarised its approach which is based on precautionary intervals (e.g. PHI) to be applied only for edible crops for which residues data showed a *Bacillus thuringiensis (Bt)* density above the level of 10^5 CFU/g., and on

the request for generating experimental data regarding the decline of *Bt* populations after application with submission of storage stability data.

The Commission informed about comments received by the applicant who disagreed with the recommendation of pre-harvest intervals and the request for additional data. The Commission highlighted that in their written comments the replying Member States agreed on the overall approach proposed, but different views were raised on details on how to apply these pre-harvest intervals and perform the monitoring.

A tour de table was made, which confirmed this general support. Six Member States were either not in a position to express their initial position, opposed strongly to set pre-harvest intervals, or preferred to set one horizontal PHI of 3 days for all strains and all crops with a level of 10^5 CFU/g expressed as *Bacillus cereus (Bc)*. The Commission questioned the suitability of a definition based on *Bc*, imposed on *Bt* authorisation holders despite the use as plant protection products is only one contributing source of *Bc sensu latto*.

Another Member State requested to request Member States to pay attention to effects on aquatic organisms, bees and non-target arthropods. The Commission reminded that *Bt* are known to be specific to certain insect taxa, so the potential of side-effects on non-target arthropods would be quite unlikely while effects on aquatic organism (*Chironomus* larvae) are not excluded with *Bt israelensis* (target taxon Diptera).

One Member State suggested to specify the intervals only to edible crops freshly consumed, not for the processed crop commodities.

e) *Bacillus thuringiensis aizawai* strain GC-91

See point A.05.00.d.

f) *Bacillus thuringiensis israelensis* strain AM65-52

See point A.05.00.d.

g) *Bacillus thuringiensis kurstaki* strain ABTS-351

See point A.05.00.d.

h) *Bacillus thuringiensis kurstaki* strain EG2348

See point A.05.00.d.

i) *Bacillus thuringiensis kurstaki* strain PB54

See point A.05.00.d.

j) *Bacillus thuringiensis kurstaki* strain SA-11

See point A.05.00.d.

k) *Bacillus thuringiensis kurstaki* strain SA-12

See point A.05.00.d.

l) Pelargonic acid

The Commission presented the updated draft Renewal Report on pelargonic acid together with the comments on it received by the applicants and the Member States. As regards the applicants' request to renew pelargonic acid as a low-risk active

substance, risks for at least one group of non-target terrestrial organisms other than vertebrates were identified for almost every representative use, which would contradict the previsions of Article 22(1) and Article 47(1) of Regulation (EC) No 1107/2009.

Member States were invited to comment by 9 January 2023, in particular if pelargonic acid can be renewed as a low-risk active substance and on what grounds.

m) Oxamyl

The Commission reminded the toxicological properties of this active substance and requested each Member States to indicate their opinion on the Commission proposal and on the draft Review Report: the majority of Member States expressed their support. The Commission then indicated that it would proceed with the preparations for a vote on this active substance during the first half of 2023.

Member States were invited to comment on by 9 January 2023.

n) *Bacillus amyloliquefaciens* QST 713

The Commission requested each Member States to indicate their opinion on the Commission proposal and on the draft Review Report: the majority of Member States expressed their support and two Member States did not agree because they would preferred to have a renewal without any specific risk mitigation measures. They both favoured instead to request confirmatory information or additional studies to be submitted at authorisation stage at national level. The same position was expressed by the applicant.

The Commission then indicated that it would proceed with the preparations for a vote on this active substance during the first half of 2023.

Member States were invited to comment on by 9 January 2023.

o) Triflusulfuron-methyl

The Commission shared the comments from three Member States, the Commission's answer to the question of a Member State, the comments from the applicant and from a stakeholder. The Commission also reported on a second meeting with the applicant held in November 2022.

Member States were invited to comment by 9 January 2023.

p) Quartz sand

The Commission presented the main findings of the EFSA Conclusions and the reasoning of the Review Report. Like for other similar active substance renewals for active substances of natural origin and unspecific mode of action, due to a risk assessment scheme more tailored for chemical active substances the EFSA conclusions pointed out certain possible risks in particular to non-target arthropods and bees. Member States were requested to provide their pros or cons concerning a renewal as a low risk substance by 9 January 20223.

q) Dimoxystrobin

The Commission informed that EFSA has issued a statement on the risk assessment of dimoxystrobin related to environmental. The statement identified a critical issue: a high potential for groundwater contamination by relevant metabolites in geoclimatic conditions represented by all the relevant FOCUS groundwater scenarios for all the representative uses assessed. Therefore, the requirements of

point 3.10 of Annex II to Regulation (EC) No 1107/2009 are considered not to be fulfilled.

Accordingly, the Commission prepared a draft Renewal Report that proposes a non renewal of the approval of dimoxystrobin. The Commission presented the comments of the applicant on the EFSA statement and the subsequent replies by EFSA and the Rapporteur Member State. The applicant had also submitted comments on the draft Renewal Report which were uploaded on CIRCA BC.

The Commission requested each Member States to indicate their opinion on the Commission proposal and on the draft Review Report: 18 Member States expressed provisional support, 7 had no position, one favoured renewal and one was absent. Most Member States requested to see the reaction of EFSA and Hungary to the latest comments of the applicant before formulating final position (those replies were uploaded on CIRCA BC on 15 December 2022).

The Member States are invited to comment by 9 January 2023.

The Commission explained that obligatory procedural steps needed to proceed with the regulatory decision making can not be completed before the expiration of the current approval period on 31 January 2023, and thus an extension of the approval of dimoxystrobin, pursuant to Article 17 of Regulation (EC) No 1107/2009 is needed (see agenda point B.10 below).

r) Aluminium ammonium sulfate

The point was postponed.

- Basic substances

s) Sodium hypochlorite

The Commission informed that comments were received from three Member States on the draft Review Report proposing an approval of sodium hypochlorite for the use as seed treatment. These Member States clarified that they are reluctant or will not be able to support the Commission's proposal. The Commission invited the other Member States to share their views by 13 January 2023.

t) Chitosan hydrochloride

The Commission presented the proposal for the revision of the GAP table in the Review Report for chitosan hydrochloride. The entry on 'fruits berries and small fruits' is proposed to be split and replaced with three entries, covering different fruit types, with application rates that are compatible with the risk envelope of the already approved uses for chitosan hydrochloride and chitosan. Chitosan is considered comparable to chitosan hydrochloride, and it is approved for uses on tall perennial crops such as olive trees and grapevine.

The Commission made available an application for an extension of use of chitosan hydrochloride covering the use on hops and turf. The Commission summarised the feedback of EFSA on the proposed revision of the GAP table and the proposed extension of use of chitosan hydrochloride, confirming that these amendments are within the risk envelope of the approved uses.

The Member States were invited to consult the application for an extension, the draft amended Review Report and EFSA's feedback. The Member States were asked to provide their positions by 13 January 2023 on:

1) The proposed revision of the GAP table;
2) Using of the short-cut approach for an evaluation of the extension for use of chitosan hydrochloride, based on the risk envelope approach;
3) Amending of the Review Report to include the uses proposed in the extension of use, based on the risk envelope approach.

A.06 Confirmatory Information:

1. Pendimethalin

The point was postponed.

2. Plant oils: Eugenol, Geraniol, Thymol, Clove oil and Orange oil

The point was postponed.

3. Thiabendazole

The Commission informed that it proceeded with triggering an Article-21 procedure, as done for acibenzolar-s-methyl due to the regulatory similarities between these two substances. The Commission wrote to the applicant and gave a 3-month deadline for commenting. The applicant is requested to outline which additional studies they have available at the moment or plan to carry out in order to assess this substance according to the new criteria under Regulation (EU) 2018/605. After the above-mentioned deadline, EFSA and Member States (on request of the Commission) would express their views on the need for additional studies to be submitted for the evaluation of the ED properties according to the new ED criteria. The Commission would then contact the applicant and request the submission of the studies deemed necessary by a given deadline. After receiving these studies, the Commission would mandate EFSA to assess the submitted data and come to a final view on whether the substance has ED properties or not. Depending on this assessment, the Commission may eventually amend or withdraw the approval.

4. Flutianil

The point was postponed.

5. Dithianon

The point was postponed.

A.07 Guidance Documents:

1. Prioritisation of Guidance Documents (to endorse)

The Commission presented two documents developed with input from Member States, EFSA and Commission which were amended with respect to the previous versions on the basis of the consideration of comments received via the consultation of stakeholders. These documents are a prioritisation list for updating or drafting guidance documents and a document which outlines a process to keep this prioritisation list updated.

The Commission asked for final comments by 9 January 2023 in view of endorsing the documents a the next meeting of this Committee in January 2023.

2. Scientific guidance on soil photo transformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products (to endorse)

The Commission informed that it had received comments from three Member States as well as the reaction from EFSA on some of these comments, and suggested to postpone the endorsement in order to give time to Member Sates to consider the comments received.

3. Data requirements and list of agreed test methods (Part A - chemicals) - Update of the Communications 2013/C 95/01 and 2013/C 95/02

The point was postponed.

4. Data requirements and list of agreed test methods (Part B - microorganisms)

The point was postponed.

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

There were no news to discuss.

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

The point was postponed.

7. EFSA Guidance Document on the use of the benchmark dose approach in risk assessment

EFSA presented this new Guidance Document and indicated that a workshop is planned to take place in Brussels on 15-16 February 2023 with additional possibility to connect virtually, for which the registration for participation is open.

EFSA clarified that the Guidance Document focuses so far on mammalian toxicology, but that the approach could be used also more in general. It would be essential to select the benchmark dose (i.e. define the protection goals) with this approach.

One Member State asked if this Guidance Document would replace the NOEL approaches. The Commission indicated that this kind of questions would need to be discussed by the Committee during the endorsement process, and invited any comments or questions by 30 January 2023.

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

1. Article 44(4)
2. Article 36(3)
3. Article 53

The point was postponed.

A.09 Microorganism and low risk Active Substances:

The point was postponed.

A.10 Safeners and Synergists:

The Commission informed about the progress of the working group activities and about the intention to present a first draft of the Commission Regulation concerning the approval of these substances during the next meeting (January 2023).

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

1. Sodium hydrogen carbonate

The Commission recalled that sodium hydrogen carbonate is currently listed twice in the Annexes to Commission Implementing Regulation (EU) No 540/2011: in Part D as a regular active substance following its approval as a low-risk active substance in 2020, and in part C following the earlier approval as a basic substance in 2015.

The Commission informed about the latest letter received from the holder of the authorisation issued by Austria (shared with the Committee ahead of the meeting), in which the holder had asked for immediate action by the Commission towards the immediate withdrawal of the basic substance approval following the authorisation in Austria, which covers two uses of the product.

The Commission asked each Member State for their views regarding either a complete withdrawal of the approval of the active substance as a basic substance, or a reduction of the scope of approval, by amending the annex to the Renewal Report, aiming to exclude the uses for which the active substance is available in an authorised plant protection product. Furthermore, each Member States was asked if an authorisation for plant protection products consisting of this substance had already been issued by them or if an authorisation procedure was ongoing.

One Member State stated that maintaining the dual status should be considered as a third option.

Four Member States did not have a preference for either of the options. Two of these Member States underlined the importance of legal certainty for the applicant. One of these Member States also indicated that in organic farming sodium hydrogen carbonate is currently only allowed to be used as a basic substance and wondered about the impact of the withdrawal of the basic substance status.

Four Member States supported an immediate withdrawal of the basic substance approval. One of those Member States indicated its support only if a deferred entry into force date would be ensured, to allow sufficient time for submitting and processing applications for the authorisations of plant protection products consisting of the active substance

Ten Member States preferred a gradual reduction of the representative uses in the review report of the basis substance.

Six Member States wished to keep the dual approval status both as a low-risk active substance and as a basic substance. Three of these Member States indicated being able to support a gradual reduction of scope in the review report, if a dual approval would not find sufficient support.

One Member State underlined the difference in sequence between, on the one hand, a substance approved first as a basic substance and a subsequent approval as a new active substance and the opposite scenario, advocating the maintenance of the dual status at least in the first scenario.

Two Member States did not have a position yet.

No Member State, besides Austria, indicated already having an authorisation in place or having an authorisation process ongoing.

The Commission informed that it will reflect and schedule a discussion of the matter in the upcoming meetings.

2. Clethodim

The point was postponed.

3. Common metabolites of pyrethroids

The point was postponed.

4. Common metabolite TFA

The point was postponed.

A.12 Article 21:

1. Acibenzolar-methyl

The point was postponed.

A.13 General issues for information / discussion:

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

   a) New cases:

      No new cases were discussed.

   b) FAQ document Fertilising Products Regulation - products out of one single substance + plant biostimulant

      The point was postponed.

   c) Phosphonates – update on status according to Fertilising Products Regulation

      The Commission reminded that Member States were already informed about the scientific data supporting the proposal to modify the Fertilising Product Regulation regarding the presence of phosphonates in EU fertilising products. The idea would be to lift the current restriction that is provided in the Fertilising Product Regulation with a max. conc. of 0,5 % w/w, for the product function category ‘plant biostimulant’. The Commission explained that this proposal would be in line with the target set out in the Farm to Fork Strategy to minimise nutrient losses resulting in reducing the use of fertilisers by 2030, as phosphonates without having a nutrient providing function are helping the plant (among other effects) to uptake nutrients from the soil.

      This topic was also on the agenda of the Fertilisers Working Group in October 2022 and at the Residues Committee in November 2022. The Commission summarised the discussion at the Residues Committee (question about proof of plant biostimulant effects; risks of exceedance of existing MRLs for a) crops for which no pesticides use exists as well as b) in case of combination of plant biostimulant use and plant protection products use on the same crop).

      Member States wondered about the possible plant protection products effect at the proposed GAP (early stage and lower application rate). One Member State

reported an observed contamination by phosphonate in mushrooms grown on wheat straws which were fertilised with a national fertiliser containing phosphonate.

Member States were invited to comment (coordinated with residues and fertiliser colleagues) by 9 January 2023.

d) Physical barriers:

The point was postponed.

2. Basic substances – general issues

The Commission summarised the comments received from the Member States. There are divergent views, interpretations and practices concerning the marketing of basic substances in the commenting Member States:

- The key issues seem to be the placing on the market and the need for more clarity and harmonisation as regards labelling regulations. The issue of dual approval (as a basic and a regular active substance) is equally important (see A.11.1).
- Several of the commenting Member States would welcome a relaxation of the current strict interpretation of the provisions of Article 23. There seemed to be a general agreement among most Member States that, in line with the requirements of Article 23, basic substances shall not be placed on the market as a 'plant protection product', meaning without the necessary authorisation as such. However, some Member States see a possibility for the placing of basic substances on the market specifically for plant protection purposes, without being labelled as plant protection products, either solely for such use, or as a 'secondary use' to the primary purpose of the product.
- As regards formulations, there is a general agreement that the marketing of basic substances containing any additive or co-formulant is not acceptable, as it would require an authorisation. Nevertheless, one Member State believed that the preparations of basic substances, as described in the Review Reports, could be also placed on the market for plant protection purposes without further authorisation.

Eight Member States took the floor during the meeting:

- Most of the Member States agreed on the need for clarification of the rules for labelling of products consisting of basic substances, including mixtures. Several Member States informed about the presence on the market of products containing basic substances that are packaged and labelled in the same manner as plant protection products. One Member State mentioned that the lack of harmonisation of labelling regulations across the EU leads to an advantage in competition for companies from some Member States.
- As regards the placing of the products consisting of basic substances on the market, the views of the Member States were divergent. One Member State informed that market controls revealed lack of compliance of the products labelled as basic substances with specifications provided in the relevant Review Reports and believed that there is a need for a better control over the products which are labelled as basic substances. One Member State mentioned national rules for product registration consisting of basic substances. Another Member

State suggested that, given that national rules are in place, there is no need for further harmonisation. Two Member States declared their support for the strict interpretation of Article 23, which does not allow the placing of basic substances on the market for the purpose of plant protection. One Member State stressed the importance of an appraisal of the predominant uses of the basic substance for which this basic substance is available on the market.

- The Member States generally agreed that formulated products containing basic substances should be subject to an authorisation as plant protection products. One Member State raised the possibility of registering basic substances as 'low risk products'.
- Several Member States indicated the need for considering an obligation of keeping records of the uses of basic substances. One Member State reported that its farmers are encouraged to keep records on uses of basic substances at a national level.

The Commission invited Member States, in particular those which have not yet commented, to provide their views, in particular concerning the current arrangements in place in each Member State, and the harmonised rules that would be desired for the future.

3. Potential follow-ups on incidents with phosphine products

The Commission summarised the ongoing discussion on the risks related to the transhipments of the content of cargos treated with products in loose formulations which generate phosphine. Furthermore, the Commission, while recognising the effort from the Netherlands to harmonise the approach in managing those risks at product authorisation level, recalled the possibility of amending the condition of approval of the three approved active substance which can release phosphine.

One Member State mentioned that restrictions would be more effective at EU level and explained that the issue is mainly the reactivation of products, for which it made suggestions for avoiding such issues (e.g. by using sleeves). This Member State is open to procedures under Articles 44 or 21, whatever gives the fastest results.

Two Member States mentioned that the issue is related to proper use, i.e. proper training and information and proper handling. One of this Member States would not support an amendment of conditions of approval as they see the prerogative of Member States as regards authorisations affected. Another Member State reminded that a consultation is on-going by the Netherlands, and mentioned that the use of sleeves is not supported by 3rd countries.

The Commission asked the Netherlands if they also intend to do an impact assessment on the proposed measures, the Netherlands informed that a public consultation is on-going in parallel to the commenting period given to the Member States.

Member States were invited to comment by 9 January 2023.

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

Germany explained the nature of support needed for the development of test protocols for bees and their international recognition at OECD. The Commission informed about suggestions by two Member States and indicated to continue developing the work plan for pollinator test guidelines in 2023.

Member States were invited to indicate by 30 January 2023 their availability to support the development of test protocols for pollinators and the official programme of OECD.

5. Review of the Pollinator Initiative

The Commission informed about the current status of the revision of the EU Pollinator Initiative.

The Commission also mentioned the successful European Citizens Initiative 'Save Bees and Farmers'. All information about European Citizens Initiatives is available online via the Commission website: https://europa.eu/citizens-initiative/_en

6. Residues on cut-flowers

The point was postponed.

7. TARIC codes

The point was postponed.

A.14 Amendment Regulation (EU) No 547/2011:

The point was postponed.

A.15 Co-formulants and assessment of formulations:

The Commission summarised the Member States' inputs to the three questions on the current practices on the risk assessment of the co-formulants and the comments received from two Member States. Based on the discussion with EFSA, the Commission proposed to organise a workshop in the first half of 2023 with Member States, ECHA and EFSA to address the issues linked to this topic.

Member States were invited to respond by 9 January 2023 to the following questions in order to organise the workshop:

- problems/challenges that need to be solved related to the assessment of plant protection products formulations
- timing of the workshop potentially linked the Committee meeting in May
- volunteers for the steering committee that will meet first (online) in the beginning 2023

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides
2. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009
3. Working Group Post Approval Issues

The point was postponed.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA), including MUST-B / APISRAM development

EFSA provided an update on the on-going peer review of active substances, reminded that a survey was launched to collect information on their practices as regards sharing

practices o documents and assessment of formulations, and reminded on the process for assessments under Article 4.7. EFSA also mentioned its Administrative Guidance document is under revision.

EFSA also provided an update on the on-going work on APISRAM.

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

There were no news to discuss.

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

There were no news to discuss.

4. Minor Use Facility (MUCF)

There were no news to discuss.

5. OECD, FAO and EPPO activities

The Commission reminded Member States about the upcoming OECD meetings of the Working Party on Pesticides end of February, beginning of March 2023.

6. Update on Water Framework Directive, Groundwater Directive and Environmental Quality Standards Directive

The Commission provided an update on the on-going work related to the water legislation.

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

The Commission informed that the Court has delivered on 24 November 2022 the preliminary ruling in case C-658/21 (Belplant, previously Phytofar), concerning the interpretation of Articles 1 and 5 of Directive (EU) 2015/1535.

The Commission informed that the reply of the Commission to a request for internal review under the Aarhus Regulation concerning the extension of the approval duration of boscalid by Commission Implementing Regulation (EU) 2022/708 has been sent to the NGO Pollinis, and is published on the Commission's website.

A.19 Exchange of information from the Pesticide Residues section of the Committee, in particular:
- possible impact on authorisations

The Commission informed that measures on the following active substances were taken at the last meeting of the Section Pesticide Residues of this Committee, held on 21-22 November 2022, which may have an impact on the authorisation of plant protection products.

Substance	**Type of change (see above)**
Isoxaben	MRLs were lowered.
Novaluron	MRLs were lowered and the residue definition was amended.
Tetraconazole	MRLs were lowered and the residue definition was amended.
Bromopropylate	Moved to Annex V (all MRLs were already at LOQ).
Chloridazon	MRLs were lowered.
Fenpropimorph	MRLs were lowered.
Imazaquin	MRLs were lowered.
Tralkoxydim	MRLs were lowered.

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed that two letters from Crop Life Europe (CLE) were received and are shared on CIRCA BC, addressing issues related to IUCLID, PPAMS, the Guidance Document on PEC soil (see point A.07.6), and microplastics.

A.21 Date of next meeting(s):

The Commission indicated that the next meeting will be virtual and take place 25 and/or 26 of January 2023.

A.22 AoB:

One Member State raised the issue that authorisation of plant protection products may be delayed due to delays in processing applications for amendments of conditions of approval (Article 7) and stressed that a smooth processing of Article 7 applications would avoid such delays. The Commission noted that it had responded to a question on metalaxyl-M, confirming that existing conditions of the approval (e.g. restrictions, limits for relevant impurities) must be respected until a decision on whether it can be amended or not has been taken.

In addition, this Member State asked for the status of the renewal of the following active substances, and the Commission with support of EFSA clarified:

- Bentiavalicarb: already under discussion at this Committee (see agenda point A.04)
- Nicosulfuron: the rapporteur Member State informed that the DRAR was submitted to EFSA in September 2022
- Dimethomorph: EFSA informed that the peer review, including ED assessment, is to be finalised but the EFSA is still waiting for comments from the Rapporteur Member State in order to be able to finalise the Conclusion.

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

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) as regards the content and format of the records of plant protection products kept by professional users pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

SANTE/10938/2021

An updated draft Implementing Regulation was made available on 12 December 2022. Considering the short time for examining the latest version, the vote was postponed to January 2023.

The Commission presented the draft Implementing Regulation, which was updated on the basis of the comments received from the Member States and during the public feedback mechanism, in particular the comments raised by Member States during the informal technical meeting with Member States which took place on 2 December 2022, and where a significant number of them had not agreed with the inclusion of recording of sowing of treated seeds, preventing them from supporting the draft act.

The Commission reiterated that it considers sowing of treated seed to be a use of a plant protection product that is subject to the recording obligation under Article 67(1), but indicated that in a spirit of cooperation with the Member States, it had removed this use

from the draft. However, this does not constitute a change of the Commission's position on the issue and has no legal effect with respect to the implementation of Article 67 of Regulation (EC) No 1107/2009. Once the Court ruling on Case C-162/21, which is expected to provide legally binding interpretation of whether sowing of treated seeds is a use of a plant protection product, becomes available, it will be analysed and if necessary, the Commission will propose amendments in the Implementing Regulation.

The Commission also mentioned that in the course of the technical meeting mentioned above, some Member States also had expressed concerns that the requirement for time-stamping of the electronic records would pose a challenge for the recording of plant protection products use by farmers (in particular for smaller farms or older farmers). The Commission believes that such a requirement will be useful to ensure the integrity of the records, but understands the concerns and also agreed to remove it from the draft.

Some Member States repeated their views that some of the data that is envisioned to be recorded (e.g. time of use, use of BBCH and EPPO codes, geolocation) are either not within the scope of Article 67(1) of Regulation (EC) No 1107/2009 or their recording creates additional burden to the users without bringing any significant added value.

Two Member States explained that they consider sowing of treated seeds to be a use of a plant protection product.

Many Member States expressed preference for later entry into force of the Implementing Regulation.

Member States were invited to comment on the draft and to inform on their voting intentions by 19 December 2022.

Vote postponed.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

SANTE/10226/2022

The Commission presented the draft Implementing Regulation, which was updated on the basis of the comments that were received from the Member States and during the public feed-back mechanism. The main concerns that were mentioned since the last Committee were:

a) The proposal should have taken into account the toxicity endpoints provided by Regulation (EU) No 283/2013 on data requirements for active substances;

b) The proposal does not address concerns related to the simultaneous presence of dangerous substances in mixtures;

c) The proposal does not address the lack of data for many co-formulants, in particular the fact that many are not registered under REACH or no data are provided on long-term toxicity in REACH registrations;

d) The first point of the Annex to the proposal should have been the one currently listed as N°10;

e) The risk assessment of the co-formulants suspected to be 'unacceptable' should be conducted directly at the EFSA level and not at the Member States level in order to avoid uncertainty and duplication/extra work. Particularly, some NGOs

think that the present proposal would be in breach of the principle of subsidiarity, for which the objectives of Article 27 should be allocated at the level where they would be best achieved.

The Commission reiterated that point a) is addressed when considering the full list of criteria from 1 to 10 in the Annex, which cover all points in Annex II to the Regulation (EC) No 1107/2009.

The Commission highlighted also that points b) and c) fall outside the scope of the Implementing Regulation, which is based on Article 27(5) of Regulation (EC) No 1107/2009 and solely establishes a procedure and criteria for identifying unacceptable co-formulants, while the points raised by the NGOs concern the methodology for conducting risk assessments and data requirements. The Commission also notes that point 4.1 of the introduction in the Annex to Regulation (EU) No 284/2013 provides that studies shall be conducted with the formulated product (i.e. including all co-formulants), unless bridging principles can be applied. In addition, co-formulants need to be identified (Annex, Part A, Point 1.4.3) and available data on co-formulants should always be submitted (see Annex, Part A, Point 7.4 'Available toxicological data relating to co-formulants'). In some specific areas (see Annex, Part A, Section 7) consideration should be given to the possible effects of components on the hazardous potential of the whole mixture. Lastly, as set out in point 1.11 of the introduction, the same information as for active substances (i.e. including long-term toxicity testing) may be required by the competent authorities for co-formulants.

As for points d) and e), the Commission reiterated that the co-regulators have foreseen in the Regulation (EC) No 1107/2009 different approaches: one for active substances, safeners and synergists (positive listing – decisions at EU level) and the other for co-formulants (only negative listing at EU level). However, in line with the subsidiarity principle, as Member States have the responsibility for the authorisation of plant protection products in their territories, they have to assess the co-formulants included in such products as well. Therefore, transferring the task to Member States to initiate the process for identifying unacceptable co-formulants is fully in line with the subsidiarity principle in this context. The further steps foreseen in the draft Implementing Regulation (either within the framework of other EU legislation as applicable for criteria 1-9 in the Annex) or the specific procedure as applicable for criterion 10 ensure full harmonisation of the outcome and thus avoid duplication or divergent outcomes.

Some Member States, however, had still some doubts with regard to the proposal (particularly as regards criterion 10 of the Annex to the proposal) and were invited to clearly identify any critical point that would prevent them from being able to support the act by 2 January 2023. The vote was postponed to January 2023.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benfluralin, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020).

SANTE/10234/2020

The Commission presented the draft Implementing Regulation and recalled how the results of the mandate issued to EFSA did not change the findings of the previous EFSA conclusion.

The Commission informed about the comments received by four Member States and recalled that, despite the received comments, the proposed risk mitigation measures and supported by the findings of the latest EFSA Conclusion, it could not identify a safe use among the supported representative uses. One Member State requested an extension of the grace period by three months to cover one extra growing season. The other Member States and the Commission accepted the request.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Trichoderma atroviride* strain AGR2 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1837 RR).

PLAN/2022/1837

The Commission presented the draft implementing act. Two Member States mentioned they do not agree to the low-risk status attributed to this substance.

The Commission proceeded to vote during the meeting

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Trichoderma atroviride* strain AT10 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1616 RR).

PLAN/2022/1616

The Commission presented the draft implementing act. Two Member States mentioned they do not agree to the low-risk status attributed to this substance.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Pseudomonas chlororaphis* strain MA 342 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/10884/2017).

SANTE/10882/2017

The Commission presented the draft Implementing Regulation and informed about the slight amendment introduced as regards the confirmatory information compared to the proposal presented at the meeting in October. The Commission summarised the comments received by five Member States.

Four Member States expressed some concern regarding the renewal of the approval due to the existing data gaps on the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR).

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of lemon essential oil (*Citrus limon* essential oil) as a basic substance 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/10240/2022).

SANTE/10238/2022

The Commission presented the draft implementing act. One Member State mentioned concerns related to the approach to evaluation of basic substances.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion 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 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 PLAN/2022/976 RR).

PLAN/2022/976

The Commission presented the draft documents and informed about two letters, one from a professional end user and one from a law firm representing two professional end users, which strongly oppose a renewal as a non low risk active substance. However, the Commission also referred to one Member State's comment (received after the October Committee) presenting reasons why rape seed oil cannot be renewed as a low risk. In the light of these comments the Commission proposed to postpone the vote to give the Member States time to reflect if they could support a renewal as a low risk despite the possible risks and/or data gaps identified in the EFSA conclusions.

Member States were requested to share their general views concerning renewal as low risk substances for active substance of natural origin but unspecific mode of action and a risk assessment scheme which may not be fit-for-purpose as tailored for chemical active substances, where EFSA conclusions indicated certain possible risks/data gaps.

Vote postponed.

B.09 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 benfluralin, benzovindiflupyr, buprofezin, cyflufenamid, fluazinam, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metiram, metsulfuron-methyl, phosphane and pyraclostrobin.

PLAN/2022/2431

The Commission presented the draft Implementing Regulation which extends by one year the approval period of 13 substances, expiring between 31 January and 31 March 2023. The extensions 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. In particular, for 7 substances the peer review is ongoing at EFSA level; among these, the assessment of endocrine disrupting properties has triggered a clock-stop to request additional data: fluazinam, flutolanil, mecoprop-p, mepiquat, metiram and pyraclostrobin.

For benfluralin, a regulatory decision was adopted during the meeting and it was removed from this Regulation.

One Member State indicted it does not agree with the extension of lambda-cyhalothrin and metiram. Another Member State does not agree with the extension of metiram while the assessment has showed that the criteria for identifying ED properties are met and that the are exceedances of ARfD for several uses that may need rapid action. EFSA explained that it expects to deliver its Conclusions in early 2023, once the Rapporteur Member State provides its final feedback.

One Member State supported the proposal but expressed its concerns due to the presence of metiram in the batch. Another Member State supported the proposal but asked why oxamyl and dimoxystrobin were not included in the same draft implementing act.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

<u>The Netherlands made the following protocol declaration:</u>

'The Netherlands supports the Commission's proposal but we acknowledge that our 'National Institute for Public Health and the Environment' has identified metiram as a substance with a similar structure as substances linked to neuro-degenerative diseases. Therefore we would like to urge the Commission to complete the decision making process of metiram as soon as possible.'

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 period of the active substance dimoxystrobin.

PLAN/2022/2499

The Commission presented the draft Implementing Regulation which extends by six months the approval period of the active substance dimoxystrobin, currently expiring on 31 January 2023. The approval, originally granted in 2006 for ten years, has been extended already six times due to delays in the renewal assessment process. These extensions have been strongly criticised: the European Parliament adopted several (non-binding) objections and the last extension has been challenged by Pesticides Action Network (PAN) through a request for internal review under the Aarhus Regulation. Following the Commission's rejection of this request, a Court case is ongoing.

Nevertheless, this extension is still necessary because it will not be possible to adopt a regulatory decision on the active substance before the expiry of the current approval, in particular as sufficient time to allow for the orderly completion of the administrative procedure and the discussions with Member States in the Standing Committee is needed.

Six Member States expressed that, since the final decision on the renewal or non-renewal will overwrite the one-year extension, a more pragmatic approach was needed that the one proposed by the Commission. Furthermore, in their opinion there is no urgency since the active substance is not a cut-off substance.

Another Member State stated that a longer period than six months is needed, in order to be able to grant time to EFSA and the Rapporteur Member State to react to the latest applicant's comments.

Therefore, the Commission amended the legal proposal with an extension of one additional year. However, one Member State considered that nine-months extension was enough.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.11 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 period of the active substance oxamyl.

PLAN/2022/2500

The Commission presented the draft Implementing Regulation which extends by nine months the approval period of the active substance oxamyl, currently expiring on 31 January 2023. The approval, originally granted in 2006 for ten years, has been extended already six times due to delays in the renewal assessment process.

The draft renewal report was presented to Member States in the meeting of the Standing Committee in October 2022. Therefore, a further extension of the approval for 9 months is still necessary because it will not be possible to adopt a decision on the renewal of approval of the active substance before the expiry of the current approval. This

extension intends to provide for sufficient time to allow for the orderly completion of the administrative procedure and the already initiated discussions with Member States in the Standing Committee.

Two Member States indicated that they do not agree to shorter than the normal period of 12 months for the extension.

The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

The Netherlands made the following protocol declaration:

'The Netherlands supports the Commission's proposal but we acknowledge that there are already risks identified for this substance. Therefore we would like to urge the Commission to complete the decision making process of oxamyl as soon as possible.'

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Yucca Schidigera* extract a as a basic substance 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/10236/2022).

SANTE/10234/2022

The Commission informed that the evaluation of the *Yucca schidigera* extract in the context of feed additives is for an application from a company to use the extract of *Yucca* combined with another extract, and that this assessment is currently on hold pending the submission of additional data. Therefore, the Commission would propose to proceed with the finalisation of the decision-making.

Member States were invited to submit comments by 9 January 2023.

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

SANTE/12268/2020

The Commission summarized the decision making process about this active substance and requested each Member State to express its position on the Commission proposal. The majority of the Member States indicated that more discussion is needed to refine the Commission proposal. The Commission informed the Member States that it will reflect on the follow-up actions.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance abamectin 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/12068/2020).

SANTE/12066/2020

The Commission summarised the changes applied to the draft Implementing Regulation and requested each Member State to express its position on the Commission proposal. With minor amendments in the wording the majority of the Member states indicated that they would support the amended Commission proposal.

Member States were invited to comment on the draft Implementing Regulation and to inform on their voting intentions by 9 January 2023, in view of the vote in the next meeting of this Committee.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of silver-stabilised hydrogen peroxide as a basic substance 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/11406/2021).

SANTE/11404/2021

This point was postponed.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of Napropamid-M as active substance 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/10808/2019).

SANTE/10806/2019

The Commission informed about the recent meetings between applicant, the Commission and the Rapporteur Member State concerning the impurity/purity profile of the Napropamid M (point regarding genotoxicity of one impurity declared in the racemic napropamid was clarified), the assessment regarding potential endocrine disruption (assessment is undergone for the racemic and would cover the isomer), and other data gaps identified by EFSA where it was suggested to present the data, in particular the study reports in accordance with the Supplementary Summary Dossier (SSD) format, so that they can be assessed and used as a basis to prepare the revised DAR for Napropamide M including the newly provided information.

Based on this trilateral discussion the Commission proposed to put on hold the decision making for napropamid-M, waiting for the finalisation of the renewal of the napropamid racemate, which would cover among others the ED aspects.

Member States were invited to comments on this way forward by 9 January 2023.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance ipconazole 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 571/2014

PLAN/2022/2562 CIS

The Commission recalled that following the evaluation carried out under Article 21 and the extensive discussions with Member States over the past year, the Commission wrote to the applicant to set out the reasons for withdrawal of the approval of ipconazole.

The applicant provided its comments on 24 October, including a document setting out why it considers that the substance should be approved in accordance with Article 4.7 for the treatment of maize seeds.

In addition, on 30 November, EU FOCUS submitted a position paper, setting out reasons why the approval should not be withdrawn. The Commission explained that the submitted document contained a number of inaccuracies and that it was preparing a response which would be shared with Member States. Another letter was also received by the Commission on 5 December 2022. All correspondence had been shared with Member States ahead of this meeting.

Concerning the application of Article 4.7, the Commission explained that since the risk to birds has still not been resolved following 3 evaluations (initial approval, confirmatory information, Article 21 review), its view was that there is no basis for considering uses under Article 4.7.

The Commission explained that after consideration of the applicant's comments, a draft Implementing Regulation for the withdrawal of approval has been put forward to the Member States and that an inter-service consultation would be launched.

Member State were invited to comment by 9 January 2023.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances.

PLAN/2022/2580 CIS

The Commission informed that the draft implementing act was uploaded on CIRCABC, reflecting the latest discussions with Member States. Another document was uploaded showing the willingness of Member States, the proposed allocation and how the distribution of work per Member State stands along the years from 2029 to 2035.

One Member State complained that not enough substances where attributed to the country, that recently has reinforced the human resources for the purpose of the assessment and is ready to assume more workload for certain periods of time. The Commission explained that the current proposal is balanced and takes into consideration the capacities of the different Member States. Furthermore, the Commission invited Member States to accept more applications for new substances, as there are indications of applicants that currently it can be difficult to find suitable rapporteur Member State willing to assess their dossiers for new active substances.

However, that Member State mentioned that it is the applicants choosing rapporteur Member States to submit their applications and that they cannot decide on their behalf.

Member States were invited to comment by 9 January 2023.