

## **EUROPEAN COMMISSION**

Health and Food Safety Directorate General

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## Standing Committee on Plants, Animals, Food and Feed Section *Phytopharmaceuticals - Legislation* 25 - 26 January 2023

*CIRCABC Link:* <u>https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/fe5134fe-fd07-4b3b-83e4-e7701c5ebceb?p=1</u>

## SUMMARY REPORT

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

The Commission informed that the summary report of the meeting in October 2022 is published, while the one of the meeting in December 2022 is under preparation.

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

1. sodium chloride – extension of use

The point was postponed.

2. chitosan hydrochloride – extension of use

The point was postponed.

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

1. Renewal process (Regulation (EU) No 2020/1740) - access to old studies

Following the discussion in the meeting of December 2022, the Commission thanked those Member States who had provided comments for their useful contributions.

The Commission underlined that regarding the difficulties to get access to old studies, so far only a few challenging cases were known, however a process to manage such cases was needed to ensure that decisions on admissibility by rapporteur Member States are not delayed.

It was also recalled that the General Food Law, as amended by the Transparency Regulation, requires that studies used to support admissible applications are made publicly available. Therefore, for renewals, all old and new studies will be published by EFSA and subject to public consultation as part of the assessment procedure. This is an important element to take into account by Member States when considering the release of old studies.

Member States were reminded that in December 2022 two cases were discussed:

1) Applicants obtaining access to old studies

2) Member States or EFSA obtaining access to old studies in case they do not have them in their own records or archives

The second case is easier to resolve: Member States and EFSA can collaborate to ensure that studies are shared between them. The Committee was informed that the first case put forward (oxyfluorfen) has now been solved. In general, Member States were asked to flag missing studies to the other Member States and EFSA so that such situations can be solved through mutual cooperation.

The Commission recalled that for renewals, it had proposed that in cases where best efforts to obtain studies have failed, Member States would make available the old studies to the applicant in order that a full dossier can be included in IUCLID and subject to public consultation after admissibility.

It was noted that overall, the Member States who reacted are not opposed to the proposal but raised four main concerns/issues: how to assess 'best efforts', timing, general concerns about providing studies to a third-party company, and resources required. Concerning 'best efforts', the Commission recalled that Article 6(3) of Regulation 2020/1740 states "where the applicant provides evidence that its attempts to obtain access from the study owner have failed", therefore the applicant is expected to show it entered into negotiations but failed. With regards to timing, it was underlined that discussions need to be started as early as possible and ideally before the notification of any new studies.

One Member State explained a case (pre-Regulation 2020/1740) where a consultant performed the sanitisation of the old studies rather than giving full not sanitised studies to another applicant. The Commission invited all Member States to reflect on the possibility of working with consultants for such tasks via a non-disclosure agreement and specific terms, in the event that a Member State needs to provide old studies to an applicant at renewal. Such consultants would be responsible for contacts with the original data owner, sanitisation and upload to IUCLID.

Finally, it was underlined that the best solution to the issue is for original data owners to reach agreements with new applicants since ultimately all relevant data must be taken into account and published as part of the renewal process.

Member States were invited to provide further comments and views by 13 February 2023.

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

The Commission informed about the launch of the call on the 18 January 2023. The 43 designated authorities from 24 Member States received the invitation to submit the applications by 25 April 2023. An info session will be organised on 14 February 2023.

3. Amendment of conditions of approval (Article 7)

The Commission reminded that for applications of amendment of conditions of approval the situations may be very variable and therefore admissibility is case by case, however in general the dossiers to be submitted are not full dossiers, but partial dossiers which include only the data which are relevant to the particular amendment of the conditions of approval which the applicant intends to address.

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

- Renewal of approval
  - 1. Clofentezine

There was no news to be discussed.

2. Benthiavalicarb

There was no news to be discussed.

3. Ethephon

The Commission informed that an EFSA is available. Member States were invited to send comments on this conclusion by 28 February 2023.

4. (3E)-dec-3-en-2-one

The Commission summarised the findings of the EFSA Conclusion and informed on the exchange of information between the applicant and EFSA on the tentatively identification of the metabolite 3-decen-2-ol. Member States were invited to comment by 13 February 2023 on the EFSA Conclusion and the applicant's comments.

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

- New active substances
  - a) Asulam-sodium

There was no news to be discussed.

b) Napropamid-M

The Commission informed that two Member States expressed support to the proposal to put on hold the dossier for napropamid-M waiting for the finalisation of the renewal of the napropamid racemate. No Member States opposed this proposal during the meeting either. The Commission will inform the applicant accordingly.

- Renewal of approval
  - c) Triflusulfuron-methyl

The Commission summarised its proposal for non-renewal, shared the revised version of the review report, the comments received from two Member States, the comments from the applicant and its responses, as well as a supporting letter from a stakeholder.

The Commission asked Member States for their indicative positions which indicated a qualified majority in support of the non-renewal. One Member State commented that applying Article 4.7 would be an option, another Member State stated that the application of 1 x 15 g a.s./ha every 2nd year, as put forward by the applicant in its letter of 20 January 2023, would probably provide a safe use.

The Commission invited Member States to comment by 13 February 2023 whether they agree that such potential safe use should be further explored and verified, and to indicate if they have granted authorisations for such a rate and frequency of use.

d) Aluminium ammonium sulfate

The Commission indicted that the two representative products have very different impact on the environment. Furthermore, given the physico-chemical properties, the legal parameters for drinking water may be exceeded in some uses, depending on the soil pH. The Commission informed that, however, renewal seems possible based on one of the reference products and some uses.

e) Cydia pomonella granulovirus (CpGV)

The Commission informed that the majority of the Member States that commented on the EFSA Conclusion support the renewal of CpGV as a lowrisk active substance. The Commission will proceed accordingly. The Member States were invited to send further comments on the EFSA Conclusion by 13 February 2023.

- Basic substances
  - f) Chitosan hydrochloride (amended review report to endorse)

The discussion focused on the draft amended Review Report for chitosan hydrochloride, amended to correct the GAP table and to include the uses on hop and amenity grassland proposed in the application for an extension of use. The Commission summarised the comments received from three Member States: two Member States expressed their support for the proposed amendments, whereas one Member State was against. That Member State is of the opinion that all aspects of the current approval should be opened for revision for both chitosan and chitosan hydrochloride.

The Commission asked Member States to provide their views. One more Member State indicated its lack of support for the proposed extension of use in hop and amenity grassland. The two Member States that were against the extension of use had not yet established their position towards the proposed correction of the GAP table.

Consequently, the endorsement of the amendments to the Review Report was postponed.

Another Member State indicated its support for both the extension of use and the correction of the GAP table in the Review Report and proposed the alignment of the GAP tables between the Review Reports for chitosan and chitosan hydrochloride. The Commission clarified that once the correction to the GAP table for chitosan hydrochloride is agreed, it intends to correct the GAP table for chitosan in the same way. As regards further alignment of the two GAP tables, the Commission reminded that an application for an extension of use of a basic substance can be submitted by any party, including a Member State, and that both chitosan and chitosan hydrochloride are included in the scope of the recently launched revision of the approval.

#### A.06 Confirmatory Information:

1. Pendimethalin

There was no news to discuss.

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

The Standing Committee agreed that no action is needed with regard to the confirmatory data due to the on-going renewal processes that supersede the confirmatory data evaluation. The respective Rapporteur Member States in the ongoing renewal procedures for these substances are invited to flag any issues leading to concerns which are indicated during the renewal processes. The Commission does recommend that the specification for clove oil is discussed in an expert meeting.

3. Thiabendazole

The Commission informed that a letter to the applicant has been sent out on 5 January 2023 requesting to submit a complete list of existing or planned studies (not yet submitted or evaluated) for assessing the endocrine disrupting properties, as well as the time schedule needed to carry out these studies. Furthermore, information on whether the exposure to thiabendazole can be demonstrated to be negligible was also requested.

4. Dithianon

The Commission informed that the EFSA reasoned opinion review of the existing maximum residue levels for dithianon according to Article 12 of Regulation (EC) No 396/2005 has been published on 9 January 2023. In this review, EFSA considered additional data available on the toxicity of the metabolites 1,4-naphthoquinone (Reg. No. 4107273) and phthalic acid (Reg. No.4005234) for which data gaps were identified during the assessment of the confirmatory data. The Commission noted that a data gap still exists on the mutagenicity potential of the metabolite 1,4-naphthoquinone.

Member States were invited to consult the EFSA reasoned opinion and to send comments by 28 February 2023. The Rapporteur Member State for the renewal was invited to confirm if any new data had been submitted as part of the renewal. Member States were also invited to liaise with their representatives of the residues sector regarding implications for setting MRLs.

5. Amilsulbrom

The Commission informed that the EFSA Conclusion was published on 9 December 2022, but that it is still inconclusive for the evaluation regarding endocrine disrupting properties as regards non target organisms. The comments received by the applicant have uploaded on CIRCA.

As the applicant had fulfilled its legal obligations regarding confirmatory data and the renewal process is already on-going, the Committee agreed to wait for the completion of the renewal process, as this will include an assessment in line with the ECHA/EFSA (2018) Guidance. The peer review will start upon submission of the renewal assessment report by the rapporteur Member State.

#### A.07 Guidance Documents:

1. Prioritisation of Guidance Documents (to endorse)

The Committee endorsed the list of prioritised guidance documents.

As regards the document which outlines a process to keep this list updated, the Commission suggested to postpone the endorsement until the next meeting of the Committee to be able to also consult the residue section of this Committee, which has its next meeting in February 2023. In addition, the Commission informed that in cooperation with EFSA, it is considering outlining a short process to guide the drafting of guidance documents by Member States, in order to ensure that the results are fit for purpose and according to the EFSA standards.

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 endorsement of the guidance documents was postponed due to comments of one Member State, which suggested to make the document also applicable to authorisation processes.

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 Commission informed that the revisions of the Part A Communications 283/2013 and 284/2013 are on-going and presented the prototype of the new database on *Guidelines and supporting documents on Active Substances and Plant Protection Products*. Member States were asked to comment on the structure and functionalities of this prototype by 13 February 2023.

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

The Commission informed on the status of the two drafts of the Communications from the Commission in the framework of the implementation of Part B of Regulations (EU) No 283/2013 and No 284/2013. In particular, the Commission specified that the inter-service consultations have been recently launched and endorsement if foreseen during the next meeting.

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

1. Article 44(4)

No notifications were received.

2. Article 36(3)

The Commission informed about the three notifications received since the last meeting of this Committee: two notifications concerned rejections of mutual recognition applications and one concerned a rejection of authorisation under the zonal system. None of the decisions was challenged at national level.

3. Article 53

See agenda point A.21 for the discussion on the judgment in case C -162/21.

The Commission informed that, following the ruling in Case C-162/21, it intends to withdraw its mandate to EFSA for the assessment of the justifications of certain emergency authorisations sent on 19 December 2022. The mandate to develop new fit-for-purpose protocols to assess such justifications will be maintained.

4. Article 56

The Commission informed about 2 notifications under Article 56 of Regulation (EC) No 1107/2009 received by Portugal in December 2022 for the active substance prosulfocarb. The approval of this active substance is currently under renewal with Portugal as the rapporteur Member State and Sweden as the co-rapporteur. The first

notification concerns a new fish early life stage study, and the second notification regards a new oral toxicity study in rats.

Member States were invited to indicate by 3 February 2023 if they received a notification under Article 56 for this active substance and to indicate if they will be the evaluating Member State for their zone as foreseen by Article 56(3) of Regulation (EC) No 1107/2009.

The Commission furthermore indicated writing a letter to the applicant to seek confirmation on the compliance with Article 56.

The rapporteur Member State informed of the availability of eight further studies on genotoxicity that will be submitted during the stop-the-clock period. EFSA informed that the assessment on endocrine disrupting properties is missing in the revised assessment report of this active substance.

One Member State informed during the meeting having received a notification under Article 56 from the applicant who proposed to address these data during the renewal of the authorisation according to Article 43 upon renewal of approval of the active substance. That Member State agreed to remind the applicant of the right procedure.

#### A.09 Microorganism and low risk Active Substances:

The Commission informed that the Biopesticides Working Group (BPWG) is drafting a document containing "explanatory notes" to support harmonised implementation and better understanding of the new data requirements on micro-organisms which became applicable in November 2022.

The Commission also informed on the discussions of the BPWG regarding the interpretation of the provisions concerning low-risk active substances and plant protection products. The BPWG suggested to limit its discussion to the low-risk aspects for the active substances, while the PAI Working Group could keep discussing on the interpretation for the low-risk status for plant protection products. The BPWG suggested to set a default precautionary sentence applicable on the labels to all the plant protection products containing micro-organisms (except virus) as regards their potential to provoke sensitising reactions and confirmed that the general practice is to recommend wearing personal protective equipment (PPE) when using micro-organisms. Thus, such recommendation is regarded as generic and should not preclude the low-risk status of the substance or the plant protection product containing it (unless the presence of co-formulants justifies it).

The Commission informed that this interpretation is not shared by one Member State which consider that low risk is decided on the basis of a hazard assessment which remains qualitative in absence of satisfactory testing/data, hence risk assessors would recommend using mask, which is, in the mind of this Member State, a specific risk mitigation measure. The Commission stated that applying such conservative approach will disqualify all micro-organisms (except virus) from the low-risk status.

#### A.10 Safeners and Synergists:

The Commission presented the draft Commission Regulation on Safeners and Synergists, highlighting the regulatory and data requirements and the procedural steps which will be needed to obtain the approval of these substances. A provisional timeline for the upcoming administrative steps, leading to the adoption of this draft Commission Regulation, were also presented.

One Member State asked whether the draft included "transitional measures" for existing products. The Commission reassured that the draft proposal included those measures.

The Member States were invited to comment on the draft Commission Regulation by the end of February 2023.

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

1. Clethodim

The Commission informed that the Rapporteur Member State for the renewal of approval had shared a preliminary conclusion of the assessment on the genotoxic potential of the metabolite 3-chloroallyl alcohol (3-CAA) in accordance with the new toxicological data submitted in the renewal dossier. 3-CAA appears not to be genotoxic in-vivo in rat studies. The Committee concluded that the renewal should continue in line with the proposal from the Rapporteur Member State.

2. Common metabolites of pyrethroids

There was no news to discuss.

3. Common metabolite TFA

The Commission recalled that a notification under Article 56 was made by Bayer in early 2021 following adverse findings in a study submitted under REACH.

In November 2022, ECHA notified the applicant under REACH that it had completed its evaluation and flagged the need for a harmonised classification and labelling procedure based on its evaluation.

The TFA Task Force is working on follow-up toxicology studies which have been discussed with Poland. Those follow-up studies will be made available for evaluation as part of submission under CLP for harmonised classification and labelling so that all scientific evidence is taken into account.

In the meantime, EFSA is using the agreed endpoints for TFA as agreed during the assessment of flurtamone. The Commission indicted it will follow up with EFSA to see if the evaluation under REACH would lead to a need to consider revising those values or not.

4. Thiophanate-methyl (TRV to endorse)

The Committee endorsed the updated toxicological reference values (TRV) of thiophanate-methyl, which were defined in the recent EFSA Reasoned Opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. The new reference values are:

Acute Reference Dose (ARfD): 0.02 mg/kg bw

Acceptable Daily Intake (ADI): 0.02 mg/kg bw/day

As a follow up, the Commission is planning to draft a measure lowering some of the MRLs for this active substance, for which EFSA identified acute risks for consumers considering the new TRVs.

#### 5. Tricyclazole (TRV to endorse)

The Committee endorsed the updated toxicological reference values (TRV) of tricyclazole which were based on a reasoned opinion of EFSA on an application for import tolerance for tricyclazole in rice.

One Member State was not in the position to endorse and explained its rationale:

During the Peer Review, tricyclazole was considered a potential genotoxicant. Overt genototoxicity was observed in a MLA but not in a gene mutation assay on adherent cells.

In an IND-based publication, a negative transgenic assay (TGA) in mice was performed (Corvaro M, Gollapudi B, Mehta J, A critical Assessment of the Genotoxicity Profile of the Fungicide Tricyclazole, Environ Mol Mutagen, 61(3):300-315, 2020), but we are not certain if the top-dose tested was sufficient.

The guideline OECD TG488 indicates that, except where the limit dose (1000 mg/kg b.w./d) has been used the highest dose should be the dose that will be tolerated without evidence of study-limiting toxicity. In the 90d ICR mouse study (DAR), tricyclazole was tested at dietary levels corresponding to 84.8, 264.8, 711.0 and 1052.6 mg/kg b.w./d in males and 96.5, 262.8, 721.4 and 990.5 mg/kg b.w./d in females, while the top-dose in the TG assay was as low as 282 mg/kg b.w./d in the published TG assay.

It remained also unclear from the PRAS notules why the carcinogenicity findings were deemed irrelevant.

Except from the TGA, we see no new data in the dossier, and it thus remains debatable if reference doses can be established.

6. Sodium hydrogen carbonate

The Commission presented a draft Review Report that excludes those uses for which sodium hydrogen carbonate is available in an authorised plant protection product as a low-risk active substance.

The Commission also informed that one Member State presented an alternative proposal which is to amend the basic substance approval so that it is only applicable in Member States where no Plant Protection Product containing sodium hydrogen carbonate as a low-risk active substance is authorised and marketed. One additional Member State indicated supporting this alternative proposal.

Member States were invited to send comments on the draft updated Review Report as well as on the alternative proposal from a Member State by 28 February 2023.

## A.12 Article 21:

1. Acibenzolar-methyl

The Commission informed that the mandate to EFSA was sent and that EFSA expects to deliver its output by 14 March 2023.

#### A.13 General issues for information / discussion, in particular:

- 1. Scope of Regulation (EC) No 1107/2009:
  - a) New cases

There were no new cases to be discussed.

b) Phosphonates as EU plant bio stimulants

The Commission informed about the reactions received from four Member States concerning a possible amendment to the Fertilising Products Regulation (FPR) regarding the status of phosphonates. The proposal, supported by two not peer-reviewed studies, was to lift the current restriction provided in the FPR with a maximum concentration of 0.5 % w/w for the product function category 'plant bio stimulant'. So far, the reactions from the Member States were not favourable to this proposal because of:

- the current ban to intentionally add phosphonates to any EU fertilising product aimed at avoiding the misuse of fertilising products for plant protection uses;
- there is no evidence that fungicidal effects could be excluded at the application rate as plant bio stimulant;
- a high potential for phytotoxic symptoms would exist due to an accumulation of the phosphonates in soil;
- the combination of the application as plant protection product and as bio stimulant may not be covered by the risk assessment conducted for the use regulated by Regulation (EC) No 1107/2009 (e.g. ecotoxicology, fate, human tox. and especially residues), even if a lower rate would be recommended for the claimed use as plant bio stimulant;
- the compliance with the existing MRL shall be fulfilled, irrespective if a substance is used as plant protection product or as bio stimulant, which would place the growers in the uncertainty in case of a combination of bio stimulant and plant protection product applications;
- the proposal will contradict the previous communication campaign towards the farmers and distributors to consider phosphonates exclusively as plant protection products.

The Commission informed that the colleagues in charge of the FPR were informed of the reactions of Member States.

The Commission invited Member States to provide further comments by 13 February 2023.

c) Physical barriers

The Commission was informed by one Member State that several producers claim that their products have a mode of action as a physical barrier and hence consider that they fall outside the scope of the Regulation (EC) No 1107/2009. The Commission explained several recent cases (sunflower oil with a UV protection for the crop/ turf; a liquid based on zeolite creating a physical protecting barrier on the plant to prevent fungal diseases to 'penetrate'; claimed function of kaolin to protect against sunburn).

The Commission reminded that the scope document gives some directions, but that clear criteria are missing as to consider a substance as a 'physical barrier'. The Commission reported about its current reflections to consider for such criteria the mode of action, the nature of the product, the effects on the pest (e.g., anaerobic conditions, dehydration, immobilisation), the mode of application, the actual direct contact with the plant/plant parts, the indirect/direct effects on the plant/plant parts.

Member States were invited to provide examples of physical barriers on their markets and their interpretation by 28 February 2023.

2. Follow-ups on incidents with phosphine products

The Commission recalled that, in recent years, two incidents with phosphine intoxications have occurred in The Netherlands. After feed and food cargos were transferred to inland vessels from one ship and three trains and declared free of phosphine, later on higher phosphine levels were measured after hospitalization of the ships' crew (all of whom recovered). This proved that phosphide tablets can be reactivated, for example, after transfer.

In both cases, the application of phosphide tablets was done outside The Netherlands. As a consequence, The Netherlands initiated actions to harmonize the use instructions for all the phosphine-based plant protection products (and biocides) covering specific use instructions in product authorisations or suggesting an EU review of the conditions for active substances approvals. Consequently, the Commission had requested the Member States' views on the necessity to review these approvals.

The Commission summarised the comments received from the Member States on a possible review of the conditions of approval of the active substances releasing phosphine. Out of five Member States which had commented, four were not in favour of a review of the approvals.

3. Review of the Pollinator Initiative

The Commission informed of the publication of the revised Pollinators Initiative in the Official Journal:

https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=COM%3A2023%3A35%3AFIN&qid=1674562540086

## A.14 Amendment Regulation 547/2011:

The Commission presented a new draft and explained its changes with respect to the version presented in July 2022, which were made under consideration of the comments received from Member States. In particular, the Commission explained: 1) the proposal for inclusion of electronic information in the label, 2) the consistency with the requirements set by the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, 3) the revision of the attribution criteria of the sentences and its link with the risk assessment of active substances and plant protection products, and 4) a proposal for a scheme to communicate to the users the type of active substance(s) contained in the plant protection product.

Member States were invited to comment by 28 February 2023.

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

The Commission informed on a European Parliamentary (EP) question on the "Compliance of the toxicity assessment of representative formulations with Regulation" that refers to a recently published study (<u>https://www.mdpi.com/2305-6304/10/11/711/pdf</u>) on co-formulants in formulations of glyphosate, quizalofop-p-

ethyl, fluroxypyr and dicamba. The Commission shared its message to EFSA on this topic and also asked the Member States to consider this study, if relevant, in the ongoing renewals. The Commission informed the Committee about the exchange of views on this topic in the EP at the ENVI Coordinators' meeting that took place on 24 February.

Member States were asked to reconsider the amendment of the guidance document to Member States on Zonal Evaluation and Mutual Recognition in parallel with the other actions aiming to achieve harmonisation of the assessments of co-formulants and formulations, mostly in the assessment of long-term effects.

As regards the Workshop co-organised with EFSA, the Commission thanked the nine Member States for their inputs. Member States who have not yet responded were invited to reply to the following questions by 13 February 2023:

- what do you see as the problems/challenges that need to be solved related to the assessment of PPP formulations
- Interest to join the steering committee

## - PFAS contamination:

The Commission informed that PAN Europe sent information about the possible contamination of pesticide formulations with per- and polyfluoroalkyl substances (PFAS) and perfluoro-octane sulfonic acid and its derivatives (PFOS) which is available on CIRCA BC. The study submitted (Lasee et al) confirmed that "major PFAS contamination [of plant protection products] has mostly been associated with industrial production and use of PFAS, sites with the use of aqueous fire-fighting foams, and municipal and industrial waste". PAN Europe suggested that action should be taken in controlling PFAS presence in plant protection products (PPPs).

The Commissions informed that its reply to PAN in mentions the actions aimed to limit the use - and consequently the contamination- of PFAS, for instance specific actions recently taken through the Regulation 2022/2388 related to MRL levels of PFAS in some foodstuff, the proposal to restrict PFAS in the context of the REACH Regulation, or supporting specific research projects such as EURION. In the same reply, the Commission committed to remind Member States, in particular the Working Group on plant protection product formulation analysis, about this issue and to check for the possible presence of PFAS/PFOS when assessing authorisation applications, and when monitoring / analysing / enforcing the correct implementation of authorisations granted for the plant protection products. Possible findings should be reported to the Commission.

#### - Formaldehyde releasers (FRs):

The Commission recalled that during the EU Workshop on Plant Protection Products about identity, physico-chemical properties and analytical methods held on 20 September 2022, a short discussion about formaldehyde releasers took place. Some Member States mentioned that they consider them as unacceptable, even if not mentioned explicitly in Annex III of Regulation (EC) No 1107/2009, while others request to add them individually to Annex III.

Meanwhile, the Commission received letters from stakeholders requesting harmonization of the criteria regarding FRs as unacceptable co-formulants, and asking about clarifications on the positions of some Member States. One Member State proposed a questionnaire (uploaded on CIRCA) for exchanging information on how Member States deal with formaldehyde releasers in more detail and about their experience facing this issue. Member States were invited to react to this questionnaire by 28 February 2023.

- Organization of the next Working Group on analytical chemistry/PPP formulation

The Commission recalled that the Working Groups on PPP formulation and on analytical chemistry have been merged. The Commission asked for a volunteer Member State to organize a meeting of this WG during 2023, with the support of the Commission.

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

1. Working group on Biopesticides

There was no news to discuss.

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

The Commission informed that two meetings took place in October and December respectively in which the draft documents "Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009" and "Compendium/list of technical use and application conditions for plant protection products" were discussed.

3. Working group Post Approval Issues

The Commission informed about the last meeting of the Post Approval Issues Working Group, held on 29 and 30 November 2022. The main points debated were: the compilation for internal use of the main agreements of the group (including the ones on Article 43), the categorisation of the data gaps identified in EFSA conclusions to be handled at product level, the responsible Member State that will take the lead for the amendment of the Guidance Document on new active substance data post-(renewal of) approval after the experience gained with the pilot project on dimethenamid-P, the ways Member States handle formaldehyde releasers at product level, the progressive need to use IUCLID in the future for PPP applications, the initiation of preparatory work to organise an EU Workshop on improvements of the zonal system for authorising plant protection products, among others.

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

1. European Food Safety Authority (EFSA)

There was no news to report.

2. OECD, FAO and EPPO activities

The Commission reminded about the upcoming OECD meetings which will take place end of February/beginning of March 2023. Member States were invited to participate to the preparatory meeting organised by the Commission on 15 February 2023.

The Commission also reported about the ongoing activities with respect to drones: ongoing data generation, guidance on best practices for pesticide applications with drones, draft ISO standard including environmental requirements and test methods to assess the horizontal transversal spray deposition, study about impact on crop residue levels, Spanish PhytoDron project, and UK PSD Event on Drone Spraying of Pesticides on 23-24 May 2023.

The Commission also mentioned the publication of the OECD Guidance Document for the Regulatory Framework for Bacteriophages on 28 November 2022.

# A.18 Exchange of information from the Pesticide Residues section of the Committee, in particular:

1. Setting of Toxicological Reference Values derived via an MRL application or MRL review process (outside an assessment for approval or renewal of an active substance)

The Commission explained that it had amended the existing document setting out the procedure for reporting and amending residue definitions for risk assessment to also include a point on toxicological reference values (TRVs) that are not set during an approval or renewal process e.g., TRVs set as part of an MRL evaluation. The Committee was informed that the item would also be raised at the upcoming meeting of this Committee (section residues) in February.

Member States were invited to comment by 28 February in view of endorsement at the next meeting.

#### A.19 Scientific publications and information submitted by stakeholders:

There were no particular issues to report.

## A.20 Date of next meeting(s).

The Commission informed that the next meeting is confirmed for 22 and 23 March 2023 in a hybrid format.

## A.21 AoB.

The Commission informed that the approval holder had submitted the information requested for the review on the approval of flupyradifurone under Article 21 related to the effects on bees. It also informed that the same company applied for renewal of the approval of the active substance. The Commission will ask the Rapporteur Member State on the renewal application to provide within three months its comments and opinion on the available information on the effects of flupyradifurone on bees.

Member States were invited to send to the Commission and the Rapporteur Member State by 28 February 2023 their comments on the information submitted by the approval holder in the context of Article 21.

The Commission informed about the delivery of the judgment in case C -162/21 (Pesticide Action Network Europe and others vs. Belgium) by the European Court of Justice on 19 January 2023. A list of questions related to this judgement which was sent shortly before the meeting by two Member States has been made available. The Commission underlined that the judgment required further analysis to fully understand its interpretation and consequences. It recalled that the Court's interpretation of Article 53(1) of Regulation (EC) No 1107/2009 is binding and has to be considered part of the acquis. Member States being at the origin of authorisations under Article 53(1), are responsible for complying with that judgment.

As regards action by the Commission, in addition to the ongoing analysis of the judgment, the Commission will inform EFSA to discontinue the assessment of the justifications provided by Member States for authorisations granted under Article 53

involving the treatment of seeds with neonicotinoids, as requested in the last mandate to EFSA. The Commission will also start to work on an update of the guidance on Article 53, as well as to analyse the impact of the ruling on the pending guidance on seed treatment. It will also monitor the follow up that Member States will give to the judgment.

In the ensuing discussion, several Member States asked for a coordinated action, to ensure uniform interpretation and implementation of the judgment and requested a dedicated meeting in the following weeks. Member States queried about handling outcomes of preliminary rulings affecting administrative acts in general, and, for the present case, the ruling's impact on authorisations already granted or decisions that are pending. Several Member States confirmed to be in such a situation. Some Member State informed that seeds had been treated under emergency authorisations already granted in December 2022. Several Member States also requested guidance for which other substances the judgment would apply. One Member State informed that it has stopped ongoing authorisation procedures and highlighted that, while alternatives are actively explored, there is currently a problematic lack of insecticides to combat aphids. It announced to send a ministerial letter to the Commission. The Commission informed that the actions by Member States were taken based on their respective administrative laws, which may therefore impact their respective reaction to the judgment.

Member States were invited to send information on the situation in their Member State impacted by the judgment as well as other information that they considered relevant, such as legal assessments conducted by their respective experts, if possible, by Friday 27 January 2023. The Commission informed that it would endeavour to organise an exchange between Member States.

The Commission informed that, as a follow-up of Member States and stakeholder requests, a workshop on zonal authorisation is being organised (similar to the one carried out in Dublin in 2015). Germany has volunteered to coordinate, together with a steering group of other Member States representing all zones and the Commission. The workshop is planned for the last quarter of 2023. Letters will be sent out to the applicant associations inviting them to raise issues which would be useful to discuss at the workshop.

The Commission informed that one Member State had submitted a proposal for a guidance document on biodiversity, which his made available on CIRCA BC together with other relevant on biodiversity reports<sup>1</sup>, which were partly already shared at previous meetings. Member State were invited to comment by 28 of February 2023.

The Commission informed on the public hearing in the European Parliament on the European Citizens' Initiative (ECI) 'Save Bees and Farmers' in the Committee Environment, Public Health and Food Safety (ENVI) and the Committee on Agriculture and Rural Development (AGRI), associated by the Committee on Petitions (PETI). The

<sup>&</sup>lt;sup>1</sup> Nationale Akademie der Wissenschaften Leopoldina, acatech – Deutsche Akademie der Technikwissenschaften, Union der deutschen Akademien der Wissenschaften (2020): Biodiversität und Management von Agrarlandschaften – Umfassendes Handeln ist jetzt wichtig.

KEMI PM2/21 Methods for assessing the effects of plant protection products on biodiversity

KEMI PM 7/21 Resilience of biodiversity to plant protection product use – the modifying influence of landscape and interventions

Alix, Bylemans, Dauber, Dohmen, Knauer, Maltby, Mayer, Pepiette, Smith, 2022. Optimising agricultural food production and biodiversity in European landscapes. Report of an online-Workshop. Tünen Report 98.

Commission furthermore informed that the reply to this ECI, in the form of a Communication, is now under preparation.

The allocated Rapporteur Member State for the active substances tefluthrin and halauxifen-methyl informed the Commission that due to the severe delays and difficulties there are facing, it proposes to transfer the assessment of the two active substances to other Member States. Therefore, the Commission invited Member States to consider their capacity and willingness to carry over the assessment and the intrinsic responsibilities as Rapporteur Member State for the renewal of approval of the active substance tefluthrin (dossier submitted in IUCLID on 23/02/2022 pending admissibility) and halauxifen-methyl (dossier submitted in IUCLID on 28/07/2022 pending admissibility).

The Commission updated the participants on the number of pending admissibility decisions from the first year of adoption of the new dossier submission system. The Commission also informed the participants that, together with EFSA, it will start a programme to facilitate the decision making on the admissibility by those Rapporteur Member States in which the workload seems to be causing those delays.

One Member State asked about news on the development of new TARIC codes, another one on on-going work on drones, and a third one provided an update on groundwater metabolites. Commission thanked for the questions and indicted that further details will be provided at the upcoming meetings.

## 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

The Commission presented the updated draft Implementing Regulation, which incorporated the comments received from the Member States and the discussions at the informal technical meeting with the Member States that took place on 2 December 2022. The changes made include:

- 1. The recording of seeds treated with plant protection products was removed from the draft act in the spirit of good cooperation. However, this removal does not constitute a change of the Commission's position on this issue and has no legal effect with respect to the implementation of Article 67 of Regulation (EC) No 1107/2009.
- 2. The requirement for timestamping of the electronic records has been removed to avoid additional burden to the users.
- 3. The date of entry into force has been changed to 1 January 2026.

Seven Member States indicted that they could not support the draft act because in their view the requested level of details (e.g., stage of the crop, timing of application) is not useful and/or falls outside of the scope of the recording requirements of Article 67 of Regulation (EC) No 1107/2009, and/or because of the additional burden that will be created to the users, especially in the non-agricultural sectors.

Another Member State supported the proposal but expressed the concern that the Implementing Regulation could create additional burden with respect to non-agricultural uses of plant protection products. It also stated that it would have been better if the transitional regime for the transfer of records into electronic format could be prolonged until 1 January 2035.

The Commission explained that no further changes can be made to the draft and proceeded with the vote.

Vote taken: Favourable opinion.

#### Belgium made the following declaration:

Belgium voted in favour of this implementing regulation but wants to indicate that they believe that in the practical implementation of this regulation care should be given regarding the access to and security of this data: the location or identification of treated area is considered sensitive information. Care should also be taken that users who have poor or no access to the internet are not put in a position where they cannot conform to these requirements. The actual filling in of this use register should be able to be delegated to a contractor. Lastly, if this Annex were at some point in the future to be amended so that the sowing of treated seeds needs to be registered, care should be taken to avoid the double counting of this use (once at the treatment of the seeds, and a second time at the sowing).

## **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.

One Member State asked for a clarification on criterion 10. The Commission reminded that criterion 10 was designed as a safety net that would allow this Implementing Regulation to work adequately and would ensure harmonisation and avoid duplication or divergent results.

Another Member State reiterated the proposal to include co-formulants classified according to Regulation (EC) 1272/2008 ("CLP") as carcinogenic/mutagenic/toxic for reproduction ("CMR") Category 2 in the criteria of the Annex of the draft Regulation. Another Member State would have appreciated a more in-depth analysis, within the draft, on the applicability of this Implementing Regulation with regard to those plant protection products whose assessments are already being carried out by national authorities.

No changes to the act were made and the Commission proceeded with the vote.

Vote taken: Favourable opinion.

**B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances whose approval expires between 31 January 2029 and 1 October 2035

#### PLAN/2022/2580

The Commission reminded that the draft regulation allocates Rapporteur Member States for active substances for which approval expires between 31 January 2029 and 1 October 2035. The programme was drafted after consultation with Member States, taking into account a balance in the responsibilities and the work to be done among Member States acting as rapporteurs. The allocation seeks to ensure that Member States can already consider where appropriate to hold pre-submission meetings with applicants to prepare the renewal dossiers.

One Member State agreed with the proposal of the Commission, however highlighted that their preference would have been to receive a higher number of "green" active substances, since they reinforced the team of assessors specialised in these types of substances. The Commission suggested to compensate by way of accepting more dossiers of new "green" active substances.

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) renewing the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12068/2020).

SANTE/12066/2020

The Commission presented the draft Implementing Regulation and the draft Review Report, which were updated on the basis of the comments that were received from the Member States during the previous meeting of the Committee and during the commenting period.

The Commission also informed about two letters sent by the applicant and a law firm requesting the Commission to revise the draft Review Report because of alleged mistakes and inaccuracies and, consequently, to postpone the vote. The Commission explained why those allegations were unfounded and that the draft Review Report could be endorsed. Finally, 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) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, (CpGV), malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram. PLAN/2022/2755

The Commission presented the draft Implementing Regulation, extending the approval periods of active substances expiring on 30 April 2023. The extensions according to Article 17 are necessary because it will not be possible to adopt decisions on the renewal or non-renewal of approval of the active substances before the expiry of the current approval.

The Commission explained that the extensions proposed are calculated on the basis of an estimate of the time still needed to complete the renewal procedure of each active substance. The remaining regulatory steps depend on where each active substance currently stands in the process and for each of the remaining steps maximum time periods are defined in the legislation. The extensions granted, thus vary from up to thirty-nine months when the draft renewal assessment report is still being drafted by the Rapporteur Member State, to fifteen and a half months when the proposal on renewal or non-renewal has already been presented to the Committee. This proposal doesn't guarantee the absence of further delays in the process but will give some more predictability to Member States to plan their own resources for handling applications.

One Member State welcomed this new approach that in their view will give more predictability and suggested to establish a closer monitoring system on the status of the active substances in order to detect delays at an early stage and suggested shorter extensions of hazardous active substances.

Another Member State indicated its support but reminded that decisions should be taken as soon as possible in the Committee.

A third Member State indicated its support but disagreed on the applicability of Article 14 (1a) to assess whether these approval criteria for rimsulfuron are met, they would prefer to renew rimsulfuron setting confirmatory data for the purposes of the assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605.

One Member State indicted it does not support because of the extension of metconazole, triclopyr and ziram.

For abamectin, a regulatory decision was adopted during the meeting, and it was removed from the draft Regulation. The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

#### Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12270/2020)

SANTE/12268/2020

No discussion took place.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance oxamyl, 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 PLAN/2022/1836 RR).

#### PLAN/2022/1836 CIS

The Commission informed that the Technical Barrier to Trade notification will be concluded in time for the following Committee meeting, so that a vote can be expected at the next meeting.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis aizawai* strain ABTS-1857 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/10282/2021 Rev. 1).

#### SANTE/10280/2021

This point was discussed together with points C.04 to C.10.

The Commission presented the draft regulations and indicted that precautionary minimum time periods are proposed that shall elapse between the application of plant protection products containing this active substance and the harvesting of edible crops intended for fresh consumption, for the cases where residue data reported by the EFSA conclusion showed a density of *Bacillus thuringiensis* (Bt) strain above the level of 105 CFU/g as recommended by EFSA (2016). In addition, more data regarding the decline of the Bt concentration after application, and storage stability data, are asked for.

The Commission described comments received from the Member States so far and underlined the general agreement on the overall approach proposed, despite some diverging views raised on how applying the minimum time period elapsing between the application and harvesting. One Member State called for a minimum period of 3 days applied to all Bt strains and all crops.

Member States were invited to provide final comments by 13 February 2023, in view of possible votes at the next meeting of this Committee.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis aizawai* strain GC-91 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/10286/2021 Rev. 1).

SANTE/10284/2021

See point C.03.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis israelensis* strain AM65-52 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/10290/2021 Rev. 1).

SANTE/10288/2021

See point C.03.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain ABTS-351 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/2022/1636 RR Rev. 2).

PLAN/2022/1636

See point C.03.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain EG2348 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/2021/11143 RR Rev. 3).

PLAN/2021/11143

See point C.03.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain PB54 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/2021/11145 RR Rev. 2).

PLAN/2021/11145

See point C.03.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-11 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/2021/10728 RR Rev. 3).

PLAN/2021/10728

See point C.03.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-12 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/2021/10753 RR Rev. 3).

PLAN/2021/10753

See point C.03.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance dimoxystrobin 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/2022/2636 RR Rev. 1).

PLAN/2022/2636

Considering the broad support for the non-renewal of the approval of dimoxystrobin expressed by the Member States due to the high potential for groundwater contamination by relevant metabolites, the Commission presented an updated draft Renewal Report and draft Implementing Regulation. Member States were invited to send further comments by 13 February 2023.

C.12 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance pelargonic acid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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/11124/2021 Rev. 2).

SANTE/11122/2021

The Commission presented the updated draft Renewal Report and draft Implementing Regulation for renewal of pelargonic acid together with additional comments received by the applicants and the Member States. No further changes have been made in the list of representative uses supported by available data.

With respect to the continuing requests by the applicants to renew pelargonic acid as a low-risk active substance, the Commission once again reminded of the risks identified during the peer review for at least one group of wild non-target terrestrial organisms other than vertebrates in almost all representative uses.

Member States were invited to comment by 13 February 2023.

C.13 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus amyloliquefaciens* strain QST713 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/ 10294/ 2021 - Rev. 1).

## SANTE/10292/2021

The Commission informed that both the draft Regulation and the Review Report have been uploaded on CIRCA BC and invited Member States to comment by 13 February 2023 in view of a possible vote at the next meeting of this Committee.

C.14 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 **Pro memoria – TBT notification (to be) launched** 

The Commission informed the Member States that the TBT notification was ongoing and that the draft Regulation would be tabled for vote in March.

The Commission also informed Member States about some correspondence it received from the applicant and about the two responses sent from the Commission.

Member States were invited to submit any comments by 28 February 2023.