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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*
27 - 28 January 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/9956349c-78a7-4da9-8b5e-6dd26fb3e8c1*

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 in October is published, while the one of the meeting in December is under preparation.

A.02 New dossiers (for information):

- New active substances

  The Commission informed that application dossiers for the following new active substances had been declared admissible by the Rapporteur Member States Austria (8-Methyl-2-Decanol Propionate) and Germany (*Pseudomonas putida* strain B2017).

- Basic substances applications

  1. Extension of use of chitosan hydrochloride

     No discussion took place, the point was postponed.

  2. Extension of use of sodium chloride

     The Commission explained that the application covers an extension of use of the basic substance sodium chloride as a fungicide to additional diseases (downy mildews, *Plasmopara viticola*), and that it seems to be within the risk envelope of the already approved uses. The Commission reported that, based on the information received from EFSA, it seems that the environmental exposure resulting from the proposed use will be within the risk envelope of the uses that were previously assessed by EFSA and approved as basic substance uses. As regards human health, no concern has been identified. However, EFSA indicated that the residues on grapes may be significant, both resulting from the uses requested in the extension, as well as from the uses which are already approved, and mentioned that uses of NaCl as basic substances might contribute to the consumer dietary intake of sodium and chloride, and that there are public health actions under way to reduce sodium chloride intakes.

The Commission presented calculations of a worst case exposure scenario, based on which it seems that the potential increase in the salt intake resulting from the proposed and current uses as basic substance would be expected to be marginal compared to the current estimated salt intake in the EU consumers and well below the recommended dietary intake.

Member States were invited to consult an application and the information provided by EFSA, and to comment by 28 February 2022 as regards (a) the need for full risk assessment by EFSA; (b) their positions on approval of requested extension of use of sodium chloride as basic substance.

- Amendment of conditions of approval

  There were no news to discuss.

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

The Commission informed about the replies received from 10 Member States to the point raised at the beginning of 2021 as regards the possibility of the Commission to provide some funding in the period of 2023 and 2028 for technical assistance to Member State authorities who lack particular expertise or capacity to complete their tasks or for horizontal tasks of Member States – such as the development of guidance or methodologies for risk assessment. Both in this Committee and the Biocide competent authorities meeting, Member States expressed a need to recruit and train experts, however they also expressed that they do not prefer such support via procurements as they would find it difficult to appropriate the results of risk assessment carried out outside of their organisations.

The Commission informed that it reflects on some possible horizontal actions that were not mentioned by the Member States, and on the possibility to change procurements into grants that would allow financial contribution to the risk assessment of pesticide and biocide files by Member States. The Commission emphasised that this support would only be temporary and the Member States should build up expertise for the future. In order to be able to evaluate the different possibilities, Member States were requested to answer 4 questions detailing the current situation and the identified needs by 15 February 2022.

– Update of Annex to Regulation (EU) No 540/2011 – deletion of no longer approved active substances

The Commission informed that for a number of the active substances listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011, the approvals have expired because applications for renewal were either not submitted or were withdrawn. All those substances are no longer approved and should be deleted from the Annex for the sake of clarity and transparency. A draft Implementing Regulation and Annex to it have been prepared and were presented.

A number of Member States supported the proposal, and noted that currently it is difficult to identify the active substances that are no longer approved. The Commission reminded that the EU Pesticide Database allows data on all active substances, including their approval status, to be exported in Excel format. At the same time the Commission took note of the concerns expressed and will reflect how to address them.

One Member State asked if such updates to the Annex will be carried out regularly in the future and the Commission explained that this will be done when the need arises.

The Member States were invited to comment by 15 February 2022 on the draft Regulation and to indicate any inaccuracies identified in the table provided which lists the status of the active substances in Part A of the Annex to Implementing Regulation (EU) No 540/2011.

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

- New active substances

  There were no news to discuss.

- Renewal of approval

  1. Clofentezine

  A summary of the state of play was provided for clofentezine, then a general discussion on application of Article 4.7 was undertaken together with points A 04.02 and A 05.b.

  The Commission summarised the comments received from Member States so far, in particular:

  – a comment from one Member State which indicated that assessing further data on endocrine disrupting properties could be useful;

  – a comment about the need to agree how 'serious danger' as stated in Article 4.7 should be interpreted;

  – comments related to the consumer assessment for clofentezine being of significant concerns due to the issues and gaps outlined precluding MRLs being set or a consumer assessment being carried out. The same Member State indicated that this would impact possible uses under Article 4.7 and that the existing MRLs could not be used to defend uses on edible crops.

  The Commission recalled that:

  – all issues need to be considered in decision-making. The potential endocrine disrupting properties are one important element but not the only one because all approval criteria that needs to be fulfilled of at least one representative use.

  – the consumer risk assessment is a key issue for decision making and in fact even if the substance was not endocrine disrupting properties this would be decisive for the decision on renewal. Acceptable consumers risk needs to be demonstrated.

  – With regard to the consumer assessment, EFSA had considered the argument of the applicant but maintained the view that a consumer assessment cannot be finalised.

  – The Commission also noted that issues identified in the original peer-review had not been addressed at renewal.

  Given the above the Commission explained that reopening the endocrine disrupting properties assessment was not viable since it could not address the problems identified for the consumer assessment.

  Since negligible exposure is not considered possible due to residue related issues, the possibility for approval under Article 4.7 was the only remaining option which could be considered. However, it was underlined that in that the risks and open

issues for non-target organisms and residues, respectively, were also relevant. In that regard, it seems that only non-edible uses grown in greenhouses would be possible candidates for a potential renewal under Article 4.7.

Member States were invited to comment by 28 February 2022, in particular on possible derogation for the two non-edible uses in greenhouse identified in the Article 4.7 assessment.

The Commission and Member States also discussed some general aspects related to how and when derogations under Article 4.7 may be possible. One Member State raised doubts about herbicides (see point A.05.00.b – asulam-sodium) meeting the requirements (since alternative non-chemical methods are available), another Member State raised concerns about non-representative uses being considered, another Member State asked about the possibility to amend an approval granted under Article 4.7 and another Member State raised general concerns about approval of endocrine disrupting substances and setting MRLs for such substances.

2. Benthiavalicarb

The Commission recalled that only four Member States had commented since the last meeting of this Committee. According to them and as considered by the Commission, negligible exposure is not demonstrated, therefore a possible renewal under of Article 4.7 may be considered. Agricultural need has been proven for onions and sugar beets, but the applications on sugar beet and onion were not assessed in the procedure for the renewal. The Commission reminded that it is responsibility of each Member States to fully evaluate such uses ensuring that an acceptable risk is achieved. This would be stressed both in the renewal report and in the legal act. In addition, a review of the MRLs would also need to be considered.

Member States were invited to comment by 28 February 2022.

3. Fish oil

The Commission informed about the main findings in the EFSA Conclusion. There were no critical areas of concern, however, a few data gaps which need further clarification and the Commission will contact EFSA on them. Two co-formulants in the formulation of the representative use raised concern and the Commission informed that the applicant was contacted for clarification. A Member State asked for clarification if the Commission talked about co-formulants or impurities, and the Commission confirmed that it was about co-formulants.

Member States were invited to comment on the EFSA Conclusion by 15 February 2022.

4. Sheep fat

The Commission informed about the main findings in the EFSA Conclusion. There were no critical areas of concern, however, a few data gaps which need further clarification and the Commission will contact EFSA on them. Two co-formulants in the formulation of the representative use raised concern and the applicant had informed that the role of TiO2 is a colorant and the one of styrene is a binder, and that they presently explore ways to replace the two co-formulants.

A Member State asked for clarification if the Commission talked about co-formulants or impurities, and the Commission confirmed about co-formulants.

Member States were invited to comment on the EFSA Conclusion by 15 February 2022.

- Basic substances

5. Calcium propionate

The Commission informed that the draft Review Report was available on CIRCABC and summarised the issues identified in the EFSA Technical Report that are relevant for the proposed decision, like a potential for eye damaging effect, the possible toxicity by inhalation etc.

So far one Member State commented, supporting the points of view of some other Member States and mentioning that they would also consider a non-approval, unless the issues around the eye damaging properties are resolved.

Member States were invited to comment on the draft Review Report by 15 February 2022.

6. Black soap

The Commission informed that two Member States had commented. One Member State raises several issues that are still unresolved like the potential adverse effects on the eyes and the lungs as well as the need for risk mitigation measures for aquatic organisms and pollinators. The other Member State however, does not consider the EFSA outcome as preventing an approval. The Commission indicated it will reflect on how and if the outstanding issues can be resolved.

Member States were invited to comment on the EFSA report by 15 February 2022.

7. Lemon essential oil

The Commission summarised the outstanding issues in the risk assessment.

As regards non-dietary risk assessment, D-limonene is classified as Skin Irritant Category 2, Skin Sensitizer Category 1, and it may be fatal if swallowed and enters airways. The assessment of exposure of operators, workers, residents and bystanders for the specific use appears necessary, but it was not available in the application.

As regards environmental exposure, a comparison of levels of limonene that may be expected as a consequence of the natural occurrence and release by plants to the exposure from proposed uses as basic substance has not been provided by the applicant. Furthermore, lemon oil and its component D-limonene have a notified classification as very toxic to aquatic life (Aquatic Acute 1) and harmful to aquatic life with long lasting effects (Aquatic Chronic 3). The aquatic exposure assessment resulting from spray drift with or without a buffer zone has not been presented in the application. EFSA indicated that this would be essential to address the possible risk to aquatic organisms arising from the intended uses. Additionally, as the substance has insecticidal properties, unacceptable effects on non-target arthropods cannot be excluded a priori and a risk assessment was not available.

Based on the available information and comments received so far from the Member States, it seems that the proposal for non-approval as a basic substance would be appropriate. Lemon oil should be rather considered a regular botanical active substance, requiring full risk assessment.

Member States were invited to comment by 28 February 2022.

8. Yucca Schidigera extract

The Commission explained that one Member State had submitted comments indicating that considering the entry in the ECHA database for a self-classification of Yucca schidigera extract, the concentration in the applied product should not be higher than 10 % to meet the requirements for human health (skin irritation and serious eye irritation). It seems that this condition would not be fulfilled for at least some of the proposed uses. Additionally, the effects on non-target organisms cannot be excluded because of missing data in the light of the known insecticidal mode of action of saponins included in the extract. Therefore, it seems that the conditions for approval are not met.

The Member States were invited to comment by 28 February 2022.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Dimethyl disulphide

  The Commission recalled that this new active substance is temporarily on hold as the applicant and Rapporteur Member State (France) are discussing the possibility of additional studies to complete the data gaps.

  b) Asulam-sodium

  The Commission recalled that only three Member States had commented and that they agree that it is not possible to conclude a negligible exposure due to residues above the LOQ for the representative use in pre- and post-emergence in spinach. Therefore a possible application of Article 4.7 could be explored.

  Agricultural need has been proven for marigold, fennel, bleached celery, leaf celery and in spinach, but one Member State questioned the relevance of essentiality ('serious danger to plant health') for an herbicide which could be substituted by non-chemical weeding methods, although EFSA found the proposed uses fulfilling the essentiality criterion. The Commission reminded that authorisations of plant protection product uses are under the responsibility of Member States including the full evaluation of such uses ensuring that acceptable risks are achieved. This would be reported both in the renewal report and the legal act. A review of the MRLs for edible crops, if relevant, would also need to be considered.

  Member States were invited to send comments by 28 February 2022.

- Renewal of approval

  c) Captan

  The Commission informed that discussions on a mandate to EFSA to assess the risks related to in-field uses are still ongoing with the Authority.

  d) *Bacillus amyloliquefaciens* strain QST 713

  Commission recalled that a comprehensive summary has been uploaded on CIRCA, mentioning two possibilities: 1) a list of restrictions and risk mitigation

measures to be applied in case of renewal of the active substance because of the concerns identified by EFSA on bees , and 2) the possibility to mandate EFSA either specifically on the strain QST 713 or as a more general mandate for all the microorganisms.

One Member State raised the issue of crops not included in the representative uses, for which the proposed restrictions should be adapted.

The Commission also informed that a Member State identified some inconsistency between the RAR and the EFSA conclusion and that EFSA was asked for clarification.

Member States were invited to comment by 28 of February 2022.

e) *Pseudomonas chlororaphis* strain MA342

The Commission summarised the previous discussion on this active substance, including the EFSA mandate on the risk for consumers from exposure to genotoxic metabolite DDR, which was identified as critical area of concern in the EFSA Conclusion, and its outcome which is now available. The Commission also summarised the biology and mode of action of this microorganism and how these aspects could be considered for the decision making as regards a potential renewal.

Member States were invited to comment by 15 February 2022 taking into consideration the biology and mode of action of the microorganism as well as on the potential concern to consumers from the metabolite DDR.

f) *Bacillus thuringiensis* (horizontal discussion)

The Commission communicated that, according to a claim recently made by a stakeholder, two Member States have recalled from the market vegetables treated with *Bacillus thuringiensis* (Bt) despite the CFU/g detected on these food items were 10^2 CFU/g of Bt, hence below the threshold of 10^5 CFU/g indicated by an EFSA Opinion from 2016. The Commission called for a more consistent approach compared to the existing knowledge on this matter.

In addition, the Commission confirmed that progresses on a possible mandate to EFSA and ECDC were made, and dialogue with the agencies was initiated.

g) *Pythium oligandrum* strain M1

The Commission informed that two Member States commented on the pathogenicity study provided by the applicant and the opportunity to consider risk mitigation measures which would be required due to sensitizing properties.

The Commission announced that a draft Renewal Report is in preparation and invited to comment by 28 February 2022.

h) Pelargonic acid

The Commission informed that it received further comments from two Member States on the results of the peer review. It was stressed that there are still open issues related to potential risks for bees, soil organisms and non-target arthropods. The Commission mentioned that it is very important that Member States share their views, in particular on: risks identified for bees and possible risk mitigation measures at national level; risks identified for non-target invertebrates (bees, arthropods, soil organisms) and possible risk mitigation

measures at national level; and representative uses which are not sufficiently supported by the data provided by the applicants. Member States were invited to comment by 15 February 2022.

i) Straight Chain Lepidopteran Pheromones

The Commission summarised the comments received from five Member States, the applicants and the Rapporteur Member State since the last meeting. Two Member States supported the way the Commission handled the inclusion of the SCLP blends in the Annex of the review report. One Member State agreed on the removal of the low risk status whereas another Member State proposed to split the SCLPs into two groups: one that fulfils the low risk criteria and one that does not. One applicant was again requesting to reintroduce the low risk status for SCLPs. Furthermore, there were some clarifying questions from one Member State about the relevant guidance documents (GD) to quote.

The Commission stressed that the blends, given in Annex II, are for illustrative purposes only. The Commission announced that a revised review report is expected to be made available in the next weeks. Member States were invited to comment by the 28 February 2022.

- Basic substances

j) Hydrogen peroxide silver stabilised

The Commission informed that since the last meeting of this Committee, one Member State had submitted comments indicating support for the non-approval of silver stabilised hydrogen peroxide as basic substance, due to the uncertainties regarding the identity of this active substance.

Member States were invited to comments on the Review Report by 28 February 2022.

k) Ozone

The Commission informed that one of the applicants had submitted a request to put on hold the evaluation of the application in order to prepare additional supporting information. The applicant indicated that they would like to postpone the conclusion of the evaluation until the finalisation of an assessment of the active substance "ozone generated from oxygen" under Biocidal Products Regulation (EU) No 528/2012.

The Commission proposed to accept the request allowing the applicant to produce more data to address the concerns identified by EFSA. The proposed deadline for submission of new data is one year. The second applicant for an approval of ozone has been informed about this request and invited to provide additional information. The two applicants were also invited to consider a further cooperation on this matter.

l) Vinegar (amended review report to take note)

The Committee endorsed the amended review report, however two Member States did not agree with the proposed amendment because they did not supported the approval of chitosan as basic substance in the past.

- Amendment of conditions of approval

  m) Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3)
  The Commission summarised the comments received from one Member State and the concerns raised about a possible increase of the risk to bees because of the extended use as a fungicide during flowering season. Furthermore this Member State raised concerns about the still existing data gaps from 2008. The Commission indicated that this is out of the scope of the amendment of conditions of approval under discussion and that it would be covered by in the upcoming renewal process. The Member State proposed that on EU level a harmonised procedure for the assessment of environmental fate and ecotoxicology of oils should be established.

  Member States were invited to comment by 15 February 2022.

A.06 Confirmatory Information:

1. Potassium phosphonates (amended review report to take note)

   The Commission summarised the comments received after the last Committee meeting. The Committee endorsed the amended report.

2. Pyridaril (amended review report to take note)

   The Commission informed that the endorsement will be postponed. One Member State that provided comments was invited to include its written proposals for the section 6 and 7 in the review report.

   Member States were invited to comment by 15 February 2022.

3. 1-decanol

   The Commission summarised the assessment of the confirmatory data specified in Commission Directive 2008/116/EC (the risk to aquatic organisms and information confirming the groundwater, surface water and sediment exposure assessments). Only one Member State sent written comments and agreed to close this confirmatory data procedure.

   Member States were again invited to comment by the 28 of February 2022, on the updated review report.

4. Acibenzolar-methyl

   The Commission informed that so far only one Member State had commented after the discussion which took place at the last meeting of this Committee, supporting the initiation of an Article 21 procedure to complete the assessment as regards endocrine disrupting properties. The Commission also reminded that internal reflections are still on-going.

   Member States were invited to comment by 15 February 2022.

5. Acequinocyl

   The Commission informed that a formal mistake in a table in EFSA's technical report needs correction and about a proposal from the incoming Rapporteur Member State to consider the risk assessment for the feeding guild of herbivorous mammals. Given the start of the renewal procedure in 2022, the Rapporteur Member State proposed to give priority to the assessment of herbivorous mammals during the renewal.

   Member States were invited to comment by 15 February 2022.

6. Pendimethalin

   The Commission presented the outcome of the consultation on the confirmatory data on the potential for bioaccumulation. Further discussion is needed on i) whether the bioconcentation factor (BCF) values should be corrected to be in terms only of the parent substance, while the metabolites are properly characterised; ii) the reliability of the additional information provided; iii) the reliability of the BCF value for zebrafish; and iv) the BCF value to be used for the secondary poisoning risk assessment for birds and mammals.

   The Commission noted that the last point is of significant horizontal importance, as in the case pendimethalin BCF have been determined on the basis of experimental data for five different fish species. At present there is no commonly agreed approach how to define BCF for regulatory purposes when data from more than one species are available.

   Considering that similar cases might arise in the future, that the accurately defined value of BCF is of significant regulatory importance in the case of pendimethalin, and that meanwhile an application for renewal of this active substance has been submitted with a similar data set, the Commission suggests to mandate EFSA on the identified open issues on bioaccumulation. A number of Member States expressed support to the proposal, and suggest to mandate ECHA as well, because how to define BCF is relevant for the risk assessment of different groups of chemicals.

   Member States were invited to comment by 15 February 2022.

7. Propyzamide

   The Commission recalled that following a mandate from the Commission for a peer review, EFSA finalised its Conclusion in December 2021. EFSA had been tasked to further consider points related to the assessment of the toxicological profile of metabolites identified in significant concentration in primary and rotational crops.

   The EFSA Conclusion highlights a number of issues which could not be solved based on the confirmatory information submitted, which led to the consumer risk assessment remaining open.

   However, as part of the mandate, a consideration of the TTC approach to address exposure to the metabolites was also requested, in view of providing risk managers with all information for decision making.

   It was noted that the applicant has generated further data to address the issues identified which was not available as part of the confirmatory submission. This includes new genotoxicity studies and new residue trials. These data are intended to be submitted in the renewal dossier due by 30 June 2022.

   The views of Member States were requested, in particular on whether TTC may be taken into account in this case or not. Member State views on the way forward were invited by 28 February 2022.

8. Penthiopyrad

   The Commission recalled that following a mandate from the Commission for a peer review on two metabolites M11 and PAM, EFSA finalised its Conclusion in December 2021.

The Commission explained that overall, despite the groundwater metabolites M11 and PAM being considered relevant, since they are not predicted to occur above 0.1 µg/L in all scenarios for all uses, safe uses remain to underpin the approval. Member States must carefully consider risks to groundwater when authorising plant protection products (already a condition of the existing approval).

It was noted that that an application for renewal must be submitted by 31 May 2022 and that the groundwater assessment should also be further addressed as part of that assessment.

The Commission explained that the proposal is to close the confirmatory assessment by updating the Review Report and that no changes to the approval are proposed.

A draft updated Review Report was made available and comments were requested by 15 February 2022, in view of endorsing this updated report during next meeting of this Committee.

A.07 Guidance Documents

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

   The Commission informed the Member States of the publication by EFSA of a supporting document with the analysis of the evidence to support the definition of Specific Protection Goals for bumble bees and solitary bees. The Commission announced an expert meeting for risk assessors and risk managers from Member States to discuss the possibilities for setting these Specific Protection Goals.

   The Commission shared with the Member States a position paper from PAN Europe on the development of a risk assessment of pesticides on bumblebees and solitary bees.

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

   The Commission made available a new summary table with the comments received on the controversial points in the draft guidance document presented during the last meeting of this Committee. Comments have been received from 8 Member States.

   The Member States discussed the remaining controversial issues, in particular the interpretation that sowing of treated seeds constitutes a use of plant protection product and whether the interzonal assessment should include all Member States or only those identified by the applicant (the so called concerned Member States). One Member State shared their interpretation of Article 49(1) which is that the sowing of seeds treated with non-authorised plant protection products is not possible even without specific national interdiction. Another Member State pointed out that there are general problems of interpretation with the current wording of Article 49. A third Member States asked the draft guidance document to be returned to a working group. Several Member States expressed the opinion that an amendment of Regulation (EC) No 1107/2009 would be necessary and that a guidance document would not be sufficient to resolve the unclear issues concerning treated seeds.

The Member States were asked to share their preliminary positions on the draft guidance document. A total of 3 Member States supported the current version, 10 Member States did not support it, and 13 Member States had no position.

On this background the Commission explained that it will not initiate the stakeholders' consultation as initially intended and will reflect on the following steps.

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

   The Commission shared an updated version of draft criteria on which basis a document would be considered as guidance document to be listed in the Communications. The Commission shared the comments of a Member State and answered the proposed actions in it.

   Member States were invited to comment by 28 February 2022.

4. Draft technical guidance on points 3.6.3. to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the demonstration of negligible exposure to an active substance in a plant protection product under realistic conditions of use (update)

   The Commission informed that following a call for nominations for a Working Group to prepare a new version of the guidance, 8 Member States had so far responded, in addition to EFSA. The Commission explained that it would prepare a first draft based on the outline previously agreed in this Committee, and then a meeting of the Working Group would be convened to refine and finalise the guidance.

   Member States who had not nominated an expert but still wished to do so were invited to inform the Commission.

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

   The Commission recalled that one Member State had submitted technical comments at the previous meeting of this Committee. Two Member States and EFSA had reacted to this comment, one of these Member States in support while the other and EFSA providing further reflections.

   Member States were invited to submit further comments in view of endorsing and implementation of this guidance document by 15 February 2022.

6. EFSA Guidance on aneugenicity assessment

   The Commission informed that 3 Member States had commented: one supporting immediate application with no transition period, another requesting more time for commenting, and a third submitting technical questions as regards the need of additional studies.

   Member States were invited to submit further comment in view of endorsing and implemention this guidance document by 28 February 2022.

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

– Article 44(4)

The Commission informed that no notifications were received.

– Article 36(3)

The Commission informed about the 8 notifications received: 3 notifications concerned rejections of mutual recognition applications, two from a Member State belonging to a different zone from the reference Member State, and 5 concerned rejections of authorisation under the zonal system. In two cases the decisions were brought to National Courts and the appeals were dismissed.

– Article 53

The Commission informed that work on introducing a new field on actual use (post-authorisation), to be used for calculation of HRI2, was ongoing.

In addition, the Commission informed that the technical reports on the evaluation of the emergency authorisation granted by 11 Member States for the use of neonicotinoids in sugar beet, published by EFSA in November 2021, are currently being discussed internally and with EFSA. Two Member States said that the applicability of non-chemical methods depend on local conditions. One Member State offered to send full details to the Commission on non-chemical methods.

A.09 Microorganism Active Substances, in particular:

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

  There were no news to discuss.

A.10 Safeners and Synergists:

The Commission informed that the drafting of a Regulation referred to in Article 26 of Regulation (EC) No 1107/2009 is in preparation. Furthermore the Commission invited Member States to express their interest to participate to a working group by 15 February 2022 to establish the data requirements relevant for these substances.

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

1. Sodium hydrogen carbonate

   The Commission informed that further correspondence with the authorisation holder in one Member State where the substance was authorised as a plant protection product had been made available via CIRCABC.

   The Commission informed that 6 Member States had commented following up on the discussion in the last meeting of this Committee: 2 Member States agreed to the Commission's view that active substances should not be double-listed as basic and regular active substances once the first product authorisation was granted, and favoured a withdrawal of the approval as a basic substances over a gradual reduction of the scope of the review report following the development of uses covered by national authorisations (i.e. removing the uses covered by authorisations from the uses allowed for the basic substance). Of the 4 Member States disagreeing with this approach, one took the view that the substance should not have been approved as a new active substance, and noted that a double-listing appeared possible as

evidenced by the current situation. Another Member State supported this view and argued that the assumption of food as a basic substance in Article 23(1) last sentence concerned all indents (a) to (d) of Article 23(1). A double-listing was supported to allow the substance to be used in a formulated form and placed on the market as a pesticide. Two other Member States joined that view, and underlined basic substances did not need national authorisations, and were not subject to approvals for a given period of time. They reminded that basis substances provide useful alternatives in small markets where industry did not seek authorisations. Two other Member States supported these views.

The Member State that had authorised the product as a low-risk pesticide informed that they had refused the applicant's request to delist the active substance as a basic substance. The Commission confirmed that this concurred with the reply given to the authorisation holder, because this would require an implementing regulation amending Regulation (EU) No 540/2011.

2. Flupyradifurone and acetamiprid

The Commission informed of the publication of the EFSA outputs on flupyradifurone and acetamiprid on 24 January 2021. No detailed discussion took place and Member States were invited to comment on the EFSA outputs by 4 March 2022.

A.12 Article 21:

1. Ipconazole

The Commission recalled that EFSA sent out its draft Statement for commenting earlier in January and would circulate the finalised Statement imminently. Once the Statement was available, the Commission would then determine the appropriate next steps.

Member States were invited to provide their views on the Statement by 28 February so that an informed discussion could take place in the next meeting of this Committee. The Commission also invited the Rapporteur Member State for renewal to indicate, if possible, how the issues considered as part of the Article 21 review had been addressed in the renewal dossier.

A.13 General issues for information / discussion

1. Illegal plant protection product use (Seminar/Training February 2022)

The Member State organising the Seminar informed that it will take place the 16 and 17 of February in a hybrid form and that registration is open.

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

a) Nitrophenolates

The Commission informed that the Rapporteur Member State sees not possibility to communicate about its views on the validity of the claimed plant protection functions or uses before the assessment report is made available for peer review. Therefore, the CHAP case or other requests for interpretation of the role of nitrophenolates could not be addressed at this stage.

b) Scope Document – new cases: Procrop/Nuvagrain, Nitrogen-based atmosphere

The Commission informed that new comments were received from three Member States concerning the new version (rev. 68) of the scope document. The latest suggestions made by one Member State as regards the borderline with the scope of the Biocides Regulation were accepted.

The proposals for interpretation for two new requests were presented and Member States were invited to comment by 28 February 2022. The suggestions made by another Member State and an external stakeholder regarding several entries concerning fertilising products (e.g. bio stimulants) will be reviewed by the Commission in view of a discussion at the next Committee.

3. Basic substances – general issues

   There were no news to discuss.

4. MS updated survey on timing of regulatory procedures

   The Commission informed that the drafting of the report on the two surveys is still ongoing.

5. Mono- and polymers as co-formulants

   The Commission recalled that again no comments were received. Meanwhile, the PAI Working Group discussed also on the intentional presence of forbidden co-formulants and on the need of harmonization in the application of the Regulation on unacceptable co-formulants as regards the limits where co-formulants are considered unacceptable. As there was no agreement among Member States about this limit, the decision was to take these two points (mono- and polymers used as co-formulants and intentional concentration of forbidden co-formulants) to this Committee.

   Member States were invited to comment by 28 of February 2022.

6. Trifluoroacetic acid (TFA)

   The Commission informed that there was currently no news to report.

7. MS-proposal PPP TARIC Code

   The Commission recalled that in the last meeting of this Committee that took place in December 2021, one Member State proposed to discuss the amendment of TARIC codes under heading 3808 in order to differentiate pesticides from biocides or even other goods, to facilitate the management of control procedures in borders and help National Authorities (even EUROPOL) to monitor illegal and counterfeit plant protection products. Two Member States sent in written their global support to this initiative.

   Member States were again invited to send their views on this initiative and to reflect on a manageable nomenclature proposal, by 28 of February 2022.

8. PPPAMS – update

   The Commission thanked the Member States who had performed testing on PPPAMS v1.40 and for their feedback and comments and then highlighted that a critical juncture in the project had been reached i.e. development of the system was complete (pending small tweaks and improvements – in particular taking into account feedback from Member States) and therefore the key question was on implementation. The Commission underlined that the views of Member States are

essential as the next steps concerning implementation will depend on their support, commitment and agreement.

The Commission informed that the comments received are being analysed. The comments vary in nature – some are technical or system/process related and others are related to implementation and general views on PPPAMS. Concerning implementation – the views received express some general concerns about use of PPPAMS, the resources needed from applicants and Member States and the scope of the system (one Member State considers that the system should only serve as a repository for authorisations and not include applications). There was also call for more training and support.

The Commission invited all Member States to provide comments and indicated that what is more critical at this stage are the views on the system per se, and on its implementation. Member States who cannot support the system as it stands were asked to provide views on what they can support and what they cannot.

In response to a comment from one Member State about the benefits of PPPAMS, the Commission reminded that PPPAMS was initiated due to the calls and needs of Member States in view of supporting and facilitating the fulfilment of the requirements of Regulation (EC) No 1107/2009 and improving the availability of information related to the authorisation of PPPs. Other stakeholders would also benefit in different ways by having access to information. The Commission recalled a number of the key objectives of the PPPAMS:

- harmonisation of the basic information submitted as part of applications for authorisation of plant protection products
- improve the mutual recognition of plant protection products
- improve the tracking of the evaluation process for authorisation of plant protection products to allow Member States and others to have a full view on activities within and between zones
- deliver correct and timely information on authorised or withdrawn plant protection products to stakeholders in a centralised database

9. Incidents with phosphine products

   The Commission reported on the information received by one Member State on the measures taken to prevent accidents related to the use of phosphine-producing substances. The Commission further informed that the issue is monitored also by DG-MOVE. The Commission invited to comment by 28 February 2022.

10. Article 68 reporting

    The Commission informed that Member States are not required anymore to submit distinct reports under Article 68, different from the reports under OCR submitted via AROC. The scopes of the reporting obligations in Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council as amended by Regulation (EU) 2017/625 and in Article 113(1) of Regulation (EU) 2017/625 are similar. Furthermore, the deadline in Article 68 of Regulation (EC) No 1107/2009 was aligned with that of Article 113(1) of Regulation (EU) 2017/625. Therefore, the Member States should include the issues to be reported under Article 68 of Regulation (EC) No 1107/2009 in their annual report (namely in Section 8 of Part II of the Annex to Implementing Regulation (EU) 2019/723).

11. Labelling of PPP imported in bulk

The Commission informed about a letter from a stakeholders association raising concern about the practice in some Member States to require import of pesticides in bulk form, including intermediate bulk containers (IBC), to be labelled in accordance with Commission Regulation (EU) No 547/2011, in the light of the current approach taken to the scope in a Questions and Answers Document available at SANTE webpage (SANCO/12415/2013, Rev. 6). The stakeholder association questions the practicability of the approach where the products are repackaged and relabelled for the end user, pointing also to Article 28(2)(c) of Regulation (EC) No 1107/2009 and the fact that Regulation (EC) No 1272/2008 (the CLP Regulation) already applies to these bulk products.

The Commission informed that the question would require also consideration by other services than DG SANTE. It invited Member States to share their views and their practices, including on IBC, and any differentiation between products for sale in their territory or merely shipped to other Member States. Member States were invited to liaise with their representatives in the Post Approval Issues Working Group.

12. Development of azole resistant *Aspergillus* from use of azole fungicides – update

The Commission announced that after the discussions and reflections held in this Committee and following discussions with the EU agencies, a mandate to further consider the issue of resistance in *Aspergillus* from environmental use of azoles had been sent to EFSA, ECHA, EMA, ECDC, EEA, with the JRC providing support to the task. EFSA will act as the coordinator. Member States were reminded that the EU agencies may contact their authorities who have specific experience or activities related to azole resistance. The Commission counts on close cooperation to ensure that this mandate delivers the expected results. Finally, Member States were informed that 30 months had been allocated for the completion of the mandate in the form of a Scientific Report.

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

The Commission discussed the scope of the draft Implementing Regulation and its relationship with other ongoing initiatives such as the SAIO proposal and the SUD revision. The Commission then presented a revised draft of the Implementing Regulation, illustrating the changes made and explaining how they related to the comments received from the Member States.

Several Member States considered that the revised draft had been improved. The following points were discussed: the inclusion of sowing of treated seeds among the uses to be recorded, the use of the data contained in the records for control and statistical purposes, the importance of avoiding duplication of records and minimising the burden for the users, concerns about third-party access to information contained in the records, the identification of the use location under the area requirement. Following some questions by the Member States, the Commission clarified that the Implementing Regulation would not prescribe the use of a specific platform and would not require the data to be transmitted to the Commission.

A.15 Report from working groups, in particular:

1. Working Group on Biopesticides

   The Commission informed that new national experts were added to the working group, and invited Member States who are not yet represented in the WG to designate their experts.

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

   The Commission informed that two new experts were nominated to the Working Group and that the Working Group continued working on the draft document on problem formulation with case studies.

   The Commission also reported about (1) the last meeting organised by the Central Zone in which it was explained how the drift reduction techniques are assessed and validated currently at national level in two Member States, in view of their implementation for the Risk Assessment and Risk Management of Plant Protection Products (2) the work on the upcoming EU list of RMM, that is expected to emphasise that risk mitigation measures can be proposed at different levels of the approval process of active substances and authorisation of plant protection products.

3. Working Group on Seed Treatments (Risk Assessment)

   The Commission informed that the Working group sent on 7 December 2021 the 17th version of the Guidance Document on risk assessment for the authorisation of plant protection products intended for seed treatment and that was made available via CIRCABC.

   Member States were invited to comment by 28 February 2022. The Commission will reflect on the next steps, especially the necessary involvement of EFSA to finalise the GD.

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 13 and 14 December 2021. The main points debated were: prioritisation of Guidance Documents (in preparation and for amendment), renewals of plant protection products containing mixtures of active substances, the access to third parties of the data matching tables, the interpretation of Article 38 of Regulation (EC) No 1107/2009, the harmonisation on the implementation of Regulation (EU) 2021/383, the withdrawal of the letters of access while the plant protection products are authorised, issues on data protection, mechanisms to avoid sending confidential information following a request via phishing emails, among others.

A.16 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

   EFSA informed about upcoming Conclusions and their planning for the next months for expert meetings and reminded about the processes related to the pre-submission advice to applicants as well as the personal data management for dossiers under IUCLID. EFSA mentioned that it received the compiled reporting tables of glyphosate on 14 January 2022, which included over 2800 comments.

EFSA also presented the updated Exposure guidance document.

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)

   Comments on the draft explanatory note which was shared with the Member States during the last meeting of this Committee have been received from four Member States. The Minor Uses Coordination Facility will discuss the comments with the Working group and prepare an updated version of the Explanatory note.

5. OECD, FAO and EPPO activities

   The Commission briefly informed about the recent documents and invitations to events sent by OECD.

A.17 Court cases.

The Commission informed about the judgment of the Court of Justice of 9 December (C-374/20 P). The judgment of the General Court (First Chamber) of 13 October 2021 (Case C-828/21 P) was appealed.

The Commission also informed that two applications for internal review have been brought by an NGO (Pesticides Action Network) under the revised Aarhus Regulation Regulation (EC) No 1367/2006:

– Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021 renewing the approval of the active substance cypermethrin as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 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, OJ L 420, 25.11.2021.

– Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin OJ L 421, 26.11.2021.

The request letters will become shortly available on: https://ec.europa.eu/environment/aarhus/.

A.18 Ombudsman cases:

There were no news to discuss.

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

There were no news to discuss.

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed about a report provided by one Member State concerning the presence of pesticides residues in organic fertilisers made from vinasses recycled from sugar beet processing, likely originating from the application of clopyralid, aminopyralid or picloram. Consequently these organic fertilisers (used by private gardeners) caused damages to the fertilised plants.

A.21 Date of next meeting(s):

The Commission informed that he next meeting of this Committee is scheduled for 30-31 March 2022, subject to confirmation.

A.22 AoB:

The Commission informed about the dates that the Better Training for Safer Food Trainings for Microorganisms are planned and invited Member States to send their participants.

The Commission informed that one Member State had informed about unintentional contamination with prosulfocarb residues. It was suggested to discuss this also in the Residues section of this Committee. Member States were invited to inform the Committee if they have found similar situation in their own jurisdiction.

On request of on Member State, it was clarified that any data matching is acceptable if it has already been carried out, and that the Rapporteur Member State does not need to repeat the data matching in the event a proper data matching table is already available.

The Commission informed about a Pollinator and Pesticides Workshop which will take place the 7 April 2022 in the context of the consultation process on the review of the EU pollinators' initiative. In the context to this review, an open consultation via a questionnaire on the EU Commission consultation webpage is expected to be launched beginning of February 2022 and expert consultations via 10 thematic workshops will take place, one of them on pesticides. This particular workshop on pesticides and pollinators will focus on risk mitigation measures and concrete, innovative solutions to protect (wild) pollinators better, when using insecticides in farms (crop protection), public areas, and by general public in homes and home gardens. A contractor will run the workshop. Participation will be possible on invitation only. Around 30 experts, with the aim to balance relevant stakeholder groups, expertise and geographical regions, will be invited. For the revision of the EU pollinators' initiative also Member States will be consulted.

The Commission provided information on the involvement in the ongoing activities related to the Chemical Strategy for Sustainability (CSS). Several interservice groups have been launched by the Directorates-General in the lead for the CSS on various actions announced. The topics mostly followed by DG SANTE are those with direct relevance for biocidal products and/or plant protection products, in particular:

- Revision of the CLP Regulation to introduce criteria for endocrine disruptors (distinguished in categories) and PBT substances. The main concern here is that the criteria already in place under the Biocide Product Regulation (BPR) and Plant Protection Product Regulation (PPPR) remain intact. At the moment there seems to be acceptance of the criteria under BPR and PPPR especially for category 1 endocrine disruptors, while the discussions are more complex on the additional categories regarding suspected endocrine disruptors.

- Enlargement of hazard categories which are the basis for the exclusion criteria to include immunotoxicity and neurotoxicity. It appears that substances classified for these properties would not in most case already pass the risk assessment under the BPR or PPPR, so at the moment it seems that a revision of the two regulations to include those criteria is not needed.
- Discussions on essential use concept. An external contractor will examine how to develop this concept in the context of REACH.
- One substance one assessment concept. Data ownership and possibility to access data submitted in different legal contexts need to be examined, as well as the implications on the IT systems in use in the various agencies. Discussions are also ongoing on the scope of the concept (whether one substance one hazard assessment, leaving out the exposure and risk or whether including all elements).
- Cumulative risk assessment, on which EFSA has already made good progress, in particular in the area of residues.
- Export bans: the preparatory work for a Regulation to prevent the exports of substances banned in the EU to other parts of the world is launched – it will cover all kinds of chemicals, including also pesticides. The interactions with the Rotterdam Convention (and the PIC Regulation) will have to be examined, also bearing in mind that some substances might be banned in the EU under one legal framework but not under other ones.

One Member Stated thanked the Commission and asked for regular updates. Another Member State wondered about the impacts on active substances and also co-formulants and safeners and synergists.

The Commission also informed the Committee about a draft opinion of the SCHEER Committee concerning groundwater quality standards for proposed additional pollutants in the annexes to the Groundwater Directive, in which non-relevant metabolites of pesticides were considered, published on 7 January, with a commenting deadline of 8 February 2022.

Finally, the Commission informed that the mandates on the active substances abamectin and benfluralin were sent to EFSA.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms.

(SANTE/10686/2021)

The Commission summarised the main changes applied to the Regulations amending Annex II to Regulation (EC) No 1107/2009, Regulation (EU) No 283/2013, Regulation (EU) No 284/2013, and Regulation (EU) No 546/2011, in particular on the last proposals concerning data requirements on ecotoxicological studies, and low-risk criteria.

The Commission informed that the envisaged launching date of the Scrutiny by the European Parliament and the Council was shifted to Q2 2022 to accommodate the translation process of the Regulations, which needs to be completed before launching

the scrutiny. This will change the entry into force date of these Regulations, however the time intervals between the entry into force and the application of the Regulations has been adapted in order to maintain the application date of the Regulations as planned before (Q4 2022), once IUCLID will be updated based on the new regulations.

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.

The Netherlands made the following protocol declaration:

"*We support the current proposals for the assessment on micro-organisms which will improve the dossiers and the assessments. Although we see that that these proposals will increase the quality of the dossiers, we do not expect them to significantly accelerate the approval process for micro-organisms because the regulatory procedure remains unchanged and a significant amount of data is still requested. In our view this was one of the goals of the review, because Micro-organisms are essential and needed on the market to make the agricultural transition which we strive to. We would therefore like to emphasize that further action is needed to accelerate the approval process for micro-organisms. We would especially like to call out for further action in order to accommodate the group-assessment of micro-organisms and to initiate the development of the necessary guidance document for harmonization. Of course, the Netherlands is willing to actively contribute to this guidance document*".

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms. (SANTE/12040/2020)

See B.01. 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.

The Netherlands made the following protocol declaration:

"*We support the current proposals for the assessment on micro-organisms which will improve the dossiers and the assessments. Although we see that that these proposals will increase the quality of the dossiers, we do not expect them to significantly accelerate the approval process for micro-organisms because the regulatory procedure remains unchanged and a significant amount of data is still requested. In our view this was one of the goals of the review, because Micro-organisms are essential and needed on the market to make the agricultural transition which we strive to. We would therefore like to emphasize that further action is needed to accelerate the approval process for micro-organisms. We would especially like to call out for further action in order to accommodate the group-assessment of micro-organisms and to initiate the development of the necessary guidance document for harmonization. Of course, the Netherlands is willing to actively contribute to this guidance document*".

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms. (SANTE/12042/2020)

See B.01. 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.

The Netherlands made the following protocol declaration:

"*We support the current proposals for the assessment on micro-organisms which will improve the dossiers and the assessments. Although we see that that these proposals will increase the quality of the dossiers, we do not expect them to significantly accelerate the approval process for micro-organisms because the regulatory procedure remains unchanged and a significant amount of data is still requested. In our view this was one of the goals of the review, because Micro-organisms are essential and needed on the market to make the agricultural transition which we strive to. We would therefore like to emphasize that further action is needed to accelerate the approval process for micro-organisms. We would especially like to call out for further action in order to accommodate the group-assessment of micro-organisms and to initiate the development of the necessary guidance document for harmonization. Of course, the Netherlands is willing to actively contribute to this guidance document*".

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms. (SANTE/10716/2021)

See B.01. 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.

The Netherlands made the following protocol declaration:

"*We support the current proposals for the assessment on micro-organisms which will improve the dossiers and the assessments. Although we see that that these proposals will increase the quality of the dossiers, we do not expect them to significantly accelerate the approval process for micro-organisms because the regulatory procedure remains unchanged and a significant amount of data is still requested. In our view this was one of the goals of the review, because Micro-organisms are essential and needed on the market to make the agricultural transition which we strive to. We would therefore like to emphasize that further action is needed to accelerate the approval process for micro-organisms. We would especially like to call out for further action in order to accommodate the group-assessment of micro-organisms and to initiate the development of the necessary guidance document for harmonization. Of course, the Netherlands is willing to actively contribute to this guidance document*".

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance *Beauveria bassiana* strain 203 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/10298/2021). (SANTE/10296/2021)

The Commission informed about some minor editorial amendments (in recitals). 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.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance 1,3-dichloropropene, 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/10814/2019). (SANTE/10812/2019)

The Commission informed that the applicant withdrew their application for approval. Therefore, a new act mentioning the procedural aspects and the withdrawal of the application will be prepared and tabled for opinion of this Committee at its next meeting.

Vote postponed.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance chloropicrin, 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/11096/2020). (SANTE/11094/2020)

The Commission informed that the applicant withdrew their application for approval. Therefore, a new act mentioning the procedural aspects and the withdrawal of the application will be prepared and tabled for opinion of this Committee at its next meeting.

Vote postponed.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015). (SANTE/10724/2020)

The Commission presented the draft Regulation and informed about a comment from the United States of America, received during the consultation of WTO members under the TBT agreement. Commission informed about one letter from a grower organisation and the position of a Member State indicating the support the proposal. Given the risks and data gaps identified, the Commission considers that the nature of these risks overrules economic considerations as brought forward.

The Commission inquired whether any Member State is not in a position to support the proposed Implementing Regulation. Five Member States indicated to vote against the proposal as they consider outdoor uses are still possible with risk mitigation measures set at Member State level. One of these Member States also mentioned the need of sulfoxaflor to control the quarantine pest *Aleurocanthus spiniferus* in citrus for which the use of spirotetramat is not enough. Two of these Member States considered that a review of available and new information should be carried out after the new Bee Guidance Document is endorsed and only then a decision should be taken.

One Member State voted against as the risk to honeybees is low and the risk to other non-target pollinators inconclusive. That Member State considers risk mitigation measures possible, considers the substance has a low persistence and favourable TOX profile and mentioned that additional studies are available that cannot be considered for formal reasons. This Member State considers the measure disproportionate.

One Member State voted against as they consider ecotoxicological risk mitigation to be the objective of zonal evaluation and national competent authorities.

Five Member States indicated to abstain as they consider outdoor uses are still possible with risk mitigation measures. One of these Member States also mentioned that confirmatory data should have been requested. Another of these Member States reminded that the renewal dossier will soon be submitted.

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: No opinion.

The Netherlands made the following protocol declaration:

"*The Netherlands agrees with the Commission's proposal on sulfoxaflor. With the proposal, the possible risks for bumble bees and solitary bees are suitably reduced. At the same time, we see that during the assessment there were no specific and adequate tools in place for assessing the chronic risks for bumble bees and solitary bees. This shows that it is of outmost importance that a new version of the guidance document on bees will become available as soon as possible, so that the latest scientific views can be used to assess the chronic risks for bees."*

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance chitosan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10594/2021). (SANTE/10592/2021)

The Commission presented the draft Implementing Regulation. The changes made with respect to previous version reflected comments made during the interservice consultation, and are mainly editorial. Since the last meeting, two Member States submitted comments informing that they would not support the Commission's proposal.

The Commission summarised the rationale behind the proposal as outlined in the Review Report. Following the approval of chitosan, the revision of the approval can be still triggered on a request of Member States. The Member States which consider that the revision of an approval of chitosan and chitosan hydrochloride is necessary were invited to provide details on the scope of the requested revision by 28 March 2022.

The Commission inquired whether any Member State is not in a position to support the proposed Implementing Regulation. Two Member States indicated that they would vote against the proposal for an approval. One of them is of the opinion that safe use has not been demonstrated for the environment for most of the uses as the only safe use is for treatment of fruit after harvest. Another Member State is of the opinion that concerning the effects on non-target organisms including honey bees an approval of chitosan from *Aspergillus niger* cannot be supported as a risk assessment is not possible due to missing data.

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.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11266/2021). (SANTE/11264/2021)

The Commission presented the draft Implementing Regulation with Annex to it and Review Report in view of the approval of SeMNPV, isolate BV-0004 as a low-risk substance in accordance with Regulation (EC) No 1107/2009. The changes made reflect comments made during the interservice consultation. No substantive comments have been made during the consultation with Member States on the draft regulation.

The Commission inquired whether any Member State is not in a position to support the proposed Implementing Regulation and no objections or reservations were raised.

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.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance carbon dioxide 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/10824/2021). (SANTE/10822/2021)

The Commission presented the slightly amended drat (editorial amendments) and informed about the latest comments received from two Member States concerning the proposal for renewal of carbon dioxide as an active substance. One Member State indicated its agreement with the proposal whereas another Member State indicated to vote against because of the impurity of benzene and its classification as “genotoxic” in the CLP 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.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance isopyrazam 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. (SANTE/10308/2021)

The Commission recalled that the TBT process had ended on 26 January 2022 and that no comments had been received from third countries. The Commission also noted that two Member States had submitted written comments indicating support for the withdrawal of approval, following the December meeting, and that no Member State had indicated that it could not support the withdrawal (nor any stakeholders).

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.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance *Metarhizium brunneum* strain Ma 43 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/10278/2021). (SANTE/10276/2021)

The Commission presented the draft Implementing Regulation. Minor changes in the draft with respect to previous version reflect comments made during the interservice consultation.

During the consultation on the draft Regulation, one Member State sent comments. This Member State considered that because of (1) the potential production of secondary metabolites and (2) that Ma43 is open to be proven that BIPESCO 5 and F52 are the same strain in terms of biological and genetic properties and there are not known differences between BIPESCO 5/F52 and the original isolate, they do not support the low risk status. The Commission reiterated its rationale on why it does not agree with these arguments, which are included in the review report. Two Member Stated indicated they would abstain.

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.14 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 substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, *Metarhizium anisopliae* (var. anisopliae) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram. (SANTE/11388/2021)

The Commission presented the draft Regulation extending the approval periods for a number of active substances, as required by Article 17 of Regulation (EC) No 1107/2009 since the evaluation procedures for the 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 and in this case, would not agree on the extension of active substances of concern, in particular malathion and ziram.

Another Member State indicated it could not support an extension of the approval of metconazol, triclopyr and ziram. A third Member State expressed its support for the need for the extensions. However, urged the Commission to adopt a decision on *Pseudomonas chlororaphis, Pythium oligandrum* and mepanipyrim.

The Commission reminded that many active substances on the list are currently under assessment for their endocrine disrupting properties according to the scientific criteria that became applicable in November 2018, and that *Metarhizium anisopliae* (var. anisopliae) strain BIPESCO 5/F52 had already been discussed in this Committee. In view of a probable favourable opinion for its renewal (point B.13), a revised version of the draft was submitted for opinion in which the mentioned active substance was removed from the draft 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.15 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 approval periods of the active substances flubendiamide, L-ascorbic acid, spinetoram and spirotetramat. (SANTE/11448/2021)

The Commission recalled that for the active substances flubendiamide, L-ascorbic acid, spinetoram and spirotetramat the approvals expired on 30 April, 30 June and 31 August 2024 but had been extended by 3 months to take into account the procedural changes introduced by the Transparency Regulation, in particular Regulation 2020/1740, which replaced Regulation (EU) No 844/2012. As no joint applications with dossier had been

submitted by the deadline established, it was appropriate to retract the extensions granted to the respective original expiry dates.

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.

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 bifenazate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11300/2021). (SANTE/11298/2021)

The Commission recalled that based on the revised EFSA Conclusion, a restricted renewal of bifenazate with restriction to non-edible crops and to permanent greenhouse as defined by Article 3.27 of the Regulation (EC) 1107/2009 is presented, due to non-finalised risk assessment for consumers and the high risk to birds.

The Commission informed that the inter-service consultation has been finalised and shared the drafts of the revised act, its annex and the review report, as well as the comments received from two Member States (one supporting the proposal, one expressing the importance of the use of bifenazate). The Commission also shared a comment from the applicant, and informed that it contains new information that cannot be taken into account in line with the provisions of Regulation (EU) No 844/2012. The TBT consultation was launched on 25 January 2022.

Member Stated were invited to send their positions and comments by 28 February 2022.

C.02 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