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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*
30 - 31 March 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/908a30bf-9276-4088-a9c6-ae6039d94691*

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 December 2021 is published.

A.02 New dossiers:

- New active substances

  There were no news to discuss.

- Basic substances applications

  1. Extension of use of chitosan hydrochloride

     No discussion took place, the point was postponed.

  2. Amendment of conditions of approval

     There were no news to discuss.

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

– Annex to Regulation (EU) No 2015/408

The Commission informed that the Annex to Implementing Regulation (EU) No 2015/408, which it implemented Article 80(7) of Regulation (EC) No 1107/2009 and established a list of active substances that are candidates for substitution contains a number of active substances that are no longer approved or the approvals of which have been renewed. They should be deleted from the Annex for the sake of clarity and transparency. The Commission presented a draft Implementing Regulation to this effect.

No Member States commented on the proposal. Member States were invited to comment by 25 April 2022.

– Overview of active substances under ED stop the clock

Due to the difficulties expressed by several Member States in the prediction of workload expected for the renewal of authorisations of plant protection products under Article 43, the Commission informed that an overview table elaborated by EFSA is available on CIRCA BC, which lists all active substances that currently are under stop the clock for the purposes of the assessment of their endocrine disrupting properties, including also indicative timelines.

– Workshop with Member States on possible grants

The Commission informed that following the response to the four questions asked at the last meeting of this Committee in January 2022, the Commission plans to transform from procurement to grants the funding available for Member State authorities aimed at reducing systematic delays in the assessment of dossiers for active substances or authorisation of products under Regulation (EC) No 1107/2009 and Regulation (EU) 528/2012.

The Commission also informed that it will organise a workshop to which competent authorities, ECHA and EFSA will be invited. The objective will be to inform about the details and conditions of the grant and listen to the Member States' views. The invitation will be sent in the upcoming weeks. Member States were requested to indicate to the Commission by 24 April 2022 if they object that the Commission shares their answers to the four questions mentioned above at the occasion of this workshop.

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

- New active substances

1. *Aspergillus flavus* MUCL54911

The Commission summarised the EFSA conclusion and the comments received by the applicant, underlining that a product containing this active substance had received emergency authorisation several times. The Rapporteur Member State specified that the emergency authorisation was granted for uses in feed crops. Member States were invited to comment by 2 May 2022.

2. *Trichoderma atroviride* strain AGR2

The Commission summarised the EFSA conclusion and the comments received by the applicant. Member States were invited to comment on the EFSA conclusion and on the feedback received from the applicant by 2 May 2022.

3. *Trichoderma atroviride* strain AT10

The Commission summarised the EFSA conclusion and the comments received by the applicant. Member States were invited to comment on the EFSA conclusion and on the feedback received from the applicant by 2 May 2022.

- Renewal of approval

4. Clofentezine

This point was discussed together with points A.04.5 and A.05.a.

The Commission thanked the Member States who had provided comments following the last meeting of this Committee and also informed that several papers

had been received from the applicant and a consultant working for the applicant, both defending renewal of approval under Article 4.7 including on edible crops. These documents had been made available to Member States.

It was noted that the letter from the consultant also provided some general views on the application of Article 4.7.

The Commission explained that several Member States consider that no renewal is possible for clofentezine, including under Article 4.7, and that so far no Member State had explicitly indicated support for a renewal of the approval of clofentezine on flower bulbs/flower tubers under Article 4.7.

One Member State indicated that although the active substance was not important for uses in its territory, it would consider supporting an Article 4.7 derogation if other Member States expressed the need for the uses identified. The Commission recalled that in case of an approval under Article 4.7, Member States would have full control over the authorisation of the uses identified in any approval.

The Commission explained that it is consulting internally to determine how to proceed and that the views of Member States are being taken into account during those reflections. Member Stats who had not reacted so far were invited to provide comments by 25 April 2022. Moreover, the Commission asked Member States to provide concrete positions on the possible renewal of approval of clofentezine under Article 4.7 for uses on flower bulbs and tubers in greenhouses only.

Two Member States asked how it was possible to carry out risk assessment for endocrine disrupting substances since in their view the setting of thresholds was not possible.

5. Benthiavalicarb

The Commission thanked the Member States who had provided comments following the last meeting of this Committee and also informed that several papers had been received from the applicant and from a consultant working for the applicant, both defending renewal of approval under Article 4.7 including on edible crops. These documents had been made available to Member States.

It was noted that the letter from the consultant also provided some general views on the application of Article 4.7.

The Commission explained that one Member State indicated that for the representative use in potato, the exposure of consumers cannot be considered negligible due to the data gap with respect to rotational crops and the exposure to non-target organisms cannot be considered negligible due to the characteristics of the use which is a spray application in the field.

The Commission reminded that agricultural needs had been proven for onions and sugar beets in accordance with Art 4.7, and that for these uses it would be the responsibility of each Member State to fully evaluate applications ensuring that an acceptable risk is achieved. This would be stressed both in the renewal report and in the implementing regulation. In addition, for these uses, a review of the MRLs would also need to be considered.

The Commission explained that it is consulting internally to determine how to proceed and that the views of Member States are being taken into account during

those reflections. Member States who had not reacted so far were invited to provide comments by 25 April 2022.

6. Fish oil

The Commission presented the draft renewal report. Member States were invited to provide comments until 2 May 2022.

7. Sheep fat

The Commission presented the draft renewal report. Member States were invited to provide comments until 2 May 2022.

- Basic substances

  There were no news to discuss.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Asulam-sodium

  The Commission thanked the Member States who had provided comments following the last meeting of this Committee and informed that the applicability of Article 4.7 to herbicides had generated mixed reactions: some Member States considered that given that there are non-chemical methods available to control weeds, a 'serious danger to plant health' should not be invoked, while other Member States referring to the relevant EFSA Guidance Document (from 2016) were of the opinion that, as soon as there is at least one Member State which cannot control a serious danger to plant health (for a specific use) by a non-chemical method, Article 4.7 may apply.

  The Commission explained that it is consulting internally to determine how to proceed and that the views of Member States are being taken into account during those reflections. Member States who had not reacted so far were invited to provide comments by 25 April 2022. Moreover, the Commission asked Member States to provide concrete positions on the possible approval of asulam under Article 4.7.

- Renewal of approval

  b) Captan

  The Commission summarised the previous discussion on this active substance, including the ongoing discussion on the possibility to mandate EFSA to clarify the risk to non-target species.

  c) *Bacillus amyloliquefaciens* strain QST 713

  The Commission thanked Member States who had commented following the previous meeting of this Committee: a majority favoured a mandate to EFSA for clarifying the concern linked to bees identified in the EFSA Conclusion. Further exchanges between EFSA and the Rapporteur Member State had been made available to Member States as well as the applicant's comment. Member States who had not yet expressed their views were invited to comment by 25 April 2022.

d) *Pseudomonas chlororaphis* strain MA342

The Commission summarised the status of the file, including the biology and ecology of the micro-organism, the outcome of the EFSA mandate on the risk for consumers from exposure to the metabolite DDR and a position paper by the Rapporteur Member State and Co-Rapporteur Member State supporting the renewal of approval of the micro-organism. The Commission informed that two Member States indicated that they would not support the renewal of approval of this active substance because of the concern about DDR.

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

e) *Bacillus thuringiensis* (horizontal discussion)

The Commission informed that preliminary discussions are ongoing with EFSA and ECDC on a possible joint mandate to clarify technical issues related to possible relations between *Bacillus thuringiensis* and foodborne outbreaks.

f) *Pythium oligandrum* strain M1

The Commission informed that one additional Member State had commented that data submitted at this late point in the renewal process cannot be used. The Commission explained that the EFSA Conclusion had been thoroughly reviewed on the basis of the available data in a weight of evidence approach. Member States were invited to comment by 25 April 2022 on the new draft renewal report which supports a renewal of the approval which considers that risk mitigation measures such as those required in general for potentially sensitising micro-organisms address the remaining concerns on pathogenicity/infectivity.

g) Pelargonic acid

The Commission informed that it had received further comments from two Member States on the results of the peer review. Member States were invited to provide any further comments by 25 April 2022.

h) Heptamaloxyloglucan

The Commission presented a draft renewal report to the Member States. One Member State wondered if this active substance falls within the scope of Regulation (EC) No 1107/2009, due to the amendment of that Regulation by Regulation (EU) 2019/1009 that removed products fulfilling the definition of biostimulants from the scope of Regulation (EC) No 1107/2009. The Commission indicated that this needs to be verified (see also point B.06).

- Basic substances

i) Hydrogen peroxide silver stabilised

The point was postponed.

j) Calcium propionate

The Commission presented the draft review report for a non-approval of calcium propionate as a basic substance. One Member State had indicated that they would support the Commission's proposal.

Member States were invited to comment by 25 April 2022.

k) Black soap

The Commission presented the draft review report for a non-approval of black soap E470a as a basic substance. The Commission explained that the EFSA technical report indicates that, even though no EU harmonised classification is available, the main hazard associated with black soap E470a would be irritation and corrosive properties, as reported in the classification and labelling inventory on the ECHA website. Due to the absence of data, it was not possible for EFSA to conclude on the non-dietary risk assessment for operators, workers, bystanders and residents. Moreover, a quantitative consumer risk assessment through dietary intake and drinking water could not be finalised.

Due to the lack of data regarding exposure or hazard, a quantitative risk assessment regarding the effects on non-target species, including pollinators, was not possible and therefore, EFSA raised the need for risk mitigation measures for aquatic organisms and pollinators.

The Commission had received comments from two Member States: one agreed with comments already raised in the past by another Member State that there are several issues that are still unresolved, the other Member State did not see the EFSA comments as preventing an approval.

Member States were invited to comment by 25 April 2022.

l) Extension of use of sodium chloride

The Commission informed that a review report for an extension of use was available on CIRCA BC and invited Member States to comment by 2 May 2022.

m) Lemon essential oil

The Commission informed that a review report for a non-approval is available on CIRCA BC and invited Member States to comment by 2 May 2022.

n) Yucca Schidigera extract

The Commission informed that a review report for a non-approval is available on CIRCA BC and invited Member States to comment by 2 May 2022.

A.06 Confirmatory Information:

1. 1-decanol (amended review report to endorse)

   The Commission informed that, after the last meeting of this Committee, a draft of the amended review report had been sent to the applicant. Additionally, one Member State had indicated that the level of exposure mitigation necessary to find a safe use for the use of 1-decanol is likely to be considerably high and questioned if it can be achieved.

   The Committee endorsed the amended review report with the exception of one Member State. In their opinion, not all confirmatory data requirements had been satisfactorily addressed, specifically the risk to aquatic organisms.

2. Penthiopyrad (amended review report to endorse)

   The Commission recalled that an amended Review Report had been prepared to close the confirmatory information points. Some minor changes to the amended report were made based on comments received from Member States following the meeting of this Committee in January 2022.

Two Member States did not agree that the confirmatory information had been satisfactorily addressed and were not in agreement with the updated Review Report. Those Member States considered that there are risks to groundwater from leaching of metabolites and expressed concerns about consumer exposure to the metabolite PAM.

The Committee endorsed the amended review report with the exception of two Member States.

3. Pyridaril (amended review report to endorse)

   The Commission informed that the report had been amended following four comments received since the last meeting of this Committee. The Commission referred to a letter from the applicant stating that all required confirmatory data had been submitted and accepted by the Rapporteur Member State (RMS). The Commission also pointed out that only one product containing the active substance is authorised in one Member State for the use in permanent greenhouses, which makes the need for a monitoring programme questionable, and that the applicant does not intend to apply for renewal of approval.

   One Member State supported the amended review report whereas another one could not support it due to the missing groundwater monitoring data. Furthermore, a Member State reiterated their written comments and the Commission suggested a compromise wording.

   It was agreed to postpone the endorsement and Member States were invited to comment by 25 April 2022.

4. Acequinocyl (amended review report to endorse)

   The Commission explained that a revised technical report had been published by EFSA and presented the amended review report for endorsement. Two Member States had indicated that issues with the feeding guild of small herbivorous mammals remain unsolved. The Commission informed that those aspects will be dealt with during the renewal process, as offered by the Rapporteur Member State, which will start in May 2022.

   The Committee endorsed the amended review report with the exception of one Member State.

5. Acibenzolar-methyl

   The Commission recalled that this is a very particular case as specific confirmatory data requirements concerning endocrine disrupting (ED) properties had been set before November 2018 during renewal and were fulfilled by the applicant. However, these had not been sufficient as stated by the peer review assessment to analyse endocrine disruption properties in light of the new ED criteria which became applicable after the confirmatory data requirements had been set.

   The Commission informed about the possibility of starting an Article 21 review procedure, giving three months' time to the applicant for commenting in which they could outline which additional studies, which were not required to fulfil the confirmatory information requirement and are needed to fully assess the ED properties in light of the new ED criteria, are now available or are planned and with which timing. After this three-month period, EFSA and Member States (on request of the Commission) would express their views on the need for these additional

studies in order to be able to assess the ED properties according to the new criteria. The Commission would then write to the applicant and request submission of the studies found necessary by a given deadline, and after receiving these studies by the deadline, the Commission would mandate EFSA and the RMS to assess the submitted data and come to a final view as regards the potential ED properties of the active substance.

6. Thiabendazole

   The Commission recalled that the EFSA conclusion had been published on 28 March 2022 concerning the confirmatory information and had been sent for comments to the applicant. In the conclusion the substance was found to meet the criteria for endocrine disruption (ED) for human health (thyroid (T)-modality), while for non-target organisms the assessment could not be finalised. EFSA had been asked to arrange a further peer review, including expert discussion where appropriate, to further assess the ED properties of thiabendazole on the basis of the available information and, if applicable, to establish which additional test(s) would be needed to conclude on such properties under consideration of the criteria established by Commission Regulation 2018/605.

   As the confirmatory data requirements had been set before those ED criteria became applicable, the Commission is reflecting how to proceed.

7. Pendimethalin

   The Commission informed that it is intending to mandate EFSA and ECHA as a follow up of the EFSA report on the confirmatory data, on the potential for bioaccumulation. The agencies will be asked to jointly provide advice on how to derive BCF values to be used for regulatory purposes in light of a weight of evidence approach when experimental data from more than one species are available.

   In addition, for closing the procedure for the assessment of confirmatory information, it will also be needed to address the four specific points identified in the EFSA Technical Report: i) whether the 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 proposed approach had been supported by several Member States in written comments.

   Member States were invited to provide any further comments by 25 April 2022.

8. Propyzamide

   The Commission summarised the comments received from Member States and explained that it was reflecting on how to move forward, taking into account the need to provide clarity as soon as possible for other ongoing (MRL) or upcoming processes (renewal of approval).

   Member States were invited to comment by 25 April 2022.

9. Flutianil

The Commission informed that the EFSA technical report had been published on 22 March 2022: based on the available data and weight of evidence, the report concludes that flutianil does not meet the criteria for endocrine disruption (ED) for human health. As regards non-mammalian species, an Amphibian Metamorphosis Assay (AMA) and a Fish Short Term Reproduction Assay (FSTRA) were submitted and EFSA indicated the need for expert discussion.

The Commission informed that a mandate to EFSA to arrange for the necessary expert discussion is in preparation.

A.07 Guidance Documents:

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

   The Commission informed of the outcome of the workshop which took place the 17 February 2022 and of the publication of the corresponding report on the Commission's website (https://ec.europa.eu/food/system/files/2022-03/pesticides_bees_20220217_report.pdf).

   The Commission also shared with Member States a letter received from PAN Europe on this subject as well as a joint letter PAN Europe, Pollinis, BeeLife and Apimondia, informed of a discussion on this subject in the Committee on the environment, public health and food safety, of the European Parliament on 3 March 2022, and provided a summary of the comments received from two Member States.

   In the absence of sufficiently robust evidence, the Commission proposed to proceed, at this stage, with an undefined threshold approach for both bumblebees and solitary bees until further data becomes available. In practice, this would imply to require by default field studies for bumblebees and solitary bees. However, in cases were the lower tier risk assessments for honeybees, bumblebees and non-target arthropods other than bees would show no effects for the respective active substance, this would appear not proportionate and such field studies would not be requested.

   Member States were asked to comment on this proposal. Some Member States expressed support, while others who had earlier preferred a defined threshold of 10% for bumblebees indicated that they needed to reflect.

   One Member State asked for a clarification on the details for field study protocols. The Commission indicated that it is expected that EFSA will include recommendations for field studies in the revised Bee Guidance Document. One Member State underlined the need to generate new data and that it is key to finalise the review of the EFSA Bee Guidance Document as soon as possible.

   Member States were invited to send in their position on the Commission's proposal by 25 April 2022.

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

   The Commission informed that due to the lack of support by the Member States for the last version of the draft guidance document, further work on it is put on hold until the judgement in court case C-162/21 becomes available.

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

   The Commission informed that it was in the process of finalising the update of the Communications and that it will share them for consultation in due time.

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 it started work on a revised draft which, once in a more advanced state, will be shared with the Working Group (WG) created by this Committee to start discussions. A Terms of Reference document for the WG was also made available to Member States.

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 informed that it had received comments from two Member States, and had asked EFSA to comment on them as they concerned some technical aspects. The Commission also informed that CropLife Europe indicated that this document is expected to have significant implications also on the environmental risk assessment in soil, including soil organisms. The mentioned comments are all available on CIRCA BC.

   Member States were invited to send further comments, in particular as regards the potential implications on environmental risk assessment, by 2 May 2022.

6. EFSA Guidance on aneugenicity assessment

   Member States were invited to comment, in particular as regards a potential endorsement with immediate implementation (as suggested by two Member States) or with a short implementation delay, by 25 April 2022.

7. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

   Member States were invited to comment in particular as regards a potential endorsement by 2 May 2022.

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

   EFSA presented the guidance document. Member States were invited to comment, in particular as regards a potential endorsement, by 2 May 2022.

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

   EFSA presented the guidance document. Member States were invited to comment, in particular as regards a potential endorsement, by 2 May 2022.

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

EFSA presented the guidance document. Member States were invited to comment, in particular as regards a potential endorsement, by 2 May 2022.

11. Update on EFSA GD Risk assessment for birds and mammals

    EFSA provided an update on the on-going revision of the guidance document for environmental risk assessment for birds and mammals. The public consultation is finalised and the finalisation of the document and a calculator is foreseen for December 2022.

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

- Article 44(4)

The Commission informed that no notifications had been received since the last meeting of this Committee.

- Article 36(3)

The Commission informed that fourteen notifications had been received since the last meeting of this Committee. Eight concerned rejections of authorisations under the zonal system and six notifications concerned rejections of applications for mutual recognition. None of the decisions had been appealed in national Courts.

- Article 53

The Commission informed that it was still analysing the technical reports issued by EFSA on the emergency authorisations for neonicotinoids for use in sugar beet that had been granted by several Member States in 2020 and 2021.

A.09 Microorganism Active Substances, in particular:

The Commission informed that it was progressing with the draft Commission Communications needed for the implementation of the new data requirements for micro-organisms and that a draft will be ready for consultation soon.

A.10 Safeners and Synergists:

The Commission recalled the previous discussions on the intentions to draft an implementing Regulation so set up a work programme for the review of all safeners and synergists and requested the Member States to express their interest to participate in a Working Group to define data requirements for safeners and synergists. Member States were also invited to comment on the terms of reference of that Working Group.

The Commission informed that so far three Member States had expressed interest to participate in the Working Group.

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

1. Sodium hydrogen carbonate

   The Commission informed that no further comments had been received from Member States nor any new letter from the authorisation holder. The Commission is reflecting internally on how to proceed. Member States were invited to send any further comment by 2 May 2022.

2. Flupyradifurone

   See acetamiprid (point below).

3. Acetamiprid

The Commission recalled that on 30 November 2020, France had invoked Article 69 of Regulation (EC) No 1107/2009 and requested to prohibit the sale and use of the active substances sulfoxaflor, acetamiprid and flupyradifurone, considering that they may pose serious risks to health and/or the environment. Some selected peer-reviewed studies were provided in support of the request. On 21 December 2020, France notified under Article 71 emergency measures taken to ban the use of these 3 substances in plant protection products in its territory, because they are considered to belong to the group of neonicotinoids or are similar as to their mode of action. In addition, in June 2020, the Dutch authorities had notified to the Commission, under Article 56 of Regulation (EC) No 1107/2009, new information on adverse effects of flupyradifurone on the wild bee species *Megachile rotundata*. In the notification the Dutch authorities informed that it was not possible to conclude if the identified higher sensitivity of that species would lead to unacceptable risks.

The Commission recalled that actions to restrict the use of sulfoxaflor were already under discussion in this Committee, and that the Commission had mandated EFSA to advise if the new evidence for acetamiprid and flupyradifurone communicated in the notifications (i.e. the selected studies submitted) indicated serious risks to humans or the environment, compared to previous EU assessments. The statements by EFSA had been made available on CIRCA BC together with comments from the authorisation holders. EFSA found that, in general, on the basis of the data analysed it cannot be concluded that acetamiprid and flupyradifurone are likely to constitute a serious risk to human or animal health or the environment.

The Commission also recalled that the approval of flupyradifurone expires on 9 December 2025 and that the authorisation holder will have to submit an application for renewal no later than 9 December 2022. The applicant needs to submit all available data, including data on *Megachile rotundata*, which will be assessed together with all other issues related to non-target organisms. Alternatively, a review under Article 21 of Regulation (EC) No 1107/2009 could be launched.

A Member State commented that requests for measures under Article 69 of Regulation (EC) No 1107/2009 should be supported by relevant data. These data unavoidably are biased in a sense that only relevant data will be the one that suggests an active substance is likely to constitute a serious risk to human or animal health or the environment.

Member States were invited to submit their views by 25 April 2022 on the following questions for both acetamiprid and flupyradifurone:

1. Considering the EFSA Statements and the upcoming renewal for flupyradifurone, whether regulatory measures under Article 69 or launching a review under Article 21 for acetamiprid and/or flupyradifurone would be justified and why;

2. Whether Member States apply or envision any measures that are expected to mitigate the risks due to the higher sensitivity of wild bees *Megachile rotundata* to flupyradifurone.

4. Quassia (update)

The Commission informed about the re-submission of the application dossier for approval as basic substance and that the task force supporting the re-submission had

informed about difficulties for the organic farming sector to find alternative substances for plant protection in apples and hop.

A.12 Article 21:

1. Ipconazole

   The Commission reminded Member States that:

   – ESFA had finalised its Statement on the assessment carried out under Article 21 of Regulation (EC) No 1107/2009 and had circulated it to Member States on 1 February 2022. The Article 21 review had been initiated to consider two aspects: classification of ipconazole as toxic to reproduction, category 1B (R1B) and the long-term risk to birds (which remained unresolved after the assessment of confirmatory information).

   – The applicant had submitted a renewal application in November 2021. Belgium is the rapporteur Member States (RMS).

   The Commission summarised the statement of EFSA (which took into account the assessment carried out by the RMS), highlighting that uncertainties were identified about whether non-dietary exposure could be considered negligible (whereas from a dietary perspective, residue levels are below the default value of 0.01 mg/kg and therefore considered negligible) and that based on an assessment of the available data and on a refined higher tier risk assessment, a high long-term risk to birds was identified both for winter and spring sown barley and wheat.

   The Committee was informed that one Member State had provided comments already, indicating that it considered the studies for operators and workers limited and insufficient to demonstrate negligible exposure. It also concluded that Article 4 is no longer fulfilled due to the risk to birds identified. The Committee was also informed that the RMS had provided additional information which had been available on CIRCA BC.

   The Commission explained that it was reflecting on how to proceed. A withdrawal of approval or an amendment to the approval could be considered. However, any amendment would need to ensure that the issues identified were solved.

   One Member State asked what would happen to the renewal application in the event of a withdrawal of approval. The Commission explained that in such a case its current interpretation is that the renewal application would be terminated since it is only possible to renew an existing approval. However, a new application for approval could then be submitted under Article 7 of Regulation (EC) No 1107/2009 if the applicant wished to do so.

   Member States were invited to provide their positions and views on how to proceed by 25 April 2022, including providing any concrete measures to address the uncertainties and risks identified (negligible exposure to operators and workers and the risk to birds).

2. Pirimicarb

   The Commission recalled that it had written to the applicant in October 2021 inviting to provide comments on several concerns identified by the Rapporteur Member State during the renewal review (subsequent to the request for additional data under the stop clock provisions of the renewal procedure to determine whether

the substance has ED properties). The applicant had submitted information to the Member States, EFSA and the Commission at the end of January 2022.

The Commission informed that it has asked the RMS to evaluate the information submitted after which the next steps would be determined (likely to be a request to EFSA to deliver its view).

In the meantime, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, Member States were asked to provide their views and comments on the information submitted by the applicant by 30 June 2022. The Commission underlined that this Article 21 review process is separate from the ongoing renewal review.

A.13 General issues for information / discussion:

1. Update Q & A document – deletion obsolete parts (to endorse)

   The Commission explained that the existing published version of the Q&A document requires a review. In the meantime a watermark had been added to the document to communicate that it is under revision.

   As an intermediate step, pending a more complete review, the Commission proposed to remove the section on endocrine disrupting properties (ED) since it became completely obsolete when the new criteria to identify endocrine disrupting properties became applicable. The Committee agreed to amend the document removing the section on ED.

2. Debriefing Illegal plant protection product use (workshop February 2022)

   The Commission informed about the International Seminar on illegal trade in plant protection products organised by the Slovak Ministry of Agriculture in cooperation and coordination with OECD, held on 16-17 February 2022.

   The aim of the seminar was to support professional activities, domestic and international cooperation, mutual communication, exchange of information, knowledge and practical experience in detecting illegal trade in plant protection products. The Commission drew the attention of Member States on the importance of this subject.

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

   a) Scope Document rev. 69

   The Commission explained the amendments brought to the document upon request of two Member States.

   b) new cases: Profume, Insect Protector

   The Commission presented four new entries in the Scope Document with a proposal for interpretation and invited Member States to comment by 25 April 2022.

   The Commission also presented the FAQ document elaborated for the Fertilising Products Regulation, in particular the amended section dedicated to “products out of one single substance” where the question of presence of substances or micro-organisms having a pesticidal effect while being contained in fertilising products is addressed. Member States were invited to send comments about the proposed interpretation by 25 April 2022.

4. Basic substances – general issues

   There were no news to discuss.

5. MS updated survey on timing of regulatory procedures

   The Commission informed that the internal review and editing work of the report on the two surveys is still ongoing. The Commission intends to present the final report in the next meeting of this Committee.

6. MS-proposal PPP TARIC Code

   The Commission recalled that several Member States had expressed their support to the initiative to amend TARIC codes under heading 3808, in order to differentiate pesticides from biocides or other goods and to facilitate the management of control procedures at borders. The Commission was now reflecting as regards the next steps. Further developments will be communicated in due time.

7. PPPAMS – update

   The Commission thanked Member States for providing comments after the last meeting of this Committee and informed that all comments were being considered in ongoing discussions about how to proceed with implementation of PPPAMS. Member States who had so far not provided comments were invited to do so by 25 April 2022.

   The Commission concluded that there are diverging views between Member States on the scope and remit of PPPAMS for numerous reasons, including the availability of existing systems and concerns about resources and duplication of tasks.

   The Commission noted that the discussions on implementation coincide with a review of the technology underpinning the existing PPPAMS system, and that work to ensure the preservation of the functionalities for emergency authorisations was ongoing. As part of that task, work to simplify and improve the use of the system for this purpose was also being undertaken. Member States were informed that the system will change its look and feel since the technology will also need to be changed. Further information, support and training will be provided to Member States and applicants in due course. It was underlined that that changes will ensure simplification and a more intuitive approach.

   The review of technology would also impact the further implementation. The Commission explained that it was considering several options to achieve the desired objectives of having compiled information on PPP authorisations, while minimising the burden on Member States and other stakeholders. The Commission indicated that Member States would be consulted once more information was available.

8. Incidents with phosphine products

   The Commission reminded Member States to send their information on incidents related to the use of phosphine generating products by 25 April 2022.

9. Labelling of PPP imported in bulk

   The Commission informed that two Member States had commented since the last meeting of this Committee. One of the Member States had taken the view that the labelling requirements would only apply to plant protection products in the package made available to the end user, relying on the wording of Article 2 of Regulation

(EC) No 1107/2009 and the definition of package and packaging in horizontal chemical legislation.

The other Member State had taken the view that the classification should be clearly visible so that it is known how the cargo should be handled in case of accidents, and clearly marked as "in transit" to avoid illegal imports.

A third Member State informed that it had also sent a contribution.

The Commission summarised that the views expressed spoke in favour of re-considering the interpretation taken in the Questions and Answers Document (SANCO/12415/2013, Rev. 6 – under revision). Other services would need to be involved too, as the plant protection product legislation as well as the general classification and labelling rules and the rules pertaining to the transport of dangerous goods needed to be considered. A background document will be prepared for possible discussion of the matter by the Post Approval Issues Working Group of this Committee.

The Commission indicated that any contribution from Member States to the discussion would still be welcome.

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

The Commission reminded of the Special Report of the European Court of Auditors titled "Protection of wild pollinators – Commission initiatives have not born fruit". This report includes a recommendation that the Commission should prepare, together with Member States, a work plan for the development of test methods focusing on wild pollinators.

In order to establish such a work plan, the Commission intends to make an inventory first and invited Member Stes to comment by 2 May 2022 on the following 2 questions:

1. Which missing test guidelines regarding wild bees need to be developed?

2. Which test guidelines are currently under development either in Member States or by third parties?

11. Long-term toxicity effects of formulations

The Commission informed that the Commission as well as ECHA and EFSA have recently received several inquiries from the European Parliament in form of petitions or questions related to the assessment of the long-term effects of PPP. The Commission shared those inquiries and the answers provided to them by the Commission, and asked Member States to provide by 2 May 2022 answers to the following questions concerning the authorisation of plant protection products:

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

12. Residues on cut-flowers

The Commission recalled that in several meetings of this Committee during 2017 to 2020, the question of potential exposure of florists to pesticide residues on cut flowers had been discussed. This discussion had also been initiated at the Post Approval Issues Working Group of this Committee, where last year the Commission had made a survey about national legislation or provisions regarding commercial cut flowers. The survey had also requested additional information related to the import of cut flowers, the systemic control of residues in imported flowers, and if specific risk mitigation measures were implemented at national level to protect people from exposure, including all the possible population groups (operators, workers, consumers, residents and bystanders).

The Commission also informed that it received a request from PAN Europe for setting MRLs and to ban residues of non-approved substances in cut flowers imported from non-EU countries, and that new publications had been made available. Member States were requested to express their views by 2 May 2022.

13. SDHI active substances

The Commission informed about Petition 1548/2019 on the impact of the use of SDHI fungicides on human health and ecosystems. The petitioner was concerned that the current toxicological test methodologies are not adequate to detect effects of this group of pesticides. Additionally, concerns about the environmental risk assessment were mentioned.

The Commission reminded that this petition had already been discussed by this Committee during its meetings in July and October 2020. However, the petition was discussed again in the Petitions Committee of the European Parliament in March 2022. The latest intervention of the petitioner had been made available via CIRCA BC and sent to EFSA in March 2022.

The Petitions Committee concluded to leave this petition open until the EFSA Conclusions on the renewal of all SDHI active substances will be available. The Commission asked all Rapporteur Member States concerned to avoid any delays in the evaluation of the pending or forthcoming applications for renewal of approval of substances belonging to the SDHI group.

One Member State informed about two opinions from their national agency on this subject which are currently under evaluation, and which concern the reference value with regard to mitochondrial effects and cumulative risk assessment. Both opinions are expected to be available by the end of 2022.

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

The Commission presented the changes made in the draft Implementing Regulation on the basis of the comments received from the Member States after the last meeting of this Committee and made clarifications in response to questions. The draft foresees that the Implementing Regulation will become applicable from 1 January 2025.

Member States were invited to comment on the draft by 25 April 2022, in particular on:

– the need to add a recital to provide an explicit link to the definition of “professional user” in Directive 2009/128/EC;

- whether it is necessary to provide for derogation(s), for which group(s) such derogation(s) would be justified, and what should be the nature of the derogation(s);
- if a period between the time of use and time of recording is introduced, how can it be ensured that control activities that require access to the records are not compromised during this period. In particular, how Member States that already provide such periods address this issue;
- should any special circumstances be recorded, e.g. fraction of agricultural plot treated, buffer zones excluded, emergency use, etc.

A.15 Co-formulants, in particular:

1. draft procedures for listing additional unacceptable co-formulants

   The Commission informed that work is progressing on a draft Implementing Regulation setting out procedures and criteria for identifying unacceptable co-formulants.

2. unaccepable co-formulants (mono/polymers)

   The Commission recalled that a discussion about unacceptable coformulant concentrations took place in the Post Approval Issues Working Group, but that no agreement was reached. Member States were invited to comment by 2 May 2022.

   About the possible presence of mono- and polymers in a coformulant, the Commission recalled the Danish proposal and invited Member States to comment by 2 May 2022.

A.16 Report from Working Groups, in particular:

1. Working Group on Biopesticides

   The Commission informed on the main outcomes of the last meeting of the Biopesticides Working Group of this Committee, in particular as regards possible further initiatives supporting the implementation of the forthcoming Regulations concerning data requirements, approval criteria and assessment methods for micro-organisms which were endorsed by Member States on 8 February 2022.

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

   The Commission informed that case studies were presented and that the draft document “Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009: a method to identify scenarios of limited environmental impacts” is ready for consultation. The draft document provides a tool to support problem formulation in Environmental Risk Assessment (ERA), and is expected to speed up placing on the market of plant protection products with active substances and uses that are likely to have no or very limited effect on the environment (for instance, micro-organisms, pheromones, plant extracts as well as uses in contained environments such as storage rooms or localised application techniques such as target liquid applications). The consultation process will start with an informative session presenting the document to Member States and stakeholders on 24 May 2022. The experts will be invited to perform case studies and to comment on the document. The case studies and comments will then be further discussed and after that, the document will be presented to this Committee.

Regarding Risk Mitigation Measures (RMM), the Commission reported about (1) the last meeting organised by the Central Zone Working Group in which the discussion on what and how different RMM could be chosen to reduce drainage as case study continued (2) a meeting with CEMA (European Agricultural Machinery Association) and (3) the work initiated to update Regulation (EC) No 547/2011.

3. Working Group on Seed Treatments (Risk Assessment)

   The Commission informed that in the light of the comments received, it would schedule a meeting with EFSA to decide on necessary steps. Member States were invited to send more comments by 2 May 2022.

4. Working Group Post Approval Issues

   The Commission informed about the outcome of the discussions in the last meeting of the Post Approval Issues Working Group of this Committee held on 8 and 9 March 2022.

   The main points treated during the meeting concerned Guidance Documents in preparation and prioritisation for updating Guidance documents, how to better handle all the new active substance data submitted for the renewal of authorisations of PPP under Article 43, the consideration to be given to new relevant impurities from new sources of active substances, the harmonisation of the consideration of the possibility to use tests and study reports involving vertebrate animals for the purpose of the application of prospective applicants when no agreements are reached among applicants, the agricultural difficulties that some Member States are already facing due to the absence of commercial interest to market PPP in their territories and lack of sufficient alternatives.

   In the framework of the interzonal Steering Committee an agreement had been reached among the three zones on a document for the exposure assessment (OPEX) of PPP intended for amateur uses that currently is not integrated in the EFSA Guidance document. Member States will perform their assessments following this guideline as from 1 September 2022. In the next revision of the EFSA OPEX model, amateur uses will be integrated and this document will no longer be applicable.

5. Working Group on PPP Formulation Analysis

   The Commission informed that the next meeting is planned for September 2022 and will be organised by Belgium.

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

   EFSA informed about the planning for the next peer review expert meetings and the progress in the peer review process for active substances. EFSA also explained the new tool for the targeted Member State consultation, and the planning for responding to the mandate related to the potential impact of azole fungicides on the development of azole resistant *Aspergillus* spp.

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

   The Commission informed on the evaluation of the Sustainable Use of Pesticides Directive and the planned revision of the Directive and the related impact assessment. In line with the Farm to Fork Strategy, the adoption of the Commission’s legislative proposal was planned for Q1 2022 (March). However,

this adoption date has been slightly delayed and is now planned for before the summer.

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

   There were no news to discuss.

4. Minor Use Facility (MUCF)

   The final version of the Minor Uses Explanatory Note had been uploaded on CIRCA BC. It will be published on the Minor Uses Coordination Facility website as well as the Commission's website. Member States were invited to publish it on their respective national webpages, too and to encourage all stakeholders to use the Explanatory Note. The Explanatory Note is available only in English for the moment but Member States are encouraged to translate it into their national language in order to facilitate its use by local farmers and agricultural organisations.

5. OECD, FAO and EPPO activities

   Member States were informed that on 9 February 2022, a meeting of the EPPO Expert Working Group on Data Harmonization for Plant Protection Products took place.

   EPPO had developed an update of its website, summarising the classification for plant protection products (PPP) uses and providing useful insights, including a link to the relevant EPPO Standard for harmonised classification and coding of the uses of PPPs (1/248)

   https://www.eppo.int/ACTIVITIES/plant_protection_products/harmonized_classification_uses

   Member States were also informed that new codes for describing the use of PPPs, including treatment codes, had been agreed and that the implementation of such codes would need to be further considered in view of ensuring better harmonisation for the expression of the use of PPPs.

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

The Commission informed of two judgments of the General Court of 9 February 2022, dismissing the applications for annulment of the respective Commission Regulations non-renewing the approvals of the active substances ethoprophos (T-317/19, AMVAC Netherlands vs. European Commission) and thiram (T-740/18, Taminco and Arysta Life Science Great Britain vs European Commission). The Commission also informed about a new court case for preliminary ruling, requested by a German Court, regarding the interpretation of Regulation (EC) No 1107/2009 in the area of labelling of parallel trade products (C-830/21, Syngenta Agro GmbH).

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

The Commission informed that in the previous meeting of the residue section of this Committee, which took place in February 2022, the following measures were voted which may have an impact on authorisations of plant protection products.

Substance	Type of change
Fluoride ion	MRLs were lowered.
Oxyfluorfen	MRLs were lowered.
Pyroxsulam	MRLs were lowered.
Quinmerac	MRLs were lowered and the residue definition was amended
Sulfuryl fluoride	MRLs were lowered and the residue definition were maintained as tentative
Methoxyfenozide	MRLs were lowered
Propoxur	MRLs were lowered and the substance was added to Annex V
Spinosad	MRLs were lowered
Thiram	MRLs were lowered and the substance was added to Annex V
1,4-dimethylnaphthalene	MRLs were lowered and the residue definition was amended
8-hydroxyquinoline	MRLs were lowered
Pinoxaden	MRLs were lowered and the residue definition was amended
Valifenalate	MRLs were lowered and the residue definition was amended
Acequinocyl	MRLs were lowered
Chlorantraniliprole	MRLs were lowered
Emamectin	MRLs were lowered and the residue definition was amended
2,4-D	MRLs were lowered
Azoxystrobin	MRLs were lowered
Cyhalofop-butyl	MRLs were lowered
Cymoxanil	MRLs were lowered
Fenhexamid	MRLs were lowered
Flazasulfuron	MRLs were lowered
Florasulam	MRLs were lowered
Fluroxypyr	MRLs were lowered

Iprovalicarb	MRLs were lowered
Silthiofam	MRLs were lowered

A.20 Scientific publications and information submitted by stakeholders:

The Commission informed about a letter from CropLife Europe and one from Ecologistas en Acción, which had been made available to Member States on CircaBc.

A.21 Date of next meeting(s):

The Commission informed that the date of the next meeting - 17 and 18 of May - is confirmed.

A.22 AoB:

As regards the new active substance pydiflumetofen, the Commission informed that the Rapporteur Member State indicated that the evaluation of additional data submitted in April 2021 is almost complete and that the updated DAR is expected to be provided in March 2022. A comprehensive set of data had been provided to address open points regarding the environmental behaviour of pydiflumetofen in soil, its endocrine disrupting properties and the genotoxicity of two dietary metabolites. The Commission informed that it intended to prepare a mandate to EFSA as the updated DAR will be subject to the EFSA peer review process again.

As regards the new active substance dimethyl disulphide (DMDS), the Commission mentioned that it was informed that a first data set had been submitted to the Rapporteur Member State, which commented on the proposed studies that would be needed to complete the application.

The Commission reminded that Member States should upload information necessary for the UK in relation to the implementation of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 in Northern Ireland, such as notifications under Article 18(4) of Regulation (EC) No 396/2005 on the CIRCA BC folder established for this purpose in 2021 (see "Note for Member States on the Implementation of the Protocol on Ireland and Northern Ireland", ARES(2021)4027976), made available earlier on CIRCA BC (for the Standing Committee and the Working Group on Post Approval Issues). The document will be uploaded again on CIRCA BC for easier reference.

The Commission informed about the interplay of the Transparency Regulation and data protection, as well as the process regarding a post approval review of technical specifications (e.g. for the cases of copper and tolclophos-methyl).

As regards guidance documents, the Commission informed that a Scientific guidance on soil phototransformation products in groundwater was published by EFSA recently and that it is expected to be proposed for endorsement at one of the next meetings.

The Commission also informed that a prioritisation for updating and/or drafting of guidance documents is ongoing with involvement of Member States, EFSA and the Commission, which will be discussed in the next meetings of this Committee. One priority was already identified as urgent, i.e. the update of templates for the Member States draft assessment reports on micro-organisms in line with the new data requirements, which would need to be available by the end of 2022. One Member State had indicated preliminary interest to work on this and will confirm.

One Member State wondered if updates of the confirmatory information process could be given on a regular basis. The Commission informed that the Post Approval Issues Working Group of this Committee is keeping an updated table of all active substances subject to confirmatory information, keeping track of the status (i.e. if the evaluation is at Rapporteur Member State or EFSA peer review level, or if the evaluation is already available). The Commission informed that currently there are no pending files at Commission / Standing Committee level, as action is taken as soon as the evaluation of the peer review becomes available.

The Commission informed that in the framework of the study on invertebrate biological control agents (IBCAs) requested by the Council from the Commission, the contractor will contact Member States in April in order to explore which national authorities are in charge of regulating the use of IBCAs. Member States were invited to respond to this survey, in order to achieve a comprehensive overview of the regulatory situation of IBCAs in the EU. In order to facilitate the process, Member States were invited to nominate contact points by 6 April 2022.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... concerning the non-approval of 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 draft Regulation, which was amended in the light of the withdrawal of the application.

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

Outcome of the vote by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... concerning the non-approval of 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 draft regulation, which was amended in the light of the withdrawal of the application.

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

Outcome of the vote by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... renewing the approval of the active substance 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, it proposed a renewal of bifenazate with restriction to non-edible crops and to permanent greenhouses (as defined by Article 3.27 of the Regulation (EC) No 1107/2009), taking into account the non-finalised risk assessment for consumers and the high risk to birds. Given the risks and data gaps identified, the Commission considered that the nature of these risk overrule economic considerations in relation to outdoor uses or uses on edible crops.

The Commission indicated that it had received comments from five Member States, four letters from stakeholders supporting continued outdoor uses, two letters from a consultancy company on behalf of the applicant, which had all been made available on CIRCA BC, as well as the reply of the Commission to the first letter (the reply to the second letter was in preparation). The TBT process ended on 25 March 2022, Peru and the USA, also on behalf of a wine organisation, sent comments to which the Commission will respond in due time.

One Member State indicated that they would vote against the proposal, three Member States indicted that they intended to abstain and two Member States indicated that they did not have yet definite positions.

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

Outcome of the vote by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 (Draft Review Report SANTE/11486/2021).

SANTE/11484/2021

The Commission summarized the amendments of the draft Regulation intending to amend the approval conditions for the three paraffin oils. Four Member States had submitted written comments indicating concerns about the completeness of the risk assessment and the risk for bees by using these oily substances as fungicides during flowering season. The Commission pointed out that the intended amendment deals only with the efficacy and use of the substances as a fungicide against powdery mildew – in addition to the already approved use as an acaricide and insecticide- and that these concern had not been raised at the approval in 2009. The Commission invited to raise these concerns during the renewal process which is already on-going.

One Member State reiterated its concerns about the scope of the risk assessment as already expressed in the written comments. Another Member State informed that it intended to abstain due to the data gaps and the incompleteness of the risk assessment. A third Member State reminded that any issues of that nature can be still solved when

authorising the formulated product at national level while another Member State reminded that this is a procedural act only.

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

Outcome of the vote by written procedure: Favourable opinion.

France made the following protocol declaration during the written procedure:

Les autorités françaises souhaitent rappeler l'importance du respect des spécifications des substances actives, qui conditionne la sécurité de leur utilisation.

Elles renouvellent leur proposition de mise en place d'un centre européen de référence destiné à appuyer les services nationaux de contrôle.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Commission Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

SANTE/10020/2022

The Commission presented the draft Implementing Regulation which intended to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 by deleting those active substances from part A of the Annex to Regulation (EU) No 540/2011, the approval of which had expired.

The Commission inquired whether any Member State was 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 by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distilation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils / clove oil, plant oils / rape seed oil, plant oils / spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea.

SANTE/10146/2022

The Commission presented the draft Regulation extending the approval period of a number of active substances, which is required by Article 17 of Regulation (EC) No 1107/2009 as the evaluation procedures for the substances were all delayed for reasons

beyond the control of the applicants. Bifenazate had already been discussed in this meeting of the Committee, which had agreed to vote on the respective draft Regulation in written procedure. Therefore, the active substance was removed from this draft Regulation.

One Member State disagreed with the extension of the approval periods in batches and disagreed with the extension of approvals of active substances of concern, in particular substances that meet a cut-off criterion. Another Member State indicated it could not support an extension of the approval of dimethomorph, flurochloridone and tebuconazole. One Member States expressed its intention to vote in favour because the draft Regulation covered a package of substances, but found the extension of the approvals of dimethomorph, flurochloridone and tebuconazole controversial, especially due to the potential of resistances to azoles for the last one. A further Member State supported the need for administrative extensions, but emphasised the importance of putting each individual substance up for a vote on renewal or non-renewal as soon as possible after the Commission's review report is available, especially if the EFSA conclusion has identified an unacceptable risk.

The Commission reminded that for many active substances on the list delays are due to the fact that they are currently under assessment for their endocrine disrupting properties according to the scientific criteria that became applicable in November 2018.

The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011. This written procedure was stopped with no result on request of the Commission because it considered necessary to remove the active substance heptamaloxyloglucan from the draft regulation, after reflecting on the discussions which took place during this meeting of the Standing Committee under point A.05.h, which indicated that this substance may no longer be within the scope of Regulation (EC) No 1107/2009, due to the amendment of that Regulation by Regulation (EU) 2019/1009 that removed products fulfilling the definition of biostimulants from the scope of Regulation (EC) No 1107/2009.

A new written vote procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 was launched with no delay covering all other active substances which were in the draft Regulation.

Outcome of the vote by written procedure: Favourable opinion.

The Netherlands made the following protocol declaration:

The Netherlands does not agree with the extension of the approval period of tebuconazole because of the risks regarding fungal resistance.

Nevertheless, because we are faced with a package of substances, we vote in favor of the entire package.

B.07 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 period of the active substance bispyribac.

SANTE/10148/2022

The Commission presented the draft Regulation that retracts an earlier extension of the approval period of the active substance bispyribac. Commission Implementing Regulation (EU) 2018/1916 extended the original expiry date from 31 July 2021 to 31 July 2023, in order to ensure a balanced distribution of the available resources for

assessment and decision-making among Member States. However, no supplementary dossier was submitted by the legal deadline and it is, therefore, appropriate to retract the earlier extension and set the date of the expiry of the approval at 31 July 2022, which is the closest possible to the original expiry date.

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

Outcome of the vote by written procedure: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Commission Implementing Regulation (EU) .../... renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk substances, Straight Chain Lepidopteran Pheromones (aldehydes), and Straight Chain Lepidopteran Pheromones (alcohols), in accordance with Regulation (EC) (No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10828/2021).

SANTE/10826/2021

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

One Member State expressed its support for the upcoming renewal and referred to a note sent to the Commission about possibilities to simplify the approval procedure of semiochemicals in the future. The Commission thanked for this note.

Member States were invited to comment by 2 May 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