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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
25 - 26 January 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/10dc1829-c3dd-4ed8-8207-901012c9b9da*

SUMMARY REPORT

Section A Information and/or discussion

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 reports of the meeting held on 22-23 October 2020 and 3-4 of December 2020 were still under preparation.

A.02 New dossiers (for information):

- New active substances

  The Commission informed that the following application dossiers for new active substances were declared admissible by the following Rapporteur Member States (RMS):

  1. *Aspergillus flavus strain MUCL54911 (*RMS Italy, fungicide in maize)
  2. *Trichoderma harzianum* (RMS France, fungicide in rape)
  3. Lysate of *Willaertia magna* C2 (RMS Austria, fungicide in grapes)
  4. OptiCHOS (RMS The Netherlands, fungicide in several crops)
  5. *Bacillus nakamurai* F727 (RMS The Netherlands, fungicide in several crops)

- Basic substances applications received (for information)

  6. *Moringa oleifera* L. leaves & extract

  The Commission informed that the application was submitted in November 2020. It concerns an extract obtained from the leaves of *Moringa* in 80 % ethanol. The application also mentions the direct use of the leaves by burying them before sowing in the amount of 1 kg/m². The proposed use of *Moringa* is as a crop enhancer in an environmentally friendly strategy for improving crop yields at the lowest possible

cost. In addition, *Moringa* is claimed to have antioxidant, antifungal, and antibacterial properties. The application covers spray applications, seed treatments and the direct burying of the leaves in the soil. It can be used in all crops, against fungi in general and microorganisms in general. The Commission is verifying admissibility.

7. Extract of *Quassia amara*

The Commission informed that the application was submitted in December 2020 but from another applicant than the initial one (there had been two earlier applications in 2012 and 2017). The Commission reminded that in 2018, EFSA had identified several data gaps in particular concerning the identity of the substance, genotoxicty of quassin, dermal adsorption study, residues tests for fruits in the Southern zone, residues tests in the Northern zone for fruits and hop, storage stability for fruit and hop, an appropriate risk assessment for residues in hop using the EFSA PRIMo-model, and a persistence study and an adsorption study.

One Member State confirmed that the initial (task force) applicant informed that the replies to the EFSA data gaps were under preparation and should become available at the end of 2021.

- Amendment of conditions of approval

8. *Clove oil*

The Commission informed that an application for amendment of conditions of approval for clover oil and eugenol had been declared admissible by Malta as Rapporteur Member State.

- Article 21 Reviews

No news to discuss.

A.03 Renewal of approval and general issues.

The Commission gave an overview on withdrawals and active substances for which no renewal dossiers will be submitted as indicated by the applicants for the third, fourth, fifth and sixth renewal programmes. This overview has a merely informative purpose and is intended as background information to Member States when withdrawing authorisations for products containing the substances concerned and considering granting periods of grace.

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

- New active substances

1. Pepino Mosaic Virus, EU strain, mild isolate Abp1

The Commission summarised the EFSA Conclusion on the two Pepino Mosaic virus strains. They are derived from natural, indigenous wild type viruses. They are used as elicitors on tomato crops in permanent greenhouses once a year before the flowering season of tomatoes. The strains are restricted to plants of the Solanaceae family. There are no issues of concern nor data gaps. The active substance would also fulfil the low risk criteria in point 5.2 of Annex II to Regulation (EC) No 1107/2009.

Member States were invited to send their comments by12 February 2021.

2. Pepino Mosaic Virus, CH2 strain, mild isolate Abp2

Discussed with the previous point.

- Renewal of approval

3. *Pseudomonas chlororaphis* MA342

The Commission summarised comments received from Member States since the last meeting of this Committee. Two Member States supported the Conclusion of the EFSA statement adopted in 2020 concerning the translocation potential by *P. chlororaphis* MA342 in plants after seed treatment and the risk to humans by its metabolite DDR. One Member State considered that a renewal of *Pseudomonas chlororaphis* MA342 is still possible. During the meeting, the same Member State intervened by inviting other Member States to familiarise themselves with the position paper made available.

Member States were invited to submit comments on the renewal of approval of *Pseudomonas chlororaphis* in the light of the EFSA statement and the position paper by 26 February 2021.

4. *Bacillus thuringiensis subsp. Israelensis* (serotype H-14) strain AM65-52

The Commission presented the key elements of the EFSA Conclusion. The applicant had provided comments which had been circulated to Member States.

The peer review did not identify critical area of concern and two issues could not be finalised: the non-dietary exposure to CRY proteins and the potential interference with the analytical systems for the control of the quality of drinking water. The issue of CRY proteins is a common issue also for other BTs and the Commission will reflect on how to address these (see point A.05.i). EFSA indicated that the consumer risk assessment would only be considered closed if no edible succeeding crops are planted on treated soils.

The Commission informed that at this point in time it envisages renewal. Member States were invited to send comments on the two issues identified by 26 February 2021.

5. *Bacillus amyloliquefaciens* strain QST 713

The Commission presented the key elements of the EFSA Conclusion. The applicant had provided comments which had been circulated to Member States.

The substance had initially been approved with the name Bacillus subtilis strain QST 713 but taxononmy changed and the renewal application was done under the current scientific name. The peer review did not identify critical area of concern and three issues could not be finalised: the production of relevant toxins/secondary metabolites, the groundwater exposure assessment and the risk to earthworms and soil micro-organisms for all the representative uses.

The Commission pointed out that EFSA recommended the non-inclusion of Bacillus amyloliquefaciens strain QST 713 in Annex IV to Regulation (EC) No 396/2005 based on the consideration that qualitative and quantitative information on non-viable residues is missing and the consumer risk assessment cannot be finalised. However it should be noted that one Member State opposed this recommendation on the grounds that it is not scientifically and technically possible

to show that no metabolites can be produced under any environmental conditions, so that this point should be further investigated.

Member States were invited to send comments on the issues identified as well as the non-inclusion of Bacillus amyloliquefaciens strain QST 713 in Annex IV to Regulation (EC) No 396/2005 by 26 February 2021.

- Basic substances

6. Sodium hypochlorite

The Commission explained that sodium hypochlorite is proposed to be used as a bactericide on mushrooms indoor, and as a seed treatment against fungi and viral diseases on vegetables, ornamentals and arable crops outdoor and in greenhouses. EFSA concluded that there is a harmonised classification of the substance for severe skin burn and eye damage and the concentrations in the formulated mixture might be high enough for this to be a problem. A non-dietary risk assessment could not be conducted due to missing exposure estimates. EFSA also considerd that rinsing the seeds with sodium hypochlorite before planting is highly unlikely to result in residues above the MRL of 0.01 mg/kg nor will it contribute significantly to human exposure to chlorate through food. However, the use on mushrooms needs to be further assessed with respect to these potential residues of chlorate.

The Commission had received written comments from three Member States. Some Member States expressed that they would not be inclined to support an approval, others could see potential in the use for seed treatment.

Member States were invited to send comments by 12 February 2021.

7. Dimethyl sulphide

The Commission explained that dimethyl sulphide is proposed to be used in plant protection as a non-lethal food attractant for truffle beetle, as a vapour releasing product to be placed into physical traps. EFSA concluded that the available information on dimethyl sulphide regarding risks to humans has not been properly assessed or considered in the application. The available published information indicates that it is an irritant to skin, eyes and the respiratory tract and a skin sensitizer. In addition, a neurotoxic potential has been identified for the similar active substance, dimethyl disulphide.

The Commission concluded that there is again a lot of crucial information missing before an approval as a basic substance can be given.

Member States were invited to send comments by 12 February 2021.

8. Sunflower oil

The application concerns an extension of use. The Commission informed that the EFSA technical report had been published in November 2020. Sunflower oil had been approved as basic substance in 2016 for the use in plant protection as a fungicide on tomato crops in field. The current request for extension of use concerns spray applications as a fungicide on vegetables (common bean, cucumber), Rosaceae (like Prunus, Fragaria, Rosa, Rubus etc.), apple, pear, grapevine, wheat, barley, potato and carrot.

EFSA concluded that potential phytotoxicity of sunflower oil could not be excluded. This issue already existed in the first application and has not been clarified.

Sunflower oil residues in crops can result in degradation-, (photo) oxidation-, transformation products that may be of concern to human health (including genotoxicity and carcinogenicity concerns). These potential degradation products were not quantified or compared with natural background levels. Exposure to these products may be relevant to consumers, workers and possibly residents. In the existing review report it is mentioned that considering previous EFSA Conclusions on similar active substances such as rape seed oil and fatty acids, it is expected that the substance is readily biodegradable. Moreover, given the properties of the substance, the rate of application and the conditions of use in tomato it is expected that the application will not result in a significant increase of the natural level of occurrence of the substance components and their possible degradation compounds.

However, in the current technical report, EFSA concludes that the information included in the application indicated that sunflower oil may not be considered readily biodegradable when it is used as applied for. Additionally, the proposed application rates are higher than the already approved rates, so that it may not be the case anymore that the use will not result in a significant increase of the occurrence of transformation products compared to natural levels.

The information in the application was insufficient to address fate and behaviour and the environmental exposure that would result from the intended uses.

Insufficient information was presented in the application to perform a robust assessment for non-target organisms. Consequently, the risk assessment for birds, mammals, aquatic organisms, non-target arthropods, soil organisms and non-target terrestrial plants could not be finalised. A low risk to bees may be concluded only when there would be no treatment during the flowering of the crop and weeds in the field.

Member States were invited to send comments by 12 February 2021.

- Amendment of conditions of approval

  No news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Dimethyl disulphide

     This point was postponed.

  b) Chloropicrin

     This point was postponed.

  c) 1,3-dichloropropene

     This point was postponed.

d) *Beauveria bassiana* 203

The Commission informed that, following the presentation of the EFSA Conclusions at the meeting of this Committee in December 2020, five Member States had expressed diverging views, some supporting a non-approval, others supporting a restrictive approval on ornamental palm trees against red weevil pests. The Commission reminded Member States that EFSA's activities initiated in 2015 to elucidate the in-vivo genotoxicity of beauvericin, the main metabolite, are not finalised. This uncertainty did however not hinder that other Beauveria strains had been approved (or renewed). The Commission also informed that, based on analytical results regarding the content of beauvericin on a wider sampling of the technical grade active substance, the average concentration appears to be in the range of concentrations observed for a very similar strain approved for the same use on ornamental palm trees.

As for other Beauveria strains the status as low-risk substance cannot be attributed to this strain, unless the uncertainty regarding beauvericin is lifted.

Member States were invited to provide comments by 12 February 2021 on the draft review report, in particular as regards the possibility to set a maximum limit for the beauvericin content in the technical specification and as regards the low-risk status.

- Renewal of approval

e) *Metarhizium brunneum* strains BIPESCO 5/F 52

This point was postponed.

f) Captan

The Commission recalled that the outcome of the peer review had resulted in a number of areas of concern for the environment for the supported field uses. Considering that the protected uses (permanent greenhouses) did not present those concerns, the draft review report proposes to restrict the renewal of approval to permanent greenhouses.

Member States were invited to comment by 12 February 2021.

g) *Purpureocillium lilacinum* strain 251

The Commission mentioned that three Member States had provided comments on the EFSA Conclusion which were overall supportive of the renewal of the approval of the active substance. The applicant had also submitted comments which had been circulated to Member States.

The Commission informed that regarding the risk to collembolans, Purpureocillium lilacinum is a ubiquitous, saprophyte filamentous fungus isolated from soil and the method of application is localised. In addition, the EFSA Conclusion indicates that the multiplication ability in the soil for this strain for the intended use is not high. Therefore, no unacceptable risk for collembolans is expected under the proposed use scenarios, hence not impeding the renewal of the approval of the active substance.

EFSA identified a data gap as the study on sensitivity to antimicrobials was on-going at the time the review was finalised - so it is not possible to confirm

whether the requirements for considering the micro-organism as low-risk are fulfilled.

Member States were invited to send comments on the draft renewal report by 26 February 2021.

h) Phosmet

The Commission informed that EFSA had corrected its Conclusion in January 2021 by deleting a data gap and the corresponding issue that could not be finalised with regard to the aquatic risk assessment for one metabolite. This revision does not change the proposal of the Commission not to renew the approval of the substance as all of the identified critical areas of concern for all representative uses remain.

The Commission had shared the draft renewal report, the comments received from the applicant on the report, the correspondence with the applicant and the law firm representing the applicant as well as the comments received from six Member States. The Commission reacted to one comment of a Member State clarifying that it would not propose further investigation into the development neurotoxicity issue (DNT) given that the applicant had not provided information to exclude DNT concerns either in its dossier or during the peer-review process. In addition, during the expert discussion all experts had agreed on the setting of the reference values and the uncertainty factor which took into account uncertainties for DNT. Furthermore, the Commission recalled that aside from the critical concerns identified for human health, there were also several critical concerns related to risk for non-target organisms.

Member States were invited to send positions and comments on the draft renewal report by 12 February 2021.

i) *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, *Bacillus thuringiensis* subsp. kurstaki strain SA-11, *Bacillus thuringiensis* subsp. kurstaki strain SA-12 (cross cutting issues)

The Commission informed that several EFSA Conclusions on Bacillus thuringiensis spp. had been recently published, all recommending non-inclusion of B. thuringiensis in Annex IV of Regulation (EC) No 396/2005 due to dietary exposure concerns. This topic had been discussed repeatedly, such as in the Biopesticide Working Group of this Committee and in bilateral meetings with the applicants, and comments had been received from Member States on specific B. thuringiensis strains presented at the previous meetings of this Committee. The Commission briefly summarised the outcome of these discussions, including information on foodborne outbreaks events allegedly linked to food items contaminated by B. thuringiensis, which however showed also significant uncertainties about the causal agents. The Commission mentioned that risk management decisions should be based on robust data, especially considering the impact on the overall approach to micro-organisms and objectives to foster availability of lower risk plant protection products.

The Commission is currently reflecting on how to address this cross-cutting issue, in order to proceed with the decision-making for the individual B.

thuringiensis strains involved. The Commission also referred to related discussion on this issue the section Pesticides Residues of the Committee.

Member States were invited to send comments by 12 February 2021.

j) *Pythium oligandrum* strain M1

The Commission informed that two Member States had commented after the last meeting of the Committee, while the applicant had indicated that they had started to generate additional data in response to the data gaps identified by EFSA: among others results about the actual production levels of tryptamine and immunoglobulin A peptidases, two metabolites of potential concern, an acute pulmonary toxicity/pathogenicity study, a study on behaviour of tryptamine and immunoglobulin A in the environment, and a revised literature search which had been considered as very insufficient during the peer review.

Despite the fact that the substance is also used in cosmetic products, the Commission pointed to the major data gaps in the renewal dossier that cannot be complemented after the peer review has been concluded as set out in Article 13(5) of Regulation (EU) No 844/2012.

Member States were invited to provide comments and positions on the proposed non-renewal by 12 February 2021.

k) Clopyralid

The Commission informed that a recent EFSA reasoned opinion (in accordance with Art 10 of Regulation (EC) No 396/2005) on clopyralid had brought new information with regard to the consumer exposure which could not be finalised during the peer review. The Commission indicated that based on this new information it will proceed drafting a draft renewal report supporting the renewal of the approval of clopyralid with the aim to present it at the next meeting of this Committee.

Member States were invited to send positions and comments by 12 February 2021.

l) Flumioxazin

The Commission explained that since the meeting of this Commitee in October 2020, one Member State had indicated that a non-renewal of approval for this substance should be considered given that the assessment of the endocrine disrupting properties was inconclusive.

The Commission informed of its intention to propose a renewal of approval with the requirement for the applicant to submit confirmatory data to complete the assessment of the endocrine disrupting properties in line with the scientific criteria to identify endocrine disrupting properties applicable as of November 2018 which had not been in place at the time when the application for renewal had been submitted.

Member States were invited to send positions and comments by 26 February 2021.

m) Famoxadone

The Commission informed that according to EFSA, the concerns identified during the peer review (both in the human and ecotox sections) could not be resolved with risk mitigation measures, selection of different focal species or recalculation of endpoints. For these reasons, the Commission announced that it will present in the next meeting of this Committee a new draft renewal report for the non-renewal of the approval.

Member States were invited to send positions and comments by 12 February 2021.

n) Cypermethrin

The Commission explained that since the meeting of this Committee in October 2020, three additional Member States had indicated that they would support a renewal of cypermethrin as proposed in May 2020 (renewal as candidate for substitution with strict conditions regarding risk mitigation to protect non-target arthropods, aquatic organisms and bees in line with Article 6(i) of Regulation (EC) 1107/2009). The Commission had shared the draft renewal report and the draft specific provisions from May last year as well as 21 comments received from the Member States.

At the meeting, the Member States confirmed their positions: 21 Member States supported the renewal as proposed in May, while 5 Member States supported non-renewal and 1 had not yet expressed its position. The Commission will further reflect on the way forward given that a qualified majority seems to support the renewal of cypermethrin.

Member States were invited to send positions and comments by 12 February 2021.

- Basic substances

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

The Committee took note of the amended review report.

Denmark made the following protocol declaration:

Denmark supports the work with approvals of more basic substances, however RMM must not be a requirement when approving a basic substance. Denmark is of the opinion that restriction to spot treatment as a risk mitigation tool is not realistic for vinegar, the application was amended to spot treatment as a risk mitigation to show safe use, and no definition is given to established how large an area 'spot treatment' is in this case.

p) Clayed charcoal (amended review report to be noted)

The Committee took note of the review report in view of non-approval of the extension of use of clayed charcoal as a wettable powder.

q) Chitosan hydrochloride (extension of use) (amended review report to be noted)

The Committee took note of the review report on chitosan hydrochloride amended to include the extension of use of chitosan hydrochloride in ornamental flower bulbs and beet crops.

One Member States commented that although they support the extension of use, they consider appropriate to review the original approval of chitosan hydrochloride as a basic substance (see point A.05.u). The Commission asked other Member States to provide their views on this issue by 26 February 2021.

r) Whey (extension of use)

The Commission explained that the application concerned an extension of the use as a fungicide and virucide to be used as foliar spray in grapevines and vegetable gardening tomato. In the amended review report, all the proposed uses are accepted as extensions of use. Specific issues had been taken into account by setting some conditions of use, e.g. that the whey solution can only be applied in growth stages before flowering, that the leaves of plants treated with the whey solution should not be used for human consumption, and that plants treated with the whey solution, which have not been subject to processing standards required by the animal by-products Regulation should not be fed to cloven-hoofed animals.

Member States were invited to send comments by 12 February 2021 in view of note-taking at the next meeting of this Committee.

s) *Equisetum arvense* (extension of use)

On 17 December 2020, the Commission had sent a letter to the applicant requesting more information on the composition and purity of the Equisetum extract as well as information on routes of exposure. In its reply on 3 January 2021 the applicant questioned the assessment made by EFSA but did not provide any reply to the questions nor the requested information.

The Commission informed it will write another letter to the applicant asking why it was not possible to provide the requested information on the composition of the substance. One Member State explained that they would also contact the applicant to ask that they deliver the requested information and also to remind the applicant that a certain level of quality of an application is needed.

Member States were asked if they agreed to not approving this extension. As several Member States had earlier expressed their wish to also review the first approval, Member States were asked to suggest how to proceed with the first approval, or any other suggestions for a way forward.

Member States were invited to send comments by 12 February 2021.

t) Willow bark and stem extract

The Commission presented a draft review report in view of non-approval of Salix spp stem extract (willow stem infusion) as a basic substance in the light of the concerns and data gaps identified in the technical report of EFSA as regards the composition and identity of the substance. There is also a lack of clarity as regards the predominant use outside of plant protection and a divergence of views between Member States on how the identified issues could be solved. Since the last meeting of this Committee, one Member State had submitted comments supporting the proposal for non-approval.

Member States were invited to provide comments on the draft review report by 26 February 2021.

u) Chitosan hydrochloride (extension of use and origin)

The Commission updated Member States on the status of the dossier. The application for extension of use of chitosan hydrochloride covers several additional uses, new source of the substance and also another form of the substance – not hydrochloride salt as in the original approval but the amino form, chitosan. There is an inconsistency in the current approval of chitosan hydrochloride as a basic substance since CAS-number listed in the Regulation does not correspond to the name of the approved substance. Additionally, the originally approved chitosan hydrochloride is directly soluble in water, whereas chitosan, as proposed in the extension, seems not to be soluble in water. The preparation for use of this form of chitosan requires lowering of the pH value by addition of acid, for example vinegar. Article 23 of Regulation (EU) No 1107/2009 requires that basic substances should be useful in plant protection either directly or in a product consisting of a substance and simple diluent. Therefore, the need for the addition of vinegar to water and chitosan poses the problem that the final mixture is not just made of chitosan and a simple diluent. On the other hand, products are exempt from authorisation for use under Art 28, if they contain one or more basic substances, and vinegar is already approved as a basic substance.

Since the last meeting, one Member State had submitted comments, supporting the extension. The Member States were invited to submit by 26 February 2021 their views on the specification of chitosan proposed in the extension and whether it would be acceptable to approve this substance given the need for addition of vinegar.

v) Calcium hydroxide (extension of use)

The Commission updated Member States on the status of the dossier. Since the last meeting of this Committee, one Member State had indicated that they could provisionally agree with the proposed extension of use. Overall, three Member States had commented, one supporting the extension, and two opposing the approval of the extension. Taking into account the comments received, and the concerns identified in the Technical Report of EFSA, the Commission had prepared a draft amended review report in view of a non-approval of the extension of use. The reasons include non-finalised risk assessment for operators, workers, residents and bystanders; unclear specification; data gaps in the area of environmental and consumer risk assessment for some of the uses in the non-dormant phase, combined with the application rates proposed in the extension that are higher than originally approved. The Member States were invited to provide their views on the draft amended review report by 26 February 2021.

- Amendment of conditions of approval

No news to discuss.

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs) - review reports updated to include the agreed TDM endpoints

The Commission had tabled updated Review Reports for the active substances mentioned below for note taking by Member States. Member States were informed

that these substances constitute the remaining triazole substances for which the reports have not so far been amended to include the agreed endpoints for the triazole derived metabolites (TDM) and where the substance is approved and continues to be supported at renewal (there are several other triazole substances the approval of which will expire in 2021 and for which an update of the review report is, therefore, not considered necessary).

For prothioconazole the updated review report also included amendments to close the confirmatory information points for that substance.

Member States took note of the updated review reports for prothioconazole, penconazole, metconazole, triticonazole, tebuconazole, tetraconazole, ipconazole, and mefentrifluconazole.

2. Pyrethrins (amended report to take note)

   The Commission postponed the note taking because the rapporteur Member State had informed that it was already in a position to share the preliminary renewal assessment with the co-rapporteur Member State by mid-February. Since the consumer risk assessment could not be finalised and the toxicity profile of the metabolites (including their genotoxic potential) could not be concluded either after the submission of the supplementary dossier and the uncertainties highlighted during the confirmatory data procedure remain, the Commission informed that it would further reflect on the way forward and update Member States in March.

3. Tri-allate

   Further to the confirmation from the rapporteur Member State for renewal that new data was included in the dossier on the areas where concerns had been identified in the Conclusion following assessment of confirmatory information, the Commission asked Member States whether they would agree to await the renewal assessment before taking further action. The Commission informed Member States that since a concern for genotoxicity was raised, it had also asked rapporteur Member State to indicate when this assessment would be available. The Commission explained that it would reflect once the rapporteur Member State had responded.

4. Geraniol, Eugenol, Thymol, Clove oil, Orange oil

   This point was postponed.

5. Propyzamide

   The Commission informed that following the publication of the EFSA Technical Report following the confirmatory information assessment, the applicant had submitted comments to the Commission which were shared on CIRCABC.

   The Commission also informed that based on the outcome of this assessment, a mandate to EFSA was under preparation to further examine several key areas where divergent views were expressed in the peer review of the confirmatory information. Once an EFSA Conclusion is available (expected by end of the 2021), the substance would be brought back to the Committee for further consideration.

6. Isopyrazam

   The Commission summarised the current state of play following the publication of the EFSA Technical Report in March 2020.

The Technical Report concludes that for metabolite 459489, a toxicological relevance assessment is not required since the metabolite is not expected to reach levels in soil that would then lead to contamination of groundwater. In contrast, metabolite 459488 is predicted to exceed 0.1 µg/Lin groundwater in all pertinent scenarios for the representative uses assessed and therefore a toxicological relevance assessment is required.

In its initial assessment the Rapporteur Member State had not considered that the parent should be classified as carcinogenic and confirmed that metabolite 459488 shared the same mode of action as the parent, and, consequently, considered the metabolite to be not-relevant. Conversely, EFSA and some Member States considered the metabolite relevant as they considered the parent to be carcinogenic.

In December 2020, the Risk Assessment Committee of the European Chemicals Agency (ECHA) had concluded that isopyrazam should be classified as toxic for reproduction category 1B and carcinogenic category 2 and, as a consequence, the metabolite should also be considered relevant since the metabolite shares the same mechanism as the parent.

The Commission explained that it was further examining all the documents and reflecting in view of providing a proposal in March. The Commission also noted that the approval of isopyrazam is set to expire on 31/03/2023 since no application for renewal had been submitted.

7. Penthiopyrad

   The Commission informed Member States that a mandate had been sent to EFSA to ask for a further peer review on the toxicological properties of two metabolites. Once the EFSA Conclusion will be available (expected by end of 2021), the substance will be brought back to the Committee for further consideration.

8. Meptyldinocap

   The Commission explained that, based on the Technical Report published in December 2020, some data gaps remained for full toxicological characterisation of two metabolites for which a groundwater assessment is required, however it had been shown that for the representative use on grapes, these metabolites are not expected to occur above 0.1 µg/L in any of the pertinent FOCUS scenarios. Therefore, safe use has been confirmed. The Commission has, therefore, updated the Review Report and invited Member States for comments by 26 February 2021.

9. *Bacillus pumilus* QST 2808

   The Commission reminded that *Bacillus pumilus* strain QST 28 08 is approved as a fungicide on grapes (wine and table) and fruiting vegetable cucurbits (cucumber, melon and zucchini). Confirmatory information had been required with respect to (a) the identification of the amino sugar produced by *Bacillus pumilus* QST 2808 and (b) analytical data for the content of that amino sugar in the production batches.

   The data had been submitted and evaluated and EFSA issued its technical report in October 2017 concluding that the data requirements were addressed. Therefore, the Commission planned to amend the review report and present it for note taking at the next meeting of this Committee.

   Member States are invited to submit comments by 12 February 2021.

10. Mandestrobin

    The Commission recalled that the applicant had to submit confirmatory data by 9 June 2016, as regards the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities, and the compliance of the toxicity batches with the confirmed technical specification. The outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mandestrobin in light of confirmatory data had been published in September 2017.

    The Commission informed that the review report will be amended accordingly to include the reference technical specification as manufactured. Member States were invited to submit comments by 26 February 2021.

11. Fluxapyroxad

    The Commission recalled that in the approval of 2012, the purity given was based on a pilot plant production. The former rapporteur Member State, in accordance with Article 38 of Regulation (EC) No 1107/2009, assessed the specification of the technical material as commercially manufactured.

    The Commission informed that the review report will be amended accordingly to include the reference technical specification as manufactured. Member States were invited to submit comments on the suggested amendment by 26 February 2021.

12. Flupyradifurone

    The Commission recalled that the applicant had to submit confirmatory data by 9 June 2016, as regards the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities, and the compliance of the toxicity batches with the confirmed technical specification. The outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for flupyradifurone in light of confirmatory data had been published in May 2017.

    The Commission informed that the review report will be amended accordingly to include the reference technical specification as manufactured. Member States were invited to submit comments on the suggested amendment by 26 February 2021.

13. Oxathiapiprolin

    The Commission recalled that the applicant had to submit confirmatory data by 3 September 2017, as regards the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities, and the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification. The outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for oxathiapiprolin in light of confirmatory data had been published in June 2018.

    The Commission informed that the review report will be amended accordingly to include the reference technical specification as manufactured. Member States were invited to submit comments on the suggested amendment by 26 February 2021.

14. Terpenoid blend QRD 460

    The Commission recalled that the applicant had to submit confirmatory data by 10 February 2016, as regards the technical specification of the active substance as

manufactured (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material, and the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for terpenoid blend QRD 460 in light of confirmatory data had been published in May 2017.

The Commission informed that the review report will be amended accordingly to include the reference technical specification as manufactured. Member States were invited to submit comments on the suggested amendment by 26 February 2021.

15. Metobromuron

The Commission summarised the current state of play following the publication of the EFSA Technical Report in August 2019. Confirmatory information had been requested with respect to:

a) the toxicological assessment of the metabolites CGA18236, CGA18237, CGA18238 and 4bromoaniline;

b) the acceptability of the long-term risk to birds and mammals.

With respect to point a), the metabolites CGA18236, CGA18237 and CGA19238 had been sufficiently investigated as plant metabolites and were found to be devoid of a genotoxic potential. However; if appearing in groundwater above the parametric drinking water limit of 0.1 µg/L, these metabolites should be considered relevant following the currently non-harmonised classification of the parent compound. Regarding 4-bromoaniline, the metabolite is not of concern as a groundwater metabolite since it would not exceed 0.1 µg/L in groundwater according to environmental fate and behaviour models.

With respect to point b), the new information adequately addresses the requirements for confirmatory data for mammals in all EU zones. The recalculated refined risk assessment resulted in low risk to mammals for the representative use of metobromuron in pre-emergence in potatoes at 2.0 kg a.s./ha. However, the new information only addresses the requirements for birds in the Southern and Central zones for that representative use.

The Commission suggested to amend the review report accordingly to request Member States to pay particular attention to the fate and behaviour of the metabolite and the uses in vulnerable areas. Member States were invited to submit comments on the suggested amendment by 12 February 2021.

16. Spiroxamine

The Commission reminded participants that spiroxamine is currently approved as fungicide in cereals and confirmatory data had been set for the proposed representative use in grapes. The Commission had sent a mandate to EFSA in December 2019 with respect to the confirmatory data. The Commission had received the EFSA Conclusion on 17 December 2020.

The EFSA Conclusion indicates that no critical area of concern was identified, neither an issue which could not be finalised. The Commission indicated it intends to present an amended version of the review report at the next meeting of this

Committee. Member States were invited to send their comments by 12 February 2021.

17. ***Pro memoria* – Postponed for next PAFF meeting** Penflufen

A.07 Guidance Documents:

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

   The Commission explained the minor changes made since the meeting of this Committee in December 2020

   The Committee took note of the Guidance. It will apply to applications submitted from 1 March 2021 onwards.

   Denmark made the following protocol declaration:

   Denmark thanks the Commission for finalizing the work on the "Guidance on emergency authorisations according to Article 53". In the opinion of Denmark, the guidance should have contained requirements that safe use should not only be demonstrated for consumers but also for human health in general and the environment.

2. 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 that comments received since the last meeting of this Committee had been included in a Reporting Table and an updated version derived from the outcome of the comments was presented for note taking.

   The Committee took note of the Guidance. It will apply to applications submitted from 1 March 2021 onwards.

   Germany made the following protocol declaration:

   Germany reiterates that the approach described in the guidance document with regard to generic products (MeToo - use of a reference product in a very broad interpretation of Article 34 of Regulation (EC) No 1107/2009) contradicts the provisions of Article 36 (1).

   According to Article 36 (1) an up-to-date assessment taking into account the guidance documents applicable at the date of application is required. This point has already been commented on several times but has not been implemented in the guidance document.

3. 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 recalled that the revision concerend partial updates of Section 2, Section 3, and Annex I and II in view of implementation of the Transparency Regulation.

   The Committee took note of the 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 Revision 10.

The revised version of the document applies to all applications for approval as basic substance submitted after 27 March 2021.

Greece made the following protocol declaration:

Greece takes note of the new guidance document for basic substances, but retains its position that according to the provision regarding foodstuff, embedded in Article 23 of Reg. (EC) No 1107/2009, all substances considered as such are eligible for plant protection use as basic substances and should not be subject to prior evaluation.

4. Draft Guidance Document on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)

   The Commission informed that the cover note had been slightly amended in order to address concerns expressed by one Member State. This Member State had also raised concerns for note taking of this guidance document, as no final user-friendly software was made available. However, the Commission, after having consulted with EFSA and the drafting Member State, reminded that for higher tier risk assessments (ad-hoc) not always a full-fledged user friendly software can be expected and that expertise will always be needed for such complex assessments. In addition, EFSA had confirmed that software is available and public. The Commission also reminded on the wide desire to take note of this guidance document with no further delay.

   The Member State which had expressed concerns recognised the importance of this guidance document and that a validated software may not be essential, however stressed that regulators have no experience so far. The drafting Member State with support of EFSA agreed to draft instructions as regards how to use the available software, which will complement the guidance.

   The cover note was amended accordingly and the Committee took note of the guidance document with implementation date 1 April 2021.

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

   The Commission informed that on 13 January 2021 it organised an information session for Member States and the stakeholder group established by EFSA, allowing for an exchange of views between all interested parties. As a basis for the discussion, EFSA had prepared a comprehensive supporting document, which is publicly available, and presented its content in detail at that meeting. The event was constructive and many questions and clarifications were made. The Commission indicated it intends to make the summary report and the answers to written comments received after the event publically available via its website. The Commission announced that it will organise a further meeting with Member States on 23 February 2021.

   One Member State asked if it would be possible to set different protection goals for each regulatory zone in the EU. Another Member State underlined the importance of a harmonised approach and welcomed that the protection goal for wild bees will be discussed after setting such a goal for honeybees.

   Member States were invited to send their views for the next discussion on setting specific protection goal(s) for honeybees by 9 February 2021.

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

   There were no news to report.

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

   The Commission gave a brief update: it continues to examine the 600 comments received from Member States and stakeholders on the revised draft Communications. The Commission plans to suggest some general points for discussion at one of the next meetings of this Committee in order to streamline the communications and make their update easier and it will consult the Member States on the revised versions of the two Communications as soon as possible.

8. 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

   The Commission recalled that in the meeting of this Committee in October 2020, discussion on the guidance on negligible exposure had been reopened - taking the previous draft version as a starting point - to explore with Member States, in light of experience gained, their views on moving forward to agree guidance in this area.

   The Commission provided feedback on the responses of Member States received, which broadly indicate that positions and views have not significantly changed since the previous discussions in 2015 – several Member States have fundamental concerns about the approach taken in the draft from 2015.

   The Commission invited more Member States to submit views or ideas on how to move forward and explained that it would further reflect thereon.

9. Draft EFSA Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure

   EFSA summarised the 136 comments received from 7 Member States, which were considered to the extent possible keeping alignment with the EFSA practical arrangements, as well as the procedural steps for finalising this guidance document. EFSA intended to adopt the Guidance in the beginning of February, with subsequent note-taking by the Committee in the meeting of the section Pesticides Residues in February. EFSA also indicated that supporting material and training is intended to be made available via the EFSA website.

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

The Commission informed that two meetings of the Working Group had taken place since the last meeting of this Committee. The Working Group had endorsed the revised outline of the next steps and the Terms of Reference of the Group (ToR), which are uploaded to CircaBC. Endorsement of the ToR by this Committee is expected at one of the next meetings.

The Commission informed that the work on the working document on pesticide scenarios will continue in the Working Group and an information session will be held on 5 February for all the participants of the previous workshops (experts from the Member States and stakeholders).

Member States were invited to comment on the Terms of Reference of the Working Group and the outline document by 26 February 2021.

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

The Commission updated about the ongoing work. Member States were invited to provide to the Commission information on any risk reduction techniques or practices recently implemented to reduce risks associated with the use of plant protection products in view of complementing the list of measures to be compiled in the planned guidance document on risk mitigation measures.

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

- Article 44(4)

  The Commission informed that one notification had been received, on the suspension of the authorisation of a product containing 1,4-dimethylnaphthalene, due to a fire in a potato storage. The authorisation holder had adapted the technical instructions to indicate that fogging with unsuitable fogging machines is forbidden.

- Article 36(3)

  The Commission informed that a total of 12 notifications had been received. All concerned rejections of mutual recognition applications from the same Member State, all went into national appeal procedures but all were dismissed.

- Article 53

  The Commission reiterated that all received notifications are made publicly available and invited Member States to add information or raise any observation or question on the published emergency authorisations. No Member State had any comment.

- Article 69

  The Commission informed that on 30 November 2020 it received a notification from France under Article 69 of Regulation (EC) No 1107/2009, asking to prohibit the sale and use of the substances acetamiprid, sulfoxaflor and flupyradifurone, taking into account the serious risks to health or the environment that they may pose. The French Authorities included in their notification references to published peer-reviewed studies to support the request.

  With regard to sulfoxaflor the Commission referred the Committee to a draft Regulation proposing to restrict the uses of sulfoxaflor to uses in permanent greenhouses only, currently under discussion (see point C.03).

  For the active substances acetamiprid and flupyradifurone, the Commission recalled that a mandate to EFSA is under preparation with a request to assess whether there are indications that the approval criteria in Article 4 are no longer met. Based on EFSA's assessment, if there are such indications, the Commission will trigger a review under Article 21. This mandate will also cover the data on wild bees for flupyradifurone notified by the Netherlands under Article 56, in particular the data on *Megachile rotundata*, which are also mentioned by France in the Art. 69 notification.

  Member States were invited to send their views on the notifications under Article 69 and 71 (next point) by 26 February 2021.

- Article 71

  The Commission informed that on 21 December 2020 it received a notification from France under Article 71 regarding the need to take emergency measures and informing of the measures taken by France for the substances mentioned in the Article 69 notification mentioned above, consisting in the adoption of a decree listing the 3 substances as belonging to the group of neonicotinoids or considered as similar as to their mode of action, the pesticide use of which is prohibited. This decree replaces a decree adopting a longer list that was in force since 2018.

  The committee was informed of comments provided voluntarily by the applicant for sulfoxaflor.

  France gave further clarifications on both notifications.

  Member States were invited to send their views on the notifications under Article 69 (previous point) and 71 by 26 February 2021.

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

There were no news to report.

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

There were no news to report.

A.13 Microorganism Active Substances, in particular:

– update of uniform principles and Annex II

The Commission explained the main changes envisaged in the amendment of part II of the Annex to Regulation (EU) No 546/2011 on uniform principles and in Annex II to Regulation (EU) No 1107/2009 on approval criteria for micro-organisms. The Commission specified that Annex II of Reg. (EU) No 1107/2009 will be amended only by inclusion of decision-making criteria on active substance which are related to a hazard (e.g. human pathogenicity of the micro-organisms), and a further specification on low-risk criteria for micro-organisms, while the other changes will be covered in the amended Regulation (EU) No 546/2011. Member States were invited to send comments to these drafts by end of February, in addition to the draft amendments of Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 on data requirements presented during the meeting of this Committee in December.

The Commission aims at discussing the four draft Regulations in the meeting of this Committee in March, where also draft Commission Communications accompanying the Regulations on data requirements for micro-organisms will be presented.

A.14 Safeners and Synergists.

There were no news to report.

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

1. Flupyradifurone

   This agenda point was discussed under point A.10

2. Acetamiprid

This agenda point was discussed under point A.10

3. Sulfoxaflor

   This agenda point was discussed under point A.10

A.16 General issues for information / discussion:

1. Brexit

   There were no news to report.

2. Illegal plant protection product use

   Germany, Poland and Bulgaria made presentations of the most common cases of illegal use of plant protection products discovered in their territories and the difficulties they encounter in the enforcement of Regulation (EC) No 1107/2009.

   The Commission made a presentation on the main points relevant for the sector discussed during the meeting of the Expert Group on the protection of health, cultural heritage, the environment and nature[1] (PARCS Expert Group; customs cooperation) in December 2020.

   The Commission reminded Member States that Article 72 of Regulation (EC) No 1107/2009 provides that Member States shall lay down appropriate penalties for the infringements of this Regulation, including the illegal use of plant protection products. As mentioned in the REFIT evaluation (p. 108), Article 72 is not properly implemented according to the audits performed by the Commission, as the sanctions in many Member States are not effective, in particular they are financially insignificant in relation to the potential profit.

   The Commission invited Member States to present information how Article 72 is implemented in the respective national legislation and what are the applicable sanctions in case of illegal use, marketing and import of plant protection products. Member States were also invited to provide information on the national restrictions on online marketing of plant protection products.

3. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate
   The Commission informed about the new position paper sent by one Member State challenging the status of nitrophenolates as plant protection active substances. Member States, in particular the Rapporteur Member State in charge of the renewal dossier, were invited to provide their comments by 26 February 2021.

4. Active Substances vs. Co-formulants (e.g. Tall oil crude, clove oil,… as co-formulant)
   The Commission informed that four Member States reacted positively to the proposal to endorse the conclusions proposed by the Post-Approval Issues Working Group of this Committee regarding the status of active substances also used as co-formulants. One Member State proposed to complement the statement of the Working Group. Other Member States did not express opposition.

[1] https://ec.europa.eu/taxation_customs/business/customs-controls/safety-health-environment-customs-controls/cooperation-between-member-states_en

The Committee took therefore note of the following:
"*The important criterion whether the 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. Whether this is the case or not can be determined based on a theoretical assessment, taking into account the function, the content, the mode of action of the substance and the context of use. In case of doubt, verification by efficacy-trial may be necessary. The applicant shall always provide clear information about the reason of adding a particular substance and this should always be apparent in the light of its intended function.*"

5. Scope of Regulation (EC) No 1107/2009:
   a) Scope Document rev.60 + ***b)*** New cases
   The Commission explained the changes provided to the introduction of the scope document following the discussion at the meeting of this Committee in December 2020. New entries were briefly presented as well. Member States were invited to provide comments on both the introduction and the entries numbered 196 to 205 by 26 February 2021.
   Member States were also reminded to send their written comments by 12 February 2021 about the document submitted by one Member State regarding the scope delineation with the Biocidal Products Regulation.

   c) In-situ generated active substances
   There were no news to report.

6. Basic substances – general issues
   There were no news to report.

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

There were no news to report.

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

There were no news to report.

A.19 Report from Working Groups, in particular:

1. Working group on Biopesticides

   The Commission informed that the members of the Working Group on Biopesticides widely supported the proposal of one Member State for group assessment of strains of the same species which could facilitate the review process for the applicant and Member States while improving consistency in the EFSA Conclusions and the decision-making process.

   Member States were invited to provide their comments about the presented approach by 26 February 2021. The Commission announced that it will further reflect about how to proceed.

2. Working group on Seed Treatments

   There were no news to report.

3. Working group Post Approval Issues

   There were no news to report.

A.20 Minor Uses.

There were no news to report.

A.21 Court cases.

The Commission informed that an application for annulment of the implementing Regulation concerning the non-renewal of mancozeb had been brought (T-742/20).

Case T-393/18 - Mellifera v Commission had been removed from the Court register, following withdrawal of the application (Annulment of Commission decision to not carry out an internal review under Regulation No 1367/2006 (the Aarhus Regulation) against a Commission Decision rejecting an application for internal review under the Aarhus Regulation of Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate).

A.22 Ombudsman cases.

There were no news to report.

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

– possible impact on authorisations

The Commission thanked Member States for their contributions to the proposal on how to manage changes to residue definitions for risk assessment – which were clear, useful and well-coordinated between representatives in both sections of the Committee.

Overall comments were very supportive and the Commission indicated that it will continue the work to move forward. The Commission explained that some Member States' comments require further discussions and coordination – in particular on the mechanisms and procedure for amendment of the residue definition and on how to manage provisional definitions and their implementation.

The Commission indicated that it would comprehensively respond to comments at the meetings of the section Pesticides Residues of the Committee in February 2021 and of the section Legislation of the Committee in March 2021.

A.24 OECD and EPPO activities.

The Commission reported on recent changes in the OECD related to pesticides. The Commission reminded participants that the OECD has many activities relevant to pesticides with several groups where the Commission and Member States are represented and actively contribute (i.e. pesticides, bio-pesticides, drones, electronic exchange of pesticides data, RNAi-based pesticides, residues, minor uses, and illegal trade of pesticides).

A voluntary grant agreement had been signed to fund OECD activities but it is up to OECD to decide how to use it as long as it fits within the terms of reference.

The Commission explained that the OECD is developing a paper on technical and regulatory issues and invited Member States having voting rights at the OECD to ensure consistency of positions with the on-going work on the revision of data requirements for micro-organisms.

The OECD will organise a seminar on efficacy in the margins of the annual meeting of the Expert Group on Biopesticides (EGBP) in June 2021 and a conference on BioPesticides in 2022.

The Expert Group on Drones had met several times in 2020. An outside contractor had been hired to review the scientific literature regarding the exposure modelling of air drift when products are applied with unmanned aerial vehicles (e.g. drones). Discussions are on-going.

A.25 Scientific publications and information submitted by stakeholders.

The Commission informed that a letter form CropLife Europe (CLE) had been received and made available to Member States. Also a response of EFSA to CLE had been made available, as it addresses some of the issues raised in the letter to this Committee.

A.26 Date of next meeting(s).

The Commission confirmed that the next meeting of this Committee will take place virtually on 24-25 March 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 (EU) adopting a standard data format for the submission of applications for the approval of an active substance or amendment to the conditions of an approval 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 reiterated the reasoning for the proposal and illustrated the changes made in the draft compared to the version previously seen by Member States. These changes resulted from the comments of the Commission services concerned. Member States supported the changes and no further comments were made during the meeting on the draft text.

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-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).

Considering the positions of the Member States which indicated that no qualified majority would be achieved, the Commission postponed the vote and indicated that it would request a statement from EFSA on whether the risk mitigation measures proposed by some Member States would ensure a safe use of the substance.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving 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 gave a brief overview on the new active substance and comments received from six Member States. The substance fulfils the criteria for a low-risk substance according to point 5.1 of Annex II to Regulation (EC) No 1107/2009.

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 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 Rev. 2).

The Commission gave a brief overview of the changes made to the final texts put forward for an opinion of the Committee (Regulation plus its Annexes and the Addendum to the Review Report) and comments received since the last meeting.

During the meeting one Member State indicated that it would vote against the proposal since it did not consider that a safe use had been demonstrated concerning groundwater whereas two Member States indicated that they would abstain due to concerns about leaching of metabolites into groundwater (one due to national specific groundwater modelling, while noting that a safe use had been shown at EU level).

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) 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 a brief overview of the changes made to the final texts tabled for an opinion of the 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.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, clopyralid, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, mepanipyrim, *Metarhizium anisopliae* (var. anisopliae) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Streptomyces* K61 (formerly '*S. griseoviridis*'), *Trichoderma asperellum* (formerly '*T. harzianum*') strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly '*T. harzianum*') strain T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram.

The Commission presented the draft Regulation emphasising that the proposed extensions were mandatory according to Article 17 of Regulation (EC) No 1107/2009 as the evaluation procedures for the substances were all delayed.

Three Member States expressed their concerns about the proposal. One indicated to be in particular against the extension of the approval period of metconazole and ziram. Another Member State understood the obligation for the extensions but disagreed on the extension of fenpyroximate, mepanipyrim and rimsulfuron. Furthermore, it urged the Commission to take a decision on abamectin, *Bacillus thuringiensis* subsp. Aizawai (strains ABTS-1857 and GC-91), clodinafop, dichlorprop-P, fosetyl, spinosad, *Streptomyces* K61 and trinexapac, as several critical areas of concern had been identified in the respective EFSA Conclusions.

A third Member State did not agree with the extension of the approval of mepanypirim, since in their opinion there is enough information to take a decision due to the evidence of its endocrine disrupting properties.

One Member State expressed its intention to vote in favour, but took the opportunity to raise - unrelated to this specific act – the request to retract the extension of the approval period of prochloraz.

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 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 the Committee with an update on the ongoing procedure for amendment, explaining that the consultation of the Commission services concerned had been finalised and the notification procedure under the WTO agreement on Technical Barriers to Trade (TBT) had been launched. Final documents had been shared with the Committee for final comments in view of a vote at the next meeting of this Committee.

The Commission explained that some changes had been introduced in the documents compared to the previous versions circulated in December 2020, specifically:

- Some editorial changes;

- The Annexes were amended to include a full replacement of the entries, rather than listing the individual components that are being modified.

The draft updated Review Report was amended to take into account Member States comments regarding submission of data on metabolites LM3 and LM6, outside of the renewal programme, if required.

Member States were invited to provide final comments by 12 February 2021.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance *Streptomyces* strain K61 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/11958/2020).

The Commission gave a brief overview of the dossier and thanked for the comments received from six Member States. The Commission referred to one concern and data gaps in the EFSA conclusions and the proposed justification why they are not considered to preclude a renewal as explained in the review report. The criteria for a low-risk substance according to point 5.2 of Annex II to Regulation (EC) No 1107/2009 could be considered met.

Due to the many data gaps, two Member States opposed the low risk status and one Member State announced the intention not to support the renewal.

The Commission invited the Member States to send comments by 26 February 2021.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and (EU) No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015).

The Commission gave a brief overview of the dossier, shared a draft proposal and thanked for the comments received from four Member States. The Commission informed of comments from the applicant on the review report for sulfoxaflor.

Member States were asked for their positions during the meeting: 4 Member Stated supported the Commission proposal, 11 Member States indicated not supporting the Commission proposal for opposing reasons (2 Member States asked for a more strict proposal while 9 Member States consider that certain field uses do not pose a risk to pollinators), and 12 Member States did not have a final position yet of which 11 Member States already indicated considering that outdoor uses should remain possible.

The Commission indicated it will reflect as regards the next steps. Member States were invited to send further views and positions by 12 February 2021.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance cyazofamid, 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/ (Draft Review Report Rev. 2 SANTE/12060/2020).

The Commission shared the draft renewal report (no changes compared to the version presented at the last meeting of this Committee), the comments of the applicant on the draft renewal report, the draft Implementing Regulation and its Annex as well as comments received from three Member States since the last meeting. So far 14 Member States indicated support for the renewal. The vote can be expected at the next meeting of this Committee. Member States were invited to send positions and comments by 12 February 2021.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance alpha-cypermethrin 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.

The Commission explained that, as no confirmatory data had been submitted by the regulatory deadline, the approval for alpha-cypermethrin has to be withdrawn in accordance with Article 21(3) of Regulation (EC) No 1107/2009. The Commission shared the draft Regulation withdrawing the approval, the comments from two Member States and a letter from a law firm acting on behalf of a company intending to become the applicant for the substance as well as the response from the Commission. The Commission informed the Committee that the notification procedure under the WTO agreement on Technical Barriers to Trade (TBT) had been launched and the vote can be expected at the next meeting of this Committee.

Member States were invited to send positions and comments by 26 February 2021.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey steeping) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/10930/2020 Rev. 1).

The Commission explained its proposal of a non-approval of fermented extract from leaves of comfrey as a basic substance due to the genotoxic potential of some components of the extract and lack of data to complete the risk assessment. One Member State had commented supporting the non-approval. The Commission presented the draft review report and draft Regulation. Member States were invited to submit comments by 12 February 2021.

C.07 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 explained that no revised documents were presented and that a revised version of the draft review report is expected for the next meeting of this Committee in March 2021.

The Commission informed that three Member States had commented on the draft review report presented at the last meeting of this committee, supporting the approval as low-risk active substance. One Member States had provided additional comments questioning the persistence of the spores in soil and their ability to produce metabolites as presented in the draft review report at the last meeting of this Committee. Therefore the Commission intended to check with EFSA and the Rapporteur Member State to clarify this point, and also the comments received from the applicant.

Member States were invited to send their comments, including the potential inclusion of *Bacillus amyloliquefaciens* AH2 in Annex IV of Regulation (EC) No 396/2005, by 26 February 2021.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance abamectin, 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/ (Draft Review Report Rev. 0 SANTE/12068/2020).

The Commission shared the draft review report (no changes compared to the last meeting of this Committee), the comments of the applicant on the draft review report, the draft Implementing Regulation and its Annex as well as comments received from Member States since the last meeting. The Commission proposes a restricted renewal to permanent greenhouses as defined by Art. 3(27) to mitigate the risks to the environment (ecotoxicology).

Member States were invited to submit comments by 12 February 2021.

C.09 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).

Pro memoria – TBT/SPS notification (to be) launched .

Miscellaneous

M.01 Copper Compounds:

This point was added on request of one Member State, which realised during the commenting of equivalence reports for copper hydroxide that some clarifications were deemed necessary as regards the relevant impurities mentioned in the Renewal Report associated to Commission Implementing Regulation (EU) 2018/1981 renewing the approval of copper compounds.

The Commission informed that the Rapporteur Member State had agreed to perform a consistency check of the specifications of all copper compounds and possibly revise the review report when necessary.

M.02 Financial support of Member States:

The Commission informed that it would have the possibility to support Member States in the area of risk assessments for plant protection and biocidal products with a total of 10 million Euro in the next 5 years via public procurement. The Commission asked if Member States would have an interest to receive such support, in particular as regards active substance assessments (as from 2022) and development of guidance documents. The Commission asked Member States to signal potential interest, as well as technical priority areas and potential timing by 26 February 2021.

M.03 Trifluoracetic Acid:

The Commission informed that a notification under Article 56 had been received by the Commission, all Member States and EFSA concerning Trifluroacetic acid (TFA), which is naturally occurring and also a metabolite of several active substances present in plant protection products.

The applicant had informed that studies are being carried out under REACH, and that a preliminary risk assessment did not indicate immediate concerns to human health. An evaluation of new evidence to be submitted under the REACH Regulation is expected by ECHA.

One Member State mentioned findings of TFA in groundwater, and wondered what the situation is in other Member States. Member States were invited to send pertinent information by 26 February 2021.

M.04 Metalaxyl-M:

One Member State expressed concerns that the existing restriction imposed at renewal, which applies from 1 June 2021 and precludes sowing of treated seeds in fields, would lead to some disruption and may result in the need for emergency authorisations for

plant protection products. Given that an application for amendment to the conditions of approval is ongoing, the Member State asked whether the entry into force of the restriction could be postponed.

The Commission explained that it had discussed the issue with the applicant and recalled that the restriction had been set based on the outcome of the renewal assessment. Postponing the restriction based on an ongoing assessment that was not finalised or peer-reviewed was not possible since the outcome cannot be pre-empted. Decisions must be based on the outcome of a full peer review. Member States could consider the use of emergency authorisation, if well justified, as a temporary solution while the assessment of the application for amendment was being finalised.

The Commission also indicated that the issue of how to manage authorisations and limit disruption to reinstating field uses (if the ongoing application resulted in a favourable outcome) was for Member States to consider and that the matter would be referred for discussion to the Post Approvals Issues Working Group of this Committee.

M.05 Azole resistance (resistance of *Aspergillus fumigatus* to medical azoles and the link with use of azole fungicides):

One Member State asked for an update on this topic, referring also to new information in relation to COVID-19-associated pulmonary aspergillosis, and in particular cases of COVID-19-associated pulmonary aspergillosis caused by azole-resistant *aspergillus*.

The Commission explained that it was examining the information provided by two Member States on the topic in view of preparing a mandate to send to the relevant EU agencies in the coming months.