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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
24 - 25 March 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/31cd0ad8-be68-445e-8e9b-aa3b3a1564c4*

SUMMARY REPORT

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

A.01 Summary Report of previous meetings.

The Commission informed that the summary reports of the meetings until December 2020 were published and that the one of January 2021 was still under preparation.

A.02 New dossiers (for information):

- New active substances

  The Commission informed that the following application dossiers for new active substances had been declared admissible by the following Rapporteur Member States (RMS): Indaziflam (RMS FR, herbicide against mono- and dicots) and Pretilachlor (RMS IT, herbicide in rice).

- Basic substances applications received

  – Magnesium hydroxide

    The Commission informed that an application had been received with a proposed use of magnesium hydroxide as fungicide on grapevine, olive trees, banana, cereals, vegetables, potatoes, ornamentals, stone fruit and rice. Food grade magnesium hydroxide is readily available on the market. The substance can be directly bought in suspension form, ready to use, or it is possible to prepare a mixture of magnesium hydroxide powder and water. The admissibility is under consideration.

  – Chitosan hydrochloride (extension of use)

    The Commission informed that an application had been submitted and is currently under assessment.

  – Sodium chloride (extension of use)

    The Commission informed that an application had been submitted and is currently under assessment.

- Amendment of conditions of approval

  There were no news to discuss.

- Article 21 Reviews

  There were no news to discuss.

A.03 Renewal of approval and general issues.

There were no news to discuss.

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

- New active substances

  There were no news to discuss.

- Renewal of approval

  a) Calcium carbonate

  The Commission informed that an EFSA Conclusion was available and invited Member States to send comments by 16 April 2021.

  b) *Bacillus thuringiensis ssp. kurstaki* strain PB 54

  The Commission summarised the EFSA Conclusion, which did not identify any critical area of concern. However, a number of issues could not be finalised (e.g. toxicity effects on humans after inhalation). EFSA suggested not to include the strain in Annex IV to Regulation (EC) No 396/2005, due to uncertainties related to dietary exposure. However, the Rapporteur Member State and the co-Rapporteur Member State disagreed with EFSA.

  As regards dietary exposure, the Commission specified that while performing a strain-specific evaluation, it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (all points concerning *B. thuringiensis* strains under A.04 and A.05). In their comments on this point, several Member States called for precaution, due to the identification of several data gaps concerning the different *B. thuringiensis* strains. The Commission invited Member States to comment on some possible approaches by 16 April 2021.

  c) *Bacillus thuringiensis ssp. kurstaki* strain EG2348

  The Commission summarised the EFSA Conclusion, which did not identify any critical area of concern. However, a number of issues could not be finalised (e.g. toxicity effects on humans after inhalation). EFSA suggested not to include the strain in Annex IV to Regulation (EC) No 396/2005, due to the uncertainties related to dietary exposure. However, the Rapporteur Member State and the co-Rapporteur Member State disagreed with EFSA.

  As regards dietary exposure, the discussion was held horizontally (see point A.04.b).

Member States were invited to comment by 16 April 2021.

- Basic substances

  d) Sunflower oil

  The Commission informed that the EFSA technical report on an application for extension of use had been published in November 2020. Sunflower oil was approved in 2016 for use as a fungicide on tomato crops in field. The current request for extension of use concerns spray applications as a fungicide on vegetables: rosacea, apple, pear, grapevine, wheat, barley, potato and carrot. Three Member States had commented so far.

  The Commission presented the main issues of the EFSA technical report and invited Member States to comment by 16 April 2021.

  e) Caffeine

  The Commission summarised the findings of the EFSA technical report on the application for approval of caffeine as basic substance. The Member States were invited to submit their comments on the EFSA technical report and eligibility of an approval of caffeine as a basic substance by 26 April 2021.

- Amendment of conditions of approval

  There were no news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Dimethyl disulphide

  The Commission mentioned that the applicant had informed that it was preparing an updated dossier including additional risk mitigation measures, which is expected to be submitted to the Rapporteur Member State in the near future.

  b) Chloropicrin

  There were no news to discuss.

  c) 1,3-dichloropropene

  The Commission informed about the status of the intended submission by one Member State of a dossier for an amendment of the existing harmonised classification under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

  d) *Purpureocillium lilacinum* strain PL11

  The Commission presented the EFSA Conclusion and the opposing views from the Rapporteur Member State (RMS). The applicant had provided comments opposing EFSA's conclusions and supporting the views of the RMS.

  The peer review did not identify critical area of concern, but there were several issues that could not be finalised due to data gaps, which are linked to the production, nature and behaviour of leucinostatin A after application for the representative uses by drip irrigation. The Commission explained that it is inclined to follow the RMS's point of view.

  Member States were invited to send their comments by 26 April 2021.

- Renewal of approval

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

The Commission indicated that the review of the EFSA Conclusions is still on-going and that no documents had yet been shared with Member States. The EFSA Conclusions indicate that *Metarhizium brunneum* should be regarded as one strain because of similarity of the biological and genetic properties of the two isolates BIPESCO 5 and F52, and the different products in the representative uses contain each a different isolate. Some issues not finalised in the EFSA Conclusion are related to the F52 isolate but not to BIPESCO 5.

f) Captan

The Commission summarised the comments from Member States received on the draft review report (in view of a renewal of approval restricted to greenhouses), some of which were calling for a review of the approach suggested. The Commission also referred to the applicants' position papers, according which safe in-field use seems to be possible. More precisely, the applicant considers that there is a safe use scenario for wild mammals. Furthermore, for the same use a few scenarios with specific zonal Risk Mitigation Measures or refinement with different focal species lead to safe use for aquatic organisms. Furthermore, although EFSA could not conclude on the point, the Rapporteur Member State stated that considering the degradation time of captan in plant materials and the effects observed in the laboratory studies, the risk should be considered as low for non-target arthropods. The Commission indicated that it will reflect on the possibility to include in-field uses under the described conditions and invited Member States to comment by 16 April 2021.

g) *Purpureocillium lilacinum* strain 251

The Commission mentioned that several Member States commented on the draft renewal report for *Purpureocilium lilacinum* strain 251. The Commission emphasised that the sensitising potential of a microorganism leading to the default precautionary sentence on the wearing of personal protective equipment (PPE) does not constitute a criteria for non eligibility to the low-risk status for an active substance, and that this approach has been applied for several years in this committee for the approval of micro-organisms active substance as low-risk. However, *Purpureocillium lilacinum* strain 251 seemed not eligible to the low-risk status due to the lack of study on the sensitivity to anti microbials. Although in the case of fungi the transfer of genes is multi factorial and thus considered unlikely, information regarding the antimicrobial susceptibility of fungi is needed to demonstrate that there are sufficient treatment options in case infections with the fungal microorganism may occur.

A revised renewal report was made available and Member States were invited to comment by 26 April 2021.

h) Flumioxazin

Discussion on this point was postponed. The Commission informed that information submitted by the applicant is available to Member States.

i) Cypermethrin

The Commission shared with the Member States a revised version of the draft specific provisions to be included in the renewal regulation and the draft review report, the comments received from three Member States and a letter from EPPA on behalf of the applicant together with the reply of the Commission.

The Commission invited Member States to submit their positions and comments on the revised draft specific provisions and the revised draft renewal report by 9 April 2021 at the latest, in order to be able to complete the process for adoption of the renewal regulation before the expiry of the current approval of the active substance. The Commission noted that if a Member State would not submit a position by the deadline, the positions indicated at the January meeting would be taken into account for the next steps.

j) *Bacillus amyloliquefaciens* strain QST 713

The Commission indicated that several Member States and the applicant sent comments on the EFSA conclusions.

The Commission referred to the critical area of concern with respect to high risk to bees identified in the EFSA Conclusion. Some Member States had recommended the submission of additional studies on pollinators, however additional studies cannot be taken into account in the context of a renewal procedure. Hence, the Commission indicated it intends to explore the possibility of setting risk mitigation measures to address this concern, noting that there is also one representative use on strawberries in permanent greenhouses. The Commissin also indicated to reflect on the issue related to the potential production of metabolites.

Member States were invited to send their comments by 26 April 2021.

k) *Pseudomonas chlororaphis* strain MA342

The Commission restarted the discussion on the renewal of approval of *Pseudomonas chlororaphis* MA342 following the adoption of the EFSA statement, which confirmed the concerns identified in the earlier EFSA Conclusion. One Member State informed that it considered appropriate to propose the renewal of the approval for the uses in seed treatments for cereal and peas.

The Commission informed about a meeting with the applicant. The applicant believes that the available data are sufficient to support the renewal of approval of *Pseudomonas chlororaphis* MA342. The applicant informed about new studies being conducted which confirm the results of the studies that had been rejected by EFSA. The applicant suggested that the additional new data could be submitted as confirmatory information. The applicant also proposed to withdraw the most critical uses from their application and mentioned that as regards the genotoxic concerns, no guideline is available and, in addition, there are technical difficulties to produce the metabolite DDR (considered by EFSA to be genotoxic) in quantities sufficient for testing.

The Commission expressed the opinion that, given the concerns identified by EFSA in both the earlier Conclusion and the Statement from 2020 it would be difficult to renew the approval even for the least critical seed treatment uses. The Commission reminded that a decision on the on-going renewal process has to be taken within the legal framework and new studies cannot be taken into account in the current decision-making. In addition to concerns as regards genotoxicity of the metabolite

DDR, there is an unresolved issue related to antimicrobial resistance. Therefore, it seems that the original proposal of the Commission for non-renewal of approval is appropriate. Member States were invited to provide views and positions by 16 April 2021.

l) *Pythium oligrandum* strain M1

The Commission reported about the comments received from four Member States supporting the statement that the dossier suffers from serious data gaps, regarding metabolites of potential concern and pathogenicity/infectivity. The Commission informed about a letter from the applicant acknowledging the data gaps and its commitment to complement the dossier, which however cannot be considered at this stage of the regulatory procedure. The applicant has been informed accordingly. The Commission invited Member States to comment by 16 April 2021.

m) *Bacillus thuringiensis subsp. kurstaki* strain SA-11

The Commission summarised the comments received from the Member States, and focused the discussion on the issue concerning the dietary exposure. The Commission specified that while performing a strain-specific evaluation, it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (see point A.04.b).

Member States were invited to comment by 16 April 2021.

n) *Bacillus thuringiensis subsp. kurstaki* strain SA-12

The Commission summarised the comments received from the Member States, and focused the discussion on the issue concerning the dietary exposure. The Commission specified that while performing a strain-specific evaluation it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (see point A.04.b).

Member States were invited to comment by 16 April 2021.

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

The Commission summarised the comments received from the Member States, and focused the discussion on the issue concerning the dietary exposure. The Commission specified that while performing a strain-specific evaluation it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (see point A.04.b).

In addition, the Commission referred to one issue which could not be finalised regarding the potential interference with the analytical systems for the control of the quality of drinking water. Considering the representative use in soil bound cropping systems in permanent green house it is expected that the exposure of ground water would be limited which is the view of the Rapporteur Member State.

Member States were invited to comment by 16 April 2021.

p) *Bacillus thuringiensis subsp. aizawai* strain ABTS-1857

The Commission summarised the comments received from the Member States, and focused the discussion on the issue concerning the dietary exposure. The

Commission specified that while performing a strain-specific evaluation it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (see point A.04.b).

In addition comments have been received from the applicant, which also indicated its intent to request correction of the EFSA conclusion with respect to the amount of CRY proteins /ha and the value of PEC in soil for CRY proteins.

Member States were invited to comment by 16 April 2021.

q) *Bacillus thuringiensis subsp. aizawai* strain GC-91

The Commission summarised the comments received from the Member States and the applicant, which are similar as for the other *B. thuringiensis* strains, and focused the discussion on the issue concerning the dietary exposure. The Commission specified that while performing a strain-specific evaluation it is important to employ a consistent approach for all the *B. thuringiensis* strains under evaluation. The discussion on this point was then held horizontally (see point A.04.b).

Member States were invited to comment by 16 April 2021.

- Basic substances

r) Whey (extension of use) (amended review report to take note)

The Commission informed that it had received a request from one Member State for evaluating and adding the use of whey for the disinfection of glove tips and mechanical cuttings tools (against viruses). EFSA had confirmed that this use is acceptable, and therefore this use was added to the extension under discussion. In addition, a paragraph was added to the review report concerning the risk of exposure of residents or bystanders to milk-proteins from the outdoor use of whey for plant protection purposes.

The amended review report was endorsed by the Committee and will be published in the pesticides database https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances.

s) Calcium hydroxide (extension of use) (amended review report to take note)

The Committee endorsed the amended review report documenting the non-approval of the extension of use of calcium hydroxide. The amended review report will be published in the pesticides database https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances.

The Commission also informed that one Member State had requested a review of the original approval of calcium hydroxide as a basic substance. In accordance with Article 23 (6) of Regulation (EC) No 1107/2009, the applicant, EFSA and Member States have to be consulted. The way forward will then be decided based on the outcome of this consultation. Member States were invited to submit their views on such a review of the original approval of calcium hydroxide as a basic substance by 26 April 2021.

t) *Equisetum arvense* (extension of use)

The Commission informed that the applicant had sent a reply with information and that also ITAB replied with an amended application in response to the letter from the Commission of December 2020. This information had been sent to EFSA to

verify whether the information provided would fill the identified data gaps. Member States were invited to comment by 16 April 2021.

u) Chitosan hydrochloride (extension of use and origin)

The Commission informed that an application concerning chitosan from fungus *Aspergillus niger* should not be considered as an extension of use of the existing approval but be considered as an application for an approval of a new basic substance with specific CAS number, different source and specification. One Member State supported this approach.

The Commission informed on a meeting with the applicant. The applicant had explained that chitosan can be prepared for use in plant protection by simple dissolution in water. Addition of acid increases solubility and facilitates handling, but is not indispensable for the substance to be useful in plant protection. The applicant had provided a modified recipe for the preparation of the substance for use in this way. Nevertheless, in case of an approval of chitosan as a basic substance, a second recipe for the preparation for use could be included in the appendix of the review report, which would include addition of the basic substance vinegar as a pH regulator so that the derogation from the authorisation requirement in accordance with Art 28 of Regulation (EU) 1107/2009 would apply.

The applicant also provided additional information as regards the notified hazard classification of chitosan (as skin and respiratory irritant). The classification was notified to ECHA's classification and labelling inventory by only five companies, out of precaution, whereas no need for classification was declared by more than 50 other notifiers. The applicant further provided data to demonstrate non-toxicity of chitosan. A recommendation for use of basic personal protective equipment in the SDS of chitosan reflects the potential hazard related to handling of any powder and is not specific to chitosan.

The applicant provided also data to support the environmental risk assessment. These include data on background natural levels of chitosan in the environment, levels resulting from other authorised uses and information on bio-degradability of the substance.

The Commission informed about its intention to correct an error in the current approval of chitosan hydrochloride (the CAS No listed in the regulation does not correspond to the name of the approved active substance).

Member States were invited to provide by 26 April 2021 (a) comments on approval of chitosan from fungus *Aspergillus niger* as a new basic substance; (b) comments on the preparations for use to be included in the Appendix to the review report in the case of an approval, i.e. 2 recipes for preparation for use (with water only, with water and addition of vinegar (approved basic substance) as pH regulator).

v) Sodium hypochlorite

The Commission presented the EFSA technical report and the main issues identified.

Sodium hypochlorite is intended 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 in field and in greenhouses.

According to the information in the EFSA Technical Report the content of sodium hypochlorite in the solution used as basic substance is higher than 10% and therefore the criteria for classification and labelling of the mixture as causing severe skin burns and eye damage are met. Sodium hypochlorite is therefore a substance of concern as defined in Art. 3(4) of Regulation 1107/2009.

Additionally, non-dietary exposure estimates were missing in the application and therefore a non-dietary risk assessment could not be conducted.

With regard to residues in food and feed, chlorate should be considered one of the residue components in food resulting from the use of sodium hypochlorite for plant protection purposes. As previously assessed by EFSA, chronic dietary exposure to chlorate is of potential concern. In particular for the use on mushrooms, there is a need for further assessment with respect to potential residues of chlorate.

Therefore, based on the available information, sodium hypochlorite does not satisfy the approval criteria for basic substances with regard to the requirements that the substance is not a substance of concern and has neither an immediate or delayed harmful effect on human health. Sodium hypochlorite should therefore not be approved as a basic substance.

The Commission had received comments from four Member States. Three Member States could support provisionally the proposal for non-approval of the Commission. One Member State would be in favour of an approval for seed treatment with the proposed limitations.

Member States were invited to comment by 16 April 2021.

w) Dimethyl sulphide

The Commission presented the EFSA technical report and the main identified issues.

Dimethyl sulphide is intended 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.

The EFSA Technical Report indicates that the available information on dimethyl sulphide had not been properly assessed or considered by the applicant. In particular, the application lacked a proper literature review, it did not consider information that is publicly available on the ECHA website, previous assessments made by EFSA as well as the assessment of the similar substance, dimethyl disulphide as a plant protection product.

The available published information indicates that dimethyl sulphide is an irritant to skin, eyes and the respiratory tract and a skin sensitizer.

Details on acute toxicity, irritation, skin sensitisation and short-term inhalation are publicly available on the ECHA website and they should have been integrated in the application to have a complete overview of the basic substance. Toxicological data on 2 metabolites are also publicly available on the ECHA website, but have not been properly integrated in the dossier.

A scientific justification for the absence of long-term toxicity and carcinogenicity concerns, considering the overall toxicity profile of the substance, had not been provided.

Even though residues in crops are expected to be low due to the type of application, further data should have been provided to show that there is no concern for consumers via dietary intake.

As regards the effects on non-target arthropods, EFSA concluded that the information provided indicates that some species may be affected by the proposed use in traps and that further data are necessary to demonstrate a low risk.

In summary, the available information is insufficient to demonstrate that the approval criteria for basic substances are met and dimethyl sulphide should therefore not be approved.

The Commission had received comments from four Member States, whocould all support provisionally the proposal for non-approval. Member States were invited to comment by 16 April 2021.

- Amendment of conditions of approval

  There were no news to discuss.

A.06 Confirmatory Information:

1. Meptyldinocap (amended review report to take note)

   The Commission recalled that an updated review report proposing to close the confirmatory information point concerning groundwater, based on the EFSA Technical Report, had already been made available for the meeting of this Committee in January 2021. One Member State had provided comments and the text was amended to take them into account.

   The Committee endorsed the amended Review Report – one Member State noted that it had voted against the approval of meptydinocap.

2. *Bacillus pumilus* QST 2808 (amended review report to take note)

   The Commission mentioned that several Member States sent comments, all supporting the outcome of the peer review indicating that the data requirements with respect to aminosugars had been addressed. The Committee endorsed the amended review report.

3. Metobromuron (amended review report to take note)

   The Commission summarised the amended parts in the review report and recalled that the confirmatory information had been timely received and solved all the open issues except the long-term risk for birds in the Northern zone to which the Member States should keep paying attention to, as stated in the review report. The Committee endorsed the amended review report.

4. Mandestrobin (amended review report to take note)

   The Commission explained that the review report had been amended to include the technical specification of the active substance as commercially manufactured, increasing the minimum purity, maintaining the limit for the main impurity and confirming that the batches used for (eco)tox testing are representative of the new proposed specification. Comments received from two Member States had also been incorporated. The Committee endorsed the amended review report.

The Commission informed that the approval of mandestrobin as enacted by Commission Implementing Regulation (EU) 2015/2085 of 18 November 2015 will be amended accordingly to incorporate the new reference specification.

5. Fluxapyroxad (amended review report to take note)

   The Commission explained that the reference specification in the review report as established at the time of first approval had been updated based on data from large scale production, the minimum purity from the new source is higher than in the reference source and maximum limits of impurities in the new source are either the same or lower than those in the reference source. No new impurities had been found. The level of the relevant impurity in the new source is lower than the maximum specified limit of the original specification. The Committee endorsed the amended review report.

   The Commission informed that the approval of fluxapyroxad as enacted by Commission Implementing Regulation (EU) No 589/2012 of 4 July 2012 will be amended accordingly to incorporate the updated reference specification.

6. Flupyradifurone (amended review report to take note)

   One Member State raised reservations to the amendments of the review report. In their view, the toxicological relevance of the impurities in comparison with the toxicity profile of the parent compound was considered “not addressed” by EFSA in the report on the outcome of the consultation on confirmatory data. Therefore, this part of the confirmatory data needs to be addressed in the review report.

   Member States were invited to comment on the current amended review report by 26 April 2021.

7. Oxathiapiprolin (amended review report to take note)

   The Commission explained that the review report had been amended to include the technical specification of the active substance based on the industrial production, maintaining the minimum purity, maintaining the observed levels of the remaining impurities within the specification generated by the pilot plant production and confirming that the batches used for (eco)tox testing are representative of the new proposed specification. Comments received from two Member States had also been considered in the amended review report. The Committee endorsed the amended review report.

8. Terpenoid blend QRD 460 (amended review report to take note)

   The Commission explained that the review report had been amended to include the technical specification of the active substance as commercially manufactured leading to slight variation of the minimum purity of each of the three main components. Any probable impurity was considered to be of no concern, due to its expected ubiquity in foodstuffs. It had also been confirmed that the batches used for the toxicological studies are representative of the new proposed specification. Comments received from one Member State had also been considered in the review report.

   The Commission thanked the Rapporteur Member State for the support provided for the amendment of the review report. The Committee endorsed the amended review report.

The Commission also informed that the approval of terpenoid blend QRD 460 as enacted by Commission Implementing Regulation (EU) 2015/1192 of 20 July 2015 will be amended accordingly to incorporate the new reference specification.

9. Tri-allate

The Commission recalled that it was awaiting confirmation from the Rapporteur Member State on the ongoing evaluation of the genotoxicity studies submitted as part of the renewal, to determine if there would be any need to act outside of the already initiated renewal process, based on the concern identified by EFSA in its recent Conclusion in the context of the assessment of confirmatory information.

The Rapporteur Member State informed that it had evaluated new studies submitted by the applicant and that in its view tri-allate is unlikely to be genotoxic, highlighting that its view would be subject to confirmation during the peer-review.

The Commission explained that although other issues were identified by EFSA after the assessment of confirmatory information which were however not directly linked to the confirmatory information (leaching of metabolites into groundwater and exposure to metabolites), given the issues would likely need further assessment in any case and that the applicant submitted more data on those aspects in its renewal dossier, it would be more proportionate and efficient to wait for the outcome of the renewal assessment, avoiding also parallel regulatory processes.

The Committee concluded that since the concern about genotoxicity seemed to be addressed, the renewal should continue and determine if the approval of tri-allate can be renewed, or not.

10. Isopyrazam

At the meeting of this Committee in January 2021, the Commission had provided a summary of the outcome of the assessment of confirmatory information, taking into account the recent opinion of the Risk Assessment committee (RAC) of the European Chemicals Agency as to the classification of the substance (toxic to reproduction, Cat. 1B and carcinogen, Cat. 2).

Following further analysis of the available information, the Commission explained that it considered that isopyrazam no longer satisfies the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009 with regards to points 3.10 and 3.6.4 of Annex II. Therefore, the Commission had sent a letter to the applicant informing about its intention to withdraw the approval of isopyrazam in accordance with Article 21 of Regulation (EC) No 1107/2009 and inviteing the applicant to provide comments and any relevant information by 31 May 2021.

Member States were invited to provide their comments, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, taking into account the situation as outlined in the letter sent to the applicant by 24 June 2021.

11. Spiroxamine

The Commission indicted that it has not received any comments on the EFSA Conclusion on confirmatory data presented during the previous meeting of this committee. The applicant commented on the proposed grouping of metabolites and also on the risk assessment for fish disputing that hatching success was not fully covered in the studies provided.

As regards the risk to aquatic organisms, the EFSA Concluions noted that the potential endocrine disrupting effects of Spiroxamine should be further investigated, however recognised that this was not part of the confirmatory data. The Commission noted that the submission of the dossier for renewal is expected by 31 March 2021 and that the assessement of these properties would be fully covered during the renewal process.

Member States are invited to send comments by 26 April 2021.

12. Dithianon

The Commission informed that it had been further exploring with EFSA the suitability of the Threshold of Toxicological Concern (TTC) approach to assess metabolite residues of dithianon. The TTC approach should not be used for substances for which EU food/feed legislation requires the submission of toxicity data, such as for dithianon. Furthermore, for the application of the TTC approach all sources of exposure to the same metabolite should be considered for a reliable consumer risk assessment, and a proper literature review and a proper assessment of the available data should be performed.

Considering the above, taking into account also that the storage stability data on residues of dithianon in grapes were not provided and that this is still a data gap, and considering that an acute intake concern had already been identified for table grapes and according to EFSA_PRIMo_rev.3.1 Model, a chronic intake concern was identified for the representative uses on pome fruit and table and wine grapes (IEDI: 109% acceptable daily intake (ADI) (NL toddler)) whilst an acute intake concern was confirmed for table grapes (IESTI: 165% ARfD) and was further identified for pears (IESTI: 118% ARfD).

Member States were invited to comment on their preferred way forward by 26 April 2021.

13. Penflufen

The Commission informed that, according to Article 21 of Regulation (EC) No. 1107/2009, a review of the approval of the active substance has been initiated, since the confirmatory information required in the approval of penflufen in accordance with Article 6(f) of that Regulation on potatoes has not been provided. The Commission had sent a letter to the applicant setting a period to submit comments. The applicant had agreed with the Commission's intention to restricted the approval of the active substance penflufen to uses for seed treatment and in order to exclude use on other propagating materials and its planting. Hence, only uses to treat seeds before or during sowing may be authorised, limited to one application every third year on the same field.

Member States were invited to submit their comments by 26 April 2021.

14. Gamma cyhalothrin

The Commission informed that EFSA had published a Statement the day before the meeting, and shared comments from the applicant. Member States were invited to comment by 26 April 2021.

A.07 Guidance Documents:

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

   The Commission informed about the meeting held with Member States on 23 February 2021, which had been organised to seek agreement on a specific protection goal for honeybees in terms of colony size reduction. EFSA had presented the outcome of its simulations of the natural variability of honeybee colony size development and information on the set-up of field studies that would be required to be able to reliably measure a given reduction in colony size.

   A total of 23 Member States had participated at that meeting and all agreed that the results of EFSA's simulations of the natural variability of honeybee colony size were more conservative than the variability observed in nature (i.e. the simulated variability is smaller than what has been observed in field studies for honey-bee colonies not exposed to pesticides). Therefore, they agreed that setting a threshold for an acceptable reduction in honey-bee colony size due to pesticides within this simulated range would offer sufficient protection. They also agreed to take account of the practicalities of field studies, as otherwise it would not be possible to actually measure whether or not the protection goal had been achieved.

   As to the actual specific protection goal, four Member States had considered that accepting a colony size reduction covering the full simulated natural variability (i.e. up to 23%) would offer sufficient protection. Eleven Member States suggested a protection goal within a range of 10% to 12.8% of colony size reduction. Four Member States indicated a preference for maintaining the same level of acceptable colony size reduction as in the 2013 EFSA Guidance Document (7%), referring also to political considerations. Four Member States did not express any preference on the acceptable level of colony size reduction and some of them had asked the Commission to make a proposal for a protection goal.

   After the summary of the Commission, all Member States who had participated at the meeting in February confirmed the same positions and those not having participated did not have any position.

   The Commission informed that on 15 March, the Chair of the Committee on the Environment, Public Health and Food Safety of the European Parliament had sent a letter reiterating the ENVI Committee's support for the 7% protection goal and calling for the issue to be taken up at political level.

   The Commission was therefore reflecting on whether to approach the Portuguese Presidency to request a discussion on this matter at a forthcoming meeting of the AGRIFISH Council. Several Member States indicated that they would welcome such a discussion in the Council and some renewed their call on the Commission to make a proposal for a specific protection goal.

2. 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 discuss.

3. 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 and shared a document on some general suggestions with regards of the revision of the Communications. Member States were invited to comment by 26 April 2021.

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

   The Commission provided an update on further comments submitted by Member States since the last meeting of this Committee. In general Member States appreciate the efforts to finalise the draft guidance document as this will ensure further harmonisation in the risk assessment process as well as in the decision-making process for the (renewal of) approval of active substances. The Commission informed that it would reflect on the comments received in view of determining the way forward on the guidance.

5. 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

   The Commission informed that the updated EFSA Administrative Guidance, expanded to also include information on MRL application procedures, had been endorsed by Member States during the meeting of the Section Phythopharmaceuticals - Pesticide Residues of this Committee held in February 2021 and that the document had been published by EFSA. The cover page setting out the implementation of the guidance had been made available in the relevant sections on the Commission's pesticides website.

6. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (follow up discussion)

   The Commission informed that the Member State preparing the instructions for regulators had found an error in one of the workable examples in the guidance document, and proposed to amend the document accordingly. As a consequence, an amended version of the document and the cover page is expected to be proposed for endorsement at the next meeting of this Committee.

7. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 rev.9) (for information)

   The Commission informed about the comments received since the last meeting of this Committee and provided a summary table and an updated version of the guidance document. Some open issues had already been debated in the Post Approval Issues Working Group of this Committee at its meeting in November 2020. In parallel, an amendment of the Guidance Document on rules for revision of assessment reports, SANCO/10180/2013– rev. 1 March 2013, will be considered. Member States were invited to submit comments by 26 April 2021.

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

- Terms of Reference (to take note)

The Commission informed that an online information session had taken place on 5 February 2021 with the participation of 84 experts (from stakeholders, Member States, EFSA, and the Commission services) and the work on the working document on pesticide use scenarios had continued in two meetings of the Working Group of this Committee created for this topic. The endorsement of the Terms of Reference of the Working Group was postponed due to late comments received from one Member State. Additional comments were requested by 26 April 2021.

The Commission also informed that Sweden had submitted a report published by the Swedish Chemicals Agency "Methods for assessing the effects of plant protection products on biodiversity".

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

The Commission informed about a project (weeding robot) and two guidance documents developed in one EEA country and encouraged Member States to continue reporting about their initiatives regarding risk mitigation measures or new risk reduction technologies.

The Commission informed about an upcoming e-learning training module under development with the new executive Agency HADEA (formerly CHAFEA) regarding risk mitigation measures.

The Commission referred as well to a scientific review provided by EFFAT **(**European Federation for Food, Agriculture and Tourism Trade Unions) covering 70 studies (published from 1986 to 2016) regarding the effectiveness of personal protective equipment and difficulties when using such equipment (e.g. discomfort, heat, stress, cost and appearance). The document had been made available via CIRCA-BC.

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

- Article 44(4)

  No notifications received.

- Article 36(3)

  The Committee took note of 15 notifications. 11 notifications concerned rejections of mutual recognition applications, one from a Member State belonging to a different zone, and 3 concerned rejections of authorisation under the zonal system.

- Article 53

  The Commission informed that since mid-February several additional notifications concerning emergency authorisations for clothianidin, imidacloprid or thiametoxam on sugar beet had been received. Several from Member States which had already granted such authorisations in earlier years, however also two Member States had notified emergency authorisations for thiamethoxam. The Commission informed that it intends to update the mandate sent to EFSA to verify the justification of the emergency authorisations, in order to cover also these new notifications.

- Article 69

  The Commission informed that a mandate had been sent to EFSA following the notifications received from France under Article 69 of Regulation (EC) No 1107/2009.

- Article 71

  The Commission informed that the issues raised under this current notification are covered by the mandate to EFSA mentnioned in the previous point.

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

EFSA informed about the upcoming Conclusions (Carbon Dioxide, Meribuzin, Aluminim ammonium sulphate, Potassium hydrogen carbonate, Benthiavalicarb and Diflufenican) and their planning for the next months for expert meetings. EFSA informed that the next meeting of the Pesticides Steering Network is planned for the 29 of March, and reminded of the new procedures which start of 27 of March, for which supporting information and guidance is availabe. EFSA also informed that the draft updated exposure guidance document is currently under public consultation.

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

The Commission informed that, together with EFSA, they have started reflections on how to improve the format of the EFSA Conclusions for microorganisms and the process for the assessments of basic substances.

A.13 Microorganism Active Substances, in particular:

- update on data requirements
- update on uniform principles and Annex II
- Commission Communications in the framework of the implementation of the data requirements

The Commission recalled that it had already presented first draft texts for amending Commission Regulations (EU) No 283/2013 and 284/2013 to update the data requirements for micro-organisms in the meeting of this Committee in December 2020, and first drafts for updating the relevant uniform principles in Commission Regulation (EU) 546/2011 and the approval criteria in Annex II to Regulation (EC) 1107/2009 in the meeting of this Committee in January 2021. The Commission informed about the feedback received from the Member States on these four drafts and presented updated versions based on these comments.

The Commission also presented two drafts texts for updating the Commission Communications for purposes of information, harmonisation, and listing test methods and guidance documents relevant to the implementation of the Regulation (EU) No 283/2013, and the Regulation (EU) No 284/2013 as regards micro-organisms. The Commission asked Member States to indicate further existing test methods and guidance documents they would consider appropriate to introduce in the updte of these Communications.

Member States were invited to comment on all documents by 26 April 2021.

A.14 Safeners and Synergists.

There were no news to discuss.

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

1. Pirimicarb

This point was postponed.

A.16 General issues for information / discussion:

1. Brexit

   The Commission informed that the notice to stakeholders of 25 May 2020 was still valid. For the exchange of information between EU Member States and the United Kingdom necessary for the implementation of the EU pesticide acquis with respect to Northern Ireland, notably in the area of authorisations, a specific CIRCA BC platform had been made available. Operational guidance on the use of that platform was under development. The Post Approval Issues Working Group of this Committee had received information in that regard.

2. Illegal plant protection product use

   The Commission informed that only eight Member States had replied to the request to inform about the implementation of Article 72 of Regulation (EC) No 1107/2009. Three more Member States indicated during the meeting that they had already sent comments. Member States were invited again to provide the requested information by 26 April 2021. The Commission informed that it intends to give an overview when all Member States had provided the requested information.

   One Member State gave a presentation on the most common cases of illicit trade and use of plant protection products in their territory. It seems that in several cases the detected illegal products had been manufactured under the derogation of Article 28(2)d) of Regulation (EC) No 1107/2009 in other Member States but instead of being exported, they had ended up on the EU market. One Member State wondered if the illegal products detected were destined for sale or directly for end-use. The Member Stated which provided the presentation informed that some cases were for end-use, but that there were also cases destined for sale.

   Another Member State expressed the view that illicit imports are very difficult to detect. The Commission remarked that the imports of illegal pesticides from third-countries shall be distinguished from the illegal marketing of plant protection products produced under the derogation of Article 28(2)d). The Commission invited this Member States to submit information as regards what measures are put in place at national level in order to comply with Article 28(2)d) in order to ensure that the plant protection products leave the territory of the Member State of production/storage and if there are any measures taken to ensure that they leave also the territory of the EU.

   The Commission informed about a question from another Member State concerning the possibility to the import of plant protection products containing non-approved active substances from a third country, to transfer them to another Member State for repackaging and storage and then to export them to a third-country. The Commission considered that in this case Article 28(2)d cannot be applied as it must

be interpreted restrictively. The Commission informed that the letter with the answer to the question is available on Circa BC.

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

   The Commission informed about a statement from one Member State (shared on CIRCA-BC) challenging that products containing nitrophenolates are falling in the scope of Regulation (EC) No 1107/2009 as they are rather corresponding to the definition of plant biostimulants in the Fertiliser Regulation. A company originating from the same Member State had requested a similar interpretation concerning a group of nitrophenols substances, similar to the nitrophenolates under discussion.

   The Rapporteur Member State informed that they were currently reviewing the data submitted by the applicant in the context of the application for the renewal of approval of nitrophenolates as active substances and will inform this Committee as soon as possible.

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

   a) Scope delineation with biocidal products

      The Commission informed about the comments received from three Member States regarding the document from one Member State presented at the meeting of this Committee in December 2020 about the delineation between biocidal and plant protection products.

      The Commission presented a proposal to delineate biocidal and plant protection products based on places under treatment and claimed uses, and invited Member States to comment by 16 April 2021. The Commission informed that the same proposal is currently under discussion of the Member States competent authorities for biocidal products and invited Member States to coordinate internally among all relevant authorities.

   b) Scope Document rev.60

      The Commission informed that rev.60 of the Scope Document had been commented by three Member States including the new introductory part. An amended version had been made available on CIRCA-BC and will be published on the Commission website unless Member States would have additional comments (to be submitted before 16 April 2021).

   c) New cases

      The Commission presented two new cases for interpretation:

      (1) a proteins/enzymes-based product with a claimed eliciting function activating structural responses related to ISR (Induced Systemic Resistance) and SAR (Systemic Acquired Resistance), which is proposed as falling under the plant protection product definition;

      (2) a product for the preservation of construction materials covered by Product Type 10 of the Biocidal Products Regulation when it concerns lichens and mould: in case it aims at destroying roots of plants affecting construction materials or moss growing on construction materials it is proposed to be considered as plant protection product.

      Member States were invited to comment on the two cases by 26 April 2021.

5. Basic substances – general issues

   The Commission gave an update on the general discussion on basic substances initiated at the meeting of this Committee in October 2020. So far only six Member States had submitted comments. It appeared that in many cases the views of Member States are divergent. Before concrete proposals for solution can be made, the Legal Service of the Commission needs to be consulted as regards interpretation of the legal provisions including on the approach on mixtures and sales arrangements. The Commission also informed on an on-going discussion with EFSA on the adaptation of the current evaluation procedure to the specific context of basic substances.

   Member States were invited to submit by 26 April 2021 their views on the following issues: placing on the market, labelling, advertising, sales modalities, but also technical aspects like dealing with mixtures of basic substances, interpretation of criteria for substance of concern, definition of simple diluent and substance specification/identity (dealing with plant extracts, allowed transformation steps for plant material).

6. Development of resistance in *Aspergillus fumigatus* to azoles used as medicines from use of azole fungicides

   The Commission reminded that the question about the development of forms of *Aspergillus spp.* resistant to azole-based medicinal products caused by the use of azole fungicides in the environment (in particular their use as plant protection products) had been raised as an emerging concern and had been discussed in this Committee over the past year in light of further knowledge on the subject and also concerns expressed by several Member States.

   Given the new information in this area, the Commission informed that it is preparing a mandate to be sent jointly to the relevant EU Agencies (EFSA, ECHA, EMA and ECDC) to further explore the topic in view of understanding better the risks and the possible ways of managing them, specifically in the context of regulatory decision-making for plant protection products and other non-medical settings including as biocidal products and veterinary medicinal products.

   Member States were invited to inform the Commission by 16 April 2021 about any relevant recently completed, ongoing or planned activities, in view of ensuring that all relevant information is referenced in the mandate.

   One Member State announced that it had just amended a number of authorisations of plant protection products to implement measures aimed at addressing the development of resistance in *Aspergillus fumigatus* from exposure to azole active substances and that it would provide further information to the Commission.

7. Use of groundwater monitoring data in EU regulatory pesticide risk assessment

   During the Pesticide Steering Network held in March 2020, one Member State had presented an initiative for a harmonised use of groundwater monitoring data in EU regulatory pesticide risk assessments, referring to scientific recommendations from a peer reviewed publication (Gimsing et al, 2019. Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009 – Journal of Consumer Protection and

Food Safety (2019) 14:1–93) on how to assess monitoring data based on examples of different groundwater exposure assessment options.

Several Member States had called on the Commission to mandate EFSA to organise a public consultation on this publication and to deliver an EFSA Statement considering the scientific and technical aspects of study designs and procedures as well as decision criteria for the assessment of groundwater monitoring data to be used in the EU regulatory risk assessment of pesticides. The Commission informed that it was working on a mandate to address this request.

8. Co-formulants

   This point was postponed.

9. Trifluoroacetic acid (TFA)

   The Commission recalled that during the last meeting of this Committee it had asked Member States to report any findings of trifluroacetic acid (TFA) in monitoring samples of water (groundwater /drinking water or other). This request followed information received from Bayer in early January 2021 about findings in an ongoing rabbit developmental study triggered in the context of REACH, where major and associated minor developmental findings had been observed. In addition, Bayer had informed that an extended one-generation study in rats is ongoing.

   Six Member States had provided comments to the Commission, indicating that there are multiple sources of TFA in the environment, including as metabolite from a number of pesticides, and that TFA is detected in groundwater in some Member States and in some cases drinking water, above the 0.1 µg/L limit. One Member States indicated findings above 10 µg/L in groundwater, whereas several had reported no detections.

   The Commission informed that in the meantime, Bayer had written to the Commission again, indicating that it wished to perform further vertebrate tests to show species-specific effects in rabbits, which are not relevant for humans, in order to exclude the relevance of the metabolite TFA. The Commission recalled that in accordance with Directive 2010/63/EU on the protection of animals used for scientific purposes it is the responsibility of Member States to consider whether vertebrate studies can be performed or not.

   The Commission indicated that at this stage, given that the final report of the rabbit study is not yet available, no immediate action is planned, however, this subject needs to be followed up.

   One Member States indicated that it was considering to set an appropriate threshold value for TFA in water to ensure protection of health and asked other Member States if they had set values. Member States were invited to provide comments by 26 April 2021.

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

The Commission gave a presentation updating on progress concerning the evaluation of Directive 2009/128/EC on the sustainable use of pesticides and the impact assessment being prepared in view of its planned revision. No Member State raised questions or comments.

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

There were no news to discuss.

A.19 Information on the proposal for a Regulation of the European Parliament and of the Council on statistics on agricultural input and output and repealing Regulations (EC) No 1165/2008, (EC) No 543/2009, (EC) No 1185/2009 and Council Directive 96/16/EC.

The Commission gave a presentation on 'Statistics on plant protection products: Use of administrative data - A way towards better statistics under the Regulation on statistics on agricultural input and output (SAIO)'. Five Member States asked for clarifications.

The Commission indicated that an Implementing Regulation to set details for keeping records as required by Article 67 (1) of Regulation (EC) No 1107/2009is being considered in order to increase harmonisation. The Commission clarified that according to the current thinking a representative sample of crops would be enough for statistical needs, but there could be other needs as well. The Commission clarified that under SAIO the plant protection product use statistics refer to agricultural use only. However, there could be other user needs for records covering other PPP uses (e.g. forestry, amenities). One Member State inquired about the possibility of using records resulting from checking the cross-compliance. The Commission replied that the SAIO Regulation proposal refers to the collection of records kept under Article 67 of Regulation (EC) No 1107/2009. One Member State referred to their new system requiring the farmers to report the use of PPPs in electronic format as of beginning of 2022.

A.20 Report from Working Groups, in particular:

1. Working Group on Biopesticides

   In addition to the activities reported under agenda point A.13 the Commission reported about the ongoing discussion concerning the suggested horizontal review of species (or sub-species and strains). The presentation given at the Biopesticides Working Group of this Committee on 9 March 2021 had been shared via CIRCA-BC. The Commission will continue to consult and reflect on appropriate mandate(s) to EFSA aiming at accelerating the review process for micro-organism dossiers.

2. Working Group on Seed Treatments

   There were no news to discuss.

3. Working Group Post Approval Issues

   The Commission informed about the outcome of discussions in the last meeting of the Post Approval Issues Working Group of this Committee held on 11 and 12 March 2021.

A.21 Minor Uses.

There were no news to discuss.

A.22 Court cases.

The Commission informed about the ruling of 4 March 2021 of the Court of Justice in Case C-912/19 –Agrimotion S.A. v ADAMA Deutschland GmbH, a judgment upon referral for preliminary ruling from a national Court. The Court provided an

interpretation on Article 52 of Regulation (EC) No 1107/2009, regarding the possibility of a company to introduce plant protection products on the market of a Member State on the basis of a parallel trade permit granted to another company. The Court clarified that only the holder of a parallel trade permit may place a plant protection product on the market of the Member State that has granted the permit.

The Commission informed about the judgment of the General Court of 17 March 2021 in case T-719/17, FMC Corporation vs European Commission. The Court had dismissed the application for annulment of Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl).

The Commission informed that the Belgian Conseil d'Etat has referred questions for a preliminary ruling concerning the interpretation of Article 53 of Regulation (EC) No 1107/2009 to the Court of Justice, in the context of a case brought by Pesticides Action Network and others against emergency authorisations involving the treatment of seeds with neonicotinoids, the placing on the market of the treated seeds and their use.

A.23 Ombudsman cases.

The Commission informed about the decision of the European Ombudsman in case 268/2021/VS. The Ombudsman found no maladministration by the Commission in a renewal procedure by refusing an applicant's requests to mandate the European Food Safety Authority (EFSA) to evaluate a population modelling report and to take into account a study, which the applicant had brought to the Commission's attention outside the time limits provided under Implementing Regulation 844/2012.

A.24 Exchange of information from the Pesticide Residues section of the Committee, in particular:

– possible impact on authorisations

The Commission gave an update on the ongoing activity to develop a process for managing changes to the residue definition for risk assessment (RD-RA), which concerns both, the Sections Phythopharmaceuticals - Legislation and the Section Phythopharmaceuticals - Pesticide Residues of this Committee.

In the meeting of the Section Phythopharmaceuticals - Pesticide Residues in February 2021, the Commission had provided a detailed analysis of the comments received form Member States, and put forward a revised proposal. The Commission explained that:

- There is consensus about the benefits of listing the RD-RA in the Review/Renewal Report for active substances typically to be done at the end of a process (e.g. approval, amendment of approval conditions, renewal, confirmatory information). However, in some cases the RD-RA would be amended due to the need arising from an MRL or authorisation process.
- In all cases, given the importance of the RD-RA, a peer review will be carried out and the decision to amend a RD-RA will be based on an EFSA output.
- The default position is to accept the RD-RA proposed by EFSA. However, Member States should inform the Commission if there are any issues to be considered for decision making and the comments should be sent to the Section Legislation of this Committee, but relevant discussions could be also held in the context of the Section Pesticides Residues of this Committee.

- The change to the RD-RA will be endorsed by the Section Phythopharmaceuticals - Legislation of this Committee

The Commission mentioned that two aspects remained open; when a revised RD-RA would apply and managing provisional definitions. Member States were invited to comment by 9 April 2021.

A.25 OECD and EPPO activities.

The Commission informed about various ongoing activities of the OECD:

- Biopesticides conference (2022):
- Seminar on efficacy of biopesticides (June 2021): reminder of the call for speakers from the EU .
- Pesticide residues in honey (2 meetings took place in February and March 2021).
- Test Guideline on Crop Field Trial to be adopted soon.
- Drone Expert Group (2 meetings took place in February and March 2021).
- RNAi technique: initiating a guidance document regarding issues of this technique regarding Human Health Risk Assessment (need to identify experts)
- Expert Group on the Electronic Exchange of Pesticides Data (EGEEPD): meeting planned on 4 and 5 May 2021 where draft IUCLID Customisation Document and many IUCLID related tools developed in the EU will be discussed.

A.26 Scientific publications and information submitted by stakeholders.

The Commission informed that letters from the stakeholder associations International Biocontrol Manufacturers' Association (IBMA), CropLife Europe (CLE), and the European Federation for Food, Agriculture and Tourism Trade Unions (EFFAT) had been made available to this Committee via CIRCA BC.

A.27 Date of next meeting(s).

The Commission confirmed that the next meeting will take place virtually on 19 and 20 May 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 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine (Draft Updated Review Report SANCO/11337/2011, Rev. 3 dated March 2021).

The Commission introduced the draft updated Review Report and the draft Regulation tabled for a vote and indicated that the notification process under the WTO-TBT agreement had ended on 23 March 2021. The Commission referred to the Member States who had already indicated previously that they would not vote in favour of the draft Regulation.

During the meeting one additional Member State indicated that it would vote against the draft Regulation since it did not consider that a safe use had been demonstrated with respect to groundwater (leaching of metabolites into groundwater).

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

Outcome of vote by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey) 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 introduced the draft Review Report and draft Regulation tabled for a vote. The Committee agreed to vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of vote by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the low risk active substance *Streptomyces* strain K61 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 Rev. 0)..

The Commission introduced the draft Review Report and draft Regulation tabled for a vote. Five Member States expressed concerns - two of them found the dossier to fragmentary and three of them had doubts about the low-risk status. The draft Regulation and Renewal Report were amended in the light of the discussion and all the references to “low risk” were removed.

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

Outcome of vote by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on the approval of the new active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 as low risk substances 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 (SANTE/10078/2021 Rev. 1).

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

Few Member States mentioned a that outdoor uses were not assessed, as the representative uses are in permanent greenhouses, and advocated to restrict the use to permanent greenhouses. The Commission informed that the applicant indicated no intention to apply for outdoor use and also recalled that the EFSA Conclusion had not identified any concern or issue that that could not be finalised that would justify such a restriction. In addition, such a restriction would contradict the low risk status. However, to accommodate the comments, the Commission amended the review report, section 6, to consider appropriate measures, in case applications for authorisation for outdoor uses are submitted.

Due to these amendments to the draft Review Report and draft Regulation presented for discussion, the Committee agreed on an additional commenting round in writing after the meeting of this Committee followed by a vote in written procedure (provided there is indication of qualified majority). This separate written procedure vote was launched 22 April 2021 in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Outcome of vote by written procedure: Favourable opinion.

The Netherlands submitted the following statement:

The Netherlands prefers an approval of this substance as low-risk substance with restriction to uses in permanent greenhouses only because of the absence of data on outdoor uses and for purposes of consistency with previous decisions on mild isolates of Pepino Mosaic virus. We note that the Commission has instead included particular points of attention to MS in the review report. Although this is not our preference, we consider this sufficient to be able to vote in favour.

B.05 Exchange of views and possible opinion 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 540/2011 (Draft Review Report Rev. 3 SANTE/12060/2020).

The Commission presented the draft Review Report, the draft Regulation, and comments received from two Member States. The draft Review Report had been revised at the request of some Member States and a paragraph on the importance of zonal coordination for the evaluation of the new data on the metabolite CCIM had been added. All Member States expressed support for the renewal.

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

Outcome of vote by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion 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 presented the draft Regulation, the comments from two Member States and further correspondence between the Commission and a law firm Acting on

behalf of a producer being interested in alpha-cypermethrin, requesting in particular longer grace periods for placing on the market and use of stocks. Member States agreed to longer grace periods and the draft Regulation was revised accordingly.

The Commission informed that comments from a third country had been received after the end of the notification procedure under the WTO-TBT agreement, to which the Commission will answer it in due time.

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

Outcome of vote by written procedure: Favourable opinion.

B.07 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 aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cyazofamid, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distilation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils / rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea.

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

The draft Regulation was revised during the meeting removing the active substance cyazofamid, as the Committee had agreed to vote on its renewal via written procedure.

One Member State opposed the extension of the approval of dimethomorf and flurochloridone, since there are already opinions of ECHA's Risk Assessment Committee available since 2017 for both substances recommending to classify them as toxic to reproduction category 1B. Another Member State disagreed in general with the extension of the approval periods in batches and in this case, specifically the extension of approval for bifenazate, famoxadone and phosmet. A third Member State did not agree with the extension of the approval of benthiavalicarb and dimethomorf, because they fulfil the cut-off criteria. Two Member States expressed their intention to vote in favour because the draft Regulation covered a package of substances, but found the extension of dimetomorf, flurochloridone and formetanate controversial and highlighted the risk of resistances that azoles can pose, such as tebuconazole. Another Member State considered that the line for Fatty Acids should be amended accordingly in Commission Implementing Regulation (EU) No 540/2011 to reflect that no applications for renewal of approval for some of the acids had not been submitted.

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

Outcome of vote by written procedure: Favourable opinion.

The Netherlands submitted the following statement:

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

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

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 approval periods of the active substances *Adoxophyes orana granulovirus* strain BV-0001 and flutriafol.

The Commission recalled that for the active substances *Adoxophyes orana* granulovirus and flutriafol, earlier applications for renewal have been withdrawn and applicants had informed that no supplementary dossiers will be submitted by the specified deadline. Therefore, it is appropriate to retract the extensions granted to the respective original expiry dates.

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

Outcome of 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) 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).

The Commission informed that, following previous discussions in this Committee, it intended to send a mandate to EFSA to clarify the open ecotoxicological issues and to consider potential risk mitigation measures. The Commission will inform the Member States of the time needed to implement this mandate at the next meeting of this Committee. One Member State restated its support for the current proposal not to renew the approval and a second one expressed its intention to change its position from abstention to in favour.

C.02 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 recalled the situation at the last meeting of this Committee and indicated that internal discussion are still on-going as regards how to further proceed. The applicant had submitted new scientific information which had been made available via CIRCA BC under A.26. One Member State asked if this new information would be considered and the Commission reiterated that internal discussion is still ongoing.

C.03 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).

No draft documents were shared with Member States, as the review report needs to be updated. The Commission indicated that several Member States commented on the relevance of the inclusion of *Bacillus amyloliquefaciens* AH2 in Annex IV of Regulation (EC) No 396/2005, and that it received divergent comments regarding the potential formation of secondary metabolites after application and the exposure to them, some Member States claimed that based on a weight-of-evidence approach using available information no further consumer risk assessment is needed. The Commission recalled that in the case of *Bacillus amyloliquefaciens* AH2, information is available on the metabolites produced by the technical grade MPCA. The metabolites are well known, have not been identified as relevant metabolites, and their production is low. Updated documents will be prepared for the next meetings of this Committee.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Salix spp* stem extract (willow stem infusion) 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/12638/2020 – Rev. 0)

The Commission introduced the current proposal for non-approval of *Salix spp*. extract as a basic substance. Among the outstanding issues are the identity of the substance, its availability on the market for another predominant use and the resulting eligibility for approval as a basic substance. It could also not be concluded whether *Salix spp.* stem extract is not to be considered a substance of concern as required by Article 23 of Regulation (EU) 1107/2009. As regards other criteria of Article 23, the substance is not a foodstuff, and no safety assessment carried out in accordance with EU legislation is available. The proposal for non-approval is based on the potential concerns and on the insufficient information available.

The Commission informed on the additional information provided by the applicant on the concentration of components in the extract that need to be still verified and evaluated. The final decision has to take into account also the fact that the intended use of *Salix spp* stem extract is very targeted and limited in time.

One Member State stated that plant extracts should not be assessed in the same way as chemical active substances. Plant extracts may also not have any primary use as they might not be available on the market. Additionally, *Salix spp* stem extract may be considered as a biostimulant and thus out of the scope of Regulation (EC) No 1107/2009.

Member States were invited to provide comments by 26 April 2021 as regards the eligibility of of *Salix spp* stem extract for approval as a basic substance and information to address data gaps in the risk assessment (in particular as regards the concentration of components of concern of the extract).

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation approving the active substance *Beauveria bassiana* strain 203 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10296/2021).

The Commission reported that, following the last meeting of this Committee, four Member States had supported the way forward proposed, consisting in a limitation of the presence of the metabolite beauvericin (maximum content of 80 µg/kg) in the product with an approval restricted to use in ornamental palm trees.

It has been clarified that with the proposed application rate, the AOEL is not exceeded when gloves, coverall and respiratory protective equipment are worn. The risks to bees and non-target arthropods can be considered as negligible considering the absence of time overlaps between application timing and bees foraging period, as well as the very local application in the crown of the palm trees with the macrogranular product limiting exposure via dust.

A new 5-batches GLP analysis with a validated method has been required from the applicant whose explanations about the ubiquitous presence of beauvericin in cereal commodities had been made available to Member States via CIRCA-BC. The decision-making will be put on hold while awaiting the new 5-batches analysis as indicated above.

Member States were invited to comment a new draft review report and the draft Regulation by 26 April 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 phosmet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12604/2020 Rev. 3).

The Commission shared the draft Regulation, the notification form to be submitted to the WTO under the TBT agreement, the draft Review Report, the comments received from one Member State and a letter received from a law firm on behalf of the applicant. The Commission informed the Member States that the notification under the WTO TBT agreement was expected to be launched soon and that EFSA had published a sanitised version of its Conclusion on phosmet on 17 March 2021.

The Commission reacted to a comment submitted by one Member State and the applicant with regards to the safety margin to derive reference values, clarifying that the approach proposed by the applicant to set a lower safety margin (by modulating the intra and inter species factors, leading to a value less than 100) is not compatible with point 3.6.1 of Annex II to Regulation (EC) No 1107/2009 which states that a safety margin of at least 100 shall be established and that an increased margin shall be considered when the critical effect is judged of particular significance, such as the case of developmental neurotoxicity. In addition, the information cited by the applicant to justify the approach cannot be taken into account since it was not part of the renewal dossier or submitted in during the relevant periods provided for in Regulation (EU) No 844/2012.

With respect to risks identified for non-target organisms, the Commission referred to the EFSA Conclusion (and its background documents) and informed Member States that the points put forward by the applicant had been checked with EFSA, who confirmed that all elements had been taken into account in the peer review.

Member States were invited to comment on the draft Review Report and draft Regulation by 16 April 2021.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance clopyralid, 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/10206/2021).

The Commission summarised the main issues concerning this active substance and the way they were addressed in the Draft Review Report.

Furthermore, the Commission informed of a study conducted in one Member State pointing at the presence of clopyralid in fertilising liquids used by non-professional growers. Member States agreed that these findings are not strictly within the scope of Regulation (EC) No 1107/2009 and that further action should be conducted by Member States potentially involving the Rapid Alert System for Food and Feed (RASFF) notification system.

The Commission indicated it intends to submit the draft Regulation renewing the approval of this active substance for possible opinion at the next meeting of this Committee. Member States were invited to comment by 16 April 2021.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance famoxadone, 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/12986/2019 Rev. 1).

The Commission reminded that this is one of the two remaining active substances of the AIR II programme and that its approval had already been extended several times. The Commission summarised the main issues described in the Draft Review Report, which led to the proposal of non-renewal. The Commission also informed the Member States that because of the requirement to submit a notification to the WTO under the TBT agreement, which entails a commenting period of 60 days, the opinion of this Committee will be sought in the meeting in July.

Member States were invited to comment by 26 April 2021.

C.09 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 Rev. 0).

The Commission summarised the main issues concerning this active substance and how they are addressed in the draft Review Report, in particular the restriction to permanent greenhouses as defined by Article 3(27) of Regulation (EC) No 1107/2009.

One Member State noted that Article 3(27) of Regulation (EC) No does not specifically mention "permanent". The Commission replied that the focus of that definition is on the "prevention of release into the environment" which cannot be achieved if the greenhouse is not permanent.

Another element in the discussion revolved around the absence of an aneugenicity (*in-vitro* micronucleus) study. The Commission explained that genotoxicity should be fully dealt with at the EU level in the approval or renewal assessment. However, for aneugenicity, a threshold can be established and for abamectin, a submitted *in-vitro* chromosome aberrations study was negative and the peer review experts did not consider the absence of the *in- vitro* micronucleus study to be so critical that reference values could not be set.

Two Member States asked to include the use via trunk injection in Appendix II to the draft Review Report since this use is very important in urban areas to contain certain pests in long living trees. The Commission reminded the participants that this use was not supported in the renewal dossier and that Regulation (EC) No 1107/2009 provides a possibility for Member States to grant authorisations under Article 53 if no other reasonable means are available to contain a danger to plant health. The Commission informed that it intends to submit the draft Regulation for opinion at the next meeting of this Committee. Member States were invited to comment by 16 April 2021.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) correcting Implementing Regulation (EU) 2015/408 as regards the deletion of the active substance propoxycarbazone from the list of candidates for substitution.

The Commission explained that propoxycarbone has to be removed from the list of candidates for substitution (CfS) established by Commission Implementing Regulation (EU) 2015/408 as the renewal of the substance in 2017 confirmed that the CfS criteria are no longer met. The Commission shared the letter informing the applicant and the draft Regulation. Member States were invited to comment by 26 April 2021.

C.11 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 notification (to be) launched

There were no news to discuss.

Miscellaneous

M.01 and M.02: Endorsement of administrative amendments to two guidance documents

The Committee endorsed the administrative amendment of the guidance documents SANCO/10181/2013 and SANCO/12545/2014, in order to reflect on the new procedures agreed in previous meetings of this committee. The amended documents will be published with no delay on the relevant Commission website.

The Commission specified during the meeting that a manual on submissions of applications for MRLs in IUCLID format is available since 23 March 2021 and that the report generator is able to create a part of the M documents and several other documents needed for the assessment will soon be available. More features will be created in the coming months to be able to generate automatically every needed document from raw data. Therefore, to use in full the IUCLID potentiality, the Commission stressed the importance to requests applicants to fill in the information in IUCLID correctly and thoroughly.

Germany made the following protocol declaration:

In the framework of the implementation of IUCLID as the data format for dossier submission, the European Commission proposes to amend the Guidance Document for applicants on preparing dossiers for chemical active substances (Doc. SANCO/10181/2013 - rev. 6) and the Guidance Documents for applicants on preparing dossiers for microorganisms (SANCO/ 12545/2014 – rev. 3).

As of 27 March 2021 the applicability of the old guidance is de facto retracted for the majority of active substances/microorganisms. Dossiers shall be submitted in IUCLID format from that date onwards.

However, the IUCLID Technical Manual and the respective Guidance for applicants to prepare dossiers in IUCLID format is still under development.

Therefore, no adequate alternatives are currently available to replace certain documents requested under the old guidance in CADDY (e. g. Documents L, M and N).

These documents are considered essential for the preparation of Assessment Reports. If the information cannot be generated from IUCLID, this will most certainly prolong the timelines for the preparation of Assessment Reports, as more workload is put on the Member States.

Since risk evaluators need access to the original study reports in order to conduct a sound risk assessment, the original study reports should be submitted as attachments. A mere transmission of the naked data via the OECD harmonised templates is not considered sufficient.

Germany would like to emphasize that we fully support the implementation of IUCLID in the framework of the Transparency Regulation.

However, we kindly ask the European Commission to take all reasonable steps to speed up the development of guidance documents and software tools necessary for a proper and smooth running of the new system under IUCLID.

M.03 Dossier submission via IUCLID:

The Commission reminded Member States that as of 27 of March 2021, for all active substances subjected to the new procedures laid down in Regulations (EC) No 2021/428 and 2020/1740, the submission of dossiers have to be done via IUCLID. No submission via CADDY is foreseen in these cases, while this remains possible for submissions of applications for the renewal of active substances which are still under the provisions of Regulation (EU) No 844/2012.

The Commission also reminded that for basic substances, submissions via IUCLID are foreseen a bit later as of April 2021.

M.04 Silver stabilised hydrogen peroxide:

The Commission informed about the letter submitted by a Member State concerning an application for approval of hydrogen peroxide stabilised with silver as a basic substance. The application is currently under evaluation by the Member States and EFSA. According to the Member State, the concentration of colloidal silver in the substance is similar to the concentration of colloidal silver in consumer products which contain silver as antimicrobial agent. It is therefore, unclear whether colloidal silver should be considered an active substance on its own. The Commission informed on the clarifications received from the applicant. The applicant claims that the only role of colloidal silver is as a stabiliser of hydrogen peroxide.

One Member State informed that products containing hydrogen peroxide stabilised with silver are already on the market for plant protection purposes. The Commission invited the Member States to take appropriate enforcement actions. Member States were also invited to provide their comments on the eligibility of silver-stabilised hydrogen peroxide for approval as a basic substance in light of the information on concentration and role of colloidal silver in the products available on the market. The deadline for submission of comments in the commenting table sent by EFSA is 2 April 2021 or to the Commission by 16 April 2021.

M.05 Better Training for Safer Food (BTSF):

The Commission gave a brief update on the status of the ongoing programme related to risk assessment for plant protection products, signalling that the next training sessions (virtual courses) would be held in June and July 2021 (on the topics of efficacy and ecotoxicology).

M.06 Guidance document on the relevance of metabolites in groundwater – update required for the assessment of genotoxicity:

The Commission acknowledged that Member States had expressed the need for updating the guidance document on relevance of metabolites in groundwater (SANCO/221/2000 – Rev.10 - final) which dates from 2003.

However, aside from a full update, the Commission explained that the section on the assessment of genotoxicity is particularly problematic as the tests listed to be provided are not in line with the current scientific knowledge on the assessment of genotoxicity, in particular for consideration of aneugenicity.

Therefore, the Commission indicated that it would be appropriate to update this section of the guidance rapidly to avoid any confusion on the necessary testing, but at this time not open up the full document for revision.

The Member States were informed that the Commission in conjunction with EFSA will therefore suggest an update to the aspects related to genotoxicity and consult Member States as soon as possible.

M.07 Chromafenozide:

The Commission informed that Poland had expressed its willingness to take over the assessment of the confirmatory data on behalf of the Rapporteur Member State in order to avoid any further delay in this procedure.
The producer had also requested the Commission to extend the approval period to have enough time to obtain at least one authorisation for a plant protection product in the EU before the renewal of approval of chromafenozide. The Commission noted that the submission of an application for renewal of approval is not conditional on the fact that the evaluation of confirmatory information has not yet been fully completed nor that plant protection products containing chromafenozide are actually authorised in Member States. Therefore, the current date for the expiry of approval of chromafenozide will remain as 31 March 2025.