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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*
17 - 18 May 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/ff77c9fd-cbcf-4dea-9ab2-ba61051b9531*

SUMMARY REPORT

The meeting took place via web conference due to measures taken to contain the COVID-19 pandemic.

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meeting of this Committee in January 2022 had been published, while the one of the meeting in March was under preparation.

A.02 New applications, in particular basic substances:

The Commission explained that since March 2021 application dossiers for the approval of basic substances have to be submitted via IUCLID and that Member States get a notification at the moment of submission, which allows Member States to be informed in real time. Therefore, this point will be removed from the agenda of the meetings of this Committee.

One Member State mentioned that it is difficult to follow notifications sent by IT systems (e.g. IUCLID). The Commission encouraged Member States to indicate their needs as regards IUCLID in the appropriate fora, and mentioned that it will reflect on the possibility to give overviews of the applications received via IUCLID occasionally at the meetings of this Committee.

1. Extension of use of chitosan hydrochloride

   Information on the new application for extension of use of chitosan hydrochloride was postponed. The Commission explained that two Member States had submitted a request to launch a review of the approvals of chitosan hydrochloride and chitosan as basic substance as outlined in Article 23(6) of Regulation (EC) No 1107/2009. They pointed in particular to concerns related to the environmental exposure assessment and the risk to non-target organisms including bees.

2. Extract of the wood of *Quassia amara* L.

   The Commission informed that the application dossier for an approval as basic substance had been submitted.

3. Hexane

The Commission informed that the application dossier for an approval as basic substance had been submitted.

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

– overview of active substances under ED stop the clock

The Commission informed that an updated overview of the substances that are currently under stop the clock in accordance with Article 13(3) of Commission Implementing Regulation (EU) No 844/2012 and for which additional information on endocrine disrupting properties has been requested had been made available on CIRCA BC.

– workshop with Member States on possible grants

The Commission informed that the organisation of the workshop was on-going and that invitations to the nominated participants for each Member State had been sent out.

– 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 an overview of the active substances for which a renewal dossier would be potentially submitted between 31 January 2026 and 1 October 2032 had been made available on CIRCA BC.

The Commission informed that it intended to work on the allocation of Rapporteur Member State and co-Rapporteur Member State for these substances so that applicants can prepare properly their dossiers in advance by making use of pre-submission advice. Member States were asked to express their preferences to act as Rapporteur or Co-Rapporteur Member State by 20 June 2022.

The Commission also stressed the important role of Rapporteur and co-Rapporteur, and in general the need of involvement of all Member States during the commenting phase of the peer review process.

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

- New active substances

1. *Aspergillus flavus* MUCL54911

The Commission informed that two Member States had provided comments raising concerns as regards the data gaps related to human pathogenicity and toxigenicity. The Commission informed that the applicant had generated new data which would prove absence of toxigenicity. However, these data had not been 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 the Rapporteur Member State informed that it would be available to evaluate this new data.

2. *Trichoderma atroviride* strain AGR2

The Commission informed that two Member States had provided comments on the two strains, AGR2 and AT10. The comments raised concerns about the data gaps that EFSA identified for the secondary metabolites peptaibols and 6-pentyl-2-pyronem (used also as food additive) as regards their concentration under natural

conditions in the environmental compartments and that triggered that several parts of the risk assessment could not be finalised.

Member States were invited to provide comments on the EFSA Conclusion as well as on the comments provided by the applicant on it by 20 June 2022.

3. *Trichoderma atroviride* strain AT10

Please see above *Trichoderma atroviride* strain AGR2.

4. Limestone

The Commission explained that, according to EFSA, limestone powder and calcium carbonate are considered the same substance and that the approval of calcium carbonate had been recently renewed, while limestone is a new active substance.

The Commission explained that according to the uses proposed, both substances present similar purity and uses as repellent but they differ in the method of application and the target pest. Calcium carbonate is proposed to be sprayed or used as painting against game browsing and fraying the antlers in coniferae. Limestone is proposed to be used as paste application to prevent browsing damage from red and roe deer and brown hare in forestry. Both substances have different applicants and Rapporteur Member States.

Member States were invited to provide comments by 20 June 2022, in particular as regards whether both substances should be considered the same or not.

- Renewal of approval

5. Clofentezine

This point was discussed in conjunction with A.04.6 and A.05.a.

The Commission informed that Member States had submitted further comments after the last meeting of this Committee and that it was reflecting about the next steps, considering also the comments raised in the previous meeting and thereafter concerning in particular the endocrine disrupting properties.

In general, the Member States who had provided comments expressed that it is not excluded *per se* to set thresholds for substances with endocrine disrupting properties, however, it depends on the available data. Several Member States expressed doubts about the current possibilities based on the existing scientific knowledge and available guidance. One Member State considered that the same approach as taken for active substances used in biocidal products should be applied. In general, Member States expressed that further technical/scientific discussion on the topic may be needed and one Member State considered that further clarifications from EFSA would be needed.

The Commission explained that it will reflect on the comments provided in the discussions for asulam-sodium, benthiavalicarb and clofentezine and other substances with endocrine disruptors properties and invited Member States to comment, also on other Member States' comments, by 10 June 2022.

6. Benthiavalicarb

This point was discussed in conjunction with A.04.5 and A.05.a. In addition, the Commission informed that Member States had commented in relation to Article 4(7).

The Commission informed that the Harmonised Classification and Labelling (CLH) process was concluded in the 60th meeting of the European Chemicals Agency's Committee for Risk Assessment (RAC) in April and that the classification of the substance had been confirmed as carcinogen, category 1B.

The Commission explained that it will reflect on the comments provided in the discussions for asulam-sodium, benthiavalicarb and clofentezine and other substances with endocrine disrupting properties. The Commission asked Member States to provide further comments by 10 June 2022.

7. Rape seed oil

The Commission informed about the outcome of the EFSA conclusion. The Commission explained that points regarding the acute and chronic risk for honey bees and their larvae needed to be clarified and that it had contacted the Rapporteur Member State in this regard.

Member States were invited to comment on the EFSA Conclusion by 10 June 2022.

8. Oxamyl

The Commission informed about the outcome of the EFSA conclusion and shared the comments of the applicant. Member States were invited to comment on the EFSA Conclusion by 20 June 2022.

9. Triflusulfuron-methyl

The Commission informed about the outcome of the EFSA conclusion. The Commission shared the comments of the applicant and the supporting letters from stakeholders. Member States were invited to comment on the EFSA Conclusion by 20 June 2022.

10. Aluminium ammonium sulfate

The Commission informed about the outcome of the EFSA conclusion and shared the comments of the applicant on the Conclusion. Member States were invited to comment by 20 June 2022.

- Basic substances

  There were no news to discuss.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Asulam-sodium

  This point was discussed in conjunction with A.04.5 and A.04.6.

  The Commission informed that four additional Member States had commented in relation to the application of Article 4(7) for a new herbicidal active substance. Some Member States indicated that asulam-sodium could not be efficiently substituted by alternative non-chemical weeding methods for the crops proposed under Art 4(7).

The Commission explained that it will reflect on the comments provided in the discussions for asulam-sodium, benthiavalicarb and clofentezine and other substances with endocrine disrupting properties. The Commission asked Member States to provide further comments by 10 June 2022.

b) Napropamid-M

The Commission explained that based on the available information a proposal for non- approval seemed to be appropriate. The Commission also explained that the Rapporteur Member State volunteered for screening the additional data and information submitted by the applicant after the publication of the EFSA conclusion.

- Renewal of approval

c) Captan

The Commission informed about the outcome of the discussion with the Rapporteur Member State and EFSA on the possibility to clarify issues related to mammal toxicity and bees for field uses. It was concluded that the available information will not change the concerns that EFSA identified in its conclusion. Therefore, the Commission decided that it will not send a further mandate to EFSA.

Based on the available information, the Commission proposed a restricted renewal for protected uses (greenhouse).

Member States were invited to comment by 20 June 2022.

d) *Pseudomonas chlororaphis* strain MA342

The Commission summarised the previous discussions on this substance including the outcome of the EFSA Conclusion and the EFSA mandate on the risk for consumers from exposure to the genotoxic metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR), which was identified as critical area of concern.

The Commission also summarised the updated position paper sent by the Rapporteur and Co-Rapporteur Member State on the potential concern to consumers from the metabolite DDR, which includes a degradation study of DDR that the applicant repeated under Good Laboratory Practice in 2018.

The Commission invited Member States to provide preliminary positions on the possible renewal of approval of this active substance during the meeting: a renewal for all the uses, a renewal restricted to seed treatment uses, or a non-renewal. 13 Member States indicated that they would support a renewal or a restricted renewal, 2 Member States would support non-renewal, and 10 Member States did not provide a position (2 Member States were absent).

Member States not having expressed a position were invited to send their positions and to provide further comments by 10 June 2022.

e) *Bacillus thuringiensis* (horizontal discussion)

The Commission informed that it had concluded a preliminary dialogue with EFSA and the European Centre for Disease Prevention and Control (ECDC) on a possible joint mandate and that it was still reflecting on the possibility of a potential mandate to the agencies. The Commission also informed that *Bacillus thuringiensis* will be discussed in the next meeting of the Biopesticides Working Group of this

Committee and that a meeting with the applicants was scheduled. The Commission explained that after these two meetings it will decide on the next steps.

f) *Pythium oligandrum* strain M1

The Commission informed that the draft renewal report had been made available on CIRCA BC and had been shared with the applicant. The Commission informed that the Rapporteur Member State had submitted comments on the draft renewal report.

Member States were invited to comment on the draft renewal report and to indicate their preliminary positions by 10 June 2022.

g) Pelargonic acid

The Commission informed that an additional comment from a Member State in relation to the EFSA conclusion had been received. The Commission explained that taking into consideration the available information and the comments received from Member States, it will prepare a draft Renewal Report.

Member States were invited to comment by 10 June 2022.

- Basic substances

h) Hydrogen peroxide silver stabilised

The Commission summarised the comments received by one of the applicants. In its comments, the applicant had submitted additional information concerning the identity and the specification of the substance. The applicant had also submitted a statement explaining that the substance should not be considered a nanomaterial and that no other additive or co-formulants are present in the substance. The applicant also claimed that the role of (colloidal) silver in the product is solely as a stabiliser and that silver-stabilised hydrogen peroxide is available on the market not only as 20 % concentrate (assessed by EFSA) but also in the less concentrated form with 7.5% of hydrogen peroxide, which would change classification for human health from Eye Damage 1 (relevant for 20% concentrate) to Eye Irritant 2.

The Commission explained that data to support the claim of absence of nano-sized particles in the colloidal silver had not been provided, whereas the application suggests that silver-stabilised hydrogen peroxide may contain silver nanoparticles. The Commission explained that silver is classified as very toxic to aquatic life and as very toxic to aquatic life with long lasting effects (Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1). The Harmonised Classification and Labelling (CLH) report recommends a separate environmental classification for silver and nanosilver and gives an increased weight to nanosilver when classifying as mixture. Based on the criteria for classification of mixtures, if silver is present in nanoform, it seems that even the product diluted for use would be classified as toxic to aquatic life with long lasting effects (Aquatic Chronic Cat. 3).

The Commission informed that the safety data sheet submitted by the applicant indicated that the commercially available product contains ortophoshoric acid in addition to silver and hydrogen peroxide and that data on combined toxicity of silver and hydrogen peroxide had not been provided.

The Commission informed that the draft review report had been revised to consider the information on the specification of the substance submitted by the applicant. The Commission also explained that the new information submitted by the applicant was not sufficient to fill the data gaps identified in the EFSA Technical

Report and did not change the outcome of the evaluation that led to the Commission proposal for a non-approval as basic substance.

Member States were invited to comment by 10 June 2022.

i) Extension of use of sodium chloride

The Commission summarised the comments received from Member States. Most of the Member States shared the view that the uses proposed in the application for an extension are within the "risk envelope" of the current approved uses of sodium chloride as basic substance. One Member State proposed to exclude the use in flowering growth stages from the GAP table. This proposal was supported by one other Member State, while one Member State pointed out that this restriction is not necessary.

The Commission explained that the original review report underlying the approval of sodium chloride as basic substance presents the rationale to justify that the risk to non-target arthropods including bees from the uses of sodium chloride as basic substance is expected to be low. Back then, Member States agreed to this rationale by endorsing the review report. Therefore, the Commission proposed that the restriction to non-flowering growth stages is not considered for the extension of use. On the request of three Member States, the Commission added to the draft updated review report the clarification that a maximum dose rate of a total of 6 kg sodium chloride per hectare per year must be respected for the uses combined.

Member States were invited to comment by 10 June 2022.

j) Lemon essential oil

The Commission explained its proposal for non-approval as basic substance, which was based on the insufficient data provided, in particular to demonstrate acceptable non-dietary risk and low risk to non-target organisms. The Commission informed that one Member State had sent comments to support the non-approval based on the classification of the substance as skin sensitizer and on the insufficient information on toxicological properties of the components of the substance.

The Commission informed that the applicant had submitted comments on the draft review report. The applicant did not agree with the proposal for a non-approval and made reference to the low in-use concentration of the substance and the categorisation of this substance as foodstuff. The Commission explained that the applicant did not submit additional information to fill in the data gaps identified in the EFSA Technical Report.

Member States were invited to comment by 10 June 2022.

k) Yucca Schidigera extract

The Commission explained its proposal for non-approval as basic substance, which was based on insufficient data provided as regards the toxicological profile of the extract and its individual components. The Commission explained that the information available was insufficient to conclude on a low or acceptable non-dietary risk, risk to consumers, risk for the environment and for non-target organisms.

The Commission informed that the draft review report had been circulated to Member States and the applicant and that no comments had been provided by any of them.

Member States were invited to comment by 10 June 2022.

A.06 Confirmatory information:

1. Pyridaril (amended review report to endorse)

   The Commission presented the latest version of the amended review report which had been made available on CIRCA BC and thanked the Rapporteur Member State for the last comments that were considered in the updated version. The Commission reminded that only one product containing the active substance is authorised in one Member State for the use in permanent greenhouses and that the applicant had stated that it does not intent to apply for renewal of approval.

   The Committee endorsed the amended review report, although one Member State had reservations because it would prefer to delete the reference to the weight of evidence approach in section 7 and another Member State informed that the text about the impurities was not to their full satisfaction yet although it could accept the sentence.

2. Propyzamide (amended review report to endorse)

   The Commission presented a revised amended renewal report that considered the comments received from Member States: one Member State had suggested further changes to the revised report and another Member State had indicated that it would not be in a position to support the revised report due to the issues related to the genotoxicity of two metabolites.

   The Commission also informed about the ongoing discussions with the Rapporteur Member State for the approval and with the Rapporteur Member State for the possible renewal of approval in relation to the existing application under Article 10 of the MRL Regulation. The application under this Article had been on hold for a certain time in light of the confirmatory information submitted and the forthcoming renewal dossier.

   Member States proposed further changes in the revised renewal report and the endorsement of the review report was postponed. Member States were invited to provide further comments by 10 June 2022.

3. Pendimethalin

   The Commission informed that it intended to prepare a mandate to EFSA and ECHA as a follow up to the EFSA report on the confirmatory data related to 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.

   Member States were invited to comment by 10 June 2022.

A.07 Guidance Documents:

The Commission reminded that two documents regarding the prioritisation of work related to guidance documents (updates or new guidance) had been uploaded on CIRCA BC and invited Member States to comment by 20 June 2022.

1. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (to endorse)

   The Committee endorsed the document with implementation date 1 January 2023.

2. EFSA Guidance on aneugenicity assessment (to endorse)

   The Committee endorsed the document with implementation date 1 January 2023.

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

   The Commission presented the positions received from 12 Member States since the last meeting of this Committee. A majority of Member States supported an undefined threshold approach for both solitary bees and bumblebees as proposed by the Commission at the last meeting. The Commission therefore maintained its proposal to proceed at this stage 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 respective active substance.

   The Commission asked all Member States present for their view on this subject. 17 Member States indicated support for the Commission's proposal for solitary bees and 16 Member States indicated support for the Commission's proposal for bumblebees. 3 Member States indicated a preference for a defined threshold of 7-10% for both solitary bees and bumblebees, 6 Member States did not have a position yet for either solitary bees or bumblebees, while one Member State did not have a position regarding bumblebees. One Member State was absent.

   One Member State asked how the final decision will be communicated to EFSA. The Commission indicated that it intended to communicate it via a letter as was done for the Specific Protection Goal for honeybees in 2021.

   Member States, in particular those who did not have a final position yet, were invited to send their position on the proposal of the Commission regarding the setting of a specific protection goal for solitary bees and bumblebees by 31 May 2022.

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

   The point was postponed.

5. 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 intended to launch the consultation on the revised Communications in the coming weeks.

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

   The Commission reiterated that some issues had been commented on by Member States and stakeholders during the last meeting, and invited Member States to send further comments by 20 June 2022.

7. 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

   The Commission recalled that EFSA had presented the guidance document at the last meeting of this Committee and indicated that it intended to propose the document for endorsement at the next meeting of this Committee.

   Member States were invited to send comments by 20 June 2022.

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

   The Commission recalled that EFSA had presented the guidance document at the last meeting of this Committee and indicated that it intended to propose the document for endorsement at the next meeting of this Committee.

   Member States were invited to send comments by 20 June 2022.

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

   The Commission recalled that EFSA had presented the guidance document at the last meeting of this Committee and indicated that it intended to propose the document for endorsement at the next meeting of this Committee.

   Member States were invited to send comments by 20 June 2022.

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

– Article 44(4)

  The Commission informed that it had received one notification since the last meeting of this Committee on five withdrawals and seven amendments of authorisations of tebuconazole and difenoconazole based products. The amendments are due to data that showed that leaching of the major soil metabolite 1,2,4-triazole to groundwater occurred in some cases, posing an unacceptable risk for some uses.

– Article 36(3)

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

– Article 53

  There were no news to discuss.

A.09 Microorganism Active Substances, in particular:

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

  The Commission informed that, for the four draft Commission Regulations on micro-organisms voted by this Committee in February 2022, the scrutiny by the European Parliament and the Council had been launched on 13 May 2022 and will last until mid-August. The Commission explained that if the European Parliament

and the Council do not oppose, the entry into applicability of these Regulations will occur as planned in November 2022.

The Commission also explained that the work on the Commission Communications for the implementation of the data requirements on micro-organisms is progressing. In addition, the Commission informed that other activities are planned to facilitate the implementation of the new Regulations: for instance, the launch of studies to determine background levels of micro-organisms that are used as plant protection products or studies to collect information about the biology and ecology of species.

A.10 Safeners and Synergists:

The Commission informed that the terms of reference of the Working Group on data requirements for safeners and synergists were made available and that so far four Member States had expressed interest in participating in the Working Group. The Commission invited other Member States to appoint experts to the WG.

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

1. Sodium hydrogen carbonate

   The point was postponed.

2. Flupyradifurone

   See acetamiprid (discussed together with point A.11.3 below)

3. Acetamiprid

   The Commission informed that five Member States had commented for flupyradifurone and three for acetamiprid as regards whether and what regulatory measures under Article 69 and/or Article 21 should be taken for these active substances.

   The Commission informed about two letters received from Pesticide Action Network (PAN) that provided references to new scientific publications on the possible hazards of flupyradifurone to human health and the environment and on potential neurotoxicity of neonicotinoids, including acetamiprid. The Commission asked Member States for their views on whether and which regulatory measures under Article 69 and/or Article 21 should be taken.

   As regards acetamiprid, 13 Member States preferred no immediate action, 8 preferred initiation of an Article 21 review or any action that will result in a fast assessment of the new data, 4 had no final position and 2 were absent.

   As regards flupyradifurone, 14 Member States preferred initiation of an Article 21 review or any action that will result in a fast assessment of the new data, 6 preferred no immediate action, 5 had no final position and 2 were absent. In addition, one Member States expressed the view that a restriction of use of this active substance to high-tech greenhouses would be justified.

   Member States, in particular those who did not have a final position yet, were invited to send their position and further comments by 10 June 2022.

A.12 Article 21:

1. Ipconazole

The Commission recalled that during the last meeting of this Committee an overview of the state of play, including a summary of the outcome of the Article 21 review had been presented and that an EFSA Statement had been made available on 1 February 2022.

Seven Member States had provided comments or positions on how to proceed after the last meeting: five Member States indicated that a withdrawal of approval would be preferred given that negligible exposure has not been demonstrated and that a risk to birds remains, and two Member States indicated that they would prefer to wait for the renewal assessment before finalising a decision. One Member State suggested during the meeting that the existing approval could already been amended to limit seed treatments to highly automated facilities only to address exposure of operators.

The Commission informed that it had attended a virtual session arranged by the applicants where they showed the treatment facilities used to minimise exposure of operators to the lowest levels possible. The presentation was available in CIRCA BC.

The Commission asked all Member States present in the meeting for their views on the next steps – not all Member States had final positions but the majority supported a withdrawal of approval with other indicating that they would support restrictions while the renewal review remained ongoing.

Member States, in particular those who did not have a final position yet, were invited to send their position and further comments, in particular on the suggestion expressed by one Member State during the meeting to restrict the existing approval, by 10 June 2022.

A.13 General issues for information / discussion:

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

a) Scope Document rev. 69

The Commission informed about the last modifications included in the scope document (version 70)

b) new cases: in particular Insect Protector, Cold Atmospheric Plasma

The Commission presented two new entries in the scope document with a proposal for interpretation subject to Member States comments: Insect Protector, Cold Atmospheric Plasma. The Commission explained one case presented by one Member State concerning a chemical substance (e.g. a polymer) sprayed on the crop to protect it from insect attacks by trapping them. The Commission explained that in its view this chemical substance is within the scope of Regulation (EC) No 1107/2009. Member States were invited to send views about this interpretation by 20 June 2022.

c) Heptamaloxyloglucan (scope discussion)

The Commission explained that the ongoing process for the renewal of approval of heptamaloxyglucan as active substance under Regulation (EC) No 1107/2009 had triggered a scope question as to whether it falls under the definition of plant

biostimulant (e.g. via a mode of action of abiotic stress tolerance) and should therefore be rather regulated by the Fertilising Products Regulation. However, the Commission explained that after consideration, the mode of action cannot be related to a stimulation of plant nutrition processes which would be required to consider the substance to be under the definition of a plant biostimulant.

Member States were invited to comment by 20 June 2022.

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

Member States were invited to send comments concerning the Frequently Asked Questions (FAQ) document for the Fertilising Products Regulation, in particular regarding the double function of one single substance, by 20 June 2022.

2. Basic substances – general issues

There were no news to discuss.

3. Member States updated survey on timing of regulatory procedures

The Commission presented the draft report on the outcome of the survey and invited four Member States to send clarifications on the information of the challenges reported to complete their authorisation procedures within the applicable deadline and the actions suggested to overcome them by 20 June 2022. The Commission informed that the draft report will be updated with the clarifications so that the final version of the report can be shared in the next meeting of this Committee.

4. Member States-proposal PPP TARIC Code

There were no news to discuss.

5. PPPAMS – update

The Commission reminded about the discussions that took place in the previous meetings of this Committee that aimed to better understand the views of Member States for achieving a full implementation of PPPAMS. During the last meeting, the Commission explained that a review of the technology underpinning the existing PPPAMS system had started. The Commission explained that work to ensure the preservation of the functionalities for emergency authorisations in the new system had also started. As regards as the next steps, the Commission explained that:

- PPPAMS in its current format cannot continue beyond 2022 due to the need to change the underlying technology;
- After a consideration of the available options a decision was taken to migrate the PPPAMS functions to the e-Submission Food Chain platform ('EFSC'), which is already being used to manage all other food sector applications except plant protection products.
- EFSC is an intuitive and easy to use solution and will offer more long-term possibilities than the current version of PPPAMS. Furthermore, there is already experience amongst stakeholder and Member States with its use and there is well established support and guidance available.
- The initial priority is to ensure that applications for emergency authorisations can be managed via EFSC by the end of 2022. The new interface will offer a

simplified process. The public database for emergency authorisations will remain the same.

– The inclusion of the other application types will be considered as a next step. Discussions will be arranged with Member States to determine the scope.

6. Incidents with phosphine products

The Commission informed that no incidents had been reported since the last meeting of this Committee and suggested to keep the point on the agenda to collect, monitor and report data on the use of phosphine generating products.

One Member State indicted it had sent letters to authorisation holders in order to assess how the risk mitigation options could be improved. This Member State asked to keep the point on the agenda.

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

The Commission informed that it had received comments from seven Member States, which all supported the establishment of a work plan for the development of test methods focussing on wild pollinators. The need for promoting research to determine adequate model species for wild bees was mentioned. One Member State provided a paper where a project on the implementation and communication of a Multiple-Stressor Bee Environmental Risk Assessment is explained.

Using the information provided by Member States and available on the website of the Organisation for Economic Co-operation and Development (OECD), the Commission presented an inventory table of the available test protocols.

Member States were invited to verify the inventory table, to send specific suggestions on what is needed to test sub lethal effects on bees, and their availability to support the official programme of OECD by 20 June 2022.

8. Debriefing workshop on crop protection measures and pollinator protection (7 April 2022)

The Commission informed about a workshop held on 7 April 2022, which was part of a broader consultation process in the context of the of review the EU pollinator initiative. The consultation consists of nine workshops about different environmental and agricultural topics that are important for pollinators together with a public consultation.

The aim of the workshop on crop protection measures and pollinator protection was to define concrete proposals on suitable policy actions in relation with pesticide use that could serve as an input for the review of the EU pollinator initiative. The workshop was moderated by a consultant and attended by 29 participants from the academia, stakeholders, NGOs and national authorities, representing different expertise and geographical origin. In addition, several Commission experts from different Directorates-General were present. Reports of the workshops and results of the public consultation will be available in autumn on the webpage of the Commission's Directorate-General for the Environment.

9. Long term toxicity effects of formulations

The Commission informed that since the last meeting of this Committee more inquiries related to the assessment of the long-term toxicity effects of plant protection products had been submitted to the Commission from the European

Parliament and from one stakeholder. 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 10 June 2022.

10. Residues on cut-flowers

    The Commission summarised the comments received so far from Member States: one Member State sent a survey conducted in a non-EU countries that exports cut flowers, and proposed to establish MRLs for cut flower setting a default value of 0.01 mg/kg. Member States showed divergent views about setting this value.

    Member States were invited to provide further comments by 20 June 2022.

11. SDHI active substances

    There were no news to discuss.

A.14 Implementation Article 67 Regulation (EC) No 1107/2009:

The Commission presented the new version of the draft Implementing Regulation, which had been updated on the basis of the comments received from the Member States after the last meeting of this Committee and clarified questions. The draft envisions that the Implementing Regulation will become applicable from 1 January 2025. The Commission aims at adopting the act by the end of 2022.

Member States were invited to comment on the draft and to inform if they will not be able to support the draft Implementing Regulation by 10 June 2022.

A.15 Amendment Commission Regulation (EU) No 547/2011:

The Commission presented the outline for an amendment of Regulation (EU) No 547/2011 as regards labelling requirements for plant protection products and clarified questions raised by Member States. Member States were invited to comment by 10 June 2022.

A.16 Co-formulants, in particular:

1. draft procedure and criteria for listing additional unacceptable co-formulants

   The Commission presented the draft Implementing Regulation on detailed rules and criteria for the identification of unacceptable co-formulants. Five Member States had provided comments since the last meeting of this Committee, which had been considered in this updated draft. Member States were invited to comment on the last draft presented by 10 June 2022.

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

   The Commission reminded of the proposal made by one Member State for establishing a guideline or an orientation document on the presence of mono- and polymers in plant protection products. Member States were invited to comment by 20 June 2022.

3. data collection on co-formulants (EFSA)

   EFSA presented an overview of a data collection on co-formulants. The data were retrieved from the information on plant protection products (PPPs) for representative uses, which were submitted as part of applications for the approval or renewal of approval of pesticide active substances.

A.17 Report from Working Groups, in particular:

1. Working Group on Biopesticides

   There were no news to discuss.

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" will start with an information session presenting the document to Member States and stakeholders on 24 May 2022. The experts involved in the consultation will be invited to perform case studies and to comment on the document. The case studies and comments will be further discussed with the participants and the draft document amended if necessary. After that, the document will be presented in this Committee.

3. Working Group on Seed Treatments (Risk Assessment)

   The Commission informed that the next step agreed with EFSA is to await for the revision of the seed-TROPEX model to align the risk assessment part of the Guidance Document for the Authorisation of Plant Protection Products for Seed Treatment.

4. Working Group Post Approval Issues

   There were no news to discuss.

5. Working Group on PPP Formulation Analysis

   There were no news to discuss.

A.18 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, including the progress in the peer review process for the renewal of glyphosate, for which the EFSA Conclusion is now expected around July 2023. EFSA also informed that – together with ECHA - it officially communicated to the Commission about the delay and this new planning for glyphosate.

   EFSA also informed that it intends to publish a table, which will be updated regularly, with the outcome of the assessments of active substances during the peer review as regards their potential endocrine disrupting properties.

2. Sustainable Use Directive (Directive 2009/128/EC)

   There were no news to discuss.

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

   There were no news to discuss.

4. Minor Use Facility (MUCF)

   The Commission informed that a Steering Group meeting is foreseen by mid-July to elect a new Chairperson who will lead the group in the coming years, to receive

feedback on the MUCF 2023 draft Working Programme and to exchange views on the upcoming second Annual General Meeting, which will be held at the end of October 2022.

5. OECD, FAO and EPPO activities

   The Commission informed about the week (13 to 17 June) of meetings organised by the OECD that aims to share and discussed updates about the recent regulatory initiatives of the organisation and its members.

A.19 Court cases, requests for internal review, Ombudsman cases:

The Commission informed about the preliminary ruling of the Court of Justice in case C-189/21 of 5 May 2022, involving aspects of compliance with Regulation (EC) No 1107/2009 under the European Common Agricultural Policy rules.

The Commission also informed that the judgment of the General Court in case T-740/18 dismissing the annulment of Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 concerning the non-renewal of approval of the active substance thiram had been appealed by one of the applicants.

The Commission explained that it had replied on 27 April 2022 to a request for Internal Review under Regulation (EC) No 1367/2006 (the Aarhus Regulation) by Pesticide Action Network Europe (PAN Europe) concerning Commission Implementing Regulation (EU) 2021/2068 as regards the extension of the approval of a number of active substances, and that the publication of its reply to a request for internal review by the same NGO concerning an alleged administrative omission regarding the ban of the substance L-cyhalothrin was imminent. All requests and, where applicable, replies given can be retrieved from the Commission's repository at the following website: https://ec.europa.eu/environment/aarhus/requests.htm.

A.20 Exchange of information from the Pesticide Residues section of the Committee, in particular possible impact on authorizations.

The Commission informed that in the previous meeting of the Residues section of this Committee which took place in April 2022 no votes took place on draft Regulation which lowered MRLs.

A.21 Scientific publications and information submitted by stakeholders:

There were no news to report.

A.22 Date of next meeting(s):

The Commission informed that the next meeting was confirmed for 14 and 15 July 2022.

A.23 AoB:

The Commission explained that one Member State had sent a proposal to extend the group of straight chain lepidopteran pheromones (SCLP) to cover also other semiochemicals according to a simplified procedures by considering a stepwise extension assuming a risk envelope approach compared to the initial group. The Commission invited Member States to comment on the proposal by 10 June 2022.

The Commission reminded that the Threshold of Toxicological Concern (TTC) approach had been developed to qualitatively assess the risk from exposure to substances at low levels. The TTC approach could be used for an initial assessment of a substance to determine whether a comprehensive risk assessment is required and is an important science-based approach for screening and prioritising the assessment of chemicals with low-level exposures that require more data over those that can be presumed to present no appreciable human health risk. However, EFSA's Scientific Committee Guidance Document states that the TTC approach should not be used for substances for which EU food/feed legislation requires the submission of toxicity data or when sufficient data are available for a risk assessment.

The Commission reminded that several Member States had previously opposed the use of TTC for decision-making on individual substances (where they considered that data should be available to establish the toxicological properties). The Commission also informed that the TTC approach as a means for assessing metabolites in certain situations is expected to be included in the guidance on deriving residue definitions that is being developed by the OECD.

The Commission asked Member States to reflect and provide comments on the possible use of the TTC approach under certain circumstances by 20 June 2022.

The Commission informed that a study strategy for thiabendazole had been made available by the applicant and that it is available on CIRCA BC.

The Commission provided an update on the state of play of the renewal procedure for glyphosate, following the announcement made on 10 May by EFSA and ECHA via their websites of a delay in delivering the EFSA Conclusion (with a new estimated delivery in July 2023). The Commission explained that the agencies also wrote to Commissioner Kyriakides explaining the reasons for the delay and that the Commissioner responded and also wrote to the Chair of the Committee on the Environment, Public Health and Food Safety of the European Parliament and to the Minister of Agriculture and Food of France (currently holding the rotating Council Presidency). Member States were informed that all letters had been published on the Commission's glyphosate webpage. The Commission also stressed 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 an extension of the current approval as required by Article 17 of Regulation (EC) No 1107/2009.

The Netherlands made the following statement to the Committee: *"On the issue of glyphosate, The Netherlands would like to express its profound concerns on the announced delay of the renewal process. There should be clarification whether glyphosate fulfils the conditions of approval according to Regulation (EC) No 1107/2009 as soon as possible. We therefore urge the European Commission to accelerate the process where possible, so that the period between the end of the current approval period and the decision making will be as short as possible. Moreover, The Netherlands fully agrees with the statement of the European Commission to immediately intervene in the approval of glyphosate when it becomes clear during the current renewal process that the substance does not meet the conditions of approval."*

Another Member State stated that it intends to remove glyphosate from its market by the end of 2023 indicating that in its view glyphosate undeniably harms biodiversity. For that reason, this Member State also informed the Commission and the other Member States that in its view renewal of glyphosate is not justifiable. The Member State also stated that it considers it is time for a harmonised approach for assessing harmful effects on biodiversity and that there is the need for an agreement on protection goals for biodiversity and for guidelines.

The Commission informed that in the Rapid Alert System for Food and Feed (RASFF) on 12 May 2022, Belgium had submitted a Food Fraud notification concerning a plant protection product marketed as Cyperkill. After different analyses, the Belgian authorities generated consistent data showing that the composition of a sample collected in Poland under "CYPERKILL MAX 500EC" brand name (batch 19000026, Internal R&D ref BA0498/22) was not matching the registered composition. The main difference was observed in the surfactant of the package. The Belgian authorities informed Member States that all batch numbers produced in Ougrée in Belgium start with BE XXX and batch numbers starting differently should be considered as counterfeit Cyperkill. Member States were requested to contact the RASFF team in case of having more information.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk substances, Straight Chain Lepidopteran Pheromones (aldehydes), and Straight Chain Lepidopteran Pheromones (alcohols), 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/10828/2021).

SANTE/10826/2021

The Commission presented the draft Implementing Regulation and informed about the latest comments received from two (of eleven) applicants and three Member States which had been considered. Two Member States expressed regret that only acetates, one out of three subgroups of Straight Chain Lepidopteran Pheromones (SCLP), would be renewed as low-risk active substances (one of it indicted it would abstain because of this reason). Two other Member States regarded all three subgroups as not low-risk substances because of classification for acute and chronic aquatic risk, category 1 (one of it indicted it would abstain because of this reason).

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: 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 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

This point was postponed because the consultation of the other Commission services concerned was still ongoing.

Vote postponed.

B.03 Exchange of views 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).

PLAN/2022/679

This point was postponed because the consultation of the other Commission services concerned was still ongoing.

Vote postponed.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Commission Implementing Regulation (EU) 2015/408 to update the list of candidates for substitution.

SANTE/10242/2022

The Commission presented and provided clarifications on the draft Implementing Regulation.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of the vote via written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance heptamaloxyloglucan.

PLAN/2022/1046

The Commission recalled that the vote on the extension of approval of the substance via written procedure after the previous meeting of this Committee had been stopped by the Commission, following some doubts as to whether heptamaloxyloglucan is within the scope of Regulation (EC) No 1107/2009. The Commission informed that, after consulting the applicant and after analysing the comments received from several Member States, it was still necessary to extend the approval period for one more year, until its mode of action is clarified.

The vote on the draft Regulation took place during the meeting.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance fish oil 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 SANTE/10076/2022).

SANTE/10074/2022

The Commission explained the latest amendments in the draft review report and the draft Implementing Regulation and indicted that a vote is intended for the next meeting of this Committee.

The Commission invited Member States to comment by 10 June 2022.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance sheep fat 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10072/2022).

SANTE/10070/2022

The Commission explained the latest amendments in the draft review report and the draft Implementing Regulation and indicted that a vote is intended for the next meeting of this Committee.

The Commission invited Member States to comment by 10 June 2022.

C.03 Exchange of views 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 Review Report SANTE/10028/2017).

SANTE/10574/2021

Pro memoria – TBT notification (to be) launched

The Commission made available the updated version of the draft implementing Regulation after the consultation of the other Commission services concerned. Even though the applicant already informed that they will no longer support a renewal of approval, the Commission still considers appropriate to proceed with the restriction of the approval conditions. A possible vote is foreseen in the next meeting of this Committee.