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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
21 - 22 October 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/2a9b1df7-3908-4d5c-aa5e-698241855545*

SUMMARY REPORT

Section A Information and/or discussion

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

A.01 Summary Report of previous meetings:

The Commission informed that the summary reports of the previous meetings are published.

A.02 New dossiers (for information):

- New active substances

  The Commission informed that the following application dossiers for the approval of new active substances had been declared admissible by the following Rapporteur Member States (RMS): *Bacillus amyloliquefaciens* AT-332 (RMS Netherlands), *Metarhizium brunneum* BNL102 (RMS Netherlands), Polypeptide, ASFBIOF01-02 (RMS Netherlands), L-Carvone (RMS Sweden).

- Basic substances applications

  The Commission informed that no new applications for the approval of basic substances had been received since the last meeting.

- Amendment of conditions of approval

  The Commission informed that an application dossier for amendment of conditions of approval of 2,4 D (ester variant) had been declared admissible by the Rapporteur Member State Greece.

A.03 Renewal of approval and general issues.

The Commission reminded Member States about the need to inform the Commission when submitting Assessment Reports (DAR/RAR) to EFSA and that as of 27 March 2021 dossiers for approval or renewal of active substances have to be submitted via IUCLID exclusively. The Commission recognised some delays in the

admissibility of dossiers submitted via IUCLID, and mentioned that these are acceptable for the time being as IUCLID is a new tool, however reminded that such delays are expected to not occur in future.

The Commission also informed about the withdrawal of the application dossier for the approval of the new active substance Pretilachlor.

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

- New active substances

  There were no news to discuss.

- Renewal of approval

  1. Clofentezine

  The Commission recalled that the EFSA Conclusion made available in July 2021 includes information on negligible exposure and an evaluation of information submitted under Article 4.7 since the outcome of the peer review was that clofentezine meets the criteria to be considered an endocrine disruptor in humans (thyroid modality). Representative uses include use in outdoor fields and in permanent greenhouses. In addition to the critical area of concern for ED in humans, the EFSA Conclusion highlighted a number of other issues that could not be finalised, in particular, the consumer risk assessment is not finalised and MRLs could not be recommended. Furthermore, a high reproductive risk to birds and mammals was identified from the outdoor uses in addition to risks to aquatic organisms and earthworms form some uses and the risk assessment for NTAs and bees could not be finalised for outdoor uses.

  The Commission informed about the availability of the applicant's comments and about a meeting held with the applicant in October on the latter's request. The applicant disputes the conclusion reached for ED (thyroid modality) and considers that it should be given an opportunity to submit more data which it considers can show non-relevance for humans. In addition, the applicant considers that despite the data gap for storage stability data, there is robust data to set MRLs, in particular for tomato and aubergine.

  The Commission also informed Member States that the Rapporteur Member State had already submitted some initial comments.

  The Commission explained that it was reflecting on the comments received and invited Member States to comment by 15 November 2021.

  2. Benthiavalicarb

  The Commission recalled that the EFSA conclusion for the representative use of benthiavalicarb-isopropyl as a fungicide on potato is available and that it has been concluded that benthiavalicarb-isopropyl meets the cut-off criterion for non-approval concerning endocrine disrupting potential for human health, for the thyroid (T) and oestrogen, androgen and steroidogenesis (EAS) modalities. An assessment of negligible exposure and an evaluation of information submitted under Article 4.7 is included in the EFSA Conclusion. As regards negligible exposure, concentrations of residues of benthiavalicarb-isopropyl < 0.01 mg/kg were demonstrated for potatoes, however, it could not be excluded that residues in other food items (rotational crops) could occur above that level. In addition, a critical

area of concern was identified with regard to the carcinogenic potential and EFSA considered that the substance should be classified as carcinogen, Cat. 1B, which is however not changing the regulatory decision making as regards the active substance as it also has endocrine disrupting properties. The applicant submitted comments expressing disagreement with the EFSA Conclusion. Furthermore, the applicant claimed agricultural needs, submitting evidence regarding the necessity of benthiavalicarb-isopropyl to control a serious danger to plant health for sugar beet/downy mildew and onion/downy mildew. One Member State mentioned that one of these uses, which had been the only one authorised in the past, was no longer authorised.

The Commission explained that it was reflecting on the comments received and invited Member States to comment by 15 November 2021.

3. *Bacillus thuringiensis subsp. kurstaki* strain ABTS-351

The Commission summarised the EFSA Conclusion, which did not identify any critical areas of concern. However, a number of issues could not be finalised.

The Commission underlined that priority needs to be given to the assessment of consumer dietary exposure horizontally for all the *Bacillus thuringiensis* strains currently under assessment before proceeding (see point A.05.g).

- Basic substances

4. Calcium propionate

The Commission informed that the EFSA technical report had been published. The application concerns a use as a spray application as a fungicide in amenity grassland and on flower bulb and flower tuber crops.

The Commission explained that EFSA raised an important issue that, even though no EU harmonised classification in accordance with Regulation (EC) No. 1272/2008 is available, according to a joint notification from 149 notifiers to the classification & labelling inventory of the European Chemicals Agency (ECHA), a classification for eye damaging effects is considered appropriate, which would lead to the need for risk mitigation measures such as wearing personal protective equipment.

Additionally, calcium propionate is a powder and a spray application is foreseen after dilution with water, so that further assessment of the toxicity by inhalation is considered necessary. The assessment of dermal toxicity, endocrine disrupting properties and immunotoxicity had been waived by the applicant without any robust justification. As a consequence, the toxicological risk assessment is considered incomplete and conclusions on the risks to human and animal health cannot be reached on the basis of the information provided.

The EFSA technical report also indicated that, although the ecotoxicological profile seems favourable and no data seem to lead towards unacceptable risks, the intended uses and proposed doses raise a concern regarding possible adverse effects on non-target organisms. This is the case for bees and non-target arthropods, earthworms and other soil macro-organisms, soil micro-organisms, and organisms involved in biological methods of sewage treatment. In addition, data are scarce and risk mitigation measures may be needed.

Due to the high application rates and the proposed uses, as well as the necessity for risk mitigation measures, one Member State had raised concerns during the peer review as reflected in the EFSA technical report.

The applicant also submitted comments on the report, which can be found on CIRCABC. Member States were invited to send their comments before 8 November 2021.

5. Black soap

The Commission informed that the EFSA technical report had been published. The application concerns a high volume spraying application of a black soap solution as an insecticide on arable crops, ornamental flower beds, house plants, plant trees, ornamental woody plants, ornamental crops, vegetables crops, berry fruit crops, pome fruit crops, stone fruit and olive tree crops; and as a fungicide on vegetables and ornamental plant crops.

As part of the admissibility check, the Commission had contacted the Rapporteur Member State and co-Rapporteur Member State (co-RMS) for the renewal of approval of the active substances fatty acids to check whether this basic substance should or should not be considered to be the same as the active substance. The co-RMS replied that because of the differences in the production process resulting in a different final product, they would not consider it to be the same. Also the CAS number is not the same as any of the approved active substances. Therefore the application had been sent to EFSA for an evaluation with the current technical report as a result.

The Commission informed that the applicant had added the reference to the food additive E470a to the title of the application in order to show that the black soap meets the criteria of this approved additive.

The Commission explained that the EFSA Panel on Food Additives and Nutrient Sources added to Food had concluded that the food additive potassium salts of fatty acids (referred to as E470a) is of no safety concern at the reported uses and levels. However, the availability of a black soap product on the market, that fulfils the specifications of the food additive E470a, that does not contain glycerol, that does not contain common additives found in soap products (i.e. dyes, preservatives, perfumes etc.) and that is not placed on the market as a plant protection product, still needs to be demonstrated. None of the links included in the application leads to a website where Black soap clearly meets the specifications of the additive as proposed by the applicant. Black soap is also used in cleaning and cosmetic products, so the presence of additives, preservatives and impurities cannot be excluded. Therefore, further indications on the toxicological profile of these substances should have been provided to rule out a potential concern for human and animal health. Additionally, only limited information is reported with regard to black soap exposure through the use for plant protection purposes and a detailed comparison of these data with exposures from other uses is missing. It is therefore not possible to conclude the non-dietary risk assessment for operators, workers, bystander, and residents.

A comparison of the exposure of ‘Black soap E470a’ as a basic substance according to the intended uses and the use as a food additive, considering all other possible routes of exposure, had not been provided. A quantitative consumer risk assessment through dietary intake and drinking water could not be finalised.

Exposure estimates relating to the requested uses regarding the effects on the environment were also not available in the application. However, the EFSA Conclusion from 2013 on C7-C18 fatty acids identified that for products containing these fatty acid active substances, mitigation measures were needed to reduce surface water exposure. It is therefore probable that risk mitigation measure would also be needed for the uses being applied for in this basic substance application.

Finally, due to the lack of data regarding exposure or hazards, a quantitative risk assessment regarding the effects on non-target species, was not possible.

The applicant had been given the chance to react to the EFSA technical report, but they did not provide an example of a black soap product that fulfils the specifications of the food additive being on the European market.

Member States were invited to send their comments on this EFSA report before 8 November 2021.

6. Hydrogen peroxide silver-stabilised

The Commission informed that the technical report from EFSA on the application for approval of hydrogen peroxide silver-stabilised as a basic substance had been published. The application concerns the use as a fungicide and elicitor in potatoes, tomato, cucumber, onion and grapevine in drip irrigation, as a spray and in hydroponic bath.

The application had originally been submitted as an extension of the already approved hydrogen peroxide. However, due to different composition as regards the stabiliser, it seems that it should be rather considered as an application for approval of a new basic substance. Furthermore, it seems that it is not fully clear whether the substance presented in the application should not be considered as a mixture of two substances – hydrogen peroxide and silver. There are indications that the role of silver is not only as a stabiliser of hydrogen peroxide as claimed by the applicant, but it provides long-lasting or even synergistic effects since silver is known to be effective against bacterial growth at very low concentrations, much lower than proposed in the application.

The Commission summarised the findings of the Technical Report by EFSA: the information provided by the applicant was insufficient to conclude the non-dietary risk assessment, on the need to conduct a consumer dietary risk assessment, and an environmental exposure assessment had not been provided by an applicant. The substance concerned by the application is a 20% solution of hydrogen peroxide, which is above the classification limit for Eye Damage category 1. However, in the preparation for use this solution is diluted to 0.2% - so below the limit of classification. Moreover, insufficient information is available with regards to exposure and hazard and for the effect of silver, especially for non-target arthropods and microorganisms, and unacceptable effects on non-target organisms cannot be excluded.

Member States were invited to submit comments by 15 November 2021.

7. Lemon essential oil

The Commission informed that the EFSA technical report had been published. The application concerns spray application as an acaricide, insecticide and fungicide in fruit trees (citrus).

The Commission explained that, according to the EFSA technical report, the main hazards regarding human and animal health are related to the presence of D-limonene. Toxicity by inhalation has been observed, triggering a H304 classification ('may be fatal if swallowed and enters airways') but also skin sensitisation properties have also been highlighted, indicating a need for risk mitigation measures, like wearing protective equipment. Additionally, not enough information had been provided to conclude on genotoxic, endocrine disrupting or neurotoxic effects. The information on natural background levels is considered not sufficient. Finally, the exposure assessment for operators, workers, residents and bystanders for the specific uses applied for has not been taken into consideration.

A dietary exposure assessment has not been provided as there is no comparison with background levels. Although, it can be reasonably assumed that the increase of D-limonene content on the treated citrus crops may be only marginal after the proposed one to two applications.

A usable environmental exposure assessment has not been provided. Lemon essential oil has been shown to be toxic to aquatic organisms. Considering that no exposure assessment has been presented, and to avoid unacceptable effects, risk mitigation measures may be necessary. D-limonene also exhibits high acute toxicity to earthworms.

The applicant submitted comment on the report, which can be found on CIRCABC.

Member States were invited to send their comments by 8 November 2021.

8. Ozone

The Commission recalled that the application for approval of ozone as a basic substance concerns its use as a bactericide, fungicide, insecticide, nematicide and viricide. Ozone is produced in-situ and then directly diluted in water to produce ozonated water. The ozonated water is intended to be applied via drip irrigation and spray irrigation on edible or non-edible crops.

The Commission summarised comments received from the Member States.

One of the unresolved issues is the definition and identity of the substance for which the approval should be considered. Ozone in gaseous form is to be classified under Regulation (EC) No 1272/2008 and should be considered a substance of concern, which means that it cannot be approved as a basic substance. On the other hand, the concentration of ozone in the proposed preparation for use – ozonated water - is equal to 8 ppm (0.0008%) and according to Regulation (EC) No 1272/2008, no classification is necessary. However, ozonated water is a mixture of ozone and water and thus it is not compliant with the definition of substance in Article 3(2) of Regulation (EC) No 1107/2009. One possible approach might be to define the substance as "ozone generated from oxygen" and further specify that it is produced in situ and directly dissolved in water at a concentration of maximum 8 ppm.

As regards the general approach to in-situ generated active substances, the starting material and the device are out of scope of Regulation (EC) No 1107/2009 but can be authorised by Member States. However, basic substances are not subject to product authorisation. The conditions for use of basic substances are defined in the review report in the section on "preparation for use". Additionally, legislation exists which regulates safety and performance of electric machinery (which is used for in-situ generation).

The Technical Report of EFSA on the application indicated a number of potential concerns, both for ozone and ozonated water. In particular, even for ozonated water with an ozone concentration of 8 ppm, there are data gaps as regards toxicological properties, data on by-products and in the ecotoxicological area. Two of the commenting Member States see these concerns as preventing the approval as a basic substance, whereas two other Member States would rather support the approval.

An application for approval of ozone as active substance is currently under assessment in the framework of Regulation (EU) No 528/2012 on biocidal products, and a proposal for harmonised classification and labelling has been submitted. Those processes are not yet finalised. A decision on the approval or not of the substance defined as "ozone generated from oxygen" as a biocidal active substance is expected for next year.

Two Member States stressed the importance of ozonated water as a basic substance, as it would help to replace soil fumigants like 1,3 D or chloropicrin. They also mentioned the use of ozone in the food chain.

Member States were invited to submit comments by 8 November 2021.

- Amendment of conditions of approval

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

  No discussion took place.

A.05 Draft Review/Renewal Reports for discussion:

- New active substances

  a) Dimethyl disulphide

  The Commission informed that a meeting with the applicants had taken place on their request in September and that new comments from the applicant had been made available on CIRCABC, which provide information on the experiences made so far with this substance, in- and outside the EU.

  Only one Member State had sent comments so far. The Rapporteur Member State informed about their intention to meet the applicants in order to discuss additional data.

  Member States were invited to send written comments before 8 November 2021.

  b) *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV)

  The Commission presented the draft Review report in view of the approval of SeMNPV isolate BV-0004 as a low-risk substance. Member States were invited to send written comments by 8 November 2021.

- Renewal of approval

  c) *Metarhizium brunneum* strain M43 (subcultures BIPESCO 5/F 52)

  The Commission presented a draft Renewal Report for the renewal of approval of *Metarhizium brunneum* strain Ma 43 as a low risk active substance. EFSA had not identified critical areas of concern, but had identified some data gaps on the production of secondary metabolites. However, considering the biological and ecological properties of the micro-organism and the absence of antimicrobial resistance, a renewal as a low risk active substance is considered feasible.

The Commission explained that the renewal is for Metarhizium brunneum strain Ma 43 because BIPESCO 5 and F52 are considered subcultures of Ma 43, as EFSA had confirmed they are identical in terms of biological and genetic properties and that there are not known differences between these subcultures and the original strain Ma 43 based on sequencing analysis.

The Commission shared the comments received from the applicant on the draft Renewal Report. Member States were invited to comment on the draft Renewal Report by 8 November 2021.

d) Captan

No discussion took place.

e) *Bacillus amyloliquefaciens* strain QST 713

The Commission informed that one Member State had commented since the last meeting of this Committee, related to the potential effects on bees, and recalled that this issue for bees had not been raised for other strains of the same species. The Commission also informed about bilateral exchange with EFSA on this matter and an overview on the available studies related to bees had been uploaded on CIRCABC.

The Commission indicated possible ways forward: 1) to restrict the application to non-flowering periods (strawberries: BBCH 67-89 and grapes: BBCH 69-89) or 2) to restrict the use to strawberries in permanent greenhouses.

Three Member States referred to the possibility to include risk mitigation measures for bees in product authorisations but not specifically in the implementing act for renewal of approval.

Member States were invited to send comments by 8 November 2021.

f) *Pseudomonas chlororaphis* strain MA342

No discussion took place.

g) *Bacillus thuringiensis* (horizontal discussion)

The Commission referred to the possibility to mandate EFSA and ECDC to improve clarity on horizontal issues concerning the potential of dietary exposure for consumers linked to *Bacillus thuringiensis* strains. The Commission mentioned that comments received so far from Member States were in support of such a mandate and that the drafting of the mandate was in progress.

h) *Pythium oligandrum* strain M1

The Commission updated on the applicant's comments which were forwarded to EFSA who commented that opportunities to close open points concerning the pathogenicity, toxicity and infectiveness were identified, as well as regarding the metabolite tryptamine produced by many fungi, and the virulence factor Immunoglobulin A peptidase for which there is evidence that it is not produced by the strain M1.

The Commission announced that a draft renewal report will be prepared for the next meeting. The Commission invited Member States to send comments about the announced way forward by 8 November 2021.

i) Straight Chain Lepidopteran Pheromones

The Commission informed that the draft renewal report is still in preparation due to the complexity to cover all pheromones appropriately and explained that the way how to handle blends of individual compounds is still being discussed. Several meetings with the applicants had taken place on their request. The original suggestion in the EFSA Conclusion to remove the blends from the substance identity description seemed to create difficulties as several single compounds are only produced as part of specific blends. Another open question is the potential status as a low-risk substance due to skin irritation properties of some alcohol and aldehyde compounds. Information submitted by the applicants had been made available in CIRCABC.

The Rapporteur Member State confirmed that the evaluation of the dossier had not been easy as it involves 11 applicants, several single substances and several blends, some of these produced as such, leading to a very complex assessment report with several annexes. One Member State mentioned that it is important how blends are addressed.

One Member State said that it supported low-risk status, due to the use in dispensers and for communication issues.

The Commission invited the Member States to comment, in particular on the handling of blends and the low-risk status by 15 November 2021.

j) Carbon Dioxide

The Commission presented the revised review report and explained that it is not possible to grant low-risk status because carbon dioxide is used in the form of a compressed gas, and therefore a risk of explosion is possible, excluding low-risk according to point 5.1.1 of Annex II to Regulation (EC) No 1107/2009. Furthermore, EFSA suggested to consider risk mitigation measures such as buffer zone and ventilation.

Member States were invited to comment by 15 November 2021.

k) Bifenazate

The Commission recalled that in 2017 based on the EFSA Conclusion it had proposed non-renewal of approval. However several Member States had opposed such a proposal. Following a mandate from the Commission, EFSA revised its Conclusion in July 2021 by assessing the risks from the lowest application rate of the representative use range and only 1 application per year, while previously only the highest application rate had been assessed.

In the light of the revised Conclusion, the Commission presented now its proposal for renewal of bifenazate with restriction to non-edible crops and to permanent greenhouses as defined by Article 3.27 of the Regulation (EC) 1107/2009. These restrictions are necessary due to a non-finalised consumer risk assessment and high risk to birds and chronic risk to bees. In addition, confirmatory information will be required as regards endocrine disruption properties.

The Commission had shared the comments received from the applicant on the revised Conclusion and the draft renewal report via CIRCABC.

Member States were invited to comment by 8 November 2021.

l) Pelargonic acid

The Commission presented the EFSA Conclusion on the peer review of the risk assessment for pelargonic acid and the comments provided by the applicants. Member States were invited to comment, in particular on the identified risks for non-target arthropods by 15 November 2021.

- Basic substances

m) Caffeine

The Commission informed that the applicant had requested to put the process of non-approval on hold. The applicant asked for additional 18 months to prepare information that could lift the concerns identified by EFSA. Consequently, the Commission proposed to suspend the procedure until new information will be made available by the applicant and assessed by EFSA.

- Amendment of conditions of approval

No discussion took place.

A.06 Confirmatory Information:

1. Pyriofenone (to take note)

The Commission recalled that a draft updated review report proposing to close the confirmatory information point concerning the toxicological relevance of impurities present in the technical specification, based on the EFSA Technical Report, had already been made available for the meeting of this Committee in July 2021. Three Member States had provided comments and the draft updated review report had been amended to take them into account. The Committee endorsed the amended review report.

2. Pyrethrins

The Commission recalled that the confirmatory data would need further assessment while the renewal procedure has already been initiated. The draft renewal assessment report is available to all Member States in the EFSA peer review workspace. Since the RMS's assessment for the renewal shows that pyrethrins are unlikely to pose problems for consumers and that the applicant will be requested to submit more data under the renewal process, the Commission considers that it would be more proportionate and efficient to wait for the outcome of the renewal assessment, avoiding that several regulatory processes run in parallel. If concerns are identified in early stages of the peer-review, the Commission can take action without further delay.

Member States were invited to provide comments on this potential way forward by 15 November 2021.

3. 1-decanol

The Commission summarised the confirmatory data requirements. The applicants submitted the relevant additional environmental fate and behaviour information by the deadline established. In addition to the fate and behaviour data, the applicants had also submitted aquatic acute toxicity studies. Overall, the Rapporteur Member State considered that the confirmatory data requirements had been satisfactorily addressed and proposed broad possibilities to prescribe risk mitigation measures for

the reduction of spray drift at Member State level. EFSA had published the technical report on the assessment of the confirmatory information on March 2016.

An updated review report addressing these confirmatory data will be presented in the forthcoming meeting of this Committee. Meanwhile, Member States were invited to comment by 15 November 2021.

4. Flutianil

The Commission informed that EFSA had made the technical report available in August 2021 and that the confirmatory information was satisfactory to address the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification, leading to the conclusion that a change in the reference technical specification for flutianil is not required. Confirmatory information is still to be provided as regards endocrine disrupting properties as well as the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.

The review report has been amended accordingly in view of endorsement at the next meeting of this Committee. Member States were invited to comment by 15 November 2021.

5. Acibenzolar-methyl

The Commission informed that EFSA had made available its Conclusion on the peer review of confirmatory data in July 2021, and that the applicant had provided comments. A meeting with applicant had taken place on its request.

The Commission reminded that the confirmatory information had been set before the new criteria to identify endocrine disrupting properties had been adopted and that from a procedural point of view the applicant had fulfilled its obligations. However, during the peer review of the submitted information it was concluded that the available data were not sufficient to finalise the assessment as regards endocrine disruptors properties and additional data would be needed on all four modalities (EATS). While the applicants agreed on the tests suggested for the EAS modalities, they disagreed as regards the suggestion from EFSA to perform in-vivo studies for the T modality preferring to start with an in-vitro strategy and only if needed to go on with an extended one generation study (EOGRTS) in vivo.

The Commission indicated that follow up actions are needed and that this is a particular case (i.e. the specific confirmatory data requirements are fulfilled, however before taking a decision in light of the new criteria further assessment is necessary), and that it is still reflecting about the best way forward. One possibility would be to trigger an Art. 21 review and give the applicant time to complete the data package. Member States were invited to comment on this potential way forward by 15 November 2021.

6. Pyridaril

The Commission presented the results of the EFSA technical report on the confirmatory information: the only open issue concerning impurity 23 (i.e. the compliance of the toxicological studies compared to the proposed specification) is expected to be addressed with the renewal application which is due in June 2022. Member States were invited to comment by 15 November 2021.

7. Potassium phosphonate

   The Commission presented the results of the EFSA technical report on the confirmatory information according to which the long term risk to frugivorous birds could be considered as sufficiently addressed. Member States were invited to comment by 15 November 2021.

8. Acequinocyl

   The Commission presented the results of the EFSA technical report on the confirmatory information. Member States were invited to comment by 15 November 2021, in particular on how to address the still open risk for small herbivorous mammals.

A.07 Guidance Documents:

1. Guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 Rev 11) (to take note)

   The Commission presented a revised version of the guidance document for endorsement, explaining the changes compared to the previous draft revision. The Commission underlined that the intention of the revision is to ensure that the minimum basic requirements for assessment of genotoxicity listed in the guidance ensure that aneugenicity is fully addressed – the current version lists three basic tests which do not address aneugenicity in light of the current scientific knowledge.

   The earlier revision had proposed alignment with the Opinion of the EFSA Scientific Committee on genotoxicity testing strategies with recommends two tests to cover the 3 genotoxicity endpoints, however, some comments received had questioned the removal of the provision of a gene mutation test in mammalian cells.

   The EFSA Working Group on Genotoxicity considered the comments and confirmed that the Opinion of the Scientific Committee is still robust and that a mammalian cell gene mutation test is not necessary in the basic battery of *in vitro* tests. Nevertheless, the Commission explained that in order to move forward without delay, the provision of a mammalian cell gene mutation was retained in the guidance document at this point in time. In addition, the proposed amendment concerning *in silico* methodologies was removed but this topic will be considered during the future full update of the guidance (as all other aspects).

   The timing of a full update of this guidance document will be determined based on the ongoing prioritisation exercise for guidance documents. The Commission also announced that it would discuss further with EFSA and ECHA with the aim of ensuring harmonisation in testing approaches across different categories of chemicals.

   Finally, the Commission informed that several Member States had submitted written comments supporting the version tabled for endorsement.

   The Committee endorsed the amended guidance document.

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

   Due to late comments received from one Member State, this point was postponed. Member States were invited to submit any further comments by 8 November 2021.

3. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 rev. 9) (to take note)

   The Commission informed that comments received since the last meeting of this Committee had been included in a reporting table. An updated version derived from the outcome of the last meeting of the Post Approval Issues Working Group of this Committee was summarised.

   The Committee endorsed the amended Guidance Document.

4. Guidance document on rules for revision of assessment reports (SANCO/10180/2013 – rev. 2 May 2021) (to take note)

   In connection with the Guidance document on the evaluation of new active substance data post (renewal of) approval, this Guidance Document needed to be amended to remind Member States that this assessments shall be included in the Assessment Report as it is already done for the revision during the peer-review prior to approval, the evaluation of confirmatory information, the amendment of conditions of approval and the renewal of approval.

   The Committee endorsed the amended Guidance Document.

5. Guidance document on data matching for applications for authorisation of plant protection products according to article 33/43 (SANTE/2016/11449 rev. 1) (to take note)

   The Commission presented an updated version derived from the consideration of the comments received since the last meeting of this Committee.

   The Committee endorsed the amended Guidance Document.

6. Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 (SANCO/10473/2003 – rev. 5) (to take note)

   The Commission informed that the comments received since the last meeting had been transferred to the Member State leading the revision of this Guidance Document. An updated summary table and a new version of the Guidance Document had been uploaded on CIRCABC.

   The Committee endorsed the amended Guidance Document.

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

   The Commission informed of the request to EFSA to continue the work on the review of the Bee Guidance Document on the basis of the specific protection goal for honeybees supported by Ministers in the AGRIFISH Council of 28 June 2021 and to set out a revised work plan for finalisation of the update of the Guidance Document. This revised outline is expected to be online on the EFSA website in November.

   The Commission also presented the feedback received from three Member States on the setting of specific protection goals for wild bees and announced an information session on this subject on 23 November 2021 in the morning for Member State representatives and in the afternoon for the EFSA stakeholder group for the review of the Bee Guidance Document. The Commission also reminded of

an online information session by EFSA on the Implementation of the agreed specific protection goal for honey bees in risk assessment on 15 November 2021.

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

   The Commission informed that it had received comments on the Draft guidance version 20 from nine Member States, which were summarised in a commenting table with answers to the Member States' comments. Several issues were discussed, in particular the definition of treated seed, the interpretation that sowing of treated seeds constitutes use of a plant protection product, treatment of seeds with non-authorised plant protection products for export only, treatment of seeds under Article 53 of Regulation (EC) 1107/2009, and labelling of treated seeds.

   Member States were invited to comment on the commenting table (on the comments of the Member States or on the Draft guidance itself) by 15 November 2021.

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

   The Commission updated on the on-going work on the revision of the Communications, the possible need for a single repository of existing guidance documents and for criteria on which basis a document is listed as guidance document in the Communications. When the draft updated Communications will be available, the Commission will launch another consultation with stakeholders and Member States.

   Member States were invited to comment by 15 November 2021.

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

    The Commission explained that following the recent discussions and the divergence of views on the existing draft, it had further reflected on a way forward in view of facilitating assessment of negligible exposure (NE) and simplifying the assessment process.

    The Commission outlined a proposal to update the draft guidance based on inverted logic compared to the existing guidance, i.e. to define a rationale to identify uses for which negligible exposure is not demonstrated rather than to identify where it is. The proposal is to develop a sequential process considering different steps. Any uses that would pass these screening steps would then be further considered by risk managers on a case by case basis. Such an approach would speed up the process for considering negligible exposure, eliminating many uses and only leaving a small sub-set for risk managers to consider. The guidance would also include consideration of negligible exposure in the environment for endocrine disrupting substances.

    Member States were invited to comment on this approach or to provide any suggestions by 15 November 2021.

11. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil

    EFSA presented the new guidance document. Member States were invited to comment by 15 November in view of an endorsement of the guidance at the next meeting of this Committee.

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

The Commission informed about the meetings of the Working Group of this Committee which continued the discussions on the draft document on problem formulation. The Commission informed that a consultation of Member States and stakeholders on this draft document is planned for the first quarter of the next year.

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

The Commission reported about (1) the ongoing work regarding an EU list of Risk Mitigation Measures (RMM), (2) the planned training activities under the Better Training for Safer Food programme (e.g. e-learning module to start), (3) discussions with EFSA concerning the way RMM may appear in the GAP table to be elaborated according to IUCLID dossiers, as well as Guidance Document (e.g. draft revised Birds and Mammals GD). The Commission also informed about the initiative of the central zone which initiated discussions about how RMM could be considered in the regulatory process of approval of active substances and authorisation of PPPs and the role of different stakeholders in proposing and validating non-standard RMM proposed by applicants (e.g. new technologies).

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

- Article 44(4)

The Commission informed that no notifications were received since the last meeting.

- Article 36(3)

The Commission informed that five notifications had been received. Three notifications concerned rejections of authorisations under the zonal system and the remaining two notifications concerned rejections of applications for mutual recognition. None of the decisions had been appealed in National Courts.

- Article 53

The Commission explained that following the agreement to include an indication of the maximum area permitted to be treated under each emergency authorisation (intended as a restriction and a mandatory piece of information to include in the notifications) some Member States had informed about experiencing some problems in adding a meaningful value.

The Commission also reminded Member States that work to create an additional field for entering the data on 'actual use' post-authorisation has begun (with the intention that this would be optional, in cases where there is a significant difference compared to the value entered for the maximum permitted use).

These figures together would be used to refine the relevant harmonised risk indicator established under the Directive on the sustainable use of pesticides (HRI2).

One Member States commented that it was better to use actual data as including a maximum permitted value can led to problems.

Member States were invited to provide views or proposals for moving forward, enabling meaningful data to be collected for use in calculating HRI2.

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

EFSA informed about upcoming Conclusions and their planning for the next months for expert meetings, that the public consultation on glyphosate is on-going, and that IUCLID 6.6 will be released 20 of October 2021. As regards active substances which are subjected to stop the clock because of the assessment of the active substances in view of the scientific criteria to identify endocrine disrupting properties applicable as of November 2018, the assessment of 27 dossiers will resume in 2022. EFSA also informed it expects the updated Guidance Document on exposure of operators, workers, residents and bystanders to be published in December 2021 and informed about the Guidance on aneuginicity assessment published in July 2021.

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

The Commission informed that it had sent a new general mandate on basic substances to EFSA (see point A 17.5) and that bilateral exchanges between Commission and EFSA had been initiated in order to improve the format of the EFSA Conclusions on active substances which are micro-organisms.

A.13 Microorganism Active Substances, in particular:

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

The Commission reminded that it intended to prepare Communications to accompany the two Implementing Regulations concerning data requirements for active substances which are micro-organisms, and plant protection products containing them (see points C.01 and C.02) as is the case for chemicals. However, different from the mentioned Regulations, they are not subjected to scrutiny of the European Parliament and Council. Consequently, priority is given at the moment to finalising the Regulations.

A.14 Safeners and Synergists:

No discussion took place.

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

1. Calcium hydroxide

   The Commission reminded that calcium hydroxide had been approved as a basic substance in 2015. In 2019, the Commission had received an application for the extension of use. Based on a new EFSA Technical Report from 2020, the proposed extension of use of calcium hydroxide had not been approved in March 2021. In November 2020 and February 2021, one of the Member States urged the Commission to review of the approval of calcium hydroxide in accordance with Art. 23(6) of Regulation (EU) 1107/2009, because that Member State considered that the current level of information does not allow to conclude that the uses of the substance are of no concern to human health or the environment.

The Commission informed on the action taken: it had invited the applicants for the original approval and for the extension of use to submit any relevant information or comments by 22 January 2022. The next steps will be based on the outcome of this consultation, and as set out in Article 23(6).

2. Clethodim

   The Commission informed that the adoption procedure for the draft Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 as regards maximum residue levels for clethodim, dazomet, hexythiazox, metam and sethoxydim in or on certain products (SANTE/11220/2019), which had been voted on in the Standing Committee in February 2021, had to be stopped. The Commission requested Member States to comment on the way forward considering the uncertainties around genotoxocity, in particular the possibility to open an Article 21 review or to await the outcome of the renewal procedure already initiated, by 8 November 2021.

3. Dimethomorph

   The Commission informed that one Member State had raised a question whether action was needed on products containing dimethomorph, in light of its classification as toxic for reproduction, category 1B (R1B), which has now become legally binding via Commission Delegated Regulation 2021/849.

   The Commission explained that dimethomorph is currently approved as an active substance and the renewal process is ongoing (the draft assessment report is under peer-review process). A decision on whether the approval can be renewed or not will be taken once the EFSA Conclusion is available.

   The Commission also recalled that, in principle, substances classified as R1B may still be approved if exposure to humans is considered negligible or under the derogation set out in Article 4.7 of Regulation (EC) No 1107/2009 – therefore the classification as R1B does not automatically mean that the approval cannot be renewed - hence why it is necessary to have the EFSA Conclusion before making a final decision. The classification as R1B is taken into account in the renewal review and therefore the Conclusion will also contain information on negligible exposure and on Article 4.7. On the other hand, Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied. Therefore, if a Member State considers that current authorisations do not meet those requirements in the light of the new classification of the active substance as R1B a process as outlined under Article 44 or Regulation (EC) No 1107/2009 may be followed.

4. Napropamid-M

   The Commission explained that it will prepare a mandate to EFSA to assess if the substance has endocrine disrupting properties, as well as to assess other open points such as the impurity profile and the reference values, the soil metabolites, the potential effects on non-target soil and aquatic organisms and the persistency of this new active substance, in coordination with the parallel review carried out by the Rapporteur Member State in charge of the racemic substance (napropamid), which would allow read-across from one dossier to another where relevant. Member States were invited to comment about the announced way forward by 8 November 2021.

A.16 Article 21:

1. Tebufenozide

   The Commission informed that the draft EFSA Statement on the relevance of metabolite RH-2651 for groundwater has been sent out for comments. The statement, requested by the Commission in the framework of an Article 21 procedure, appears to confirm the absence of genotoxic activity in vivo. This result, if confirmed in the final statement, would conclude the process for the assessment of the confirmatory information. The next step would be to propose a revised review report for endorsement in the next meeting of this Committee. Member States were invited to comment about the announced way forward by 8 November 2021.

2. Isopyrazam

   The Commission explained that following the launch of the Article 21 procedure in February 2021 and after a consideration of the comments submitted by the applicant, the Commission considers that the approval criteria are no longer fulfilled and that a withdrawal of the approval of the active substance is therefore appropriate. A mandate to EFSA is not considered necessary. A draft Regulation for withdrawal of approval is under preparation and is expected to be discussed at the next meeting of this Committee in December and a vote could be foreseen in January 2022.

3. Pirimicarb

   The Commission recalled that the peer-review process in the context of the renewal assessment is currently ongoing and that EFSA had requested further information on endocrine disrupting properties setting a deadline of 13 July 2022 for providing the requested information. The applicant is working on providing data to comply with that request.

   The Rapporteur Member State had subsequently informed the Commission that during the peer-review process concerns had been identified regarding genotoxicity of metabolites, non-dietary exposure and acute risk to birds. Given the fact that the renewal process remains ongoing but the concerns need to be addressed, the Commission explained that it would launch an Article 21 review of the existing approval. Following a consideration of the comments and information submitted, the next steps, including any impact on the renewal process would be determined.

   The Commission underlined that this is a highly exceptional case due to the specific circumstances of the process and the issues identified.

4. Ipconazole

   The Commission informed that the Rapporteur Member State had submitted its assessment of the additional information submitted as part of the Article 21 review to EFSA and the Commission. The Commission will send a mandate to EFSA to consider the information provided by the applicant and the assessment of the Rapporteur Member State and to deliver a statement. Once the statement is available, the next step will be determined.

A.17 General issues for information / discussion:

1. Brexit

   No news to report.

2. COVID-caused delays

   The Commission reminded that it is responsibility of the Rapporteur Member States to inform with no delay the Commission and this Committee about any expected delays of submission of (parts of) application dossiers caused by COVID reminding also that requests for acceptance of delays should be duly justified by applicants.

3. Illegal plant protection product use

   The Commission informed that it had finalised an overview regarding the implementation of Article 72 of Regulation (EC) No 1107/2009 on penalties and will make it publicly available on its website.

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

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

   a) Scope delineation with biocidal products

      The Commission explained the proposal presented by one Member State to further illustrate with claims and uses the scope delineation between plant protection and biocidal products, which is already incorporated in the Scope Document in a general way (i.e. a decision tree to delineate the scope). Member States were invited to comment by 15 November 2021.

   b) New cases:

      The Commission reminded about recent cases (Wood-coat, Rhizo-Power) and presented the new border case, chabazite, for which an application for approval as basic substance had been submitted. Member States were invited to comment by 15 November 2021.

5. Basic substances – general issues

   The Commission informed that EFSA had accepted an updated general mandate that considers the new procedures introduced by the recent update of the Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 and that defines the role of EFSA in the process. The Commission stressed the more important role Member States play in the context of this mandate, in particular as regards identifying additional uses for basic substances. This is expected to reduce the need for extensions, and therefore the administrative workload for all concerned regulatory authorities.

6. MS updated survey on timing of regulatory procedures

   No discussion took place.

7. Mono- and polymers as co-formulants

   The Commission informed that one Member State had submitted a document for discussion, in which they ask for a guidance document on assessment and requirements for polymers and monomers used as co-formulants in plant protection products. Member States were invited to comment by 15 November 2021.

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

   The Commission reported about the ongoing discussion in the context of the REACH Regulation concerning a possible restriction of the use of microplastics in various mixtures, including in Plant Protection Products.

9. BTSF-training on ED

   The Commission reminded that a BTSF training course on the criteria to identify substances with endocrine disrupting properties which are applicable since 2018 will take place from 15 to 17 December 2021 by videoconference (3 half days). Member States are invited to nominate participants for the training.

10. Art. 68 submissions

    The Commission reminded Member States to send their reports on Art. 68 of Regulation (EC) No 1107/2009 in time.

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

The Commission informed about the progress as regards the REFIT evaluation of Directive 2009/128/EC on the sustainable use of pesticides (SUD). A meeting of the SUD working group of Member States experts took place on 29 September 2021, a public stakeholder event on 5 October 2021, and a study validation workshop on 6 October 2021 for which all Member States had been invited to attend. The Commission intends to submit a proposal for a revision of the Sustainable Use Directive in March 2022 to the Parliament and the Council, as indicated in the Farm to Fork Strategy Action Plan. The relevant website is being kept updated on the overall process as additional information becomes available.

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

No discussion took place.

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

The Commission informed about the ongoing discussions within the Council and the Parliament on the proposed Regulation on statistics on agricultural input and output (SAIO), underlining the importance of cooperation at national level among the relevant services and informing that grants will be launched for the improvement of pesticide data collection. Webinars on Digital recording of pesticide use data were being held, allowing Member States to share their experience in the area.

The Commission also gave a presentation on the digitalisation of PPP use records within the Integrated Administration and Control System (IACS) and explained that secondary legislation under the Common Agricultural Policy (CAP) could define the IACS platform for electronic recording of data on pesticide use, stressing that a phasing-in period would be required and that support to the Member States could be provided.

The Commission reiterated the relationship and distinction between the Implementing Regulation under Article 67 of Regulation (EC) No 1107/2009 under discussion and SAIO. The draft of the act and a revised Annex were presented, where, compared to earlier discussions, modifications concerned in particular the identification of crops in

line with EPPO codes, the identification of the area of use, and the requirement for the BBCH code as part of the time identification.

The following points were raised by the Member States: need for the information requirements to be understandable for farmers; flexibility, e.g. allowing Member States to require additional records; difficulties of implementing IT tools of this kind and the related need for a transitional period; concerns over increased costs versus the potential added value; need to state that the data can be used for control purposes. Several Member States considered that the requirement to register the geographical location of the area treated goes beyond the requirements in Article 67 and one Member State expressed doubts as to whether the Implementing Regulation can require that records are kept in an electronic format.

The Commission agreed on the need that the information requirements are understandable for users; indicated that it would reflect on the request for flexibility; considered that the indication of geographical location is covered by Article 67 under the "area" requirement; mentioned some examples of requirements for the use of electronic formats; confirmed that a transitional period would be foreseen and invited the Member States to indicate how long they think this period should be.

Finally, the Commission recalled that this initiative was launched in response to the Member States' requests for supporting the collection of pesticides use data in view of meeting the obligations in the proposed SAIO Regulation on pesticide statistics, and to have more harmonised data available across all Member States. The Commission also emphasised that this initiative is relevant for monitoring purposes in addition to statistical needs, and asked again all the relevant services (PPP Regulation, statistics, CAP and SUD) at national level to cooperate and provide joint comments.

A.21 Report from working groups, in particular:

1. Working group on Biopesticides

   No news to report.

2. Working group on Seed Treatments (Risk Assessment)

   The Member State chairing the Working Group for drafting of the Guidance Document on seed treatments (risk assessment) informed that the updated draft is close to finalisation.

3. Working group Post Approval Issues

   No news to report.

A.22 Minor Uses:

No discussion took place.

A.23 Court cases.

The Commission informed about rulings in the following cases:

– T-518/19: The Court dismissed the application seeking annulment of Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothanolil.

– T-153/19: The judgment dismissed the application for annulment of Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds as candidates for substitution.

A.24 Ombudsman cases.

No news to report.

A.25 Exchange of information from the Pesticide Residues section of the Committee, in particular:

– possible impact on authorisations

– residue definition for risk assessment (to take note)

The Commission informed that following the last meeting of the section Pesticides Residues of the Committee, the Committee had given favourable opinions on draft Regulations concerning MRLs for the following active substances; which may impact on authorisations of plant protection products containing them:

Substance	Type of change	SANTE doc number
Dazomet	MRLs were lowered and the residue definition was amended.	SANTE/10942/2021
Hexythiazox	MRLs were lowered and the residue definition was amended.	SANTE/10942/2021
Metam	MRLs were lowered and the residue definition was amended.	SANTE/10942/2021
Methylisothiocyanate	MRLs were lowered and the residue definition was amended	SANTE/10942/2021

As regards the residue definition for risk assessment, the Commission thanked Member States for providing additional comments following the July and September meetings of this Committee and explained that all comments had been considered. The Commission recalled that the document prepared is not a guidance nor a formally binding decision, but rather sets out a common understanding of how residue definitions for risk assessment (RD-RA) will be agreed and reported in the review/renewal reports, including any needed amendments of the RD-RA. The document will not be published but will be kept available for Member States on CIRCABC.

The Committee endorsed the document, which may be updated based on experience gained. The Commission explained that Review/Renewal Reports prepared as from 1 January 2022 will include information on RD-RA.

A.26 OECD and EPPO activities:

The Commission informed the Member States about ongoing OECD activities or calls for comments or contributions concerning (1) the re-organisation of the Pollinators Expert group, (2) the guidance on human health risk assessment of ds-RNA (e.g. RNAi), and (3) the Working Group on Drones (e.g. declassification of the report on drones and its attached literature review).

A.27 Scientific publications and information submitted by stakeholders:

The Commission informed that it had made available via CIRCABC letters and information submitted by Pesticides Action Network (PAN) Europe, PAN Europe and Health and Environment Alliance (HEAL), International Confederation of European Beet Growers (CIBE), International Institute of Sugar Beet Research (IIBR), and CropLife Europe (CLE).

A.28 Date of next meeting(s):

The Commission confirmed the date of the next meeting (1 and 2 December 2021) and announced the dates foreseen for the meetings in 2022: 27-28 January, 30-31 March, 17-18 May, 14-15 July, 13-14 October, and 8-9 December.

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

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance phosmet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12604/2020).

SANTE/12602/2020

The Commission informed that EFSA had revised its Conclusion, which is now available, and that based on this Conclusion the proposal for non-renewal remains unchanged due to high risks identified for human health and non-target organisms. The Commission explained that the sanitisation process of the revised Conclusion was on-going, that EFSA published its redacted version on 21 October 2021, and that it will publish a non-redacted version once the sanitisation process is finalised. The Commission shared the correspondence sent to the Commission and EFSA by two firms that act on behalf of the applicant.

One Member State indicated that it would abstain and one Member State that it did not yet have a position.

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

The Netherlands submitted the following protocol declaration:

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

Hungary submitted the following protocol declaration*:*

With the non-renewal of approval of phosmet, only pyrethroid-like a.s. and acetamiprid remain in rapeseed culture to control rapeseed beetle, which unfortunately predicts the

development of resistance and the long-term impossibility of control until other a.s. would be available.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning renewing the approval of the active substance cypermethrin as a candidate for substitution 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 11527/2018).

SANTE/10590/2021

The Commission recalled that it proposed renewal of approval as candidate for substitution with restrictions and conditions as regards risk mitigation. The Commission shared the comment from one Members State and informed that no comments had been received via the consultation of WTO members under the TBT agreement.

The Commission explained that as this was the first time that such restrictions and conditions concerning risk mitigation were proposed to be set and that it may request in the future information on granted authorisation or on monitoring schemes put into place by the Member States. Concerning the message sent by several NGOs, the Commission recalled the discussions which took place in 2018 and 2019 in this Committee about potential endocrine disruption properties and informed the Committee that it plans to reply to the NGOs to inform about these.

Two Member States indicated that they would vote against the proposal and three Member States that they would abstain.

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

Germany submitted the following protocol declaration:

Germany appreciates the new approach of the Commission to combine the approval with specific provisions for risk reduction that member states may achieve through their national risk mitigation measures. However, in the specific case of cypermethrin, Germany thinks that a required reduction of the environmental risk by far more than 95 % cannot be achieved with reasonable means.

Outcome of the vote by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the new active substance *Purpureocillium lilacinum* strain PL11 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10418/2021).

SANTE/10416/2021

The Commission presented the draft implementing Regulation and referred to comments received from four Member States and the applicant.

Two Member States indicated that they would abstain, one because it could not support the low-risk status and the other one because of open questions for the risk to certain soil organisms (*Collembolae*).

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

Outcome of the vote by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance *Purpureocillium lilacinum* strain 251 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12462/2020).

SANTE/12460/2020

The Commission pointed to an error in the draft Regulation, as the title mistakenly refers to a renewal as a low-risk active substance, while in reality the substance would not be renewed as a low-risk substance because of its non-susceptibility to antimicrobials. The applicant had been informed about this in April 2021. The Commission referred to the comments received from seven Member States.

One Member States indicated that they would abstain because of the risk for soil organisms (*Collembolae* in particular).

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

Outcome of the vote by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance flumioxazin, 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 and to Commission Implementing Regulation (EU) 2015/408 (Draft Review Report SANCO/12512/2014).

SANCO/12510/2014

The Commission presented the draft Regulation, comments received from two Member States, a letter from Members of the Committee on the Environment, Public Health and Food Safety of the European Parliament and a joint letter from two NGOs.

One Member State considered it problematic that the assessment of the endocrine disrupting properties was not fully completed and could only support the proposal if the renewal period would be shortened to 7 years. Another Member State indicated only being able to support the renewal if the substance would remain a candidate for substitution and as such the renewal period would be shortened to 7 years and the time to submit confirmatory data would be shortened to 12 months after renewal came into force. The Commission explained that in the light of the final outcome of the assessment there was no basis to consider the substance as a candidate for substitution or to shorten the renewal period, but emphasised that if the assessment of the confirmatory data

would indicate that the approval criteria would not be met, the Commission would take immediate action.

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

Outcome of the vote by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10730/2018).

SANTE/10729/2018

The Commission presented the draft Regulation and introduced a comment from the US received during the consultation of WTO members under the TBT agreement as well as the comments received from the applicant. Given the risks and data gaps identified, the Commission considers that the nature of these risks overrules economic considerations as brought forward in the comments.

On the request of nine Member States, the Commission agreed to prolong the maximum grace periods that Member States can grant from 6 to 9 months.

Four Member States indicated not supporting the non-renewal of indoxacarb due to its agricultural importance for minor crops. One Member State indicated not being able to support the proposal as it considers that safe uses in maize are possible.

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

Outcome of the vote by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl, and pyraclostrobin.

SANTE/11120/2021

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 for reasons beyond the control of the applicants.

One Member State disagreed with the extension of the approval periods in batches which include active substances of concern, in particular substances that meet a cut-off criterion, in this case especially metiram.

Another Member State indicated they could not support an extension of the approval of metiram, oxamyl and dimoxystrobin.

A third Member State could not support the extension of benfluralin.

A fourth Member State expressed its support for the need of the extensions, but found the extension of the approval of metiram controversial.

The Commission reminded that many active substances on the list are currently under assessment for their endocrine disrupting properties according to the scientific criteria that became applicable in November 2018, and that according to the legal framework additional time to finalise these assessments is needed. In particular, a regulatory decisions cannot be taken while there are no EFSA Conclusions available. In the case of metiram, during the peer-review where all Member States are involved, it was decided to request additional information from the applicant.

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

Outcome of the vote by written procedure: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, to specify criteria for the approval of microbial active substances.

SANTE/10686/2021

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

The Commission informed that the consultation of the other Directorates-General concerned will be closed soon, and explained the main changes with respect to the earlier versions of the draft Regulations presented to this Committee during the meeting in July. The public consultation via feedback mechanism, which will follow after the closure of the internal consultation, will give stakeholders and the general public the possibility to provide comments.

The Commission underlined the intention that the four Regulations presented under C.01 to C.04 are applicable as of October 2022, when IUCLID, the tool for submitting data contained in the dossiers for active substances, will be updated based on the amended data requirements on active substances which are micro-organisms.

Member States were invited to comment on the draft Regulations by 15 November 2021.

C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 283/2013 setting out the data requirements for active 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.

SANTE/12040/2020

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

C.03 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, 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.

SANTE/12042/2020

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

C.04 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

SANTE/10716/2021

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

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015).

SANTE/10724/2020

The Commission informed Member States that the consultation of all Commission services concerned had been launched and of letters received from stakeholders on this subject. After closure of the consultation the draft Regulation will be notified to the WTO under the TBT agreements.

One Member State indicated not being able to support the proposal. Taking into account the positions expressed at earlier meetings of this Committee, the situation is as follows: 11 Member States supporting the proposal, 10 Member States not supporting the proposal as they are either against or abstaining; 6 Member States not having a final position yet.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance chitosan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10594/2021).

SANTE/ 10592/2021

The Commission indicated that it intended to submit the draft Regulation for vote at the next meeting of this Committee in December.

Member States were invited to comment by 8 November 2021 on (1) the draft review report and draft Regulation and (2) the draft amended review report for vinegar.

C.07 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).

SANTE/10298/2021

The Commission informed that the applicant had provided complementary information about the beauvericin content in the microbial active substance as manufactured confirming that the maximum concentration of 80 µg/kg is not exceeded in the formulated product. Based on the addendum to the RAR drafted by the Rapporteur Member State a draft review report had been sent to the applicant for commenting with a proposal for approval with a restriction of use to ornamental palm trees. The Commission also explained the situation as regards the low-risk status and reminded of previous *Beauveria bassiana* strains which had not been approved as low-risk due to beauvericin.

Member States were invited to comment on the draft review report and the low-risk status and the related argumentation provided by the applicant by 8 November 2021.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non- approval of the active substance 1,3-dichloropropene, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/10814/2019).

SANTE/10812/2019

The Commission informed the Member States about the comments received from the applicants on the draft review report: they were asking for the continuation of the review procedure pending the finalisation of ECHA's opinion on the proposal for harmonised classification of the active substance, in particular its genotoxicity. The Commission presented all relevant elements of information in the applicant's argumentation. Some Member States agreed with the applicant's views, including the Rapporteur Member State.

The Commission also informed that ECHA had 'stopped' the proposal for harmonised classification submitted by one Member State at the accordance check and an updated submission is still awaited by ECHA.

The Commission invited the Member States to comment and confirm their position on the draft Regulation by 8 November, in view of the vote planned for the meeting of this Committee in December 2021.

The Commission also referred to a survey received from a non-governmental organisation regarding the conditions under which emergency use authorisations have been delivered in one specific Member State, which had been made available via CIRCABC.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non- approval of the active substance chloropicrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/11096/2020).

SANTE/11094/2020

The Commission informed about the comments received from the applicant on the draft review report: the applicant was in particular calling for the continuation of the review procedure pending the submission of an additional genotoxicity study. The Commission presented all relevant elements of information in the applicant's argumentation, as well as the suggestions for further restriction of use (only some crops, half-application rate, geographical limitations). Some Member States agreed with the applicant's views, including the Rapporteur Member State.

The Commission invited the Member States to comment and confirm their position on the draft Regulation by 8 November, in view of the vote planned for the meeting of this Committee in December 2021.

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANCO/10762/2021).

SANTE/10760/2021

The Commission presented the review report and draft Regulation as well as applicant's comments and indicated its intention so submit this proposal to a vote at the next meeting of this Committee.

The Commission invited the Member States to comment and confirm their position by 8 November 2021.

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen and repealing Implementing Regulation (EU) 2018/185 (Draft Review Report SANTE/10028/2017).

SANTE/10574/2021

Pro memoria – TBT notification (to be) launched

Miscellaneous

M.01 Incidents with the use of phosphine-producing plant protection products and biocides - information from MS:

The Commission informed about a recent communication from one Member State informing about incidents with the use of phosphine-producing plant protection products and biocides. The importance of paying attention to the risks for workers related to transporting gassed cargoes was discussed, especially when the plant protection product used is in the form of loose pills mixed into the cargo upon departure for transport. It appears that these pills can be re-activated during transhipment in the Member States (or third countries) of destination, and can start producing phosphine again, with great safety risks for workers.

The Commission invited Member States to send information on the subject or comments by 15 November 2021.

M.02 Scientific publication (Siviter et al, 2021, Nature 596, 389-392) entitled "*Agrochemicals interact synergistically to increase bee mortality*":

A Member State informed the Commission of a scientific publication (Siviter et al, 2021, Nature 596, 389-392) entitled "*Agrochemicals interact synergistically to increase bee mortality*". This article discusses a meta-analysis of 90 studies in which bees were exposed to combinations of agro-chemicals, nutritional stressors and/or parasites. That Member State furthermore mentioned that also the EFSA MUST-B project identified the need for considering synergistic effects.

The Commission explained that some aspects mentioned in this publication are already covered in the procedures related to the authorisation of plant protection products (PPPs). In particular, Member States must assess these for plant protection products containing more than one active substance, and that enhanced availability of data on the actual use of plant protection products by farmers – as will be proposed in the revision of the Directive on the sustainable use of pesticides – will provide a better basis for considering exposure to multiple pesticides in the same field. Furthermore, research, including model development, such as the EFSA ApisRam model, is ongoing to assess synergistic effects more elaborately in the near future.

The Commission invited Member States to send comments, views and/or suggestions regarding the assessment of synergistic effects of pesticides on bees by 15 November 2021.

M.03 Rimsulfuron:

A Member State asked for an update on the decision-making for rimsulfuron, indicating that there are some problems for the product authorisation process due to the issues identified in the EFSA Conclusion for metabolite IN-E9260.

The Commission explained that it had sent a revised mandate to EFSA in September 2021. This mandate covers a number of aspects related to IN-E9260 and next steps depend on the outcome of that mandate. The Commission also reminded that, as part of product assessments, data that were not part of the renewal assessment could be taken into account, which may also help Member States with their assessments pending the final decision taken at EU level concerning the renewal of approval of rimsulfuron.

M.04 Groundwater monitoring:

The Commission informed that following discussion in previous meetings, a mandate had been sent to the PPR Panel on the topic of groundwater monitoring.

M.05 CIRCABC "Interest Group PPPs":

The Commission invited Member States to update their respective list of users of CIRCABC "Interest Group PPPs".

M.06 Additional TARIC Code for plant protection products:

One Member State suggested to discuss the possibility of additional TARIC Code for plant protection products, on the basis of a proposal to be presented for the next meeting of this Committee.

M.07 Update on Chemical Strategy for PFAS:

The same Member State asked for an update on the ongoing discussions as regards the Chemical Strategy in particular for PFAS. The Commission reminded that this Member State (in cooperation with another one) was in the lead for preparing a proposal for restrictions of PFAS under the REACH Regulation and invited the Member States to coordinate internally.

M.08 Arrangement for the organization of upcoming PAFF meetings:

Finally, one Member State asked for an outlook of how the next meetings would take place in view of the COVID-19 pandemic (i.e. virtual or in person). The Commission explained that this will depend on the development of the sanitary situation in the EU.