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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
1 - 2 December 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/40db7ac9-bfa3-427b-a70a-ce1a486bc24b*

SUMMARY REPORT

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

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the last meeting (October) was still in 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 State Netherlands: *Cryptophlebia peltastica* nucleopolyhedrovirus, strain South Africa, Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE), and *Trichoderma afroharzianum* Th2RI99.

- Basic substances applications

  The Commission informed on the submission of two applications for approval of basic substances: Ginger extract and *Capsicum frutescens*. These are the first applications for basic substances submitted via IUCLID, and they will also be the first applications to be assessed under the recently updated guidance on basic substances.

- Amendment of conditions of approval

  There were no news to discuss.

A.03 Renewal of approval and general issues.

Following several recent questions on the scope of applications for amendment to the conditions of approval, the Commission recalled that such applications can be submitted in accordance with Article 7 of Regulation (EC) No 1107/2009 and that in such cases the dossier can be limited to the areas which need to be addressed for the

particular amendment e.g. to remove a particular restriction. As set out in Article 7, a scientifically reasoned justification for not providing certain parts of the dossier shall be made. This is also important in cases where a dossier to support a different form of the active substance is supported (e.g. acid, ester) where justifications for not providing specific studies must also be provided. Applications for amendment of approval are not intended to include a full reassessment of the active substance, which is rather the purpose of the periodic renewal assessments.

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

  The Commission recalled the key issues identified in the EFSA Conclusion, and explained that only one Member State had submitted comments following the meeting of this Committee in October 2021.

  That Member State had highlighted the different problems identified. The Member States expressed the view that new data which the applicant considers should be evaluated for thyroid effects would not address the endocrine disruptor criteria for the androgen (A) and steroidogenesis (S) modalities, nor for non-target organisms. Furthermore, risks are identified for the field uses and other issues remain open.

  On the basis of the EFSA Conclusion, the Commission recalled that notwithstanding the need to also consider the issues identified by EFSA in the area of consumer risk assessment and the risks to non-target organisms, the options for any possible renewal of approval were limited to a consideration of whether negligible exposure to humans could be demonstrated or whether a derogation under Article 4.7 of Regulation (EC) No 1107/2009 was possible. Given that the use of clofentezine is expected to lead to residues in crops (and that MRLs above the default value are currently established for various uses), negligible exposure from dietary exposure is not demonstrated. Therefore the Commission explained that only the derogation under Article 4.7 might be relevant.

  The Commission introduced some general points on Article 4.7 derogations also in the context of agenda points 04.02 (benthiavalicarb) and 05.b (asulam-sodium).

  For clofentezine, Member States were asked to consider if they would support renewal under Article 4(7) (restricted to some limited uses, only in greenhouse due to risks to non-target organisms) and to provide their views and comments by 13 January 2022. The Commission mentioned that further consideration would be required of how the MRL and consumer related issues would need to be addressed under such an approval.

  2. Benthiavalicarb

  The Commission recalled that the EFSA conclusion reports that benthiavalicarb-isopropyl meets the cut-off criterion concerning endocrine disrupting potential for human health, for the thyroid (T) and oestrogen, androgen and steroidogenesis (EAS) modalities. Negligible exposure and information submitted according to Article 4(7) of Regulation (EC) No 1107/2009 was assessed. As regards negligible

exposure, concentration of residues of benthiavalicarb-isopropyl are expected to be below 0.01 mg/kg for potatoes. However, EFSA noted that it could not be excluded that residues in other food items (rotational crops) could occur above the level of 0.01 mg/kg, and thus the residue definitions for rotational crops remained open.

A critical area of concern was identified with regard to the carcinogenic potential observed in liver and uterus in two different species and EFSA considered classification as Carcinogen, Cat. 1B appropriate, which was also supported in the Risk Assessment Committee (RAC) of the European Chemicals Agency by several MSs, while others were supporting Carcinogen, Cat. 2. The applicant disagreed with EFSA's view on the classification. In any case, the regulatory consequences of a classification as carcinogen, Cat. 1b are the same as forbeing identified as endocrine disruptor.

The possible fulfilment of the conditions in Article 4 (7) had been demonstrated only for one use in one Member State for sugar beet/downy mildew and in two Member States for onion/downy mildew. Some clarification had been received from one Member State where the agricultural need is relevant.

A meeting with applicant had taken place on its request, where the applicant had requested to await the finalisation of the RAC opinion in order to define the classification of the substance.

Member States were asked to consider if they would support renewal under Article 4(7) and to provide their views and comments by 13 January 2022.

- Basic substances

3. Calcium propionate

Member States were invited to comment by 13 January 2022 on the EFSA Technical Report.

4. Black soap

Member States were invited to comment by 13 January 2022 on the EFSA Technical Report.

5. Lemon essential oil

The Commission summarised comments received from the Member States. One Member State commented and agreed with the findings of the Technical Report. That Member State is of the opinion that lemon essential oil does not fulfil the requirements of Article 23 as a basic substance. In particular, lemon essential oil has a notified classification. It may be fatal if swallowed and enters airways, which is due to presence of D-limonene and therefore risk mitigation measures are necessary, including PPE such as gloves, respiratory protection and eye-protection. Additionally, even the applicant originally proposed a 20 m unsprayed buffer zone to surface water bodies as a risk mitigation measure. The application lacked any exposure assessment (thus also risk assessment) for operators, workers, residents and bystanders, as well as for environmental fate and non-target organisms. In addition, it is unclear if the product is placed primarily on the market for a purpose other than for plant protection.

Member States were invited to comment by 13 January 2022.

6. *Yucca Schidigera* extract

The application concerns an approval of *Yucca Schidigera* extract as a basic substance to be used as fungicide and bactericide in arable crops, (leaf) vegetables crops, fruit crops, head *Brassica* crops and seed potatoes. The Technical Report of EFSA identified a substantial number of data gaps. The recipe for preparation to be used is not clear. There is insufficient information to support usefulness as a plant bactericide. The information on the identity and toxicological profile of the components of the extract is missing and, consequently, it was not possible to perform the non-dietary and also consumer risk assessment. The environmental exposure assessment was considered insufficient. As regards the effects on non-target organisms, a risk for aquatic organisms was identified and risk mitigation measures are recommended. Adverse effects could not be ruled out also for other non-target organisms because of insufficient data available.

The Commission made available to the Member States the comments of the applicant on the EFSA Technical Report and a number of letters of support sent by different organisations.

Member States were invited to consult the available documents and provide comments by 13 January 2022.

- Amendment of conditions of approval

7. Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3)

The Commission informed that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied for the extension of use as a fungicide. EFSA furthermore concluded that there are no critical areas of concern. Therefore, the restriction limiting the use of the three paraffin oils as insecticide and acaricide only could be lifted.

Member States were invited to comment by 3 January 2022.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

a) Dimethyl disulphide

The Commission informed that, since the last meeting of this Committee, a new study strategy had been submitted by the applicant. This had been also submitted to the Rapporteur Member State and made available to Member States. Discussions among the applicant and the Rapporteur Member State are ongoing.

b) Asulam-sodium

The Commission outlined the EFSA Conclusions concerning the potential endocrine disrupting (ED) properties (thyroid (T) modality) and the related assessment of negligible exposure and of potential derogation according to Article 4 (7) of Regulation (EC) No 1107/2009. The Commission indicated that negligible exposure could not be demonstrated due to possible residues in treated and succeeding crops. In line with the other substances currently under review with similar regulatory situation (A.04.01 clofentezine, A.04.2 benthiavalicarb), Member States were asked to consider if they would support renewal under Article 4(7) and to provide their views and comments by 13 January 2022.

- Renewal of approval

c) Captan

The Commission informed that discussions on a EFSA mandate to assess whether certain field uses could be acceptable are still ongoing with EFSA and the Rapporteur Member State.

d) *Bacillus amyloliquefaciens* strain QST 713

The Commission informed that the Rapporteur Member State had commented on the potential effects on bees and the comments had been made available to Member States together with an EFSA reply to these comments. The Commission reminded that for other strains of the same species, no issues for bees had been raised and that several exchanges with EFSA on this matter took place. An overview of the available studies related to bees had been uploaded on CIRCABC.

In view of the unresolved issue for bees, the Commission suggested two options that could allow to renew the approval of this strain with risk mitigation measures and/or restrictions, and reminding that an application for amendment of conditions of approval could be submitted by the applicant:

1) to restrict the possible application to non-flowering periods (strawberries: 67-89 and grapes: 69-89), with a probable reduction of the efficacy, and requiring risk mitigation measures to reduce drift;

2) to restrict the use to strawberries in permanent greenhouses and adding the sentence "Member States should pay particular attention to the risk to bees and bumble bees released for pollination in permanent greenhouses" (This risk mitigation measure was supported by 3 Member States, including the Rapporteur).

Member States were invited to comment, in particular concerning these possibilities, by 3 January 2022.

e) *Pseudomonas chlororaphis* strain MA342

No discussion took place.

f) *Bacillus thuringiensis* (horizontal discussion)

The Commission informed that a possible mandate to EFSA and ECDC is being considered.

g) *Pythium oligandrum* strain M1

The Commission summarised the comments received from two Member States which were wondering about the precedent that a renewal of approval could generate in view of the scarcity of data in the application dossier. The Commission indicated that it was reflecting as regards how the currently available data could be sufficient to allow a renewal of approval of the substance.

h) Straight Chain Lepidopteran Pheromones

The Commission presented the draft review report. No critical areas of concern were identified in the EFSA Conclusion. For some individual substances the risk characterisation could not be finalised due to the absence of information for some representative uses, however this is not considered to preclude a renewal of the approval.

The renewal application concerned 35 individual substances, which are alcohols (8), acetates (23) or aldehydes (4), and 12 blends consisting of different combinations of these single substances. In the EFSA Conclusion blends were not specifically assessed. The Commission explained that blends which were in the application are listed in the Appendix to the review report for transparency reasons, in particular because some of these blends are produced in single continuous manufacturing processes.

As SCLPS are characterised by high volatility and rapid dissipation in air, their residues are expected to be negligible and below 0.01 mg/kg. Nevertheless, EFSA had concluded that a general suggestion for inclusion of SCLPs to Annex IV to Regulation (EC) No 396/2005 cannot be given, as the use of (E,E)-8,10-dodecadien-1-ol in combination with spray application, residues in apples cannot be excluded. However, the particular study had not been performed in line with the GAPs. Therefore, as it is not expected that a use in accordance with the GAPs will lead to residues, and the Commission considers that SCLPs can be included in Annex IV to Regulation (EC) No 396/2005.

The Commission also mentioned that SCLPs considered as a whole group cannot be regarded as low risk substances because the criteria for classification for skin sensitisation are met for SCLPs belonging to the alcohol and aldehyde sub-groups and therefore they do not meet the criteria as described in point 5.1.3 of Annex II to Regulation (EC) No 1107/2009.

Member States were invited to comment, in particular the listing of the blends in the review report, by 3 January 2022.

i) Pelargonic acid

The Commission informed that one Member State had commented on the results of the peer review. Member States were invited to comment by 3 January 2022 in particular on: risks identified for bees and possible risk mitigation measures at national level; risks identified for non-target invertebrates (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.

- Basic substances

j) Hydrogen peroxide silver stabilised

The Commission recalled that the application for an approval of hydrogen peroxide silver-stabilised as a basic substance had originally been submitted as an extension of the already approved hydrogen peroxide, but that it appears that it should be treated as an application for approval of a new basic substance.

The Commission informed on the comments submitted by one Member State. That Member State highlighted the poor quality of the application and lack of data as regards specification, hazard profile, human health, environmental exposure assessment and risk to non-target organisms.

The applicant had been invited to provide comments on the Technical Report of EFSA, however, they did not react.

The Commission provisionally proposed not to approve silver-stabilised hydrogen peroxide as a new basic substance. The reasons are outlined in the draft Review

Report that was made available. In summary, the information on identity, composition and specification of silver-stabilised hydrogen peroxide provided in the application is not sufficient. It seems that the substance presented in the application is not compliant with the definition of "substance" in Regulation (EC) No 1107/2009, and therefore not eligible for approval under Article 23. It was not possible to conclude that silver-stabilised hydrogen peroxide is not to be considered a substance of concern as required by Article 23(1)(a). The non-dietary risk assessment could not be concluded, and a consumer risk assessment could not be performed. There was insufficient information available regarding the environmental exposure assessment and the risk to non-target organisms. Lastly, silver-stabilised hydrogen peroxide does not fulfil the criteria of a 'foodstuff', and no relevant evaluation, as referred to in Article 23(2) of Regulation (EC) No 1107/2009, is available for this substance.

Member States were invited to comment by 13 January 2022.

k) Ozone

The Commission informed that the application concerned an approval of "ozone generated in situ from oxygen and directly dissolved in water at concentration of maximum 8 ppm" as a basic substance. Since the last meeting of this Committee, one Member State had provided comments. This Member State was of the opinion that the criteria of Article 23 of Regulation (EC) No 1107/2009 are not met. The reasons include lack of toxicological data that would exclude health risk, the potential occurrence of disinfection by-products in soil, water, air and plants; not enough data to conclude on the risk for non-target organisms and the environment. According to that Member State, the lack of data cannot be disregarded as ozone is highly reactive and can produce very toxic reaction products.

The Commission informed on the feedback from EFSA concerning the additional information submitted by the applicant in their comments on the EFSA Technical Report. It appears that the applicant did not provide any further scientific evidence, and the argumentation brought forward by the applicant was not sufficient to modify the conclusion of the EFSA Technical Report. A dossier for ozone is currently under assessment in the framework of Regulation (EU) No 528/2012 on Biocidal Products but the final validation of the toxicological/ecotoxicological endpoints has not been completed. Therefore, EFSA cannot accept those endpoints and consider them in the risk assessment. As regards the potential by-products of water ozonation, the applicant submitted a study to demonstrate that the formation of such by-products was absent or low in the environment; however, this study was considered not acceptable, in particular as regards data on formation of bromate.

Several Member States commented on the appropriate procedure to approve ozone/ozonated water for use in plant protection, the regulatory status of ozone generated in situ that is currently available on the market for other uses, and the status of an approval of ozone as a biocidal active substance. Another point raised was the issue of commercialisation of basic substances. This topic is a part of a general discussion on basic substances which is ongoing.

The Commission informed that an approval as a 'regular' active substance (and not as a basic substance) seems to be more appropriate taking into account aspects such as the unresolved toxicological profile of a substance, and the fact that no relevant evaluation of safety of ozonated water is available, as referred to in Article 23(2) of

Regulation (EC) No 1107/2009. Biocidal products based on ozone generated in situ are available on the EU market benefitting from the transitional measures set in Article 89 of Regulation (EU) 528/2012 on biocidal products.

One Member State opined that the evaluation of ozone under the Biocidal Product Regulation does not concern ozonated water which has a different hazard profile.

The Member States were invited to comment by 3 January 2022.

- Amendment of conditions of approval

  There were no news to discuss.

A.06 Confirmatory Information:

1. Flutianil (amended review report to take note)

   The Commission recalled that the confirmatory information requirements were satisfactorily addressed for the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification lead to the conclusion that a change in the reference technical specification for flutianil is not required. An amended review report was endorsed by the Committee.

   Two confirmatory information requests remain open and will be assessed in due time (endocrine disruptors properties and the effect of water treatment processes on the nature of residues present in surface and groundwater).

2. Potassium phosphonate

   The Commission informed that an updated review report had been made available with the intention to endorse at the upcoming meeting of this Committee. Comments had been provided by one Member State.

   Sufficient information had been provided to address the long-term risk to insectivorous birds. However, the risk assessment for frugivorous birds was also carried out including a refined risk assessment. EFSA considered the outcome of this particular risk assessment not as sufficient and robust enough to exclude a high risk to frugivorous bird in a quantitative way, however the rapporteur Member State concluded that the confirmatory data show an acceptable risk for birds in a weight of evidence approach. The renewal dossier of the active substance is expected to be submitted the latest in January 2023. Therefore, in the draft updated review report it is highlighted that Member States should pay particular attention to the risks for frugivorous birds when carrying out assessments for authorisation of plant protection products.

   Member States were invited to comment by 3 January 2022.

3. Pyrethrins

   The Commission reiterated the explanations given at the last meeting of this Committee, reminding that the open issues of confirmatory data would likely need further assessment in any case and that the renewal procedure was already ongoing. Since the RMS's assessment for the renewal shows that pyrethrins are unlikely to pose problems for consumers, it would be more proportionate and efficient to wait for the outcome of the renewal assessment, avoiding parallel regulatory processes. The Committee concluded that the renewal should continue and determine if the

approval of pyrethrins can be renewed, or not. If concerns are identified in early stages of the peer-review, the Commission can take action without further delay.

The Commission explained that since the last meeting, no Member State expressed concerns on this way forward and that, therefore, this point can be considered as closed.

4. 1-decanol

   The Commission informed that, after the last meeting of this Committee, only one Member State shared its opinion and in their view not all confirmatory data requirements had been satisfactorily addressed, specifically the risk to aquatic organisms. Meanwhile, an updated review report had been uploaded on CIRCABC, describing possibilities to prescribe mitigation techniques to guarantee the maximum reduction for spray drift at Member State level. Taking into consideration that the other aspects of the confirmatory data were successfully addressed and that the renewal dossier, already submitted at the end of August 2021, may contain updated and more complete information, Member States were invited to provide their comments by 13 of January.

5. Acibenzolar-methyl

   The Commission recalled that the confirmatory information requirements had been set before the implementation of the scientific criteria to identify endocrine disruptors were adopted and that from a procedural point of view the applicant had fulfilled its obligations. However, as explained in previous meetings of this Committee, follow up actions are needed.

   The Commission stressed this is a particular regulatory case (i.e. the specific confirmatory data are fulfilled, however further assessment is needed to determine whether the scientific criteria to identify endocring disrupting properties are met), and that it is still reflecting about the best way forward. One possibility would be to trigger a revision in accordance with Article 21 of Regulation (EC) No 1107/2021 and give the applicant the possibility to complete the data package. Member States were invited to comment on this potential forward by 13 January 2022.

6. Pyridaril

   The Commission summarised the submitted confirmatory information and the outcome of its assessment:

   1) Toxicological and ecotoxicological information to address the relevance of the impurities 4, 13, 16, 22 and 23. The Commission concluded that the data provided by the applicant were sufficient.

   2) The relevance of the metabolite HTFP and, concerning that metabolite, the groundwater risk assessment for all uses on crops in greenhouse. In some scenarios for all representative uses of pyridalyl, HTFP is predicted to occur below 0.75 µg/L and in one scenario it is even below 0.1 µg/L. Therefore, safe scenarios of use are identified but Member States need to pay particular attention to the risk to groundwater when evaluating application for authorisation of plant protection products.

   3) Risk to aquatic invertebrates. The Commission noted that the Rapporteur Member State considered that the risk for aquatic organisms could be considered acceptable for the proposed greenhouse uses, provided that end

of pipe risk mitigation is included on the label. EFSA considered that the information provided was not sufficient to address the risk to aquatic invertebrates with particular reference to the high risk identified for *Asellus aquaticus*. Nevertheless, as the approval of pyridalyl is restricted to use in permanent greenhouses only, the exposure to the environment is considered negligible under the conditions mentioned by the rapporteur Member State.

A draft of the amended review report had been uploaded on CIRCABC. Member States were invited to comment by 3 January 2022.

7. Acequinocyl

The Commission informed that a draft of the amended review report had been made available and that the confirmatory data requirements were fulfilled for the analytical method for residues in body fluids and tissues and the acceptability of the long-term risk to small omnivorous and small herbivorous mammals in outdoor ornamentals. However, the third point of the confirmatory information requirement, i.e. additional information to confirm an acceptable long-term risk to small granivorous birds and small herbivorous and frugivorous mammals in apple and pear orchards could only be addressed sufficiently for small granivorous birds and small frugivorous mammals in apple and pear orchards. The risk to the feeding guild of small herbivorous mammals like voles for all uses (orchards and ornamentals) was assessed differently by EFSA and the rapporteur Member State. The Commission asked the Member States to comment by 3 January 2022 on that particular open point.

A.07 Guidance Documents:

1. Updated (errata) Guidance document on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)

   The Commission took note of the amendment guidance document.

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

   The Commission informed about two information sessions on the setting of specific protection goals for bumble bees and solitary bees which was held on 23 November 2021: in the morning for Member States Experts and in the afternoon exactly the same session for the EFSA dedicated stakeholder group for the review of the Bee Guidance Document.

   During these sessions, EFSA presented the available evidence, which could be used to define specific protection goals for bumble bees and solitary bees, and Member States and stakeholders had the opportunity to provide input to EFSA on this subject, in view of finalising a supporting document. In none of the sessions, a discussion on the specific protection goals took place.

   Participants were offered to send in further information to EFSA after the meeting which one Member State did. A report on both sessions will be prepared, which will include the presentations given, and will be made available on the website of the Commission. Commission clarified that EFSA is now finalising the supporting document for setting these protection goals. The resulting document will be published on the website of the EFSA. A discussion on the basis of that supporting document will be scheduled in the beginning of 2022.

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

   The Commission summarised the comments from the Member States received so far on the draft guidance document and presented the most controversial issues. Member States were invited to comment on these controversial issues by 13 January 2022. The Commission indicated that it would ask for the position of each Member State on the draft Guidance Document during the meeting of this Committee in January 2022.

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

   The Commission updated on the on-going work on the revision of the Communications, and shared a proposal to set criteria on which basis a document is considered to be listed as guidance document in the Communications and which are out of scope. Member States were invited to comments by 13 January 2022.

5. 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 recapitulated the alternative way forward announced in the meeting of this Committee in October and explained that several Member States had submitted comments, which in general were supportive of the approach, however, highlighted some important considerations and challenges that still remain to be addressed. The Commission recalled that the idea put forward was only a starting point and that further intensive discussions would be required.

   For that reason, the Commission supported the suggestion of one Member State to restart a Working Group. The Commission recalled the composition of the Working Group established in 2013 and which had worked on the earlier draft guidance document in 2015.

   Member States were invited to send comments on the outlined approach if they had not already done so and to indicate if they would like to be part of the Working Group, nominating one expert for the activity (the need for additional experts would be considered on a case by case basis).

   The Commission also informed the Committee about a position paper that PAN Europe had submitted, expressing its views on how negligible exposure should be considered.

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 informed that one Member State had sent comments a few days ago which would trigger some additional revision, and invited other Member States to comment on these by 13 January 2022.

7. EFSA Guidance on aneugenicity assessment

   EFSA presented the Guidance on aneugenicity assessment (https://www.efsa.europa.eu/en/efsajournal/pub/6770). Member States were

invited to comment by 13 January 2022 in view of endorsing the guidance document.

A.08 Defining Specific Protection Goals for environmental risk assessment.

The Commission informed about the meetings of the Working Group, which continued the discussions on the draft document on problem formulation. The Commission informed that a consultation of Member States and stakeholders on this draft document is planned for the first quarter of 2022. The Commission invited Member States who have not yet nominated experts to the Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009 to nominate an expert, should they wish so.

A.09 Commission Regulation (EU) No 547/2011 and risk mitigation.

The Commission reported about (1) the ongoing initiative of the Central Zone WG which initiated discussion about how Risk Mitigation Measures ('RMM') could be inserted in the regulatory process of approval of active substances and authorisation of Plant Protection Products and the role of different stakeholders in proposing and validating non-standard RMM proposed by applicants (e.g. new technologies), (2) the work on the intended EU list of RMM, (3) discussions with EFSA concerning the way RMM may appear in the GAP tables in IUCLID dossiers, (4) the outcome of the Horizon 2020 research project INNOSETA (http://www.innoseta.eu/) that had developed an inventory of innovative spraying equipment and technologies, training materials and advisory tools available in the EU.

A.10 Notifications under Regulation (EC) No 1107/2009 (for information):

- Article 44(4)

  The Commission informed that two notifications had been received from one Member State, on the non-renewal of the authorisation under Article 43 of two products containing glyphosate and pelargonic acid, intended for non-professional users. The risk for operators appeared to be unacceptable.

- Article 36(3)

  The Commission informed that six notifications had been received since the last meeting of this Committee and all concerned rejections of mutual recognition applications. For three of them applicants had triggered national appeal procedures but these had been dismissed.

- Article 53

  No Member State took to floor as regards emergency authorisations published under https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home.

  EFSA informed about the outcome related to the mandate concerning the assessment of emergency authorisations granted by 11 Member States for the use of neonicotinoid-based insecticides on sugar beet in 2020/21, which was published 18 November 2021.

  The Commission informed that it was analysing the technical reports and reflecting on the next steps.

A.11 News from European Food Safety Authority (EFSA).

EFSA informed about upcoming Conclusions and their planning for the next months for expert meetings. EFSA also mentioned that currently there are 93 active substance dossiers under "stop the clock" to evaluate the endocrine disrupting properties according to the scientific criteria which became applicable in November 2018 and that for 27 of these active substances the evaluation is expected to resume in 2022.

EFSA also reminded (Rapporteur) Member States about the protection of personal data in IUCLID which needs to be checked before deciding on admissibility, and on the progress on the peer review for the draft assessment report for glyphosate, for which the consultation and commenting phase finalised on 22 November 2021 and the expert meetings are intended for July 2022.

A.12 Improving the efficiency of the process of a.s. approval / renewal.

There were no news to discuss.

A.13 Microorganism Active Substances, in particular:

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

There were no news to discuss.

A.14 Safeners and Synergists.

The Commission informed the participants that internal reflections on the draft Regulation are still ongoing.

A.15 Updates, clarifications & questions on specific active substances:

1. Clethodim

   The Commission informed that the Rapporteur Member State for the renewal had sent its comments on the possibility to trigger a review under Article 21 of Regulation (EC) No 1107/2009. In their view, it would be preferable to avoid parallel processes. They informed that the expected date for sending the draft renewal assessment report (dRAR) to the Commission, EFSA and ECHA, and Member States is in July 2022. They also informed that the necessary genotoxicity study is expected to be finalised in February 2022 and therefore will be included in the renewal dossier. The Rapporteur Member State will inform the Commission without delay (and before the submission of the dRAR) if after the assessment there are indications that it is still not possible to conclude on the genotoxic potential of the metabolite 3-chloroallyl alcohol or whether the conclusions are adverse. If needed, the Commission could then take action, by triggering an Article 21 review.

   After the previous meeting of this Committee, only one Member State had sent written comments stressing the need to pay particular attention to the toxicological relevance of the groundwater metabolites during the renewal assessment of the substance. A preliminary review showed that some of the studies had considerable deficiencies and, thus, the available data package can no longer be considered sufficient to meet the requirements of the Guidance Document on relevant metabolites. In their view, the application of the ADI value of the parent substance

for the metabolites Clethodim Oxazole Sulfone (R47797) and Clethodim Sulfone (RE-47253) must also be re-assessed.

The Committee concluded that the renewal should continue in line with the proposal from the Rapporteur Member State.

2. Dimethomorph

   There were no news to discuss (this point was carried over erroneously from the previous meeting).

3. Napropamid-M

   There were no news to discuss.

4. Sodium hydrogen carbonate

   The Commission informed of two authorisations for products containing the new active substance sodium hydrogen carbonate in Austria. These authorisations had been applied for during the approval process under Article 37(3) of Regulation (EC) No 1007/2009 and are therefore aligned to the representative uses that were part of the approval dossier. Consequently the authorised uses in Austria are much narrower than the uses approved for this substance under its basic substance approval.

   An exchange of letter with the applicant, regarding its expectation of the withdrawal of the basic substance approval, had been uploaded on CIRCABC.

   The Commission explained during the meeting its intention to withdraw the basic substance approval for this substance given that it is now marketed as a plant protection product. A prolonged deferral period would allow producers of this substance to obtain authorisations in other Member States and/or for more uses. Another option would be to gradually delete those uses listed in the review report that accompanied the approval as basic substance, which are already covered by a national authorisation of plant protection products containing the active substance.

   One Member State indicated not supporting a withdrawal of the basic substance approval as it will be difficult to enforce and very difficult to explain to farmers. Another Member State supported this view and considered that the requirement in Article 23(1) of Regulation (EC) No 1007/2009 only applies at the moment of approval of the basic substance.

   The Member States were invited to send comments by 13 January 2022.

A.16 Article 21:

1. Tebufenozide (amended review report to take note)

   The Commission informed that the results of the EFSA mandate confirmed the absence of genotoxic effect of the concerned metabolite. Consequently, all the points affected by the confirmatory information required under the first approval can be considered closed. Accordingly, the Commission presented a revised review report which was endorsed by the Committee.

A.17 General issues for information / discussion:

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

The Commission reminded that a workshop of the OECD Network on illegal pesticides (ONIP) on illegal plant protection products will be held on 16 and 17 February 2022 in Slovakia. All Member States are invited to contact the delegate of Slovakia if they want to join.

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

   a) Scope delineation with biocidal products

   The Commission pointed to the last amendments in the Scope Document (introductory part) following two suggestions from one Member State. Entry 139 (chlorine used to hygienise harvested crops) was also discussed.

   b) Scope Document rev. 67

   The Commission reviewed its initial position concerning chabazite, for which an application for approval as basic substance is under evaluation, based on a previous interpretation (entry 32 – kaolin) to consider it as falling within the scope of (EC) Regulation No 1107/2009.

   The Commission briefly discussed the concept of 'multiple use substances' presented by a stakeholder in relation to substances (for instance, micro-organisms, phosphonates) with two claimed functions, e.g. plant protection and plant biostimulant (falling under the Fertilising Products Regulation).

   Member States were invited to comment by 13 January 2022 on the amended version of the Scope Document and about the concept of "multiple use components" and the related cases discussed during the meeting.

3. Basic substances – general issues

   There were no news to discuss.

4. Member States updated survey on timing of regulatory procedures

   The Commission presented an analysis of the results of the Member States' surveys on the compliance with deadlines of the regulatory procedures on plant protection products authorisation covering the years 2017 to 2020 and indicated that a report is in preparation.

5. Mono- and polymers as co-formulants

   The Commission informed that one Member State considers that a guidance taking into account the assessment and requirements of mono- and polymers used in plant protection products as co-formulants is needed and that a document explaining the situation submitted by this Member State had been uploaded on CIRCABC. Member States were invited to comment by 13 January 2022.

6. Microplastics / REACH: Ongoing regulatory activities regarding restrictions of use under REACH

   The position paper of one stakeholder organisation concerning the ongoing discussion about a possible restrictions of use of microplastics in plant protection products was briefly presented.

7. Synergistic effects of pesticides on pollinators

   The Commission recalled the discussion held during the last meeting of this Committee reminding that synergistic effects are partly covered in the procedures related to the authorisation of plant protection products (PPPs). In particular,

Member States must assess these for formulated PPP containing more than one active substance, and enhanced availability of data on the actual use of PPP by farmers will provide a better basis for considering exposure to multiple pesticides in the same field.

The Commission presented the feedback received since last the last meeting from one Member State which confirmed this point of view and indicated having specific risk mitigation measures in place for tank mixtures of pyrethroids and azole/EBI-fungicides. No futher comments were made, so that the discussion point can be considered closed for the time being although discussion can resume if warranted by new information.

8. Trifluoroacetic acid (TFA)

   The Commission updated the Member States on two points:

   1) Update on the REACH evaluation and the Article 56 notification related to the toxicological properties of TFA: The Commission recalled that Bayer had sent an update to the Commission and the Member States on 30 November 2021, explaining the status of the evaluation under REACH. Based on the initial results, further studies are being initiated to understand the developmental effect observed in rabbits (which seems to be specific to the rabbit) and its relevance for humans. Bayer considers that there are no concerns for consumers based on a generic risk assessment it has carried out.

   2) Consideration of TFA in the context of ongoing evaluations: Member States were reminded to be vigilant when assessing active substances in which TFA may form, to ensure that a thorough assessment is undertaken, in particular the exposure assessment. In addition the Commission informed that during the late stages of the peer review of tritosulfuron, the applicant informed the Rapporteur Member State and EFSA that it had some new data, which had detected the formation of TFA in soil and rotational crops. Given the link with the Article 56 notification for TFA this data will be taken into account during the renewal review. The applicant considers that there is no concern from exposure to TFA due to the expected low levels of formation of TFA from the uses of tritosulfuron.

9. MS-proposal PPP TARIC Code

   Upon request of one Member State, the Committee discussed the possible amendment of TARIC codes under heading 3808 in order to differentiate plant protection products from biocidal products and to facilitate border controls. In the view of that Member State, the current custom declarations do not allow to differentiate flows of different goods and, consequently, the relevant flows of plant protection products cannot be monitored. Seven Member States generally supported this initiative.

   The Commission acknowledged that it had so far expressed a reservation to the request of some Member States during the PARCS meeting (Coordination of activities on the protection of Health, Cultural Heritage and the Environment) in December 2020. The use of TARIC additional codes 2500 and 2501 would be more practical than the creation of 10-digit TARIC codes because additional codes are independent from the goods nomenclature. However, creating these additional codes would only be possible if specific legal provisions existed to create TARIC

codes. This is not the case currently and therefore, it is not possible to implement this solution in the TARIC database.

From a legal point of view, nothing prevents the creation of 10-digit TARIC codes in Annex 10 of the CN (Combined Nomenclature). However, reservations on this proposal still exist. In the last 20 years, the number of 10-digit TARIC codes has almost doubled so that the Commission wishes to keep the creation of TARIC codes proportionate to the policy need expressed. In addition, the need expressed here concerns controls carried out by the national customs authorities. Although these controls are indeed required by the EU legislation, how they are carried out remains responsibility of the Member States.

One Member State asked whether it would be easier to create TARIC codes for biocidal products, considering that a list of biocidal products exists at EU level, contrary to the situation for plant protection products. The Commission informed that creating TARIC codes for biocidal products would not be easier because this would have the same impact on the goods nomenclature as creating TARIC codes for plant protection products, without a stronger justification.

Furthermore, the proposal by the Member State concerns only heading 3808. However, not all plant protection products are classified under 3808 and it should be further clarified by the interested Member States if they wish to cover only heading 3808 or all plant protection products.

Member States were invited to comment by 13 January 2022.

10. PPPAMS – update

The Commission provided an update on the state of play including a short presentation on the newly designed version of PPPAMS (v1.40) which enables upload of existing authorisation data and for applications for amendment, renewal or extensions for minor use as well as withdrawal of authorisations. The Commission outlined the next steps which include a period for Member States to test v1.40, followed by possible pilot cases and then full implementation which could be supported by an Implementing Regulation requiring the use of PPPAMS.

Member States expressed various views on the use of PPPAMS for managing applications (one referred to possible clashes with national rules, while another expressed the opposite view). The Commission acknowledged that there was a need for more discussion to ensure a smooth implementation but also highlighted the benefits as supported by some Member States.

A.18 News from Sustainable Use Directive (Directive 2009/128/EC).

There were no news to discuss.

A.19 News from Health and Food Audits and Analysis (SANTE, Directorate F).

There were no news to discuss.

A.20 Implementation Article 67 Regulation (EC) No 1107/2009.

The Commission recalled the aim of the draft Implementing Regulation and explained the relationship between the draft Implementing Regulation and other relevant ongoing initiatives. It also reiterated the intention to foresee flexibility for Member States wishing to require additional details in the records to be kept by professional users of

plant protection products and recalled that, while the act aims to make electronic record-keeping mandatory, it does not prescribe the use of a specific electronic tool. The Commission emphasised that a sufficient transitional period is envisaged as well as coordination with other legal acts, and invited Member States to communicate the transitional period they consider necessary.

The main points in the discussion concerned the length of the transitional period, with various Member States indicating the timing they would consider reasonable, and the issue of the use of the data for control and statistical purposes. The Commission clarified some data protection concerns raised by the Member States.

A.21 Report from working groups, in particular:

- Working group on Biopesticides

  The Commission called upon Member States to designate additional national experts to participate in the activities of the Biopesticides following the ongoing training activities regarding the risk assessment for micro-organisms organised under the Better Training for Safer Food initiative.

- Working group on Seed Treatments (Risk Assessment)

  The Member State coordinating the update of the draft guidance document indicated that the draft update will soon be forwarded to the Commission.

- Working group Post Approval Issues

  There were no news to discuss.

A.22 Minor Uses.

A representative of the Minor Use Coordination Facility indicated that a draft Explanatory note on minor uses procedures according to Regulation (EC) No 1107/2009, prepared by the Minor Uses Coordination Facility, had been uploaded on CIRCABC. Member States were invited to comment by 13 January 2022.

A.23 Court cases.

There were no news to discuss.

A.24 Ombudsman cases.

The Commission informed about the recent decision of the Ombudsman in Case 1402/2020 on the way in which the Commission had invited an expert in her personal capacity and managed conflicts of interest in the workshops organised for reviewing the protection goals for assessing environmental risks of pesticides, which had been triggerd by a complaint from the Pesticide Action Network Europe (PAN) to the Ombudsman in August 2020.

The Ombudsman had decided that there had not been maladministration and had made recommendations for improvement to the Commission.

A.25 Exchange of information from the Pesticide Residues section of the Committee, in particular possible impact on authorisations.

There were no news to discuss.

A.26 OECD, FAO and EPPO activities.

The Commission informed Member States about the different ongoing activities and consultations launched by OECD (Guidance Documents on baculovirus and bacteriophages; illegal pesticides training; drones; scoping document of the Testing Methods Conference) and FAO/WHO (aerial spraying).

A.27 Scientific publications and information submitted by stakeholders.

The Commission informed Member States about a letter from one stakeholder organisation to different Commissioners and Heads-of-Government about the need to fast-track the placing on the market of low-risk active substances and plant protection products. Other stakeholders had also reported difficulties and serious delays to submit their applications for innovative biopesticides due to the lack of capacity of Member States to act as rapporteurs for the evaluation.

The Commission invited Member States to share their experiences and suggestions to improve the situation.

A.28 Date of next meeting(s).

The Commission confirmed the dates of the next meeting of this Committee (27/28 January 2022), and indicated the planned dates for the meetings of this Committee in 2022: 30/31 March, 17/18 May, 14/15 July, 13/14 October, and 8/9 December.

A.29 AoB.

The Commission informed about the upcoming Better Training for Safer Food related to the scientific criteria to identify endocrine disrupting properties, which was to take place on 15 to 17 December 2022 virtually with EFSA and ECHA experts giving the training, and invited Member States to send participants.

The Commission also invited Member States to communicate names of colleagues who are lawyers and would have an interest to join the next workshop on legal issues.

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) …/… concerning the non-renewal of approval of the active substance phosmet, 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/12604/2020).

SANTE/12602/2020

The Commission informed that the written procedure of the vote carried out in October 2022 after the last meeting of this Committee had been closed without results at the request of two Member States and that therefore the vote would take place during the meeting.

One Member State informed that it would support the act, although it would have preferred shorter grace periods, and asked for a fast review of the MRLs. Two Member States indicated that they would not support the draft Regulation. The Committee proceeded to vote during the meeting.

Vote taken: Favourable opinion.

In the meeting of this Committee in October 2021, two Member States made protocol declarations, which are repeated here:

The Netherlands favours a grace period with a maximum of 6 months. Now there is no qualified majority for such a grace period, we support the current proposal in order to avoid further delay. In addition, we ask the Commission to swiftly come with a proposal for an amendment of the MRLs for phosmet.

Hungary stated: With the non-renewal of approval of phosmet, only pyrethroid-like a.s. and acetamiprid remain in rapeseed culture to control rapeseed beetle, which unfortunately predicts the development of resistance and the long-term impossibility of control until other a.s. would be available.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) …/… 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/10296/2021).

SANTE/10298/2021

The Commission informed about the arguments from the applicant who wished to obtain approval as low-risk active substance, which is however not supported by the Rapporteur Member State, due to the substantiated potential sensitisation property by inhalation of the active substance and hence the need for specific risk mitigation measures. This is also justified by the limitation of content of beauvericin in the final product and the restriction of use to ornamental palm trees.

One Member State made an editorial remark and another Member State indicted that it would not support the draft Regulation because of potential ecotoxicological risks.

The vote was postponed because the internal consultation process in the Commission was still on-going.

Vote postponed.

B.03 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 presented the slightly amended text of the draft Regulation (editorial amendments) and the latest information received from the applicant concerning the proposal for re-classification of the substance under the CLP Regulation, as well as the latest proposals for restriction of use and risk mitigation measures.

The Commission explained that this information was not sufficient to modify its proposal for non-approval. The Commission questioned all Member States individually

about their intention of vote. Four Member States indicated that they would not support the draft Regulation, while two indicated not having yet a position.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011. The procedure was stopped with no result following the request of one Member State.

Vote postponed.

B.04 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 presented the slightly amended text of the draft Regulation (editorial amendments) and the latest information concerning the additional genotoxicity study which was committed by the applicant and discussed with the Rapporteur Member State. The Commission questioned all Member States individually about their intention of vote. Four Member States indicated that they would not support the draft Regulation, while two indicated not having yet a position.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011. The procedure was stopped with no result following the request of one Member State.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) …/… approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45, 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/10762/2021).

SANTE/10760/2021

The Commission presented the draft Regulation which had been slightly amended compared to the version presented at the meeting of this Committee in October 2021 (editorial amendments). Only one Member State had indicated (provisional) support before the meeting. The Commission questioned all Member States about their intention of vote. One Member State indicated that it supported approval but not with low-risk status.

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 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

Points C.01 to C.04 were discussed together.

The Commission reported about the comments received via the feedback mechanisms (i.e. the public consultation) from 26 October 2021 to 23 November 2021 for the draft 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.

About 270 reactions were received during the feedback period, some of them including several comments in one submission. The majority of respondents were business associations (41%), companies/business organisations (16%), EU citizens (11%), public authorities (9%), NGOs (9%), trade unions (5%). The majority of comments (63%) were from respondents located in three Member States (the Netherlands, Belgium, and Germany). One comment was from a respondent located outside the EU.

In general, the comments received considered the amendments as significant improvements for the approval/authorisation processes for micro-organisms and plant protection products containing them. They underlined in particular the increased clarity of the provisions, appreciating the different approach taken for micro-organisms compared to chemical active substances and products. The comments also welcomed the bigger importance given to biology and ecology of the micro-organism and the weight of evidence approach enabling to replace animal studies.

However, several issues were raised, summarised below:

- Some stakeholders claimed that more drastic actions than the proposed amendments of data requirements and approval rules should have been presented, such as revising the approval/authorisation process to further simplify access to the market, or mitigating the discrepancy with similar regulatory frameworks (e.g. plant biostimulants). The Commission reiterated that such amendements are outside the scope and possibilities of the draft Regulations and that the Commission has no empowerment to enact such drastic changes.
- Other stakeholders underlined the concern of not having enough and evenly distributed expertise among Member States for evaluating applications related to micro-organisms. The Commission explained that it was aware of the situation and recalled that several actions were already taken (e.g. the Better Training for Safer Food Training Programme) and that there are more possibilities for experts to share experience and consult with peers from other Member States (e.g. in the Biopesticides Working Group and the Post Approval Issues Working Group of this Committee, or the EFSA Pesticides Steering Network). The Commission encouraged Member States to re-inforce their internal expertise for assessing micro-organisms by participating in the training activities (e.g. Better Training for Safer Food), and to foster the participation of their experts in these exchange platforms.
- Some respondents also mentioned that the flexibility and the conditionality of the data requirements as well as the weight of evidence approach might lead to

inconsistencies in interpretation and hence possible uncertainties for applicants on how their dossiers will eventually be interpreted by the 27 Member States despite the expected simplification for their applications. The Commission explained that, due to the wide group of micro-organisms to be addressed by legal texts, a flexible approach is required and a right balance between flexibility and legal certainty was needed. The Commission explained that the best way to mitigate the risk of different interpretation of the legal texts would be increasing expertise and fostering participation at Working Groups and other platforms as described in the previous paragraph, as well as making good use of the pre-submission meetings – including through involvement of EFSA - foreseen under the Transparency Regulation.

– Some comments mentioned the need for guidance documents to support the implementation of the new provisions. The Commission explained that indeed further actions will be taken to support access to the market for micro-organisms (e.g. the publication of Commission Communications listing testing methods and guidance documents to implement data requirements for micro-organisms), and that there is already an ongoing activity with OECD focused on testing methodologies for micro-organisms.

The Commission informed that it had considered all the comments received, and that some changes had been made to the draft Regulations as a consequence. For instance, in order to harmonise the terminology used with that at OECD level, the earlier 'microbial active substance as manufactured' (MASAM) had been replaced with 'technical grade-microbial pest control agent' (TG-MPCA).

The Commission also summarised the comments received from Member States on the draft Regulations, in particular concerning the low-risk criteria described in the draft amendment to Annex II of Regulation (EC) No 1107/2009, and the interaction of these criteria with Article 22(1) and Article 22(2) of the same Regulation.

The Commission informed that the four draft Regulations revised based on the comments received by Member States and through the feedback mechanism were available on CIRCABC and the vote is planned for the next meeting of this Committee.

C.02 Exchange of views 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 point C.01.

C.03 Exchange of views 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 point C.01.

C.04 Exchange of views 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 point C.01.

C.05 Exchange of views 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).

The Commission informed that the notification of the draft Regulation to the WTO under the TBT agreement had been submitted and is publicly available (*http://tbtims.wto.org/en/RegularNotifications/View/175368?FromAllNotifications=True*). The Commission indicated that a vote is foreseen for the next meeting of this Committee.

The Commission informed of letters from several growers associations asking to maintain uses in open field crops, which were made available to Member States via CIRCABC.

C.06 Exchange of views 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 Regulation which intends to approve chitosan from fungus *Aspergillus niger* as a basic substance.

The Commission informed about the modifications to the table of intended uses in the Appendix to the draft amended Review Report as requested by the applicant. The Commission had consulted EFSA on the requested modification which was found to be within the risk envelope for the risk assessment as included in the EFSA Technical Reports. The draft amended Review Report and the feedback received from EFSA had been made available to the Member States via CIRCABC.

The Commission informed on the comments received. One Member State supported the approval. One Member State was against the approval and proposed to request more information from the applicants for chitosan and chitosan hydrochloride, and to review the approval of chitosan hydrochloride currently in force. The reasons included the missing data and non-finalised risk assessment for non-target organisms including honey bees, for both, chitosan from *A. niger* and chitosan hydrochloride from crustaceans. The Commission recalled the similar observations made previously by another Member State.

The Commission asked Member States who had not done so to indicate whether they would support the draft Regulation – from the information available so far it appeared that there would be sufficient support.

Member States were invited to send comments by 13 January 2022.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) …/… approving the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11266/2021).

SANTE/11264/2021

The Commission presented the draft Regulation and draft Review Report in view of the approval of SeMNPV, isolate BV-0004 as a low-risk active substance in accordance with Regulation (EC) No 1107/2009. Two Member States expressed preliminary support for the approval as low risk.

The Commission informed that the vote is planned for the next meeting of this Committee and invited Member States to comment by 3 January 2022.

C.08 Exchange of views 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 referred to the last meetings of this Committee in which the decision on the renewal of approval of carbon dioxide had been discussed and reminded that the draft Regulation intended to renew the approval without low risk status because carbon dioxide is used in the form of a ”compressed gas”, which can be explosive and consequently does not qualify as low risk. The Commission referred to comments received from one Member State concerning the impurity benzene.

The Commission informed that the vote is foreseen at the next meeting of this Committee and invited Member States to comment by 3 January 2022.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) …/… approving the 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, Rev. 1)

SANTE/11298/2021

The Commission recalled that based on the revised EFSA Conclusion, the intention is to renew the approval of bifenazate with restriction to non-edible crops and to permanent greenhouse as defined in Article 3(27) of Regulation (EC) No 1107/2009 due to the non-finalised risk assessment for consumers and high risk to birds.

The Commission shared the comments received from four Member States, three supporting the proposal from the Commission and one indicating that it supported non-

renewal. The Commission informed about a meeting with the applicant in November 2021, and shared the comments from the applicant on the draft review report and the slides presented at the meeting. The Commission informed the Committee that the review report and the implementing act explain that the restriction of the approval to use only in permanent greenhouses also addresses some additional concerns identified by EFSA such as the risk to honeybees as well as to mammals in case of some representative uses.

The Commission invited Member States to comment by 13 January 2022.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) …/… concerning the renewal of approval of the active substance *Metarhizium brunneum* strain M43 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 a revised Renewal Report, which considered the comments from Member States and the draft Regulation for the renewal of approval of *Metarhizium brunneum* strain Ma 43 as a low-risk active substance. The Commission explained that BIPESCO 5 and F52 are considered subcultures of Ma 43, which is the original strain, and that EFSA had confirmed these strains are identical in terms of biological and genetic properties and that there are no known differences between these subcultures and the original strain Ma 43 based on sequencing analysis.

The Commission informed that the vote is foreseen at the next meeting of this Committee and invited Member States to comment by 10 January 2022.

C.11 Exchange of views 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/10308/221

The Commission informed that the notification of the draft Regulation to the WTO under the TBT agreement had been submitted and invited Member States to provide any comments or feedback on the draft Regulation by 10 January 2022 ahead of a possible vote at the next meeting of this Committee.

C.12 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