EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2023)407610

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
13 - 14 October 2022

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/d7008139-b860-4bee-95bd-f872eb30c834?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that all summary reports of previous meetings are published.

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

- Natamycin

The Commission informed about the withdrawal of the application for an approval of natamycin as basic substance by the applicant. Consequently, the evaluation process of EFSA has been discontinued and no Technical Report will be issued.

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

The Commission informed about an email received from one Member State as regards peer review participation which is made available via CIRCA BC, and suggested to discuss this at the Pesticide Steering Network chaired by EFSA.

The Commission also referred to a letter received from one Member State on behalf of the Northern Zone which was made available via CIRCA BC, in which difficulties for planning the work and resources as regards authorisation of plant protection products were highlighted and in which the Commission was asked whether a database as regards the peer review and decision making process could be made available.

The Commission replied that a significant part of the process is in the hands of Member States (in their role as rapporteurs) and EFSA, and that therefore this information is not available in detail to the Commission. Further, the Commission stressed that as soon as the EFSA Conclusion is available, discussions in this Committee are initiated with the aim to proceed withing the legal deadlines of presenting a review report and a draft implementing act within 6 months. The Commission acknowledges that in some cases discussions are complex and may require more time, however this is not foreseeable by the Commission as it depends on the views of Member States. Finally, the Commission refers to the increased transparency due the publication of the draft legal acts proposed in Section C and B of the agendas of the Committee meetings, and refers to the overview of EFSA as regards the active substances that are affected by a “stop the

clock" in accordance with Regulation (EU) No 844/2012 to assess their potential endocrine disrupting properties.

In addition, the following specific points were discussed:

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

   The Commission informed that 24 Member States nominated their competent authorities for the grants of financial assistance to Member States in the context of the plant protection products and biocidal products regulations between 2023 and 2027. The Commission also informed that letters were prepared on request from some Member States to explain the needed commitments regarding transition towards a full-recovery system. Finally, the Commission indicated that the grant is expected to be launched by end of 2022 or beginning of 2023.

2. renewal of active substances: allocation of Rapporteur Member States for active substances which expire between 31 January 2029 and 1 October 2035

   The Commission presented a draft proposal on the allocation of Rapporteur Member States and co- Rapporteur Member States for the active substances for which their approval expires between 2029 and 2035. The allocation of active substances to Member States was based on the preferences expressed by Member States in writing, and considering a balance in the responsibilities and workload among Member States.

   Member States were invited to comment by 4 of November 2022, in particular the Member States that were not assigned any active substance in case that would hamper the maintenance and continuity of the experts in their administrations.

3. update on several ongoing renewal reviews of active substances

   The Commission informed that it had recently sent mandates to EFSA for two substances where critical concerns were identified during the ongoing renewal procedures: s-metolachlor and dimoxystrobin. The Commission explained that, if the concerns are confirmed in the EFSA outputs such that the approval criteria are not fulfilled, it would act smoothly with the respective regulatory decision making.

   In particular, for S-metolachlor EFSA had informed the Commission of critical concerns (groundwater contamination and risks to birds) identified when drafting the Conclusion. A mandate was sent to EFSA to deliver the conclusion by 31 January 2023 (excluding the ED assessment). Once the EFSA Conclusion is available, the Commission will consult the applicant before deciding how to proceed.

   For Dimoxystrobin. EFSA informed the Commission before requesting additional information on ED properties, that the rest of the assessment had been completed and that critical concerns had been identified concerning groundwater contamination by relevant metabolites and a risk to aquatic organisms. The Commission mandated EFSA to produce a statement limited to the environmental assessment, and EFSA made its statement available to Member States and the applicant on 11 October 2022. Member States were invited to provide comments and views on the EFSA Statement by 4 November 2022. The applicant has also been consulted on the statement. The Commission reminded that all comments will be considered before proceeding.

4. IUCLID

The Commission mentioned that the admissibility declaration of Rapporteur Member States of dossiers submitted via IUCLID is delayed in many cases, and asked Member States to inform about the reasons for this by 4 of November 2022.

One Member State mentioned that the main reason is the accessibility to old studies, for which confidentiality has expired, to which many applicants have not gotten access by the owner. This Member State mentioned that they cannot fulfil the administrative task to upload themselves these studies to IUCLID and offered concrete examples.

Another Member State admitted delays and informed it expects to solve them by end of 2022.

Two Member States informed that the dossiers submitted by applicants in IUCLID are often not properly done, and that some rules of IUCLID do not make sense and prevent declaring admissibility.

The Commission also mentioned that it seems that Rapporteur Member States have different procedures as regards sharing the updated Draft Assessment Reports with applicants, and suggested to initiate discussions as regards a harmonised approach among all Member States to guarantee equal treatment of applicants.

The Commission informed the participants about manuals, training materials and functional mailbox where to seek advice:

- Link to the EFSA tool kit webpage containing (but not limited to) several manuals on different IUCLID topics: https://www.efsa.europa.eu/en/applications/toolkit
- Link to the webinar on confidentiality: https://www.efsa.europa.eu/en/events/webinar-confidentiality-assessment-and-content-sanitisation-context-transparency-regulation
- Functional mailbox to request pre-admissibility advice and to send the final result of the admissibility checks (fdp@efsa.europa.eu)

The Commission also reported on the latest developments of IUCLID presented at the Pesticide Steering Network. The main discussions with stakeholders and Authorities were focused on dossier validation business rules (which defines a valid IUCLID dossier), admissibility issues (discussed above) and the new table of content for microorganism IUCLID dossiers.

Furthermore, the Commission reminded that it is legally required to submit dossiers for active substance approval or renewal via IUCLID and that there is no legal basis to request additionally dossiers via CADDY.

In addition, the Commission mentioned that on the medium and long term it expects that in several years IUCLID would also be used as submission portal for dossiers of plant protection product authorisations since most of the data would be already in the form of IUCLID, following approval or renewal for the active substances for which the dossiers were submitted via IUCLID. This would lead to a reduction of administrative burden and reduction of duplication of work. The Commission suggests anticipating this situation and to initiate discussions, where relevant.

5. PPPAMS

The Commission informed about a meeting held on 20 September 2022 with all Member States to discuss the plans and possible implementation of PPPAMS.

Different views and concerns about implementing a full application and authorisation system were discussed – it became clear that some Member States have limits on what they can and cannot support. It was recalled that Member States were invited to provide further views and comments by 14 October 2022, which would form the basis for further reflections.

The Commission informed that, based on the discussions, it is clear that:

- The existing use of PPPAMS for managing emergency authorisations is supported and that functionality will continue – the migration to ESFC is underway and further information would be communicated to users in due course;
- In general there is agreement that having access to information on applications and authorisations would be useful and facilitate a smoother authorisation process;
- The implementation of a full system which includes application and authorisation data is challenging and some Member States currently do not support it;
- Duplication of work, compatibility with national systems and rules, as well as the overall resources needed are the key concerns.

All Member States who did not yet react, were invited to provide views and comments by 21 October 2022 at the latest.

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

- New active substances

1. *Aspergillus flavus* strain MUCL54911

The Commission informed that no news was available, as discussion between the Rapporteur Member State and the applicant is on-going on potential additional data on human toxicology.

2. Limestone

The Commission informed that limestone and Calcium Carbonate (CaCO3, already approved) are chemically the same substance and that this has been stated clearly by EFSA in the Conclusion of limestone. The Commission therefore considers pointless to have two approved active substances which are chemically identical. Consequently, the Commission intends to act in accordance with Art. 13 (1) and (2) of Regulation (EC) No 1107/2009 and to amend the entry for CaCO3 within Regulation 540/2011, adding the synonym ‘limestone’ and the CAS number for it based on all representative formulations.

- Renewal of approval

3. Aluminium ammonium sulfate

The Commission informed that one Member States had commented that this substance cannot be considered a low-risk active substance due to non-dietary

exposure issues and the need for personal protective equipment to mitigate those risks.

4. Clofentezine

   The Commission informed that so far there are no news, as internal reflections are still on-going as regards the implementation of Art 4.7.

5. Benthiavalicarb

   The Commission informed that so far there are no news, as internal reflections are still on-going as regards the implementation of Art 4.7.

   The Commission also informed that the applicant objected to the published RAC Opinion that proposed to classify benthiavalicarb as a Cat. 1B Carcinogen and Cat. 2 Toxic for Reproduction.

6. Quartz sand

   The Commission informed that quartz sand is mostly used by professionals as a game repellent. It is composed largely of the mineral quartz, the major constituent of which is silicon dioxide. Quartz Sand/silicon dioxide is a major component of nearly all mineral soils and many aquatic sediments, in some regions even of the groundwater aquifers. In the EFSA Conclusion there are neither critical concerns nor issues that could not be finalised. The Commission intends to present a first draft of a review report at the next meeting.

- Basic substances

  There was no news.

- Amendment of conditions of approval

  There was no news.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Asulam-sodium

  The Commission informed that so far there are no news, as internal reflections are still on-going as regards the implementation of Art 4.7.

  b) Isoflucypram

  The Commission informed about the main findings of the EFSA Conclusion, and that the applicant requested a meeting. The Commission highlighted the concerns:

  - The unfinished consumer risk assessment since the risk assessment residue definition in livestock, rotational and processed commodities is provisional, due to pending genotoxicity data on some metabolites (M50, M66, M67 and M77), and the storage stability during storage data for two metabolites (M01 and M06).

  - The mutagenic potential and the content of the relevant impurity BCS AA10447 (IUPAC name: N,N-dimethylcyclohexanamine). However, as for many new active substances, the toxicological profile of isoflucypram relied upon toxicity studies performed with a technical material that was different

from a commercial scale production. The applicant claims that there is no mutagenic potential and that would be in line with the ECHA data. However, checking the ECHA database and as well in the Vol 4 of the DAR, it is clearly stated that no assessment has been conducted on a European level by ECHA.

- The groundwater exposure to metabolite M12. However, this would not preclude approval since there is at least one scenario where the metabolite is below 0.1 µg/L and in addition in alkaline soils the metabolite is predicted to be less than 0.1 µg/L.

Furthermore, EFSA could not finalise the endocrine disruption properties of isoflucypram for the T-modality for humans.

Member States were requested to provide their comments by 4 November 2022, on the concerns listed above.

- Renewal of approval

c) *Pseudomonas chlororaphis* strain MA 342

The Commission informed that the draft review report proposing a renewal restricted to seed treatment uses was shared with Member States and the applicant before the meeting of this Committee. The Commission informed on the comments received from two Member States and the applicant.

The Commission invited Member States to provide their preliminary positions on this draft review report: 18 Member States indicated support, 2 Member States would not support the draft, 1 Member State would abstain, and 6 Member States had no position yet.

The Commission indicated that, since the majority of Member States supports the draft review report, it intends to propose a draft implementing act for opinion at the next meeting of this Committee.

Member States were invited to comment by 4 November 2022.

d) *Bacillus thuringiensis aizawai* strain ABTS-1857

Concerning this strain and the following ones covered by points A.05.e to A.05.k, the Commission presented the review reports and informed about the comments received from three Member States which were considered for these reports. The draft Renewal Reports were also made available to the applicants.

Member States were invited to comment by 14 November 2022, in particular as regards the proposed conditions of authorisations and restrictions of use.

e) *Bacillus thuringiensis aizawai* strain GC-91

See above point A.05.d.

f) *Bacillus thuringiensis israelensis* strain AM65-52

See above point A.05.d.

g) *Bacillus thuringiensis kurstaki* strain ABTS-351

See above point A.05.d.

h) *Bacillus thuringiensis kurstaki* strain EG2348

See above point A.05.d.

i) *Bacillus thuringiensis kurstaki* strain PB54

See above point A.05.d.

j) *Bacillus thuringiensis kurstaki* strain SA-11

See above point A.05.d.

k) *Bacillus thuringiensis kurstaki* strain SA-12

See above point A.05.d.

l) Pelargonic acid

The Commission presented a Renewal Report proposing the renewal of approval of pelargonic acid. It also informed that letters had been received from some of the applicants where they argue that this active substance should receive low-risk status.

Member States were invited to comment by 14 November 2022.

m) Rape seed oil

The Commission presented the Renewal Report and the comments received since the last meeting of this Committee. The applicant, backed up by two garden companies, argue that this active substance should receive low-risk status. The applicant argues that rape seed oil will only cause acute – and not chronic - effects.

The Member States were invited to comment by 4 November 2022.

n) Oxamyl

The Commission presented the draft review report, describing the severe dietary and non-dietary exposure issues and highlighting the overall poor quality of the submitted dossier. The Commission also reminded that the substance's approval has been extended already six time and that it is a candidate for substitution. Furthermore, the Commission also informed the participants about the meeting held with the applicant and the subsequent consultation of EFSA experts. The applicant stated that risk mitigation measures and protection factors can be applied during the application of the product to protect operators. EFSA, consulted on these issues, replied that without new data it is impossible to determine the real protection factor of the proposal of the applicant nor to accept the risk mitigation measures proposed by the applicant.

The Rapporteur Member State supports the view of the applicant.

The Member States were invited to comment by 4 November 2022.

o) *Bacillus amyloliquefaciens* QST 713

The Commission recalled that in March 2022 this Committee had discussed to send a mandate to EFSA to solve the critical area of concerns for bees as identified in the EFSA Conclusion. However, after extensive bilateral discussions among the Commission and EFSA, concluded in August 2022, the Commission prefers to move forward with a renewal which contains risk mitigation measures to bees.

The Commission stated that the draft review report is now available for comments. The draft review report has also been sent also to the applicant who disagreed about the proposed risk mitigation measures and supported the possibility that *B. amyloliquefaciens* should be considered as a low-risk active ingredient.

The Rapporteur Member State indicated that it does not agree with the restrictions, however the Commission reminded that EFSA had identified a critical area of concern for bees.

The Member States were invited to comment by 4 November 2022.

p) Rimsulfuron (short update)

The Commission informed that, following the previous meeting where the plan to mandate EFSA to finalise the Endocrine Disruptors (ED) assessment was outlined, three Member States had submitted comments. No Member State opposed the plan although one highlighted the need to carefully consider the need for restrictions or conditions to manage the risk for groundwater contamination.

Another Member State called for a decision on renewal to be taken now and for data on ED properties to be requested as confirmatory information. The Commission explained that this is not possible given the current assessment of rimsulfuron which indicates that further assessment is needed before decision making, in line with the provisions laid down in Regulation (EU) No 844/2012. One of the applicants had also provided some additional comments to address the groundwater exposure assessment for metabolite IN-70941.

The Commission confirmed that it had sent a mandate to EFSA for the completion of the ED assessment and underlined that a final decision on renewal would be taken once the ED assessment is completed. Until that time the substance would be removed from the agenda of this Committee.

q) Triflusulfuron-methyl

The Commission presented a draft Renewal Report proposing non-renewal, and shared the comments from one Member State, from the applicant, and from a stakeholder. The Commission also reported on the meeting with the applicant held in September 2022.

Member States were asked to send their positions and/or comments by 4 November 2022.

- Basic substances

r) Sodium hypochlorite

The Commission reminded that sodium hypochlorite was an approved active substance until its expiry in 2019. After this, the Commission started the evaluation process for the possible approval as basic substance.

The Commission presented the draft Review Report for an approval of sodium hypochlorite as a basic substance. The Commission explained that sodium hypochlorite is classified as causing severe skin burn and eye damage, as well as severe chronic and acute toxicity to aquatic organisms. After discussions, the applicant agreed to change the application to a final solution that contains <1%

sodium hypochlorite. By diluting the substance, the criteria for classification and labelling are no longer met, and according to the applicant it should still be effective at this concentration for the proposed uses.

In the application, two uses are proposed: 1) as seed treatment on vegetables, ornamentals and arable crops against fungi other than *Phytiaceae* and seedlings diseases and 2) on mushrooms against bacterial blotch.

With regard to residues in food and feed, chlorate could be an issue resulting from the use of sodium hypochlorite as a plant protection product. For the seed treatment use, EFSA considers that, if the seeds are rinsed before planting, it is highly unlikely that the chlorate coming from the use of sodium hypochlorite as a basic substance would significantly contribute to the human exposure through food. However, according to EFSA, the potential occurrence of residues of chlorate from the use on mushrooms needs to be further assessed.

When the seeds are rinsed at least 3 times with 5 to 10 litres of water/kg seeds or an abundant rinse under water flow with clean water, after which the seeds are dried, EFSA concluded on a low risk for non-target organisms as well as for environmental fate and behaviour.

The proposed approval is only valid for the use of sodium hypochlorite in seed treatments. The use on mushrooms cannot be accepted based on the available information concerning the potential residues of chlorate on mushrooms.

The applicant intends to send an updated application as quickly as possible.

Two Member States doubted the presence on the market of a solution of sodium hypochlorite of <1%. One Member States requested to also mention the concentration of the substance in “degrees” instead of only “percentages”. Another Member State asked the Commission whether it was considered that the water used for the rinsing of the seeds also possibly contains sodium hypochlorite.

The Commission indicated it will reflect on the questions raised.

Member States were invited to comment by 4 November 2022.

s) Chitosan hydrochloride

The Commission gave a short update on the dossier. Three Member States provided comments agreeing that the GAP table in the Review Report of chitosan hydrochloride should be clarified. They think that for the proposed extension of use to hops and fruit trees in nurseries the additional information should be submitted and that a further evaluation should be performed before an approval can be granted.

The Commission mentioned that the risk envelope of the approved uses of the substance chitosan (which has been recently approved and is considered comparable to chitosan hydrochloride) seems to cover the uses requested in the extension. Additionally, it seems that the instructions for use of chitosan hydrochloride, which are available on the national websites, are inconsistent and some of them include the use on fruit trees. Finally, the Commission reminded that the revision of the approval of chitosan hydrochloride and chitosan has already been launched and this process will provide an opportunity to better define the list of approved safe uses soon.

Member States were asked to comment by 4 November 2022 as regards (a) their positions on approval of the requested extension of use of chitosan hydrochloride (to hops; fruit, small fruit and berries in nursery and orchards; managed amenity turf) as basic substance and (b) the need for a full risk assessment by EFSA; (c) comments on the update of the GAP table in the Review Report for chitosan hydrochloride to include EPPO codes, in particular to replace "fruits berries and small fruit" with the non-taxonomic code "fruit crops" 3 FRUC.

A.06 Confirmatory Information:

1. Propyzamide (amended Renewal Report to endorse)

   The Commission informed that the Renewal Report had been further updated. In addition to the elements discussed previously, the report was reformulated to ensure the reasoning is more concise and reflects all relevant elements. The Commission also explained that it has responded to a letter from PAN on the topic.

   The Commission explained why it was important to agree on the report, to ensure a stable base for ongoing regulatory processes – renewal of approval, product evaluations and MRL assessments.

   Member States endorsed the updated Renewal Report.

2. Pendimethalin

   The Commission informed that it is finalising a mandate to EFSA and ECHA as a follow up of the EFSA report on the confirmatory data and the potential for bioaccumulation. In the mandate, the agencies will be asked to jointly provide advice on how to derive bioconcentration factor (BCF) values to be used for regulatory purposes considering a weight of evidence approach when experimental data from more than one species are available. In addition, for closing the confirmatory information, the Commission will mandate EFSA to address the four specific points identified in the EFSA Technical Report.

3. Plant oils

   The Commission presented an overview table for the confirmatory data for the plant oils geraniol, eugenol, thymol, clove oil and orange oil.

   Member States were invited to comment on that table by 14 November 2022.

4. Thiabendazole

   The Commission informed that considering the similarities of the files, it intends to follow a similar procedure as for acibenzolar-s-methyl, i.e., to trigger an article 21 procedure and therefore give 3 months' time to the applicant for commenting. The applicant at that point should be able to outline which additional studies they have available or plan to carry out. After this 3-month period is concluded, 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 criteria under Regulation (EU) 2018/605.

   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 then mandate EFSA and the Rapporteur Member State to assess the submitted data and come to a final view on whether the substance has ED

properties or not. If found necessary, the Commission would eventually amend or withdraw the approval accordingly.

Member States were invited to comment on this proposed procedure by 4 November 2022.

5. Flutianil

The Commission informed that there is currently a discussion among EFSA and the applicant about the MTC (maximum tolerated concentration) in AMA and FSTRA studies linked to limit of solubility in water. EFSA informed that, based on all the information and the expert discussions, it was not possible to draw a robust conclusion on whether the hazard was properly characterised for flutianil. In particular, it was agreed that, in the first instance, it could be further demonstrated that it is not possible to test higher concentrations than the limit of solubility in water, by using proper solvents.

A.07 Guidance Documents:

The Commission referred to the prioritisation of guidance document, for which two documents were presented at the last meeting of this Committee which were consulted with stakeholder associations. Comments were received for International Biocontrol Manufacturers Association (IBMA), Crop Life Europe (CLE) and European Crop Care Association (ECCA). The Commission informed that updated versions of the documents are intended to be presented for endorsement at the next meeting of this Committee.

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

The point was postponed.

2. 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 the Committee that 220 comments have been submitted by Member States and stakeholders because of the second consultation. The Commission will consider those comments into account before finalizing the draft Communications for launching the Interservice Consultation.

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

The Commission informed that a stakeholder's consultation has been conducted on two Communications from the Commission in the framework of the new data requirements on micro-organisms. The Commission informed that the Interservice Consultation is about to be launched.

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

The Commission informed that the public consultation, organised by the EFSA on the draft updated Guidance Document, ended on 3 October 2022. All comments received are publicly available and can be consulted via https://open.efsa.europa.eu/consultations/a0c7U000001MVM9QAO?search=bee

A joint workshop was held by EFSA and the Commission on 5 October 2022 with Member States and stakeholders to discuss their comments on the draft. The

Commission clarified its intention to publish the report of this workshop on its website in the coming weeks.

The EFSA will now carefully consider all comments received and expects to finalise the revised Guidance Document in the first half of 2023. Afterwards the Commission will seek endorsement and prepare the necessary implementing legislation without delay. The Commission clarified on request of a Member State that the necessary acts for endorsement will be decided once the final revised Bee Guidance Document is available.

One Member State asked for a clarification on the specific protection goal (SPG) for wild bees. The Commission acknowledged the need to ensure a harmonised understanding of the SPG for wild bees during the endorsement phase of the revised Guidance Document. The Commission does not regard 'aged residue' studies with non-target arthropods as falling under the lower tier risk assessment.

5. 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.

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

1. Article 44(4)

   The Commission informed that it had received one notification since the last meeting of this Committee on an amendment of an authorisation of a dodine based product. The amendment was due to the exceedance of the MRL of dodine in honey. The authorisation holder was suggested to apply for an amendment of the MRL.

2. Article 36(3)

   The Commission informed about the eight notifications received since the last meeting of this Committee: six notifications concerned rejections of mutual recognition applications and two concerned rejections of authorisation under the zonal system. One of the decisions was challenged at national level, however it was dismissed.

3. Article 53

   The Commission informed that it intends to send a follow-up mandate to EFSA to evaluate the emergency authorisations granted for the no longer approved neonicotinoid active substances for the use in sugar beet during the 2022 growing season. The mandate will also include a request to develop an updated protocol to evaluate Article 53 - emergency authorisations in plant protection.

A.09 Microorganism Active Substances:

The Commission informed that the four Regulations amending data requirements, uniform principles and decision-making criteria on micro-organisms have been adopted by the Commission on 31st August 2022. They will enter applicability in November 2022.

The Commission highlighted that other initiatives are on-going and under planning to support the implementation and harmonised interpretation of these Regulations.

A.10 Safeners and Synergists:

The Commission informed on the progress on the draft Commission Regulation and of the working group that is discussing on the data requirements which should be listed in the annex of that Regulation for the approval of these substances.

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

1. Sodium hydrogen carbonate (no news)

   There was no news to discuss.

2. Acetamiprid

   The Commission informed that a mandate was submitted to EFSA to 1) re-evaluate the toxicological properties of this active substance and its metabolites; 2) re-evaluate the residue definitions for this substance in plant protection products; and 3) perform a targeted review of maximum residue levels (MRLs). The outcome of the mandate is expected by July 2023.

A.12 Article 21:

1. Ipconazole

   The Commission informed that it had written to the applicant in early September setting out reasons for the withdrawal of the approval. The applicant provided some initial reactions but asked for extra time to provide full comments, which was granted by the Commission. It was explained that once comments have been received, the Commission will carefully consider them before deciding how to proceed.

   The Commission also informed Member States about some exchanges with the Rapporteur Member State (RMS) for the ongoing renewal procedure, in view of understanding the current status and any conclusions reached by the RMS so far.

2. Acibenzolar-methyl

   The Commission informed that a review on the approval under Article 21 was initiated to evaluate if the active substances fulfil the criteria to identify endocrine disrupting properties, and the applicant proposed a plan with a deadline to submit additional studies plus summary reports of some finalized studies.

3. Flupyradifurone

   The Commission informed that a review on the approval of flupyradifurone under Article 21 was initiated. A letter was submitted to the authorisation holder with a request to provide by the end of 2022 all the data they have on the effects of flupyradifurone on bees as well as an evaluation of the relevant scientific literature. This data and information will be evaluated by the same Rapporteur Member State of the renewal.

A.13 General issues for information / discussion:

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

   a) Scope Document rev. 70 and new cases

The Commission informed that two comments from Member States, confirming the latest proposed entries, were integrated in the new version of the Scope Document which was re-published on the Commission website.

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 presented the arguments supported by scientific studies showing that phosphonates have been demonstrated as bearing (also) plant biostimulant functionalities. Therefore, an amendment of the restriction of use in the Fertilising Products Regulation (EU) 2019/1009 could be envisaged.

Member States were invited to comment by 14 November 2022 concerning this proposal for amendment to allow phosphonates only in plant biostimulants and only when they are intentionally added.

2. Basic substances – general issues

The Commission informed on the comments received from three Member States concerning current practices on labelling of basic substances and the management of the products containing basic substances as requested during the last meeting.

Given the low number of the comments received so far, the Commission called on the remaining Member States to submit their comments on the above-mentioned topics by 14 November 2022.

3. MS updated survey on timing of regulatory procedures

The Commission informed that the report is published on its website: https://food.ec.europa.eu/system/files/2022-09/pesticides_ppp_report_ms-survey_regulatory-procedures-timing_2017-20_0.pdf

4. Incidents with phosphine products

The Commission summarised the issue on the risks related to the transhipments of cargos treated with phosphine-releasing products. The Netherlands described the discussions with the major companies producing those products. The Commission reported on the discussion held with one of the major producers, who does not agree with the Netherlands on its request to amend all the authorisations of phosphine-releasing products. The company would prefer the burden of keeping an acceptable risk to be on the Member States' enforcements.

The Commission informed that the renewal of the approval of the three phosphine-releasing active substances is planned in 2023 and 2024. The Rapporteur Member State for the three substances informed that they intend to include risk mitigation and instruction of use suggestions in the Renewal Assessment Report.

The Commission indicated that it would reflect on the way forward.

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

The Commission presented an updated inventory on needed test guidelines for pollinators which considered the comments received from one Member State. That Member State also requested support from other Member States for the procedure

at OECD for the ring tested protocols for the chronic oral toxicity for both bumblebees and solitary bees to become official OECD test guidelines.

The current inventory focusses on chemical pesticides but a separate inventory may be necessary for microbial pesticides. The Commission will follow-up on a symposium from the International Commission for Plant Pollinator Relationships (ICPPR) and with EFSA to further complete the inventory of test guidelines needed.

Member States were invited to comment by 14 November 2022 on the inventory and to indicate their availability to support the official programme of OECD for the recognition of test guidelines.

6. Report from workshop on crop protection measures and pollinator protection (7 April 2022) / Review of Pollinator Initiative

   The Commission informed about further comments received from two Member States, generally supporting the measures identified in the workshop.
   The Commission informed, that the revision of the pollinator initiative will be finished by the end of 2022. A dedicated homepage of DG Environment provides information and updates about: EU Pollinators Initiative - Environment - European Commission (europa.eu).

   The Commission will update the Committee about any progress there.

7. Long term toxicity effects of formulations

   The Commission informed about the letter of the ENVI Committee of the European Parliament to Commissioner Kyriakides, the EFSA report on co-formulants, and shared the revised overview based on Member States information as regards the current practices how Member States evaluate long-term toxicity of the plant protection products. The Commission pointed out some further actions:

   1) Possible update of the guidance document "Zonal Evaluation and Mutual Recognition" addressing the cases where insufficient information is provided by applicants on the aspect of long-term toxicity for co-formulants/mixture,
   2) possible update of the template for the draft Registration Report to ensure that the assessments are reported in a consistent way in view of ensuring more transparency
   3) continue the discussion with Member States and EFSA on this subject

   Member States were invited to send their comments and inputs by 14 November 2022, in particular on the following questions:

   - Do you systematically check the registrations for co-formulants under REACH to determine their hazard properties?
   - In how many cases have you requested further studies on a co-formulant and/or on the whole product?
   - Do you have a list of co-formulants that are authorised in PPPs on your market?

8. Residues on cut-flowers

   The Commission informed that the proposal suggested by one Member State to address the potential risks posed by pesticide residues on flowers to florists, by developing a methodology for dermal absorption studies for dried residues, was supported by another Member State, which also suggested that it could be addressed

by legally expanding the scope of MRL's in Europe to include the residues on ornamentals, stopping at the same time the imports of plants or flowers treated with active substances which are not authorized within the EU.

The Commission indicated it is still reflecting on the best way forward.

9. Pheromones

The Commission informed about the discussions at the Biopesticides Working Group and about the recent exchange with industry concerning existing regulatory approaches in Chile and USA. The Commission confirmed that it will keep looking for the best way forward to proceed with the proposal made by one Member State at previous meetings of this Committee, to extend the approach from SCLP to other semiochemicals.

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

The Commission reported about the comments received from Member States concerning the draft presented at last meeting.

The Commission asked the Member States to reply to four questions presented during the meeting and to comment to the draft Regulation by 4 November 2022.

A.15 Coformulants, in particular:

1. unacceptable co-formulants (mono/polymers and unacceptable concentrations)

The Commission informed that an initial discussion had been started in the PPP Working Group, where one Member State submitted a proposal for regulating the use of mono- and polymers as coformulant.

One comment had been received from another Member State which agrees that information on the content of the monomer in a co-formulant that is a polymer should be requested in case it is suspected that it exceeds the relevant concentration limits, according to Regulation (EC) No 1272/2008 (CLP) or Commission Regulation (EU) 2021/383. At the same time, residual monomers in co-formulants that are polymers should be evaluated in the same way as other impurities and that additional information on the polymer (or tests with the product) could be requested only when it is presumed to be toxicologically relevant.

The Commission reminded also that a similar discussion is currently ongoing in a more general way, under the evaluation for regulating the use of intentionally added micro-plastic in the context of Regulation (EC) No 1907/2006 (REACH).

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

There were no news to report.

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

The Commission informed that comments were received from 11 Member States and 6 stakeholders on the draft document "Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009: a method to identify scenarios of limited environmental impacts". In addition, 23 case studies

were provided by Member States and stakeholders. The Commission is reflecting with the WG on the next steps.

Regarding Risk Mitigation Measures (RMM), the Commission informed that a draft document "Compendium/list of technical use and application conditions for plant protection products" is being discussed in the WG.

3. Working Group Post Approval Issues

The Commission informed about the last meeting of the Post Approval Issues Working Group held on 14 and 15 September 2022. The main points debated were: the way to handle at product level the data gaps identified in EFSA conclusions and the possible amendment of the Guidance Document on new active substance data post-(renewal of) approval, the legal entities such as applicants and producers located in third countries (such as in the United Kingdom), ways to handle the authorisations when contain cut-off substances in the best harmonised way, the new application techniques and the new routes of exposure that need to be incorporated in the risk assessment, exchange of experiences when using IUCLID, its adaptation to microorganisms dossiers and the activities behind the low quality of the dossiers, among others.

4. Working Group on PPP Formulation Analysis

The Commission informed that the minutes of the meeting were under preparation by the organising Member State and that Member States asked for yearly meetings of this Working Group. In addition, Member States had also requested that EFSA foresees a meeting on active substances to be held in 2023, with a similar outline as it was done in the past.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

EFSA informed about the planning for the next peer review expert meetings and the progress in the peer review of active substances, in particular also the peer review on glyphosate.

EFSA also gave an overview on the assessment of active substance in accordance with the new criteria to identity endocrine disruption properties which became applicable in November 2018, including the active substances to which an ED-stop the clock applies, and referred to the regularly updated report published on their website (https://www.efsa.europa.eu/en/applications/pesticides).

EFSA referred to a Technical report on co-formulants published in August (https://www.efsa.europa.eu/en/supporting/pub/en-7547) for which discussions were initiated at the Pesticide Network Meeting in October, and informed about the progress on the on-going mandates mentioning in particular the adopted opinion on common pyrethroid metabolites.

Finally, EFSA informed about the status of the number of IUCLID dossiers received so far and mentioned the Pesticide Steering Network on IUCLID which took place the 20 October 2022.

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

There was no news.

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

   There was no news.

4. Minor Use Facility (MUCF)

   The Minor Use Coordiantion Facility (MUCF) informed that it held meetings in the beginning of October 2022 in Brussels with commodity experts and horizontal experts (Horizontal Expert Working Group, HEG). Over 2.5 days, more than 100 European experts met and exchanged views on minor use issues and solutions. There was a plenary session on low-risk and basic substances.

   At the HEG it was decided to explore the possibility of establishing criteria for a European harmonised "definition of a minor crop" in a HEG sub-working group and to supplement the “Explanatory Note on minor uses” with an addendum containing a template for a simplified draft registration report Part A. It was also decided to set up a new MUCF working group to investigate proposals for new residue extrapolation possibilities. This working group would like to reach out to residue experts to participate in this working group in 2023 (residue experts who would like to contribute to this work should please contact the MUCF).

5. OECD, FAO and EPPO activities

   The Commission informed about the latest activities regarding biopesticides (September Conference on innovative microbial pesticides testing, start of work on consensus documents on *Beauveria* and *Bacillus amyloliquefaciens*), regarding drones WG (launch of in-field study) and concerning two surveys (e-labelling, exposure assessment guidances).

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

The Commission provided an overview on a Court decision of 14 September 2022 in Joined Cases T-371/20 and T-554/20, Pollinis France vs. European Commission. The Member States were invited to comment on the decision by 28 October 2022.

Moreover, the Committee was informed about delivery of Advocate-General Kokott’s opinion in Case -162/12, “Pesticide Action Network Europe and Others” of 8 September 2022.

Finally, the Commission informed that its reply to an NGO to an internal review request under the Aarhus Regulation had been challenged by that NGO: T-536/22 - Pesticide Action Network Europe vs European Commission: Action for annulment of Commission reply to the Applicant’s request for internal review of Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021 renewing the approval of the active substance cypermethrin as a candidate for substitution in accordance with Regulation (EC) No 1107/2009.

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

- possible impact on authorisations

The Commission explained its intention to send to EFSA a mandate for a risk assessment of the Maximum Residue Levels (MRLs) for **oxamyl** using the new lower Toxicological Reference Values (TRVs) derived by EFSA during the peer review following the application for renewal of this active substance and including considerations for setting Limits of Quantification (LOQ) lower than 0.01 mg/kg to

ensure consumer protection. The Commission explained that such mandate would usually be carried out after the finalisation of the renewal process and once the new TRVs are published as part of the Renewal Report endorsed by this Committee. However, in view of the risks for consumers identified by EFSA during its peer review, the Commission considered preferrable to initiate work on the MRLs without delay and asked Member States to confirm already their support for the new TRVs.

In case they would have any objections on the new TRVs, Member States were invited to express them by 21 October 2022.

The Commission also informed about the update of **toxicological reference values (TRV) of thiophanate-methyl**. In a recent EFSA Reasoned Opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl, EFSA proposed revising the toxicological reference values for thiophanate-methyl that were established by Commission Directive 2005/53/EC. The new reference values recommended are as follows:

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

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

The Commission is now 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. Before proceeding, the new TRVs need to be endorsed by this Committee soon.

Lastly, 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 26-27 September 2022, which may have an impact on the authorisation of plant protection products.

Substance	Type of change
1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM) (i.e., a main metabolite of penthiopyrad)	MRLS were set for products of animal origin, not relevant for products of plant origin
Beta-cyfluthrin and cyfluthrin	MRLs were lowered.
Cycloxydim	MRLs were lowered and the residue definition was amended.
Cyflumetofen	MRLs were lowered and the residue definition was amended.
Metobromuron	MRLs were lowered and the residue definition was amended
Penthiopyrad	MRLs were lowered and the residue definition was amended
Abamectin	MRLs were lowered.
Clothianidin	MRLs were lowered (environmental concerns of global nature).
Thiamethoxam	MRLs were lowered (environmental concerns of global nature).
Cyromazine	MRLs were lowered.
Topramezone	MRLs were lowered.
Triflumizole	MRLs were lowered.
Benalaxyl	MRLs were lowered.
Bromoxynil	MRLs were lowered.
Chlorsulfuron	MRLs were lowered.
Epoxiconazole	MRLs were lowered.
Fenamiphos	MRLs were lowered.
Chlorpropham	MRLs were lowered.
DDAC	MRLs were lowered.
Flutriafol	MRLs were lowered.
Metazachlor	MRLs were lowered.
Nicotine	MRLs were lowered.
Profenofos	MRLs were lowered.
Quizalofop-P	MRLs were lowered.
Sodium aluminium silicate	MRLs were lowered (active substance moved out of Annex IV to Annex V)
Thiabendazole	MRLs were lowered.
Triadimenol	MRLs were lowered.

A.20 Scientific publications and information submitted by stakeholders:

The Commission referred to four letters received from Crop Life Europe and one letter received from Pesticide Action Network.

A.21 Date of next meeting(s).

The Commission informed that the next meeting is confirmed for the 8 and 9 of December 2022, and that the meetings for 2023 are scheduled for 25/26 January, 22/23 March, 24/25 May, 11/12 July, 12/13 October, and 11/12 December.

A.22 AoB.

The following points were additionally raised:

- Tolclophos methyl: The Commission explained the request of the Rapporteur Member State (RMS) concerning the necessary update of the technical specification of tolcophos-methyl post renewal of the approval. Despite the increase of the concentration of the relevant impurity, methanol, between the pilot scale and the full-scale production, the RMS assessed it as acceptable. Nevertheless, this amendment requires a review of the conditions of approval in accordance with Article 21 of Regulation (EC) No 1107/2009. RMS was therefore invited to send the addendum to the DAR for comments of the applicant, Member States and EFSA.

  The recommended procedure implements the provisions of the guidance document SANCO/10328/2004– rev 9. However, the Commission indicated that the peer-review should likely not be necessary for such simple case.

  At the same time, the Commission recommended to withdraw the draft guidance SANCO/6075/2009 which appears to be obsolete.

- Comparative risk assessment: The Commission recalled that discussions took place during 2021 during two meetings with Member States Competent Authorities and dedicated experts to simplify the comparative assessment during the product authorisation.

  During the first meeting, the main difficulties that prevent the substitution were presented by experts of the three regulatory zones and after the second meeting a survey was circulated to gather the main actions suggested by Member States as regards Annex IV of Regulation (EC) No. 1107/2009 and the Guidance Document on Comparative Assessment and Substitution (SANCO/11507/2013 rev. 12). Many countries shared public sites where non-chemical and prevention methods are publicly available.

  The Commission is currently reflecting how to move forwards.

- The Commission gave an overview of the current activities as regards the update of REACH and CLP regulation, in the context of the Chemical Strategy.

- The Commission informed about a new admissible European Citizen Initiative "Save bees and farmers! Towards a bee-friendly agriculture for a healthy environment". It has reached over one million statements of support from EU citizens. The initiative calls on the Commission to propose legal measures to phase out synthetic pesticides by 2035, to restore biodiversity and to support farmers in this transition. The Commission has until 7 April 2023 to present its official reply.

- The Commission asked Member States to provide by 4 November 2022 a full list of the plant protection products they have authorised which contain microorganisms as active substances, and which are the concentrations of the active substances in the respective plant protection products.

- One Member State expressed interest to work on guidance documents on non-target plants, groundwater metabolites, and amphibians and reptiles. The Commission thanked for the offer and suggested to discuss this in the context of the prioritisation of guidance documents.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate.

(PLAN/2022/1620 CIS)

The Commission presented the draft Regulation, recalling the reason for the delay in the peer review process for glyphosate as explained in the previous meetings held in May and July 2022, following the announcement by EFSA and ECHA.

The Committee was reminded that in cases where **for reasons beyond the control of the applicant**, it appears that the approval is likely to expire before a decision has been taken on renewal, Article 17 of Regulation (EC) No 1107/2009 provides that the Commission must prolong the approval for a period sufficient to complete the renewal assessment. Accordingly, given that additional time was/is required by the AGG and EFSA to carry out a full assessment and peer review and so far, neither the AGG, ECHA or EFSA have identified evidence demonstrating that glyphosate no longer fulfils the approval criteria laid down in Regulation 1107/2009, there is a clear legal obligation to extend the approval, which should be respected by all.

The Commission underlined that the extension is without prejudice to the future decision on whether the approval of glyphosate can be renewed or not, which will have to be taken once the evaluation and peer-review is completed.

Six Member States indicted that they did not support the presented act.

One Member State indicated support but expressed criticism about the delay and called for a shorter period of extension (6 months) and only for some uses to be permitted (excluding use on permeable and sealed surfaces and as a desiccant). Another Member State indicated it would make a protocol declaration (see below).

The Commission proceeded to vote during the meeting.

Vote taken: No opinion.

The Netherlands made the following protocol declaration:

We agree with the extension of approval, but at the same time we want to appeal to the Commission that it is ensured that no further delays will occur, and a decision can be made as soon as possible.

The Commission informed Member States that it would refer the measure to the Appeal Committee for further deliberation, in accordance with the comitology rules.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance fish 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10076/2022).

(SANTE/10074/2022)

The Commission presented a slightly amended version of the annex of the draft implementing regulation which takes into consideration the comment received by one Member State during the last meeting of this Committee in July 2022. The Commission proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Pythium oligandrum* strain M1 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/10332/2021).

(SANTE/10330/2021)

The Commission presented the draft implementing act and informed about the slight amendment introduced via the inter-services consultation compared to the proposal presented at the meeting in July.

Two Member States expressed some concern regarding the renewal of the approval from a human health perspective due to the many existing data gaps, and due to the evaluation of the pathogenicity and the consumer risk assessment which, in their views, cannot be finalised.

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 low-risk active substance heptamaloxyloglucan 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10198/2022).

(SANTE/10196/2022)

The Commission recalled about the discussion on the regulatory scope of this active substance which took place during the last meetings of this Committee. After consultation with DG GROW (responsible of the Regulation on fertilisers) and academia and taking into account the comments of the applicants and Member States, the substance was confirmed to be a phytopharmaceutical substance because its mode of action does not influence the nutritional processes of the plants. The Commission also reminded about the low-risk nature of the active substance. 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) as regards the content and format of the records of plant protection products to be 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 draft Implementing Regulation, which was updated on the basis of the comments that were received from other Commission services during the interservice consultation and from the Member States.

Some Member States commented that some of the data that is envisioned to be recorded (e.g. time of use, use of BBCH codes) 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.

In particular, some Member States stated that they do not consider sowing of treated seed to be use of plant protection products. This view was opposed by other Member States.

The Commission reiterated its position that sowing of seeds is use of plant protection products and that it should be recorded as it is significant with respect of protection of human health and the environment. It suggested that the Implementing Regulation is adopted with the requirement to record sowing of seeds treated with plant protection products. If at any stage before its entry into force of the act emerges that sowing is outside of scope of Article 67(1) the Implementing Regulation shall be amended accordingly.

The Commission informed that it had received a letter from non-governmental organisations in support of the adoption of the Implementing regulation. It has been provided to the members of this Committee.

Member States were invited to comment on the draft and to inform on their position by 4 November 2022. The Commission further informed that it still aims to adopt the act by the end of 2022.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) setting rules and procedures according to Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market as regards the identification of unacceptable co-formulants in plant protection products.

(SANTE/10226/2022)

The Commission presented the draft Implementing Regulation emphasising the fact that this latest version was the result of the interservice consultation, and that several changes had been implemented since the last time this draft was presented to the Member States in July 2022. However, these changes and additions had been done to increase the readability and consistency of the text and to clarify the legal obligations but that, in substantial, nothing was changed. The Commission also informed that the four-week public consultation will be launched soon.

C.03 Exchange of views 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 informed about the revised draft review report and Implementing Regulation. Those documents were slightly amended to reflect the finding of a mandate as described in the EFSA conclusion 2022. Although two out of three metabolites were found to be less toxic then initially assessed, a high risk to several groups of non-target organisms was confirmed by EFSA in ecotoxicology in relation with the parent compound and the third metabolite.

The Commission informed that it intends to present a draft for opinion in the December 2022 meeting. Member States were requested to comment by 4 November 2022.

C.04 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 it seeks a non-approval of *Yucca schidigera* extract as a basic substance, based on the data gaps identified in most of the areas of the risk assessment and a risk for aquatic organisms. The EFSA provided feedback on the comments of the applicant concerning the EFSA's Technical Report. Overall, the information submitted by the applicant could not change the outcome of the evaluation summarised in the Technical Report.

The Commission informed on the intention to consider the outcome of the evaluation of the *Yucca schidigera* extract as a new feed additive that is due in November 2022, before the final vote on the current proposal on non-approval as basic substance takes place.

Member States were invited to comment by 14 November 2022.

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 extensive comments submitted by the applicant arguing against the non-approval proposal. The position of the Rapporteur Member States and EFSA concerning these comments were presented in detail. The relationship with the ongoing renewal process of the racemate napropamid, were also explained.

The Commission invited Member States to comment by 4 November 2022.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12270/2020).

(SANTE/12268/2020)

The Commission informed about the draft Implementing Regulation and the revised draft review report which was slightly amended to reflect the comments received by the Member States. The Commission also indicated to have received more than 40 letters from fruit producers who were asking to renew the approval for field uses of captan.

Few Member States commented on the importance of captan in orchard cultivations and asked the Commission to revise the proposal. The Commission explained that based on the EFSA Conclusion only greenhouse uses were safe and that high risk to several groups of non-target organisms was confirmed in ecotoxicology by EFSA, who also informed the Commission that no refinement of those risks was possible without new data. Furthermore, the Commission referred to the possibility to amend conditions of approval (Article 7 of Regulation 1107/2009) which, with the help of the interested parties, may allow a quick amendment of the condition of approval.

Additionally, the Commission stated that it intends to present a draft for opinion in the first quarter of 2023. Member States were invited to comment by 14 November 2022.

C.07 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 informed about the revised draft review report and the draft Implementing Regulation which were slightly amended to reflect the finding of a mandate as described in the EFSA conclusion 2022. The re-assessment of the uses at the lower concentration in the GAP table, identified a safe use in permanent greenhouses. However, a high risk to several groups of non-target organisms was confirmed in ecotoxicology in the updated EFSA conclusion for all the other uses. Furthermore, the Commission informed that it intends to present a draft for opinion in the first quarter of 2023.

Few Member States commented on the importance of this active substance on field applications and in trunk injection applications as insecticide. The Commission recalled the possibility of applications under Article 7 of Regulation 1107/2009 which, with the help of the interested parties, may allow a quick amendment of the condition of approval.

Member States were invited to comment by 14 November 2022.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance *Trichoderma atroviride* strain AGR2 as a low-risk 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1837 RR).

(PLAN/2022/1837 CIS)

The Commission presented the review report and draft legal act and recalled that most of the comments received were in favour of the low-risk status.

One Member State requested clarifications about the production of secondary metabolites at manufacturing site and in situ.

The Commission indicated it intends to present a draft for opinion at the next meeting of this Committee and invited Member States to comment by 4 November 2022.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance *Trichoderma atroviride* strain AT10 as a low-risk 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1616 RR).

(PLAN/2022/1616 CIS)

The Commission presented the review report and draft legal act and recalled that most of the comments received were in favour of the low-risk status.

One Member State requested clarifications about the production of secondary metabolites at manufacturing site and in situ.

The Commission indicated it intends to present a draft for opinion at the next meeting of this Committee and invited Member States to comment by 4 November 2022.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of hydrogen peroxide silver-stabilised 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)

The point was postponed.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of lemon 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 made available to the Member States the drafts of the regulation and the review report prepared in a view of a non-approval of a lemon essential oil as basic substance. The main hazard related to this substance is the presence of d-limonene. The non-approval is proposed because the available data is not sufficient to demonstrate acceptable non-dietary risk and acceptable risk to non-target organisms. Based on the comments received so far from the Member States, the proposal will be supported.

The Commission indicated it intends to present a draft for opinion at the next meeting of this Committee and invited Member States to comment by 4 November 2022.