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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
14 - 15 July 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/b4fe15da-969e-48c2-bbc1-b95867359841*

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary reports of the meetings of this Committee which took place in March and May are in preparation.

A.02 New applications, in particular basic substances:

- Chitosan hydrochloride extension of use

The Commission informed that the revision of the approval of chitosan and chitosan hydrochloride as basic substance had been launched, as requested by two Member States. The scope of the revision covers the environmental exposure assessment and the risk to non-target organisms including bees. The applicant responsible of the approval and the ones responsible for extensions of use about the revision of the approval were invited to submit relevant information by 30 October 2022.

The Commission also informed that there is a new application for an extension of use of chitosan hydrochloride concerning additional uses on hops, fruit trees in nurseries and amenity turf. EFSA confirmed that these uses fall within the risk envelope of the uses currently approved. The Commission explained that the Good Agricultural Practice (GAP) table included in the Review Report of chitosan hydrochloride may lead to different interpretations. Therefore, the Commission intends to update the GAP table using the European and Mediterranean Plant Protection Organization (EPPO) codes to describe the list of crops of the approved uses. The Commission proposed to proceed with the evaluation of this new application for an extension of use in parallel with the revision of an approval of chitosan hydrochloride.

Member States were invited to comment by 9 September 2022 on the procedure to be employed for the evaluation of this application: a procedure based on risk envelope vs. a standard procedure asking EFSA for Technical Report. Member States were also invited to comment as regards the update of GAP table in the Review Report for chitosan hydrochloride to include EPPO codes.

A.03 General issues on approval and renewal of approval processes, in particular:

- financial assistance to Member States in the context of Plant Protection Products (PPP) and Biocides Product Regulation between 2023-2027

The Commission informed about the workshop organised by DG SANTE in the context of the Plant Protection Products Regulation and the Biocidal Products Regulation, that took place on 3 June 2022 and in which Member States, the European Food Safety Agency (EFSA), the European Chemical Agency (ECHA), and the European Health and Digital Executive Agency (HADEA) participated. During the workshop, the Commission presented its intention for a call for grants aiming to reduce delays in regulatory processes in Member States. During the workshop, the Commission also mentioned the conditions that Member States would need to fulfil to be eligible for these grants. The Commission explained the procedural steps, in particular that the Permanent Representations of the Member States will need to appoint the relevant entities that will subsequently receive an invitation from HADEA to submit an application for the call once it is open.

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

The Commission informed that eleven Member States expressed their preferences to act as Rapporteur or Co-Rapporteur Member State of the active substances for which a renewal application would need be submitted between 31 January 2026 and 1 October 2032. Member States that did not react were invited to send their preferences by 2 September 2022.

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

- New active substances

1. *Aspergillus flavus* strain MUCL54911

   The Commission explained that there are still uncertainties on human pathogenicity and the possible production on toxins by this fungus. The Commission informed that the applicant had generated new data which would prove absence of toxigenicity. However, these data were not included in the dossier and therefore cannot be taken into account for decision-making unless it is reviewed by risk assessors. Since *Aspergillus flavus* MUCL54911 is a new active substance this would be possible and the Rapporteur Member State informed that it would be available to evaluate this new data and to include it into a revised Rapporteur Assessment Report (RAR).

2. *Trichoderma atroviride* strain AGR2

   The Commission presented the main considerations as regards a possible low risk status of this active substance. One Member State reacted supporting the Commission.

   Member States were invited to comment on the draft review report by 2 September 2022.

3. *Trichoderma atroviride* strain AT10

   The Commission presented the main considerations as regards a possible low risk status of this active substance. One Member State reacted supporting the Commission.

   Member States were invited to comment on the draft review report by 2 September 2022.

4. Limestone

   The Commission reminded that according to the EFSA conclusion of limestone, limestone and calcium carbonate – an already approved active substance - should be considered the same substance. In view of this, the Commission explained the regulatory possibilities to proceed, and Member States were invited to comment by 2 September 2022.

5. Isoflucypram

   The Commission summarised the outcome of the EFSA conclusion. Member States were invited to comment by 2 September 2022.

- Renewal of approval

6. Oxamyl

   The Commission explained that EFSA identified concerns as regards the operator exposure for all the representative uses which would indicate a non-renewal. The Rapporteur Member State stated that in its view the safety factor of 1000 is too conservative and that there is a possibility of a safe use for drip irrigation. The Commission explained that no Developmental Neurotoxicity study was submitted in the dossier and stressed the overall high toxicity of the substance, which if renewed would be a candidate for substitution. The Commission also explained that EFSA considers the refinement proposed by the applicant for the assessment of the drip irrigation use unable to solve the issue of the operator acute exposure.

   Member States were invited to comment by 2 September 2022.

7. Triflusulfuron-methyl

   The Commission shared one comment received from a Member State as regards the EFSA Conclusion. Member States were invited to send further comments by 2 September 2022.

8. Aluminium ammonium sulfate

   The Commission summarised the outcome of the EFSA conclusion. Member States were invited to comment by 2 September 2022.

9. Clofentezine (no news)

   There were no news to report.

10. Benthiavalicarb (no news)

    There were no news to report.

- Basic substances

  There were no news to report.

- Amendment of conditions of approval

  There were no news to report.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Asulam-sodium (no news)

There were no news to report.

b) Napropamid-M

The Commission informed that the draft review report that proposes a non-approval of this active substance was made available on CIRCA BC and that the applicant is being consulted. Member States were invited to comment by 2 September 2022.

- Renewal of approval

c) Captan

The Commission informed about the outcome of the discussion with the Rapporteur Member State and EFSA to clarify issues related to mammal toxicity and bees for the field uses submitted in this renewal dossier: even when considering the lower application rates, the concerns for risks for mammals and bees remain. Therefore, based on the available information, the Commission proposed a renewal restricted to protected uses (greenhouse).

The Commission reminded that it remains possible to the applicant to amend the conditions of approval according to Article 7 of the Regulation (EC) No 1107/2209. During the meeting, four Member States explained the importance of Captan in pome fruit farming and stated their wish for an efficient regulatory processes in case the applicant would apply for amendment of conditions of approval.

Member States were invited to comment by 2 September 2022.

d) *Pseudomonas chlororaphis* strain MA 342

The Commission shared the positions received from Member States since last meeting of this Committee as regards a possible renewal for all the uses, a restricted renewal only for the seed treatment uses, or a non-renewal. Based on the preliminary positions which indicate that a majority of Member States would support a renewal or a restricted renewal, together with the previous discussions and comments received from Member States and the applicant, the Commission suggested to proceed with a renewal restricted to seed treatment uses.

The Commission informed that the renewal report is expected to be shared with Member States and the applicant before the next meeting of this Committee.

e) *Bacillus thuringiensis aizawai* strain ABTS-1857

The Commission explained that after bilateral discussions on a potential mandate with EFSA and the European Centre for Disease Prevention and Control (ECDC), a proposal for a renewal of approval setting risk management conditions seems the most appropriate way to proceed. The Commission suggested to address the uncertainties on dietary exposure based on the information available for each strain, and explained the possible application of withholding periods and requests for monitoring data on residues.

The Commission informed that the applicant's task force expressed its interest to provide data to clarify the possible dietary risk when Bacillus thuringiensis strains are used as biocontrol agents. However, they also expressed the technical

difficulties regarding the choice of the ad-hoc experiments to conduct, and the need of a preliminary discussion with Rapporteur Member States on this topic.

Member States were invited to comment by 2 September 2022, and to coordinate their views with their delegations appointed the residue meetings of this Committee, for which the next meeting is scheduled on 26-27 September 2022 and where the appropriateness of setting MRLs will be discussed.

f) *Bacillus thuringiensis aizawai* strain GC-91

See point A.05.e

g) *Bacillus thuringiensis israelensis* strain AM65-52

See point A.05.e

h) *Bacillus thuringiensis kurstaki* strain ABTS-351

See point A.05.e

i) *Bacillus thuringiensis kurstaki* strain EG2348

See point A.05.e

j) *Bacillus thuringiensis kurstaki* strain PB54

See point A.05.e

k) *Bacillus thuringiensis kurstaki* strain SA-11

See point A.05.e

l) *Bacillus thuringiensis kurstaki* strain SA-12

See point A.05.e

m) Pelargonic acid

The Commission reiterated that for all representative uses risks for bees, soil organisms and/or non-target arthropods have been identified.

Member States were invited, to provide any further comments by 2 September 2022, in particular whether the risks identified could be lowered using suitable risk mitigation measures.

n) Rape seed oil

The Commission informed that the review report is in preparation and invited Member States to comment by 2 September 2022.

- Basic substances

o) Extension of use of sodium chloride (amended review report to endorse)

The Commission summarised the amendment proposed to the review report which refers to the inclusion of the extension of use of the basic substance as a fungicide to control downy mildew (Plasmopara viticola). The Commission reiterated that the approval of sodium chloride as basic substance already considered the risk to non-target arthropods including bees from the uses of sodium chloride as basic substance, and that it is expected to be low.

The Committee endorsed the amended review report. Two Member States did not support because they considered that the use during flowering growth stages should not be approved.

A.06 Confirmatory Information:

1. Propyzamide (amended review report to endorse)

The Commission explained the updates made to the last draft of the renewal report and informed about two letters sent by Pesticide Action Network (PAN) Europe – one address to Commissioner Kyriakides and another to Member States – and that had been uploaded in CIRCA BC.

The Commission recalled that in its view, there is not an issue for consumers for the representative use on oilseed rape. One Member State asked whether the Rapporteur Member State for the renewal of approval could prioritise the evaluation of the new studies on the metabolites.

The Commission agreed with Member States to postpone the endorsement of the amended renewal report. In this way, the Rapporteur Member State would have some time to reflect and the Commission can include some drafting changes in the report. The intention is to endorse the Renewal Report at the next meeting of this Committee.

Member States were invited to comment by 2 September 2022.

2. Pendimethalin

The Commission explained that it is drafting 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 in light of 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 the assessments on the confirmatory data for the plant oils geraniol, eugenol, thymol, clove oil and orange oil. The Commission shared the comments received from the applicant of geraniol, eugenol and thymol and a comment received from a Member State.

The Commission explained that renewal procedures are ongoing for all the five plant oils ant that it is discussing internally on the way forward.

Member States were invited to comment by 2 September 2022.

A.07 Guidance Documents:

1. EFSA Scientific Committee (2017) Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971 (to endorse)

   The Committee endorsed the guidance document with implemention data of 1 January 2023.

2. EFSA (2017) Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):512 (to endorse)

   The Committee endorsed the guidance document with implemention data of 1 January 2023.

3. EFSA Scientific Committee (2017) Guidance on the assessment of the biological relevance of data in scientific assessments. EFSA Journal 2017;15(8):4970 (to endorse)

   The Committee endorsed the guidance document with implemention data of 1 January 2023.

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

   The Commission recalled that during the previous meeting of this Committee a majority of Member States indicated their support to proceed at this stage and in the absence of sufficiently robust evidence with an undefined threshold approach for both bumblebees and solitary bees until further data become available, and to require in practice, by default and in case of exposure, field studies for bumblebees and solitary bees unless:

   - the lower tier risk assessments for honeybees and non-target arthropods other than bees show no effects for the active substance, or
   - semi-field (cage or tunnel studies) with bumblebees and solitary bees show absence of effects.

   Furthermore, semi-field or field testing with bumblebees would also not be required if laboratory studies show a Lethal Dose (LD50) higher than 100 µg active substance/bumblebee following the OECD test methods No 246 and 247. The Commission shared on CIRCA BC the letter sent to EFSA where it communicated the outcome of the discussions with Member States on the specific protection goals for bumblebees and solitary bees.

   The Commission also summarised the comments received from Member States after the last meeting of this Committee and mentioned that further details can be discussed when the revised Bee Guidance Document is endorsed.

   The Commission also shared a joint letter from the NGOs Pesticide Action Network (PAN Europe), Apimondia, Pollinis and Beelife, in which they explain why they consider an undefined threshold inappropriate and were they plead for an a priori threshold for wild bees of 3% or even 0%.

   The Commission announced the launch of the public consultation by EFSA on the revised draft guidance document as well as the intention of the Commission and EFSA to jointly organise a workshop on 5 October 2022 to discuss the draft guidance document.

   During the meeting, one Member State expressed its concerns arguing that wild bees will not be sufficiently protected as the honey bee is not a suitable representative for wild bees and that the assessment of non-target arthropods cannot provide reliable information on the risk for wild bees. Another Member State supported this argument and remarked that field studies may be waived with limit tests that only look at lethal effects. The Commission clarified that for a field study to be waived both the conservative lower tier risk assessments for honeybees and non-target arthropods other than bees have to show no effects, and that sub lethal effects should be recorded daily according to OECD test methods No 246 and 247. Field tests would be considered necessary if such effects are noted during the limit tests.

One Member State asked if the Commission will revise the Regulation regarding the Uniform Principles and Commission replied the need for this will be considered once the final revised Bee Guidance Document is available.

5. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009

   There were no news to report.

6. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02

   The Commission informed that it has launched the consultation on the revised Communications and invited Member States to comment by 15 September 2022. The Commission informed that it will consult stakeholders in parallel.

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

   There were no news to report.

8. Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products

   The Commission informed that this EFSA guidance document is available and suggests to endorse it at the next meeting of this Committee. Member States were invited to comment by 2 September 2022.

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

- Article 44(4)

  The Commission informed that no notifications were received since last meeting of this Committee.

- Article 36(3)

  The Commission informed about the five notifications received since last meeting of this Committee: two notifications concerned rejections of mutual recognition applications (one on the basis of the European Free Trade Association transitional measures) and three concerned rejections of authorisation under the zonal system.

  None of the decisions were challenged by Member States.

- Article 53

  The Commission informed that it intends to prepare 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.

  One Member State inquired about the possibility to add to the mandate the question on how to solve the problem on sugar beet crop protection and stressed the particular situation during this year as regards food security, in addition this Member State stressed that these mandates are an administrative burden for Member States. Another Member State wondered why only neonicotinoids are in

scope and suggested to also look at other active substances and that a broader discussion on the reasons behind these emergency authorisations is needed. One Member State wondered if the mandates only refer to sugar beet or also other crops.

The Commission informed that it intends a more detailed analysis of the notifications on emergency authorisations and presented preliminary results.

Eight Member States asked for technical clarifications on these results. The Commission thanked for these views and indicated it will continue workign on the analysis with the intention to present an updated analysis in due time.

A.09 Microorganism Active Substances, in particular:

- Commission Communications in the framework of the implementation of the data requirements

The Commission informed that the draft Commission Communications concerning data requirements on micro-organisms used in biological plant protection products (i.e. in the framework of the Parts B of Regulation (EU) 283/2013 and Regulation (EU) 284/2013) were circulated by email to Member States and that some comments were already received. Further comments are welcome by 19 August 2022.

The Commission also informed that a consultation of stakeholders will also be launched.

A.10 Safeners and Synergists:

The Commission informed that efficacy data requirements and national authorisation procedures were discussed during the first meeting of the Working Group on data requirements on Safeners and Synergists. The Commission informed that the second meeting will be held on 13 September 2022.

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

1. Sodium hydrogen carbonate

   This point was postponed.

2. Flupyradifurone

   The Commission recalled the preliminary positions of Member States as regards whether regulatory measures under Article 69 and/or Article 21 are justified: 14 Member States preferred initiation of Article 21 review or any action that will result in fast assessment of the data, 6 preferred no immediate action, 5 had no final position and 2 were absent. In addition, one Member State indicated that the restriction of use of this active substance to high-tech greenhouses would be an option and can be justified.

   The Commission informed that it plans to initiate a review on the approval of flupyradifurone under Article 21. In this regard, the authorisation holder will be requested to provide all the data they have on the effects of flupyradifurone on bees and an evaluation of the relevant scientific literature. This data and information will be evaluated by the Rapporteur Member State of the renewal, who is already informed and agreed to it.

3. Acetamiprid

The Commission recalled the preliminary positions of Member States as regards whether regulatory measures under Article 69 and/or Article 21 are justified: 13 Member States preferred no immediate action, 8 preferred initiation of Article 21 review or any action that will result in fast assessment of the data, 4 had no final position and 2 were absent.

The Commission informed that it is preparing a mandate 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 summarised the comments and preliminary positions received from Member States since the last meeting of this Committee. The Commission asked those Member States who were not in favour of withdrawal of the approval to explain their reasons.

The Commission informed that the applicant had submitted a paper that explains how in its view the issues identified during the review of approval under the Article 21 can be managed. The paper was available in CIRCA BC.

The Rapporteur Member State for the renewal remarked that the outcome of the renewal risk assessment might differ due to the changes on the representative use when compared to the approval (seed treatment for maize is assessed for the renewal and seed treatment for wheat and barley was assessed for the approval).

The Commission explained that it will consider all the views of Member States and also the letter from the applicant before making a proposal.

The Commission asked the Rapporteur Member State to provide comments on the ongoing renewal review by 5 August 2022.

2. Pirimicarb

The Commission explained the state of play of the review of the approval of this substance and recalled that a review of the approval under Article 21 and the renewal are not the same processes.

Member States were reminded that the Rapporteur Member State had prepared an assessment, which was shared with EFSA and Member States on 16 June 2022. The Commission explained that is preparing a mandate to EFSA to review this assessment.

A.13 General issues for information / discussion:

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

a) Scope Document rev. 70

The Commission explained the comments provided by two Member States regarding the interpretation proposed by the Commission for the product PROTECTOR, the cold atmospheric plasma technique, crop-coat and STYX.

The Commission also explained that it will publish the current revision of the scope document on its website in the following weeks.

Member States were invited to 1) comment on the new revision of the Scope Document including the new entries and 2) provide their experience on authorisations of plant protection products used as herbicides on roofing felts by 2 September 2022.

b) new cases: in particular Crop-coat, STYX and herbicides on roofing felts

See previous point.

c) Heptamaloxyloglucan

The Commission explained the outcome of the internal reflections on the scope of this active substance: since there is no interaction with the nutritional process of the plant, this active substance cannot be considered a bio-stimulant and would therefore fall under the scope of Regulation (EC) No 1107/2009. The Rapporteur Member State agreed with this interpretation. Member States were invited to comment by 2 September 2022.

The Commission also reminded Member States of the importance of identifying at an early stage if applications for approval or renewals of approval of active substances under Regulation (EC) No 1107/2009 would rather fall under the definition of bio-stimulants, so that any discussion and decision on the scope could be taken at the beginning of the respective renewal process.

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

The Commission informed on the reactions received from two Member States regarding the FAQ document drafted in the context of the Fertilising Products Regulation, which concerns fertilising products containing a substance known as plant protection active substance but not fulfilling the plant protection function. The commenting Member States agreed with the Commission's interpretation that, in such a case, the product can keep its fertilising product status, as long as the absence of plant protection effects is duly demonstrated.

As regards the situation where the product bears a dual claim, e.g. plant fertilising and protecting functions, where the legal obligations from both sets of obligations shall be fulfilled, the commenting Member States considered that this should not be up to authorities in charge of Regulation (EC) No 1107/2009 to assess the fertilizing part of a product because the procedures under the two regulations are different.

The Commission informed that this information will be forwarded for further discussion in the working group concerning fertilizers.

2. Basic substances – general issues

The Commission informed on a letter from Crop Life Europe (CLE) and AEPLA (La Asociación Empresarial para la Protección de las Plantas) concerning labelling of basic substances. The letter included industry's views on how products containing basic substances should be labelled, including a suggestion for a label

template. The Commission replied in accordance with the working document on basic substances and Q/A document, under which basic substance must not be placed on the market as a full-fledged PPP with related claims.

One Member State asked for receiving information on how other Member States manage the products containing basic substances, in particular as regards (a) the content of additives or preservatives, (b) their preparation in chemical processes, (c) and placing on the market without authorisation.

Member States were invited to comment on both issues by 9 September 2022.

3. MS updated survey on timing of regulatory procedures

   The Commission presented the final report that includes clarifications on the previous version sent by three Member States. The Commission informed that the report will be published on its website.

   The Commission also explained that it intends to collect regularly data on the performance of Member States competent authorities in complying with the deadlines set for product authorisations in Regulation (EC) No 1107/2009.

4. PPPAMS – update

   The Commission provided an update on the future plans for PPPAMS and informed that a discussion on this will be scheduled with Member States in September.

5. Incidents with phosphine products

   One Member Sate presented a document with indications to reduce the risks linked to the trans-shipment of cargos in which phosphine producing products have been used.

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

   The Commission presented an updated inventory that contains the available test protocols for pollinators together with those under development and those that are needed. The inventory includes a test guideline for bee brood.

   One Member State raised its concern of no having proper capacity to be actively involved in the development of test guidelines besides providing comments. This Member State wondered if EFSA could be mandated to perform this task.

   Member States were invited to send specific suggestions on for test guidelines on and their availability to support the official programme of OECD by 2 September 2022.

7. Report from workshop on crop protection measures and pollinator protection (7 April 2022)

   The Commission shared the report of the workshop "Let them be(e) – Policy actions for better protection of pollinators when controlling pests in the European Union".

   One Member State suggested to organise a Better Training for Safer Food (BTSF) on protection of pollinators. Another Member State informed about its national pollinator strategy which includes monitoring, training, advice and risk mitigation measures for the protection of pollinators.

   Member States were invited to send feedback on the policy options included in the report of the workshop and to suggest any other option to strengthen the pesticide policies regarding pollinators by 2 September 2022.

8. Long term toxicity effects of formulations

   The Commission informed that it received further inquiries from the European Parliament on the long term toxicity effects of formulations, and shared an overview of the answers received so far from Member States as regards how they evaluate long-term toxicity of the plant protection products.

   The Commission invited the Member States that had not yet replied to the three questions presented during the last meeting of this Committee, to answer them by 2 September 2022.

9. Residues on cut-flowers

   The Commission informed that currently there is no clear suggestion on how to deal with this issue and reminded that Maximum Residue Levels cannot be set for non-edible flowers.

   Member States were invited to comment by 2 September 2022.

10. Pheromones

    The Commission summarised the comments received from three Member States and EFSA concerning the proposal of one Member State to extend the Straight Chain Lepidopteran Pheromones group to cover also other semiochemicals, and informed that this proposal was also discussed at the Biopesticides working group. In general, the commenting Member States agreed to explore whether the risk envelope approach would be fulfilled for the stepwise extension of the group, as long as the process is scientifically robust, while EFSA suggested to wait the study of OECD on background level of pheromones before deciding on the next steps.

    Member States were invited to comment on the proposal by 2 September 2022.

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

The Commission presented a draft Regulation repealing Regulation (EC) No 547/2011, explaining in particular new aspects, i.e. general safety statements, colour coding, and electronic labelling. Member States asked several questions on these aspects that were answered during the meeting, as well as a question on the relationship between the CLP regulation and this proposal.

Member States were invited to comment by 30 August 2022.

A.15 Co-formulants, in particular:

1. draft procedures for listing additional unacceptable co-formulants

   The Commission explained that comments from three Member States were received, as well as a position paper from PAN Europe.

   The Commission informed that it intends to launch the InterService Consultation in the next weeks and that the public consultation on the draft will be initiated after this consultation is closed.

   The Commission invited Member States to comment on the current draft by 5 August 2022.

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

   The Commission suggested that the proposal forwarded by one Member State is discussed at the next WG on PPP formulation, which will take place in September 2022.

A.16 Report from Working Groups, in particular:

1. Working group on Biopesticides

   The Commission informed about the last Biopesticides Working Group meeting held on 28 June 2022, and that the discussions focused on actions to foster the implementation of the new Regulations concerning micro-organisms used in pesticides.

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

   The Commission informed that the consultation process of 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" started and that Member States and stakeholders were invited to perform case studies and to comment on the document. The Commission explained that it will reflect on the feedback and case studies provided during summer.

   The Commission also informed that a first draft document "Compendium/list of technical use and application conditions for plant protection products" has presented to the Working Group for their comments and that discussions will continue after summer.

3. Working group on Seed Treatments (Risk Assessment)

   There were no news to report.

4. Working group Post Approval Issues

   The Commission informed about the discussions that took place in the last meeting of the Post Approval Issues Working Group held on 14 and 15 June 2022. The main points debated were: the possibility to use agreed templates for letters of access, reflections about the statement "*enough efforts*" when data sharing of vertebrate studies is needed, the possibility of a follow-up Workshop from the one held in Dublin in 2015 on the functioning of the zonal system, the presence of unacceptable co-formulants below 0,1% when added intentionally, the presence of new relevant impurities in different low-risk active substances, the moment on which the different concerned Member States perform the completeness check of the requirements for the applications as set out in Articles 33 and 34 of Regulation (EC) No 1107/2009, issues on data protection, the volunteering of Member States to update the draft registration report template for microorganisms before the entry into force of the new data requirements, and ways to handle the changes of membership in task forces at the moment of the authorisation, among others.

5. Working Group on PPP Formulation Analysis

   Commission informed that the next WG on PPP formulation will be held in September 2022.

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. EFSA also informed that the public consultation on the draft updated guidance document on the risk assessment for bees will take place between the 18 of July and the 3 of October 2022, and that a workshop with Member States and stakeholders is planned for the 5 of October 2022.

   EFSA also stressed the importance of the Substance Identity Check (SID), in which EFSA is cooperating with ECHA and which should take place at an early stage of the EFSA processes. Furthermore, EFSA informed about the progress on the mandate on *Aspergillus* and informed about the most frequent issues identified during the completeness checks done by EFSA on the assessment reports delivered by Member States.

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

   The Commission presented the proposal for a Sustainable Use Regulation.

   One Member State wondered about the timing and the process for revising the risk indicators. Another Member State asked why in the National Action Plans which would be requested, there is a specific part for organic agriculture, as this is not only about plant protection but also covered by other legislation and, in addition, it implies duplication of reporting. This Member State also stressed the high burden introduced to farmers with this proposal.

   Two Member States mentioned that the baseline has changed over the last decades as regards plant protection products, and that the illegal use of pesticides is expected to increase due to the withdrawal of plant protection products.

   The Commission clarified and thanked for the questions and informed that discussions have been initiated with Member States at Council.

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

   There were no news to report.

4. Minor Use Facility (MUCF)

   The Commission informed that the next Steering Group meeting will be held by videoconference on 18 July 2022.

   The purpose of this videoconference is: to appoint a new Minor Uses Coordination Facility (MUCF) Steering Group Chair for the next three years, to provide an activity update on the work of the MUCF in the first months of 2022 including an overview of funding contributions received from 2018 to 2022, to provide a draft Work Programme for 2023 and the Budget proposal for 2023. Further, it is intended to discuss the revised MUCF Basic Rules, Terms of Reference for the Commodity Expert Groups (CEGs) and the Horizontal Expert Group (HEG), the eligibility criteria for chairing a MUCF Commodity Expert Group, and when to hold the next Annual General Meeting (AGM) in Autumn 2022.

5. OECD, FAO and EPPO activities

The Commission informed about the recent meetings of the Expert Group on Biopesticides and the Working Party on Pesticides (WPP) organised by the OECD, in particular the progress made by the respective expert groups on the residue definition, on EGEEPD, on drones, biopesticides, RNAi, minor uses and pollinators.

Attention was drawn on new projects agreed by the WPP regarding the background levels for pheromones and the consensus documents for the species Beauveria bassiana and Bacillus amyloliquefaciens.

The Commission invited Member States to actively take part in the upcoming Conference on Testing Methods for microorganisms which is planned in the week of 12 September 2022.

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

The Commission informed about a judgement of the General Court of 13 July 2022, dismissing the application seeking the partial annulment of Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl.

The Commission also informed about three requests for preliminary rulings brought by a Dutch court (College van Beroep voor het bedrijsfleven) in the context of proceedings brought by an NGO against product authorisations granted by a Member State's competent authority. In addition, a new court case (T-412/22- PAN Europe v. European Commission) was initiated against the Commission following a reply to the internal review under the Aarhus Regulation concerning extension of the approval periods.

The Commission had also received and replied to two requests from PAN Europe for Internal Review under the Aarhus Regulation concerning an alleged administrative omission regarding the ban of the substance L-cyhalothrin and Commission Implementing Regulation (EU) 2021/2049 renewing the approval of the active substance cypermethrin as a candidate for substitution, respectively. In addition, a request for internal review was received from Pollinis concerning Commission Implementing Regulation (EU) 2022/708 as regards the extension of the approval periods of active substances.

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

- possible impact on authorisations

  There were no news to report.

- Bifenazate: acute health risk identified for peaches

  The Commission reminded that the Commission Implementing Regulation (EU) 2022/698, of 3 May 2022, renewing the approval of the active substance bifenazate, and the restrictions contained in it, shall apply from 1 July 2022. Member States were reminded to check the compliance of the authorised plant protection products in their territories with the new conditions of the renewal of bifenazate. For the amendment or withdrawal of the authorisations of bifenazate based plant protection products, Member States can decide on the duration of the grace period.

In addition, the Commission informed that there is an indication on an acute intake concern for peaches. Therefore, delegates were advised to consider granting a shorter grace period for the plant protection products containing peaches among the authorised uses, to make sure that treated peaches are in compliance with the expected Commission draft Regulation lowering all the MRLs to the limit of quantification (LOQ).

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed that a letter of Crop Life Europe had been received and made available on CIRCA BC for information.

A.21 Date of next meeting(s):

The Commission informed that the next meeting is planned for the 13 and 14 October 2022, subject to confirmation.

A.22 AoB.

As regards the on-going renewal process of the active substance Rimsulfuron, the Commission informed that, following a mandate from the Commission to further review certain aspects of the risk assessment, EFSA made available its updated Conclusion in June 2022. Following the re-assessment, the critical concern related to one metabolite groundwater has been removed. The Commission explained that on the basis of the updated Conclusion it considered that the assessment of ED should now be finalised. Therefore, the intention is to mandate EFSA to arrange for the completion of the ED assessment. The Commission asked Member States to indicate by 22 July 2022 if they would object to this proposed next step.

As regards the on-going renewal process of the active substance Glyphosate, the Commission recalled that in the previous meeting an update on the state of play was given to Member States – in particular regarding the delay with the peer-review and the delivery of the EFSA Conclusion - and reminded Member States that the dedicated glyphosate webpage has been updated with all relevant information.

Since the last meeting of this Committee, the Committee for Risk Assessment (RAC) of ECHA delivered its opinion on glyphosate – confirming the existing harmonised classification (Eye Damage category 1 and Aquatic Chronic category 2). The Commission informed Member States that following criticism from HEAL about the assessment of carcinogenicity, ECHA prepared a response which has also been added to the glyphosate webpage.

The Commission also reminded Member States that if evidence emerges at any point during the forthcoming work by EFSA or ECHA that the approval criteria laid down in the EU legislation are no longer fulfilled, the Commission will take immediate action. If, however, no such evidence emerges during the ongoing work, and to allow the completion of the scientific evaluation as required by EU legislation, the Commission will, in due course, have to propose the temporary extension of the current approval. 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. Taking this into account, Member States were informed that if no evidence emerges in the coming months, the

Commission intends to put forward a Regulation to extend the approval of glyphosate for a vote at the next meeting of this Committee.

The Commission informed that it had received a letter from a consultant representing an applicant that was uploaded on CIRCABC. They complain on the application of the provisions of mutual recognition in one Member State. For the case presented in the letter, the same authorisation holder obtained an authorisation through the zonal system and for the same product, the application following the mutual recognition procedure was rejected in that Member State, even though belonging to the same zone as the reference Member State. In their view, the alleged issues raised by the assessment body have been answered during the currently on-going renewal process of the substance at European level. However, the additional data submitted was dismissed and not assessed. In their opinion, this prevents the harmonised availability of plant protection products on the EU market and is against the principle of free movement of goods within the European Union. Additionally, they denounce that the mentioned Member State recently granted an authorisation to a similar PPP from a different authorisation holder. In their view, this is contrary to the principle of fair competition and equal treatment.

The Commission stated that it will await for the reception of the corresponding notification according to Article 36(3) to have a broader understanding and justification from the mentioned Member State.

As regards guidance documents, the Commission informed that comments received from one Member State on the Exposure guidance document were made available on CIRCA BC.

In addition, the Commission reiterated the invitation to Member State to comment on the prioritisation of guidance documents made available at the last meeting of this Committee. The Commission reminded the need of updating a template for Assessment Reports for microorganisms compliant with the new data requirements, and invited Member States to volunteer for updating such template.

The Commission informed that an overview of the active substances currently under ED-stop the clock has been made available under point A.03.

The Commission also informed that the 4th ED Forum will be held on 21-22 September 2022 in Brussels and that the registration will be opened starting from 18 July 2022.

The Commission informed that for the on-going Better Training for Safer Food on risk assessment on micro-organisms, some participants informed about the difficulty for chemists in following parts of the training, in particular on biology aspects. The Commission highlighted that the purpose of the training is not to solve the lack of relevant expertise in the competent authority, but rather to support and develop already existing relevant expertise. The Commission encouraged again Member States to recruit relevant experts, such as life scientists and microbiologists, and to keep enrolling them for the following training sessions of this BTSF training which are planned for 27 to 30 September and 22 to 25 November 2022.

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) concerning the non-approval of calcium propionate 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/11490/2021).
(SANTE/11488/2021)

The Commission presented the draft implementing act and proceeded to vote during the meeting.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of black soap E470 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 PLAN/2022/679 RR).
(PLAN/2022/679)

The Commission presented the draft implementing act and 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 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 informed that one Member State had sent comments which still need to be verified. For this reason, the vote was postponed.

Vote postponed.

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 sheep fat 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 SANTE10072/2022).
(SANTE/10070/2022)

The Commission presented the draft implementing act and 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 conditions of approval of the active substance penflufen and repealing Implementing Regulation (EU) 2018/185 (Draft Updated Review Report SANTE/10028/2017).
(SANTE/10574/2021)

The Commission presented the draft implementing act derived from the non-submission of confirmatory data established in the approval of the active substance penflufen.

The Commission explained that the applicant had to submit confirmatory information as regards the relevance of the metabolite M01 (penflufen-3- hydroxy-butyl) for groundwater if penflufen was classified under Regulation (EC) No 1272/2008, as "carcinogen category 2". In accordance with Article 21 of Regulation (EC) No 1107/2009, since the confirmatory information required in the approval was not submitted after the classification of penfluflen, the Commission is obliged to adopt a Regulation to withdraw or amend the current approval.

Therefore, the approval conditions are amended and only uses to treat cereal seeds before or during sowing may be authorised, limited to one application every third year on the same field. The use with planting of any other propagating material (such as potatoes) is excluded. Member States can determine the appropriate period of grace for the continued use of penflufen based PPP and are better placed to assess the groundwater scenarios representative in their territories.

Furthermore, the applicant already announced that is no longer supporting the renewal of approval.

One Member State indicated that in its opinion, this creates a difficult situation for applicants for authorisations which are not the main applicant for the active substance, which cannot submit any data for the active substance even though having it available, losing their authorisations.

The vote was taken during the meeting.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron.
(PLAN/2022/1367)

The Commission presented the draft Regulation extending the approvals for a number of active substances, which is required by Article 17 of Regulation (EC) No 1107/2009

as the evaluation procedures for these substances were all delayed for reasons beyond the control of the applicants.

One Member State disagreed with the extension of the approval periods in batches which include active substances of concern, in particular active substances such as 8-hydroxyquinoline, clofentezine, quizalofop-P-tefuryl and triflusulfuron. Another Member State indicated they could not support an extension of the approval of 8-hydroxyquinoline and clofentezine. A third Member State expressed its support for the need of the extensions, but found the extension of the approval of 8-hydroxyquinoline, clofentezine, MCPA, Lenacil, Triflusulfuron and Prosulfocarb controversial. A fourth Member State expressed its intention to vote in favour because the draft Regulation covered a package of substances, however they did not agree with the extension of the approval period of difenoconazole because of the risks regarding fungal resistance.

The vote was taken during the meeting.

Vote taken: Favourable opinion.

Denmark made the following protocol declaration:

Denmark supports the need for administrative extensions, but Denmark emphasize the importance of putting each individual substance up for a vote on renewal or non-renewal as soon as possible after the Commission's review report has been published, especially if the EFSA conclusion has identified an unacceptable risk.

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 updated draft Implementing Regulation, which considered comments received from other Commission services and from the Member States and clarified questions and comments.

Member States were invited to comment on the draft and to inform if they cannot support the implementing Regulation by 2 September 2022.

The Commission further informed that it 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) concerning the non-approval of hydrogen peroxide silver-stabilised 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/11406/2021).
(SANTE/11404/2021)

The point was postponed.

C.03 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-2022-10236).
(SANTE/10234/2022)

The point was postponed.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of lemon essential oil 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/10240/2022).
(SANTE/10238/2022)

The point was postponed.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Pythium oligandrum* strain M1 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, and amending Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10332/2021 Rev. 3).
(SANTE/10330/2021)

The Commission presented the draft proposal for renewal of approval of *Pythium oligandrum* M1.

The Commission also explained that the reason why it is not proposed to qualify the substance as low-risk is because of the need for specific risk mitigation measures, namely personal protective equipment which is considered necessary to mitigate the risks for the operator's respiratory system. These risk mitigation measures would also cover the sensitivity potential which is by default expected for micro-organisms.

Member States were invited to comment by 2 September 2022.