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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
3 - 4 December 2020

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SUMMARY REPORT

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

Section A Information and/or discussion

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meeting held on 28-29 September 2020 was published, while the one of the meeting held on 22-23 October 2020 was still under preparation.

A.02 New dossiers:

New active substances

The Committee took note of the admissibility declarations from the Rapporteur Member States for the following new active substance dossiers: a) Fluoxapiprolin, b) *Bacillus amiloliquefaciens* FZB42, and c) *Trichoderma harzianum* T78.

The Commission explained also that as from the next meeting this point will be for information only.

Basic substances applications received (for information)

d) Didecyldimethylammonium chloride (DDAC)

The Commission informed that the uses presented in the application are for general disinfection. Therefore, biocidal products containing DDAC can be used for this disinfection, an application for approval as regular active substance can be considered if the applicants insist and if the intended uses are actually within the scope of Regulation (EC) No 1107/2009.

Amendment of conditions of approval

e) Metalaxyl M

The Commission informed the Member States that the applicant had submitted an application to amend the conditions of approval of metalaxyl-M (in view of removing the restriction to sowing of treated seeds in greenhouses only). The rapporteur Member

State, Belgium, informed that it was already carrying out the assessment of the application.

Some Member States asked whether there would be a way to ensure continuity of the sowing of seeds in field, if the assessment indicated that the restriction could be removed. The Commission recalled that the restriction set in Regulation (EU) 2020/617 applied from 1 June 2021. Therefore, the procedure for amendment would not be completed in time, even assuming a smooth peer review process.

Article 21 Reviews

f) Ipconazole

The Commission informed Member States that the applicant had submitted comments and information in November 2020. The rapporteur Member State, Belgium, will evaluate the information and then the Commission will mandate EFSA for an opinion.

A.03 Renewal of approval and general issues:

The Commission explained that Member States and EFSA had requested clarification on the status and procedure for an amendment of the residue definition for risk assessment (RD-RA), and that therefore reflections are initiated in both sections of the Committee, i.e. Legislation (this meeting) and Pesticides Residues (November 2020). The reflections also consider the potential implications of an amendment of the RD-RA for applicants, authorisation holders, and Member States.

The Commission recalled that the endpoints for active substances are derived by risk assessors and formally adopted by risk managers. The legal acts approving (or renewing) or not approving (or not renewing) active substances refer to the Review Report/Renewal Report, which in turn lists explicitly the toxicological reference values and refers to the EFSA Conclusion for other endpoints.

Given the requests for clarification, the Commission proposed to always include the RD-RA explicitly in the Review Report, as is done for toxicological reference values. Review Reports are publicly available in the EU Pesticides database. To avoid confusion, the Commission proposed to have always the section Legislation of this Committee to endorse a revised Review Report, and not the section Pesticides Residues.

Member States were invited to comment by 08 January 2021, in one coordinated reply per Member State, covering both sections of the Committee.

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

New active substances

1. *Beauveria bassiana* 203

The Commission informed that EFSA had identified several data gaps preventing to finalise the consumers and operators risk assessment due to the presence of a potentially genotoxic metabolite of concern reported in the specification at higher concentration than an approved similar strain used under similar conditions of use. Member States were invited to send positions and comments by 13 January 2021.

Renewal of approval

2. *Bacillus thuringiensis* subsp. *aizawai strain ABTS-1857*

The Commission summarised the EFSA Conclusion and some of the comments received by the applicant. The peer review did not identify any critical area of concern, however a number of issues could not be finalised. For instance, the peer review identified some uncertainties as regards risks for non-target soil micro-organisms, and for dietary exposure due to possible production of toxins by spores germinating in the human intestine, triggering the EFSA suggestion on the non-inclusion of the strain in Annex IV of Regulation (EC) No 396/2005. The Rapporteur Member State and co-Rapporteur Member State disagreed with these conclusions.

Member States were invited to send positions and comments by 13 January 2021.

3. *Bacillus thuringiensis* subsp. *aizawai strain GC-91*

The Commission summarised the EFSA Conclusion and some of the comments received by the applicant. The peer review did not identify any critical area of concern, however a number of issues could not be finalised. For instance, the peer review identified uncertainties as regards risks for certain non-target organisms (e.g. bees, non-target arthropods), and for dietary exposure due to possible production of toxins by spores germinating in the human intestine, triggering the EFSA suggestion on the non-inclusion of the strain in Annex IV of Regulation (EC) No 396/2005. The Rapporteur Member State disagreed with these conclusions.

Member States were invited to send positions and comments by 13 January 2021.

4. Phosmet

The Commission informed that EFSA identified several critical areas of concern for all representative uses as well as several issues that could not be finalised. The Conclusion has not been published yet due to the on-going sanitisation procedure. The Commission shared the correspondence with the applicant. Some Member States informed the Committee that they had already been contacted by a third country who asked for their views on the substance.

Member States were invited to send positions and comments by 6 January 2021.

5. *Pseudomonas chlororaphis* MA342

The Commission summarised the issues that led, after the meeting of this Committee in July 2019 to a mandate to EFSA requesting to provide scientific advice on the translocation potential of *Pseudomonas chlororaphis* MA342 in plants after seed treatment of cereals and peas and, if applicable, a revision of the assessment of the risk to humans by its metabolite DDR.

The Commission summarised the EFSA statement published in October 2020. The concerns identified in the EFSA Conclusion of 2017 were still considered valid. The Commission informed Member States on the comments submitted by the applicant in a reaction to the statement of EFSA. The applicant is of the opinion that the dossier provides enough information to conclude on a safe uses of *P. chlororaphis* MA342 and, consequently, allowing renewal of approval.

The Member States were invited to send comments and positions as regards the renewal of approval of *Pseudomonas chlororaphis* Ma342 in the light of the EFSA statement and input from the applicant by 13 January 2021.

6. *Pythium oligandrum* strain M1

The Commission informed that EFSA identified several data gaps concerning a metabolite of potential concern and lack of evidence about clearance of the micro-organism in mammals, as well as potential persistence in soil and water. Member States were invited to send positions and comments by 13 January 2021.

Basic substances

7. Chitosan hydrochloride (extension of use and origin)

The Commission summarised the comments received from two Member States and EFSA. They seemed to agree that the chitosan of fungal origin should be considered as an extension of use of the already approved substance. One Member State considered the addition of vinegar to adjust pH in order to solubilise chitosan as being within the scope of "a simple diluent" in the context of Art 23 of Regulation (EC) No 1107/2009. One Member State indicated that it would be appropriate to re-evaluate the current approval of chitosan because the current risk envelope is not well supported by data or the risk assessment. Member States were invited to send comments by 13 January 2021.

8. Calcium hydroxide (extension of use)

The Commission summarised the comments received from two Member States since the meeting of this Committee in October. The Member States do not support the proposed extension of use. One Member State suggested to start a review of the original approval in accordance with Art 23(6) of Regulation (EC) No 1107/2009. Member States were invited to send by 13 January 2021 their comments and positions on approval based on the EFSA Technical Report, comments of other Member States, and the basis for original approval.

9. ***Pro memoria*** **– Postponed for next PAFF meeting (January 2021)**: Sodium hypochlorite, Dimethyl sulphide

Amendment of conditions of approval

No news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

New active substances

a. Dimethyl disulphide

The Commission proposed to discuss this point together with the two subsequent points as the substances concerned are all soil fumigants and share similar concerns due to their properties (e.g. volatility) that would require specific testing protocols and ad hoc approach to perform sound risk assessment. The Commission noted that the EFSA Conclusion had identified numerous data gaps that would require additional studies and the need for confirmation of the actual risk reduction provided by the mitigation measures proposed by the three applicants. Member States were invited to send comments by 13 January 2021, taking into account previous presentations on these active substances, more recent information submitted by the rapporteur Member States, applicants, non-governmental organisations and producers' federations.

For DMDS in particular, the Commission noted that only few comments had been received from the Member States since the meeting of this Committee in October, most of them supporting non-approval due to the areas of concern and data gaps identified by EFSA. However, consideration should be given to the fact that DMDS could

represent a priori a less hazardous substitute to chloropicrin and 1,3-dichloropropene. The Commission invited the Member States who had so far not reacted, in particular from the Southern Zone, to share their views by the 13 of January 2021.

b. Chloropicrin

Discussed together with the previous point.

c. 1,3-dichloropropene

Discussed together with the two previous points.

Renewal of approval

d. Bifenazate

The Commission reiterated the reasons for its proposal for non-renewal of approval: two critical area of concern (high risk to birds and mammals and to non-target arthropods (NTA) for all the representative uses and the non-finalised risk assessment for consumers and aquatic organisms. So far, 18 Member States had reacted: 5 Member States indicated their potential support of non-renewal, while 13 Member States would support renewal. The Commission shared the comment from one Member State sent since the last meeting of this Committee and from the applicant received in October 2020.

The Commission informed Member States that it had sent a mandate to EFSA to clarify these aspects with a deadline of 30 June 2021. Therefore, the discussion on the substance is expected to be resumed in this Committee in July 2021. Member States were invited to send any additional comments by 13 January 2021.

e. Cyazofamid

The Commission informed that EFSA in its updated Conclusion on 28 July 2020 identified no critical area of concerns, but three issues that could not be finalised. Based on the available data, it can be expected that cyazofamid can be used safely under certain conditions (e.g. in potatoes) in the EU. Therefore the Commission considers that renewal of approval of the substance is possible. Comments received from the Member States and a revised version of the draft Review Report as well as five supportive letters from stakeholders had been shared. Member States were invited to send comments by 6 January 2020.

f. Clodinafop

The Commission informed that it had mandated EFSA to carry out an assessment of the endocrine disrupting properties according to the new scientific criteria, which entered into force in November 2018. Decision-making will be completed once the assessment will be finalised.

g. *Streptomyces* K61

The Commission informed that in the EFSA Conclusion one critical area of concern and six issues that could not be finalised were identified and focused on two core issues:

The high mortality found in the acute intra-tracheal studies with rats and intraperitoneal studies with mice that did not allow to conclude on the infectivity and pathogenicity, and the nature of a non-fully characterised secondary metabolite during manufacturing thus leading to an unfinished consumer and non-target organisms risk assessment. The Commission explained that, considering the evidence from all available studies and literature, background exposure, and the nearly 25 years of use of the micro-organism

in plant protection products with no reported adverse effects nor clinically significant findings or symptoms associated during manufacturing and application, an approval of renewal as a low risk substance could be proposed. Comments had already been received from three Member States.

One Member State voiced concerns about the low risk status due to new evidence concerning anti-microbial resistance. Member States were invited to provide their comments by 13 January 2021.

h. *Metarhizium brunneum* strains BIPESCO 5/F 52

The Commission presented the key elements of the EFSA conclusions which did not identify any critical area of concern and listed 3 issues which could not be finalised: the production of toxins/secondary metabolites cannot be excluded, in particular related to swainsonine which is considered to be toxicologically relevant as it is identified as causal agent of food poisoning in livestock, and the risk assessment to honeybees and soil micro-organisms. *Metarhizium brunneum* BIPESCO5/F52 is sensitive to several antimicrobials although is not inhibited by Amphotericin B and anidulafungin.

Member States were invited to provide their comments by 13 January 2021.

i. Captan

The Commission presented briefly the key elements of the EFSA Conclusion and informed that a new version of the Conclusion had recently been published to rectify a few inconsistencies in the proposed risk mitigation measures and, in particular, the risk to fish from the use of strawberries in permanent greenhouses. The Member States were invited to comment by 6 January 2020.

j. Abamectin

The Commission presented the key elements of the EFSA Conclusion, which identified ecotoxicological concerns for all the intended uses. For this reason, the Commission proposed a renewal of approval restricted to permanent greenhouses (according to the definition in Art 3(27)).

Furthermore, the Commission reported on the feedback received from Member States in relation to the acute reference dose (ARfD) proposed by EFSA in the Conclusion. The majority of Member States confirmed that the toxicological values that were agreed by the experts during the peer review meeting should be considered valid. The ARfD of 0.0012 mg/kg bw and the acceptable daily intake (ADI) of 0.0012 mg/kg bw/day should therefore be considered in the framework of the forthcoming renewal/non-renewal decision and as well in the mandate to EFSA to review the existing MRLs. The Committee endorsed this approach.

k. *Purpureocillium lilacinum* strain 251

The discussion was postponed.

l. ***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Clopyralid, Famoxadone, *Bacillus thuringiensis* subsp. kurstaki strain SA-11, *Bacillus thuringiensis* subsp. kurstaki strain SA-12, Flumioxazin

Basic substances

m. Vinegar (extension of use) (amended review report to be noted)

The Commission explained that recently EFSA confirmed that, assuming a worst-case scenario of applying pure acetic acid, and based on the recommendations of ECHA

(HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, 2011) as well as approaches taken for negligible exposure assessment, it can be considered that the concentration of acetic acid in the air after application at the newly proposed lowered application rate of 6-12 kg vinegar/ha will be well below 1 mg/m³ (the AOEC set for acetic acid).

The Commission intended to present a finalised Review Report for the approval of the newly proposed uses in non-agricultural areas at the next meeting of this Committee for note-taking. Member States were invited to comment by 6 January 2021.

n. Whey (extension of use)

The Commission presented the draft Review Report. The application concerns an extension of the use as a fungicide and virucide to be used as foliar spray in grapevines and vegetable gardening tomato. The Commission proposes to accept all the proposed uses in the extension. The potential issues regarding allergenicity, should still be considered sufficiently addressed by the conditions of use, which mention that the whey solution can only be applied in the growth stage before flowering, that the leaves of plants treated with the whey solution should not be used for human consumption, which limits the use of grapevine leaves. Also included in the conditions of use is that plants treated with the whey solution, which have not been subject to processing standards required by the animal by-products Regulation ((EU) No 142/2011), should not be fed to cloven-hoofed animals. In this way, all the comments and requests made by Member States should be fulfilled. Member States were invited to comment by 6 January 2021.

o. *Equisetum arvense* (extension of use)

The Commission explained that some Member States had requested more clarity in the Review Report as regards the rationale behind the first approval even though there had been many uncertainties identified by EFSA in its past technical report as well as in the current report. Member States indicated that the reasoning should be better explained.

The Commission therefore proposed to request from the applicant information on the purity of the extract and exposure to it in the EU. This should be possible as it is available in food supplements and teas for many years now. The Commission will also check with EFSA whether they took into account a final assessment report from the European Medicines Agency from 2016 on *Equisetum arvense* since this report was not mentioned in the references of the dossier. Member States were invited to comment by 6 January 2021.

p. Comfrey steeping

The Commission gave an update on the positions of the Member States. Since the last meeting of this Committee, two Member States had provided comments indicating support for the non-approval of the fermented extract from leaves of Comfrey as a basic substance. Member States were invited to send any additional comments by 6 January 2021.

q. Willow bark and stem extract

The Commission summarised comments received from four Member States and EFSA since the last meeting of this Committee. There is a divergence of views among the Member States as regards an approval and as regards the definition of the identity of the substance. The composition and specification of the substance is not clear. Willow stems and their extract contain some components of concern, which are not fully characterised as regards their concentration and toxicological properties. It seems that

it is not possible to conclude that the constituents of the extract which might raise concern will be present at the concentrations below the level leading to a classification for hazard properties under the CLP Regulation. Member States were invited to send comments by 6 January 2021.

r. Chitosan hydrochloride (extension of use)

The Commission summarised comments received from three Member States indicating that the proposed use (in ornamental flower bulbs and beet crops) is within the already approved risk envelope. Thus, there is no need to conduct an additional full risk assessment. The Commission presented a draft amendment of the Review Report to include the extension. Member States were invited to provide comments by 6 January 2021.

s. ***Pro memoria*** **– Postponed for next PAFF meeting (January 2021)**: Clayed charcoal

Amendment of conditions of approval

No news to discuss.

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs)

The Commission updated the Committee on the reactions received from Member States following the discussion in the meeting of this Committee in October. Member States had agreed that the Review Reports for all triazole substances should be amended to include the agreed endpoints endorsed by this Committee in December 2019. The Commission informed that it would move ahead to update these Review Reports in the next meetings.

One Member State also commented that the classification of 1,2,4-triazole as toxic for reproduction, category 1B, should also be mentioned. The Commission explained that this classification applies anyway.

Commenting Member States also agreed that the new data generated on the TDMs by the Task Force to address data gaps, should be evaluated at EU level to ensure harmonisation and avoid duplication of work and divergent opinions.

The Commission confirmed that so far no Member State(s) had volunteered to carry out the assessment, however, an alternative approach was also under consideration i.e. that the Rapporteur Member State for an upcoming renewal could carry out the assessment of the studies since the majority would be required for the substance evaluation anyway. Thereafter, the peer-review process could confirm if the data leads to any changes to endpoints. This option would also avoid duplication of work. The Commission informed that it was reflecting on this possibility but asked again that any Member State that has capacity to carry out a standalone review of the new data should inform the Commission by 13 January 2021.

2. Pyrethrins (amended report to take note)

The note taking was postponed as two Member States asked for further clarifications as regards the already on-going renewal procedure and the possibility for the Rapporteur Member State to inform the Commission without delay if it considered that the consumer risk assessment raises concerns.

3. Benzovindiflupyr (amended report to take note)

The Committee took note of the amended Review Report maintaining the conditions of approval, in view that a renewal procedure is already on-going and any remaining uncertainties would be addressed there.

Denmark made the following protocol declaration:

Denmark would prefer to amend the review report and the approval Regulation including a new relevant impurity, otherwise the substance will remain approved for another three years under the existing conditions posing a potential risk.

4. Isofetamid (amended report to take note)

The Committee took note of the amended Review Report which had been slightly modified to incorporate comments received from four Member States. The applicant had also been consulted on this version of the Review Report. Although the purity level remains the same as for the initial approval, the specifications were changed from the pilot scale batches to the specifications of the commercial batches, because the list of relevant impurities had not available at the time of the initial approval and a new impurity was now identified.

5. Gamma-cyhalothrin

The Commission informed that it intends to mandate EFSA to address two non-finalised confirmatory information issues: one mandate related to two metabolites that are common for several pyrethriods (horizontal mandate) and another mandate to confirm the safe use of the substance with regard to wild mammals under certain circumstances.

The Commission shared the comments and information received from Member States on the existing national authorisations.

Member States were invited to send any additional comments by 13 January 2021.

6. Tri-allate

The Commission recalled the key issues identified in the recent EFSA Conclusion following assessment of confirmatory information in particular regarding the assessment of genotoxicity, consumer risk and groundwater contamination. It emphasised that on the one hand modelling indicated that metabolites of tri-allate may occur above 10 ug/L in all pertinent scenarios, whereas on the other hand, the renewal process is ongoing and the applicant has stated that monitoring data is available to show that the metabolites are not expected to reach groundwater at high concentrations.

The Commission thanked the rapporteur Member State for renewal (the Netherlands) for providing an update on the ongoing renewal assessment and on whether the concerns identifed have been addressed by the applicant in its renewal dossier. The rapporteur Member State indicated that new information was available and that the assessment was ongoing.

The Commission informed that it would further reflect on the way forward. Member States were invited to submit comments on the way forward by 13 January 2021.

7. Sulfoxaflor

The Commission presented the draft amendment of the Review Report with the proposal to restrict the uses of sulfoxaflor to greenhouses. 15 Member States had provided feedback on this proposal in writing before the meeting of this Committee.

Out of those who responded, only one Member State indicated support for such a restriction and suggested an additional prohibition to tranfer plants outdoors after treatment in greenhouses.

The Rapporteur Member State (Ireland) sent a position paper explaining why outdoor uses are considered possible at Member State level. This position paper was supported by eight Member States.

One Member State was hesitant to draw a final “high risk” conclusion based on a screening assessment which contains a high degree of uncertainty and indicated furthermore that the decision on sulfoxaflor should not necessarily depend on the decision for cypermethrin as there are many more uncertainties in the sulfoxaflor file.

One Member State, although not having a final position yet, did not consider a restriction to indoor uses necessary at this time and asked the Commission to carefully consider the risk mitigation measures that are already part of current authorisations in Member States for sulfloxaflor.

The Commission asked the 12 Member States who had not sent comments since the last meeting of this Committee for their positions. Two of them confirmed their earlier positions to support or indicatively support the proposal of the Commission. Three other Member States indicated supporting the Commission, one Member State indicatively supported the RMS, and the remaining six Member States did not have a position yet and were asked to send their position in writing to the Commission by 6 January 2021.

One Member State indicated not being able to support the proposal if no prohibition to plant crops outdoors after treatment is included. The Rapporteur Member State confirmed that sulfoxaflor is not persistent enough to have effects on pollinators, and indicated having granted recently an authorisation for use on winter cereals in autumn when pollinators are not active in that Member State. This Member Stated reiterated that subsidiarity has to be respected.

Member States were invited to comment on the draft Review Report by 6 January 2021.

8. Dithianon

The Commission summarised the comments received from Member States since the last meeting of this Committee as regards the possibility to withdraw the approval, since the same concerns and open points remain after evaluation of additional information. In their comments, eight Member States supported the Rapporteur Member State, reiterating the possibility to find safe use scenarios by applying the TTC approach. Three other Member States would support to maintain the approval for restricted uses. Three Member States considered the TTC approach as not suitable when a genotoxic potential cannot be excluded for all metabolites and therefore would support to withdraw the approval. The Commission indicated that it will reflect on the next step based on the feedback from Member States.

9. Amilsubron

The Commission informed that the applicant had submitted the confirmatory data within the deadline, indicating also that fish studies are on-going and will be finalised by summer 2021. The Commission also reiterated that the renewal dossier is expected by September 2021.

10. Tebufenozide

The Commission recalled that in the previous meeting of this Committee the Member States had been invited to comment on the possible decision pathways concerning the metabolite RH-2651 which is predicted to occur in groundwater above 0.1 µg/L in all FOCUS scenarios for the representative uses. Considering that a genotoxic potential of this metabolite could not be excluded during the assessment of the confirmatory information and taking into account that in 2018, the applicant, after EFSA finalised its Technical Report, provided a new study aiming at demonstrating the non-relevance of the aforementioned metabolite. The majority of the Member States who commented, opted to start an Article 21 procedure followed by a mandate to EFSA to review the new information available. The Commission then indicated it intends to proceed like this, consequently further comments were not requested to the Member States at this stage.

11. Bentazone

The Commission informed about the ad-hoc approach taken by the Rapporteur Member State (The Netherlands) setting a stop the clock for the confirmatory information process. The applicant had to submit by 1 February 2019 confirmatory information as regards Level 2/3 tests as indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of bentazone. The Rapporteur Member State had preformed a preliminary assessment and considered that, since the new scientific criteria for the assessment of endocrine disrupting properties should be applied and to ensure a conclusive assessment according to these new criteria, additional information should be requested from the applicant. Therefore, the Rapporteur Member State set a deadline in accordance with the timelines for renewal procedures which had started before the new criteria were applicable (max. 30 months). Consequently it had set a deadling for additional information to be submitted by 31 January 2022.

12. Penflufen

The Commission recalled that in the last meeting of this Committee two notifications referring to the withdrawal of two authorisations of penflufen-based products had been noted. It also recalled that the Regulation amending the conditions of approval of the active substance penflufen had requied the applicant to submit information as regards the relevance of the metabolite M01 (penflufen-3- hydroxy-butyl) for groundwater if penflufen was classified as “carcinogen category 2”. In 2018, the Risk Assessment Committee (RAC) of the European Chemicals Agenchy (ECHA) had adopted an opinion that penflufen is to be classified as carcinogenic category 2, which gave rise to the referred obligation.

By letter dated 18 March 2019, the applicant had announced that it would not submit information related to the metabolite M01 as regards potatoes. However, it recalled that the use in cereals has been approved at EU level and passes 5 out of 9 groundwater scenarios.

The Commission considered that, since confirmatory information had not been submitted, according to Article 21(3) of Regulation (EC) No 1107/2009, a Regulation to withdraw or amend the approval shall be adopted. Member States were invited to comment on these possibilities by 13 January 2021.

13. Alpha-cypermethrin

The Commission explained that the applicant had informed the Commission, the rapporteur Member State and EFSA on 14 October 2020, that it would not submit any confirmatory data as required when the renewal of approval of the substance had been adopted in 2019. In accordance with Article 21(3) of Regulation (EC) No 1107/2009 the approval for alpha-cypermethrin has to be withdrawn, and the Commission intended to prepare a draft Regulation to this effect.

Member States were invited to send any comments by 13 January 2021.

14. Mesotrione

The Commission indicated that, in line with the technical report of EFSA, it will mandate EFSA to further discuss the endocrine disrupting properties of the active substance in an experts' peer review consultation. EFSA will be requested to indicate which additional tests would be needed to conclude the assessment, if applicable. The mandate will also cover the toxicological profile of the metabolit AMBA, which is considered relevant to consumer exposure, even if the technical report concluded that the metabolite AMBA is unlikely to be genotoxic.

15. Thiabendazole

The Commission indicated that, as suggested in the technical report of EFSA, it will mandate EFSA to further discuss the endocrine disrupting properties of the active substance in an experts' peer review consultation. EFSA will be requested to indicate which additional tests would be needed to conclude the ED assessment, if applicable.

16. ***Pro memoria*** **– Postponed for next PAFF meeting (January 2021)**: Geraniol, Eugenol, Thymol, Clove oil, Orange oil

A.07 Guidance Documents:

1. Draft update of Guidance on emergency authorisations according to Article 53 (to take note)

   The Commission explained the changes made to the draft following comments submitted by Member States during the last meeting of this Committee and in writing thereafter. Overall, Member States were content with the draft, however, some final points were raised. The Commission therefore agreed to postpone the note-taking until the meeting of this Committee in January 2021 and to update the draft to incorporate the final comments and points raised.

2. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers (to take note)

   The Committee took note of the Guidance with an implementation date of 1 August 2021.

3. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11) (to take note)

   The Commission informed about the comments received via a Reporting Table and an updated version of the guidance document presented for note taking. However, several Member States expressed concerns about various aspects in the text and made suggestions for further changes. Major comments expressed in writing and during this meeting related to Articles 34 and 40 of Regulation (EC) No 1107/2009 and the applicability of the first paragraph of Article 36(1) to this type of

applications. The Commission indicated the need to seek for efficiency and coherence in the applicability of the same assessment principles as applied in other regulatory contexts, such as for the authorisation and supervision of medicinal products for human and veterinary use. Therefore, note taking was postponed and Member States were invited to provide further comments by 6 January 2021 in view of finalising the document.

4. Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (SANCO/10363/2012) (to take note)

   The Commission gave an update on the issues related to the drafting of the revision of the guidance for basic substances and informed that the draft revised document would be soon circulated to Member States. It is necessary to align the procedures and wording between the guidance on basic substances and the Practical Arrangements of EFSA which are not yet finalised. Member States were asked to send comments as soon as possible after the draft would be made available, in view of taking note of the guidance document in the next meeting of this Committee in January 2021.

5. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching)

   The Commission recalled that both Member States and applicants expressed interest to endorse this draft guidance document without delay and that only few technical comments had been received in the last commenting round in this Committee.

   The Commission informed that, after having consulted with EFSA and the Member State who had taken over the finalisation of the drafting, the most appropriate solution was to endorse this guidance document as a Commission document, adding a cover note which would include the comments received as well as the date of application. The Commission proposed 1 April 2021 as application date.

   The Commission presented the cover note and invited Member States to comment by 6 January 2021, with the intention to take note of the document at the next meeting of this Committee in January 2021.

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

   The Commission recalled that at the last meeting of this Committee, Member States had been invited to send proposals on the setting of a specific protection goal for bumble bees and/or solitary bees. The feedback received from three Member States was discussed and made available to all Member States.

   The Commission informed the Committee of its intention to organise a next meeting on the procedure to set specific protection goals for honey bees in January 2021. A risk assessor and risk manager per Member State will be invited as well as the members of the dedicated EFSA stakeholder group for the review of the Bee Guidance Document. The meeting will be organised as an information session during which EFSA will explain in detail the principles of the approach taken, the simulations done and their results, followed by a question and answer session. EFSA is currently finalising a supporting document for this meeting which is expected to be made available together with the invitation before the end of December.

One Member State inquired if it would be possible to discuss the option to move the risk assessment for solitary bees to the Guidance document for non-target arthropods. The Commission confirmed that all options can be put forward for discussion.

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

   No news to discuss.

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

The Commission informed that one meeting of the Working Group had been held since the last meeting of this Committee. Discussion is on-going on the working document on pesticide application scenarios and the terms of reference of the Working Group. As soon as those documents are agreed, they will be shared with this Committee. In addition, the Commission plans a meeting with stakeholders on 5 February 2021 to update on the state of play. The comment received from one stakeholder was shared with the Committee.

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

No news to discuss.

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

- Article 44(4) (to take note)

No notifications received. The Commission explained that from the next meeting this point will be for information only. This was supported by two Member States.

- Article 36(3) (to take note)

The Committee took note of one notification received, originated in the zonal assessment of the renewal of the authorisation of an acetamiprid-based product and following the adoption of the RAC opinion on the classification of acetamiprid as reprotoxic, category 2, which has direct implications on the classification of the plant protection product. Ready-to-use products that can be used by and sold to non-professional users are only allowed under the national law of the Member State who notified, if they do not include certain human health hazard statements in their labels.

The Commission explained that from the next meeting this point will be for information only. This was supported by two Member States.

- Article 53

The Commission reiterated that all received notifications are made publicly available and that at regular intervals (approximately yearly), a detailed analysis will be provided as regards all the notifications received.

The Commission invited Member States to add information or raise any observation or question on the published emergency authorisations. No Member State had any comment.

A.11 News from European Food Safety Authority (EFSA), in particular:

1. Update on EFSA practical arrangements on PPP confidentiality in accordance with 7(3) and 16 of Regulation (EC) No 1107/2009.

   EFSA informed about the consultation with the Member States on its draft Practical Arrangements (PAs) concerning confidentiality in accordance with the empowerment set out in Articles 7 and 16 of Regulation (EC) No 1107/2009. Furthermore, EFSA provided a brief overview of the comments received from the Member States, and of its positions taken with regard to the input received. During the written consultation, EFSA had received 28 comments from four Member States, stemming from general considerations on the process and structure of the draft PAs to more specific ones on individual provisions of the document. EFSA shared its written replies to the comments from the Member States.

   In addition, EFSA provided an overview of the draft PAs on the pre-submission phase and public consultations, focusing on how the new proposed provisions laid down in such PAs will apply in the field of pesticides under Regulation (EC) No 1107/2009.

2. Update on development on IUCLID as IT tool for notification and on the Hypercare programme for first dossier submissions

   EFSA gave an update of the Hypercare programme for the first dossier submissions in IUCLID. There will be a targeted support to Member States and applicants for early submitters of applications for the renewal of active substances and for a few MRL applications. Around 15 substances with legal deadline for submission in July-August 2021 will be included. The programme will be used to refine EFSA help desk support, IUCLID training materials, IUCLID implementation (link to IUCLID release schedule). Member States were asked to nominate their representatives to be part of the Pesticide Steering Network sub-group IUCLID hypercare. Furthermore, EFSA is preparing training material (including demos recorded, technical documentation, factsheets, online videos etc.).

   EFSA also gave an overview of the progress in the peer-review process for some active substances and informed about the active substances to be discussed in the experts' meetings in 2021.

   In addition, EFSA provided an update on the Administrative Guidance Document revision that has been undertaken as part of the need to revise all of EFSA's existing sectorial guidance to include the new requirements arising from the Transparency Regulation. EFSA's Administrative Guidance Document is updated in line with the Practical Arrangements (from practical point of view but not aiming to repeat what is already in Practical Arrangements). The update is centralised via a dedicated EFSA-SANTE core group on the implementation of the Transparency Regulation to ensure harmonisation across all food sector areas; the focus of the update of Administrative Guidance Document is to inform applicants and Member States about the new provisions coming from the Transparency Regulation, in line with the Practical Arrangements (which are still considered high level documents).

   The updated Administrative Guidance Document is foreseen to apply for applications submitted to competent authorities as of 27 March 2021 as well as assessment reports evaluating those applications, with the exception of substances subject to renewal procedure falling under the previous measures as laid down in Commission Implementing Regulation (EU) 2020/1740).

EFSA informed Member States on the content of the Administrative Guidance Document:

- chapter 2 on guidance on the peer review procedure required full revision to reflect changes required by the Transparency Regulation (from the pre-submission phase to the adoption of final EFSA output) as well the new Implementing Regulation on renewals (Regulation 2020/1740);
- chapter 3 on practical guidance for preparing dossiers and/or assessment reports on how data should be submitted required partial revision aiming to improve the quality of dossiers and reports;
- new chapter 4 introduced to specifically address the provisions set out by the Transparency Regulation for MRL applications;
- The majority of appendices from the previous Administrative Guidance Document have been removed and will be made available via the IUCLID user manual, to allow more flexibility and their possible future integration with IUCLID;

EFSA indicated that following the consultation with the Pesticide Steering Network, the next step is for this Committee to take note of the Guidance either in January (Section Legislation) or February (Section Residues) 2021.

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

No news to discuss.

A.13 New Transparency rules: General Food Law amendment and implementation.

No further news discussed in addition to A.11 and C.01.

A.14 Microorganism Active Substances – update data requirements:

The Commission recalled that the Biopesticides Working Group of this Committee is working on amendments of four Regulations concerning micro-organisms: data requirements active substances and plant protection products, uniform principles and decision-making criteria.

The Commission presented the drafts for the updated data requirements amending Commission Regulations (EU) No 283/2013 and 284/2013, and in particular the scientific rationale behind the new drafts, which reinforces the importance of the biological properties of the micro-organisms in the risk assessment. The Commission highlighted that consistent with the Farm to Fork objective of promoting access to market of biological active substances, the data requirements are organised in a tiered (step-wise) approach, higher tiers being triggered only when certain contidions apply. This is expected to faciliate a "weight of evidence approach" based on already existing knowledge (e.g. use of peer-review literature) and to reduce unnecessary burden for the applicants and risk assessors.

The Commission announced that the amendment for the Regulations on uniform principles and decision-making criteria for micro-organisms as active substance and plant protection products containing them will be presented in the next meeting of this Committee in January 2021. It is expected that discussion on all the four Regulations will proceed throughout the year 2021, before being proposed for vote at this Committee towards the end of 2021.

A.15 Clarifications & questions related to specific active substance:

1. Potential resistance to azoles with demethylase inhibitor as mode of action

The Commission informed that the European Crop Protection Association (ECPA) had submitted some additional information on the work it has/is carrying out to better understand the development of resistance to azoles.

The Commission explained that it is reflecting on how to proceed to increase the knowledge in the area, in particular with respect to risk assessment.

2. Residues in ornamental cut flowers

The Commission informed that following the invitation at the last meeting of this Committee, one Member State had submitted additional information, i.e. a peer reviewed study in their territory.

The Commission thanked for the information received and suggested to continue the exchange of views in the Post Approval Issues Working Group of this Committee, for reporting later at a forthcoming meeting of this Committee.

3. Flupyradifurone

The Commission informed of further comments received from four Member States on the Article 56 notification from the Netherlands about potential negative effects of the active substance flupyradifurone on the wild bee species *Osmia bicornis, Osmia cornuta* and *Megachile rotundata*. Two Member States support the Dutch proposal of which one Member State presented the reasons why wild bees should be assessed as non-target arthropods. Two Member States indicated supporting a review of the approval of flupyradifurone under Article 21 of Regulation (EU) No 1107/2009. Also an environmental NGO had asked in writing to invoke Article 21 of Regulation (EU) No 1107/2009. This letter was made available to the Member States.

The Commission referred to the Article 69 notification by France discussed under agenda point M.06. The Commission explained that the mandate to EFSA as a follow-up to the Article 69 notification will also cover all data provided by the Netherlands in the notification under Article 56.

Member States were invited to provide further comments by 13 January 2021.

A.16 General issues for information / discussion:

1. Brexit preparedness

No news to discuss. The Commission informed that dedicated meetings of the Standing Committee for all sections are being organised in December 2020.

2. Illegal plant protection product use

This point was postponed.

3. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate

The Commission informed about the latest positions from two Member States which consider these substances as plant biostimulants and falling outside the scope of the Plant Protection Products Regulation. The rapporteur Member State for the renewal of the approval considered the contrary stating that the claimed functions are belonging to

the scope of the Plant Protection Products Regulation. Additional information was shared with Member States, who were invited to provide comments by 13 January 2021.

4. Active Substances vs. Co-formulants (e.g. Tall oil crude, clove oil,… as co-formulant)

The Commission informed about the discussion in the Post Approval Issues Working Group of this Committee in September and shared its provisional conclusions: *"The important criterion whether a substance is considered as an active substance or a co-formulant is its function in the respective product. If the substance is added to the product, e.g. as a solvent, a wetting agent or an emulsifier, it is a co-formulant. If the substance can be assigned to the same function as the product (e.g. fungicide or insecticide) and its content contributes significantly to the intended effect of the product, the substance is considered as an active substance."* Member States were invited to comment by 13 January 2021.

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

   a) Scope Document rev. 59

      The Commission presented a draft document, which presented the main principles followed until now by this Committee on this issue. One Member State suggested to add also some procedural aspects. The Commission invited Member States to provide further comments by 13 January 2021.

   b) New cases

      The Commission informed about its proposed interpretation for three new cases: Fortisol + Ca (proposed to be considered as PPP), urea (PPP), Vitiseal (not PPP).

      The Commission also presented a document submitted by one Member State regarding the scope delineation with the Biocidal Products Regulation in particular the specific cases presented in the following table, and noted that this discussion is taking place in parallel in the meetings of the competent authorities for the implementation of the Biocidal Products Regulation.

Use/claim
Disinfection of flower bulbs
Control of algae
Disinfection in empty storage rooms
Disinfection of water in hydroponic systems to prevent clogging
Disinfection of stables and transport carriages for animals
Hand disinfection
Disinfection of surfaces in mushroom growing areas
Disinfection of greenhouses
Disinfection of instruments / materials used for cultivating or processing plants
Disinfection of storage containers of plant and plant products

      Member States were invited to send comments by 13 January 2021.

   c) In situ generated active substances

      No news to discuss.

6. Basic substances – general issues

   The point was postponed as internal reflections are ongoing in the Commission services.

A.17 News from Sustainable Use Directive (Directive 2009/128/EC):

No news to discuss.

A.18 News from Health and Food Audits and Analysis (SANTE, Directorate F):

No news to discuss.

A.19 Report from working groups, in particular:

1. Working Group on Biopesticides

   The Commission thanked Member States for the support via this Working Group, in particular as regards the drafts presented under point A.14.

2. Working Group on Seed Treatments

   No news to discuss.

3. Working Group Post Approval Issues

   The Commission informed that during the last interzonal Steering Committee meeting, Member States debated on the remaining open points after the commenting round to adapt accordingly the Guidance Document on the evaluation of new active substance data post (renewal of) approval SANCO/10328/2004 rev.9. The guidance may also include the process to be agreed concerning the inclusion of the residue definition for risk assessment in the review report.

A.20 Minor Uses.

The Commission welcomed the new representative for the Minor Use Coordination Facility.

A.21 Court cases.

The Commission informed about a new judgment (3 December 2020, Case C-352/19 P: Région de Bruxelles-Capitale v Commission) on the appeal against the order of the General Court of 28 February 2019 (in case T-178/18w) declaring inadmissible the Region's application for annulment of Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate (T-178/18). The Court confirmed the order of the General Court and therefore dismissed the appeal of the Region in its entirety.

A new case (T-629/20 Delifruit /Commission) was lodged concerning an application for annulment of Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products (as regards the MRL for chlorpyrifos).

A.22 Ombudsman cases.

The Commission informed that the Ombudsman had published its Decision on the joint cases 1570/2018/JF-JN and 1973/2018/JF-JN on how the European Commission

approves substances used in plant protection products (pesticides), and which concerns in particular the use of confirmatory data, on 30 November 2020.

A.23 Exchange of information from the Pesticide Residues section of the Committee, in particular:

There were no new MRL measures with a possible impact on authorizations discussed at the last meeting of the section Pesticides Residue of this Committee.

A.24 OECD and EPPO activities:

No news to discuss.

A.25 Scientific publications and information submitted by stakeholders:

The Commission informed that a letter from ECPA had been received and made available to Member States. This letter referred to issues related to the isomer guidance document, the aged sorption guidance document, specific protection goals and the implementation of the transparency regulation, all points for discussion at this meeting of this Committee.

A.26 Date of next meeting(s).

The Commission informed that the next meeting of this Committee is confirmed for 25 and 26 January 2021.

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 renewing the approval of the active substance blood meal 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11236/2020).

The Commission introduced its proposal for renewal of approval blood meal as a low risk active substance, and informed about a few minor editorial modifications introduced in the Annex to the Implementing Regulation.

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

Outcome of the vote by written procedure: Favourable opinion.

<u>Greece submitted the following statement:</u>

According to the provision regarding foodstuff embedded in Article 23 of Reg. (EC) No 1107/2009, 'blood meal' and 'garlic extract' should for the purpose of the Regulation be considered as basic substances.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance benfluralin, 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/10236/2020 Rev. 0).

A number of Member States considered that with risk mitigation measures the ecotoxicological issues identified in the EFSA Conclusion can be solved and the approval can be renewed. Although a majority of Member States supported the Commission proposal, they did not represent the required share of the population for a qualified majority. The Commission announced that will reflect on the way forward. The Member States were invited to comment in case they would change their position on the Commission proposal by 6 January 2021.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenpyrazamine (Draft Review Report SANTE/10690/2012 Rev. 3).

The Commission recalled that, as a consequence of the assessment of the confirmatory information the approval conditions and the Review Report should be amended including a maximum concentration for hydrazine as relevant impurity. This reflects the change in production from pilot to commercial scale.

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 approving the active substance 24-epibrassinolide as 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/11348/2020).

The Commission presented the draft Regulation and recalled that in the EFSA Conclusion no critical areas of concerns nor critical areas that could not be finalized were identified. The substance qualifies as low risk in line with the provisions in point 5 of Annex II to Regulation (EC) No 1107/2009.

The Commission informed that it had received comments from five Member States after the last meeting of this Committee which had been considered in the presented draft documents..

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.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance garlic extract 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/11050/2020 Rev. 2)

The Commission reiterated the reasoning for the proposal and explained the changes made following comments from one Member State.

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.

Greece submitted the following statement:

According to the provision regarding foodstuff embedded in Article 23 of Reg. (EC) No 1107/2009, 'blood meal' and 'garlic extract' should for the purpose of the regulation be considered as basic substances.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of of extracts from *Capsicum annuum* L. var. *annuum*, longum group (cayenne extract) as a basic substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11544/2020 Rev. 1).

The Commission reiterated the reasoning for the draft Regulation and explained the changes made compared to the draft previously seen by Member States in the last meeting of this Committee.

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.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of the approval of the active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) as 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11952/2020 Rev. 1).

The Commission reiterated the reasoning for the draft Regulation and explained the changes made compared to the draft previously seen by Member States in the last meeting of this Committee.

One Member State commented on the low risk status and the data gap of EFSA on the resistance/sensitivity to antimicrobial agents. The Commission explained that a rationale addressing this issue is provided in the Renewal Report.

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.08 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 benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin.

The Commission presented this administrative measure, which is required by Article 17 of Regulation (EC) No 1107/2009 as the evaluation procedures for the substances were all delayed.

One Member State opposed the extension of the approval of benfluralin and urged to seek for the finalisation of the assessment of mecoprop-P. Another Member State disagreed in general with the extension of the approval periods in batches and in this case, specifically on the extension of dimoxystrobin and mepiquat. A third Member State did not agree with the extension of the approval of dimoxystrobin, metiram and oxamyl. Another Member State expressed its intention to vote in favour because the draft Regulation covered a package of substances, but found the extension of mepiquat controversial.

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 <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) adopting a standard data format for the submission of applications for the approval or amendment of the approval of active substances as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

The Commission presented the draft Implementing Regulation, responded to the questions from the Member States and clarified the scope of the draft Regulation.

The Commission informed that the consultation of all Commission services concerned was still ongoing and that, therefore, the draft could still be subject to some changes following this consultation. The Commission announced that it intends to submit a draft Regulation for vote at the next meeting of this Committee in January 2021.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of *Bacillus amyloliquefaciens* AH2 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/11938/2020).

The Commission informed that following the last meeting of this Committee five Member States had commented, all expressing their support for the approval of *Bacillus amyloliquefaciens* strain AH2 as low-risk active substance.

One Member State had commented on the extrapolation of conclusions from the species *Bacillus amyloliquefaciens* on fate and behaviour, noting that the strain AH2 would belong to the species *Bacillus siamensis* and not *Bacillus amyloliquefaciens*. The Commission recalled that this point had been debated during the peer review and it was acknowledged that the taxonomy of *Bacillus amyloliquefaciens* strains has evolved within the *Bacillus subtilis* group over the years. The text of the EFSA Conclusion was updated considering that it was proposed that the *B. amyloliquefaciens* clade should be considered as a taxonomic unit above species level, designated as "operational group *B. amyloliquefaciens*", consisting of the soil borne *B. amyloliquefaciens* and plant associated *B. siamensis* and *B. velezensis*.

Member States were invited to send comments by 6 January 2021.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2017/375 and (EU) No 540/2011 as regards the conditions of approval of the active substance prosulfuron (Draft Addendum to the Renewal Report SANTE/12092/2020).

The Commission provided a summary of the comments received from Member States following the last meeting of this Committee. Most comments were favourable towards the removal of the existing restriction, however, one Member State raised the need to finalise the relevance assessment for several groundwater metabolites at EU level. The Commission agreed that assessment of the relevance of metabolites, given the critical nature for determining whether authorisations can be granted or not, should be agreed at EU level to ensure harmonisation between Member States. It also indicated that the Renewal Report had been updated to further address the comments received.

Another Member State asked for confirmation that an up-to-date literature review for applications for amendment to the conditions of approval should always be provided, in all areas and not only those being reviewed as part of the amendment application, noting that this was not the case for prosulfuron, however, acknowledging that the renewal procedure would commence in mid-2021. The Commission agreed that any relevant scientific literature should be considered and also recalled that in any case adverse data must be submitted by the applicant at any time and if any concerning findings are identified in public literature by Member States or others, it is always possible to consider a review under Article 21 of Regulation (EC) No 1107/2009.

The Commission informed Member States that a vote on the draft Regulation is planned for January 2021. Member States were invited to submit final comments on the documents made available by 6 January 2021.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 820/2011 and (EU) No 540/2011 as regards the conditions of approval of the active substance terbuthylazine (Draft Updated Review Report SANCO/11337/2011).

The Commission provided a summary of the comments received from Member States following the last meeting of this Committee and informed Member States that the comments from the applicant on the revised Review Report were also available.

Member States were informed that a new version of the revised Review Report was available – in particular to clarify the situation with respect to the specification and that both the draft Regulation and the draft Review Report would be further revised to correct the maximum level of relevant impurities (simazine and propazine) to 9 g/kg.

One Member State also asked that additional data on two metabolites (LM3 and LM6) could be assessed before or in parallel with the renewal process, in line with the guidance on new active substance data post-approval.

The Commission agreed that the relevance of metabolites should ideally be assessed at EU level (also referring to the discussion under Point C.03), however, recalled that in this case the data is not needed in all cases, if the metabolites are below 0.75 ug/L in groundwater.

The Commission indicated that it would further reflect on this topic when updating the Review Report. Member States were also asked for further views on the matter.

Member States were informed that revised documents would be presented at the meeting of this Committee in January 2021 and that, since a TBT notification is required, a vote could take place only later.

Member States were invited to send further comments by 13 January 2021.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) 2017/1529 of 7 September 2017 approving the basic substance sodium chloride 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 amended Review Report SANTE/10383/2017).

The Commission gave an update on the positions of Member States received since the last meeting of this Committee and summarized that there seems to be general support from Member States for the approval of the extension of use of sodium chloride as an herbicide against *Baccharis halimfolia*. The Commission had made available the draft amended Review Report to include the proposed extension, and the text of the draft Regulation which revokes the current restriction to use as a fungicide and an insecticide, and allow for the proposed use as an herbicide. The vote on the draft Regulation is foreseen for the meeting of this Committee in January 2021.

Member States were invited to send final comments on the documents made available by 6 January 2021.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, 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/10730/2018 Rev. 2).

The Commission informed the Member States of the current status of the procedure for the proposal on indoxacarb and discussed comments received from three Member States. One Member State considered that the risks identified could be mitigated at Member State level. One Member State was of the opinion that only a very restricted approval would be possible and their preliminary position is that a non-renewal of approval as proposed by Commission would also be justifiable. One Member State indicated supporting the proposal for non-renewal of approval and requested submission of a proposal for vote as soon as possible.

The Committee was informed about one more email from the applicant regarding the persistence criterion. This issue had been clarified in the last meeting of this Committee.

Memer States were invited to send final comments on the documents made available by 6 January 2021.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance aqueous extract from the germinated seeds of sweet Lupinus albus 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/11962/2020 Rev. 1)

The Commission summarised the findings of the EFSA Conclusion on the new active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*, which did not include critical areas of concern nor issues that could not be finalised. The Commission recalled, that the new active substance aqueous extract from the germinated seeds of sweet Lupinus albus fulfils all criteria for the approval as a low risk substance set out in point 5 of Annex II to Regulation (EC) No 1107/2009.

The Commission informed that one Member State had signalled agreement with the proposed approval.

Another Member State indicated that it could agree with approval, but not as a low risk substance because of the not yet available analytical method for the determination of the total quinolizidine alkaloids.

Member States were invited to provide comments by 13 January 2021.

***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Cypermethrin.

Miscelanneous

M.01 The Commission informed that the confirmatory data for chromafenozide, which were submitted by the deadlines established in the approval Regulation (30 September 2015 and 31 March 2017) have not been evaluated yet by the Rapporteur Member State. The delay of this assessment of new data has direct implications on all product applications and is of significant concern as regards placing on the market, as the assessment is needed for authorisation of products, so that in fact no plant protection product containing chromafenozide is authorised in the EU despite the fact that the substance has been approved since 1 April 2015.

As regards residues for consumers, since no authorised uses were reported to EFSA during the data collection period, the Maximum Residue Levels (MRL) of chromafenozide for all commodities were lowered to the corresponding Limits of Quantification (LOQs).

Due to the difficulties of the Rapporteur Member State to conclude the assessment of confirmatory data, the Commission asked Member States to reflect if another one could take over this assessment and invited to send as soon as possible expression of interest to assess this confirmatory data.

M.02 The Commission informed of a notification under Article 69 of Regulation (EC) No 1107/2009 received on 30 November 2020 from France on acetamiprid, flupyradifurone, and sulfoxaflor. The Commission informed that it intends to mandate EFSA for an opinion in relation to acetamiprid and flupyradifurone as foreseen in Article 69, while for sulfoxaflor this is not considered necessary due to the ongoing discussion in this Committee on a proposal for restricting its use to permanent greenhouses.

Member States were invited to send comments and, in particular additional evidence concerning these three active substances, by 6 January 2021.