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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
22 - 23 October 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/4420c3f7-f1c1-437f-b947-7020a0d43cbb*

SUMMARY REPORT

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

A.01 Summary Report of previous meetings:

The Commission informed that the summary record of the meeting held on 16-17 July 2020 was published and that of the meeting held on 28-29 September 2020 was expected to be published in the coming days.

A.02 New dossiers:

- New active substances

  This point was postponed.

- Basic substances applications received

  a. Grape seed extract

  The Commission informed that an application for the approval as basic substance of an extract from grape seeds had been received in July 2020. The extract is intended to be used in preventive applications against fungi and oomycetes. The application covers foliar spray treatments on grapevine, pome fruits, potatoes and vegetable crops in open field, as well as the use in greenhouses for vegetable crops. The admissibility of the application is currently being assessed.

  b. Lemon essential oil

  The Commission informed that an application for the approval as basic substance of lemon essential oil (also called Lemonene) had been received in June 2020. It concerns an oil extracted from citrus shells (from oranges and lemons). It is intended to be used as an insecticide in citrus crops against white fly, aphids, tetranychid mites and scales. The admissibility of the application is currently being assessed.

  c. Eggshell powder

  The Commission informed that an application for the approval as basic substance of eggshell powder had been received in June 2020. It concerns a powder of waste eggshells dried at high heat (300°C). The application refers to fungifuge and

desiccation effects and is for dusting the powder over grapevines and fruit trees. The admissibility of the application is currently being assessed.

d. CO2 hop extract

The Commission informed that an application for the approval as basic substance of a CO2 extract from hops had been received in June 2020. The product is intended to be used in a preventive and curative manner against the development of secondary infection of *Pseudoperenospora humuli* or *Phytophtora infestans* on hop and potato crops. The admissibility of the application is currently being assessed.

The Commission also indicated that, based on the experience gained with a number of applications, it intends to have a more general discussion on basic substances and presented a thought-starter on several aspects of interpretation of the provisions for basic substances in Regulation (EC) No 1107/2009. It recalled that the content of Article 23(1)(d) was included in the original proposal for the Regulation in 2006, with a slightly different wording and that for instance the provision that foodstuff was to be considered as a basic susbstance had been added during the negotiation process. The Commission explained its understanding of the rationale of the legislators for including basic substances as follows:

(1) to ensure availability of substances that had proven useful for plant protection but might not receive sufficient economic interest to ensure an application (this was also mirrored by the fact that Member States and "interested parties" could submit approval dossiers);

(2) to avoid overregulation of traditional private uses which would become illegal as both placing on the market and use required an authorisation (Article 28(1)(a));

(3) to treat the use for plant protection purposes as ancillary to another, "primary" use of the active substance.

In any event one of the clear requirements in Article 23 is that basic substances are not placed on the market as plant protection products. Accordingly, in the Commission's interpretation, it is not allowed to advertise a basic substance for plant protection use (pursuant Article 66) while it is permitted to provide information that a substance is approved as basic substance. Clear and harmonised rules for labelling are absent as the labelling rules of the Regulation are linked with an authorisation and therefore not suited to basic substances. It is also not clear how import, sale and use of basic substance for plant protection should be recorded as an important element for market surveillance (for authorised plant protection products, clear rules are set out in Article 67).

As a second topic and following increasing queries from Member States, plant protection producers' associations, and companies trading basic substances, the Commission enquired about the sales modalities applicable in the Member States. Divergent approaches could be observed: whereas self-standing marketing of basic substances as such, including by internet, could be observed in some Member States, other Member States appeared to take a more restrictive approach, requiring that the usefulness for plant protection purposes could only be mentioned on the packaging of products containing the basic substance sold for another primary use.

Finally, the Commission presented several technical aspects such as the transformation steps for a (basic) substance that could be acceptable as "preparation

for use", the impossibility to approve mixtures as basic substances, or the approval of substances which have some properties of concern.

Several Member States welcomed that a more in–depth discussion on the interpretation of the provisions related to basic substances was being initiated.

One Member State informed that it took the view that an active substance that is foodstuff always has to be approved as a basic substance, and that, it would have preferred that all regular substances for which an application for approval is received that were actually recognised as foodstuff would be automatically listed as basic substances. In its views, approved basic substances are authorised (under the special scheme as basic substances) for plant protection use and can therefore also be advertised as such. The Commission recalled that not all foodstuff is automatically inoffensive (referring to the example of vinegar) for human health or the environment. One Member State echoed this view, referring to sunflower oil.

One Member, supporting the increased availability of basic substances and therefore increased approvals of basic substances in parallel to approvals as a regularly approved active substance, reminded that a careful assessment is needed to be carried out by EFSA (mentioning in particular active substances falling also under animal by-product regimes (e.g. milk, blood meal). A third Member State also supported dual approvals as regular active substance and basic substance, pointing to the legislator's intention to avoid overregulation. It also emphasised that a basic substance could only be used on its own, which was not the case for a mixture with co-formulants, which would be a regular plant protection product. Two Member States opposed such dual approval, as it would create severe difficulties with labelling, sales modalities, enforcement and they pointed to the example of carbon dioxide, which showed that not all foodstuff should be available with low regulatory conditions.

The Commission invited Member States to submit comments on the issues for discussion by 23 of November 2020.

- Amendment of conditions of approval

  The Commission informed that a dossier for amendment of conditions of approval for mecoprop-p had been received and the Rapporteur Member State had considered it admissible.

- Article 21 Reviews

  No news to discuss.

A.03 Renewal of approval and general issues:

The Commission recalled that any requests related to delays for submitting supplementary dossiers due to the impact of COVID-19 should be made by applicants to the relevant rapporteur Member State. The rapporteur Member States should consider the evidence and justification provided when determining if a delay was acceptable or not (this may be for the full submission of parts thereof). If delays are agreed, the rapporteur Member States should inform the Commission as soon as possible.

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

- New active substances

  No news to discuss.

- Renewal of approval

  1. Captan

  The Commission presented the key elements of the EFSA conclusion. Issues have been identified for all representative field uses (especially for ecotoxicology). Safe uses have been identified in permanent greenhouses. Member States were invited to comment by 9 November 2020.

  2. Abamectin

  The Commission presented the key elements of the EFSA conclusion. Issues have been identified for all supported uses (especially for ecotoxicology). A restricted approval for permanent greenhouses uses meeting the definition in Article 3(27) would lead to safe uses. Member States were invited to comment by 9 November 2020.

  3. *Purpureocillium lilacinum* 251

  The Commission presented the key elements of the EFSA conclusion. The substance was initially approved with the name *Paecilomyces lilacinus* strain 251. The applicant provided comments which have been circulated to Member States. The peer review did not identify any critical area of concern and only one issue could not be finalised.

  The ecotoxicological risk assessment for representative uses was considered to lead to a low risk for all relevant non target organisms except for collembolans, which, however, is not expected to impede the renewal of the substance. Member States were invited to comment by 9 November 2020.

  4. *Bacillus thuringiensis subsp. kurstaki* strain SA-11

  The Commission summarised the EFSA Conclusion and some of the comments received by the applicant. The peer review did not identify any critical area of concern. However, a number of issues could not be finalised due to some uncertainties related to short-term toxicity effects on humans after inhalation, and to the relevance of toxins production in human intestine after dietary exposure. Due to the uncertainties related to dietary exposure, EFSA suggested the non-inclusion of the strain in Annex IV of Regulation (EC) No 396/2005. Both the Rapporteur Member State and the co-Rapporteur Member State disagreed with this proposal. Member States were invited to comment by 23 November 2020.

  5. *Bacillus thuringiensis subsp. kurstaki* strain SA-12

  The Commission summarised the EFSA Conclusion and some of the comments received by the applicant. The peer review did not identify any critical area of concern. However, a number of issues could not be finalised due to some uncertainties related to short-term toxicity effects on humans after inhalation, and to the relevance of toxins production in human intestine after dietary exposure. Due to the uncertainties on dietary exposure, EFSA suggested the non-inclusion of the strain in Annex IV of Regulation (EC) No 396/2005. Both the Rapporteur Member

State and the co-Rapporteur Member State disagreed with this proposal. Member States were invited to comment by 23 November 2020.

- Basic substances

6. Willow bark and stem extract

The Commission gave an update on the issues relevant for the decision on (non)approval of willow bark and stem extract. Since the last meeting of this Committee, three Member States had provided comments. Member States had expressed divergent views as regards the identity of the substance,. The Commission explained that the proposal to define the substance as "chopped willow stems" instead of "willow stem infusion" or "extract" is related to the requirement for a predominant use of the substance outside plant protection in Article 23 of Regulation (EC) No 1107/2009. No such use was identified for the infusion or extract, whereas "chopped willow stems" are used as biomass. As regards the toxicological properties of the substance and the support for the approval, one Member State supported only the use in ornamental plants, one Member State indicated no support for the use in herbs and fruit trees, and one Member State considered that no safe use had been identified.

Member States were invited to comment by 9 November 2020 as regards (a) the identity of the substance; (b) their positions on approval (c) their positions on restriction of use to ornamentals.

7. Sodium hypochlorite

The Commission summarised the EFSA technical report. Sodium hypochlorite is intended to be used in plant protection as a bactericide on mushrooms indoors, and as a seed treatment against fungi and viral diseases on vegetables, ornamentals and arable crops in field and greenhouse crops. There is a harmonised classification for severe skin burn and eye damage and the concentrations might be high enough to create health problems and a non-dietary risk assessment could not be conducted due to missing exposure estimates. EFSA considered that the use of sodium hypochlorite to rinse seeds before planting is highly unlikely to result in residues above the MRL of 0.01 mg/kg and/or significantly contribute to human exposure to chlorate through food. However, the use on mushrooms needs to be further assessed with respect to potential residues of chlorate.

Member States were invited to comment by 23 November 2020.

8. Dimethyl sulphide

The Commission summarised the EFSA technical report. Dimethyl sulphide is intended to be used in plant protection as a non-lethal food attractant for truffle beetle (*Leiodes cinnamomeus*), as a vapour releasing product to be placed into physical traps. The available information on dimethyl sulfide regarding human risk could not be assessed properly. The available published information indicates that it is an irritant to skin, eyes and the respiratory tract and a skin sensitiser (EFSA FEEDAP Panel, 2013). In addition, a neurotoxic potential has been identified for the similar substance dimethyl disulfide, which has been assessed as active substance in plant protection products (EFSA, 2019). Due to the type of application (vapour release dispensers), residues in crops are expected to be low and exposure of soil and surface water expected to be negligible. Member States were invited to comment by 23 November 2020.

9. Chitosan hydrochloride

The Commission presented two applications for extension of use of chitosan hydrochloride as a basic substance.

The first extension concerns the use as a spray or by dipping on ornamental flower bulbs, and the use on beet crops by spraying. The extension concerns uses which seem to be within the risk envelope of the already approved uses as confirmed by EFSA, which indicated that the uses proposed in the extension could be considered comparable to the already approved uses, and that a full risk assessment does not seem to be necessary. Member States were asked to comment by 23 November on (a) the need for a full risk assessment by EFSA; (b) their positions on approval.

The second extension covers chitosan of fungal origin (the originally approved substance was of crustacean origin). The new uses include horticulture, olive trees, grapes, grass and post-harvest treatment of fruits. The Technical Report of EFSA, published in July 2020 indicates no concerns as regards toxicity and no need for a consumer risk assessment. As regards ecotoxicity and the risk to non-target organisms, it revealed largely the same concerns already identified during the first approval. According to the notified classification available on the ECHA website, chitosan is considered to have eye, skin and respiratory irritation potential. This was not raised during the first approval and the applicant provided additional information to alleviate those concerns and proposed the use of personal protective equipment.

The Commission informed about questions related to the identity of the substance. Based on the provided specification, the application seemed not to concern an extension of use of chitosan hydrochloride but rather an application for approval of a new substance chitosan. The preparation for use would require an adjustment of pH through addition of an acid. However, Article 23 of Regulation (EC) No 1107/2009 requires that basic substances should be useful in plant protection either directly or in a product consisting of a substance and simple diluent, which actually does not allow the addition of co-formulants (such as an acid).

Member States were invited to comment by 23 November 2020 as regards (a) the identity of the substance covered by the second extension; (b) their positions on approval.

10. Calcium hydroxide

The Commission recalled that the application for extension of use concerns the use as fungicide in grapevine and peach, and as insecticide in grapevine, plum, peach, apricot, apple, pear, almond and strawberry.

The Technical Report of EFSA, published in June 2020, re-iterates concerns that were already indicated at the time of the first approval. According to the notified classification on the ECHA website, calcium hydroxide is an irritant for the skin, the respiratory tract and can cause eye damage. The risk assessment for operators, workers, residents and bystanders cannot be finalised. It was not possible to conclude on the similarity of the calcium hydroxide proposed as basic substance and used as a food processing aid or food additive, and on the contribution of the toxicologically relevant impurities to the toxicity profile of the substance. As regards the risk for consumers, EFSA accepted the waiver put forward by the applicant for some uses on plants in the dormant phase, but found it not acceptable for uses after fruit formation. The applicant had not provided an environment

exposure assessment. There were no concerns identified for non-target organisms, however, the information was considered insufficient for bees and non-target arthropods.

At the time of the first approval as a basic substance, the arguments supporting the approval decision included classification as a foodstuff, the essential use in organic farming, and the fact that products containing calcium hydroxide available on the market are suspensions in water and have to be labelled according to the provisions of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, implying that the necessary precautionary statements and communication on risk mitigation measures are available to the users.

Member States were invited to comment by 23 November 2020.

- Amendment of conditions of approval

  No news to discuss.

A.05 Draft Review/Renewal Reports for discussion:

New active substances

a. Dimethyl disulphide

The Commission explained that so far only few Member States had sent comments. The applicant had informed about stewardship programs and suggested a reduced rate of application of 200 kg/ha, limit the use to greenhouses, and application once every 2 years from May to October to limit the release into the environment during rainy periods. The application would only be done by professionals duly trained for this specific substance and mode of application. The plant protection product would be marketed as a "package" solution with a gastight barrier film (Dimethyldisulphyde Approved Film, containing ethylene vinyl alcohol copolymer –EVOH) and the certification of the professional user.

Six Member States indicated that they would support non-approval due to the scarceness of information in the dossier.

The Commission mentioned that consideration might be given to the fact that this substance may be less hazardous compared to other soil fumigants. Member States were invited to comment by 9 November 2020.

b. Chloropicrin

The Commission reported about the various reactions received from seven Member States concerning the EFSA conclusions, the applicant's comments and the way forward proposed in July which was complemented after the last meeting of this Committee by the Rapporteur Member State.

As regards genotoxicity the Rapporteur Member State and many delegations are of the opinion that an additional in vivo test (e.g. TGR mutation model assay by inhalation route) would clarify the situation for both chloropicrin and its the main metabolite and impurity DCNM.

The Commission pointed out that many test guidelines are not fully appropriate due to the high volatility of the substance, thus requiring an appropriate ad-hoc risk assessment approach. The main risk mitigation measures proposed by the applicant (e.g. application in strips, halving the application rate) supported by the rapporteur

and other Member States were not quantitatively assessed during the risk assessment.

Member States were invited to comment on this overview and the points of principles discussed by 9 November 2020.

c. 1,3-dichloropropene

The Commission invited the Member State having expressed willingness to submit a new proposal for harmonised classification in the context of the CLP Regulation to provide by 9 November clear indications about the planned date of submission of the file to ECHA.

d. Aqueous extract from the germinated seeds of sweet *Lupinus albus*

The Commission explained that the conclusions of EFSA did not indicate any critical areas of concern nor critical areas that could not be finalised. In addition, the new active substance fulfils the criteria for a low risk substance according to Annex II of Regulation (EC) No 1107/2009. However, there were a few aspects that needed to be confirmed such as the GLP five-batch data of the total quinolizidine alkaloids and a corresponding specification, as well as analytical method for the determination of total quinolizidine alkaloids in the product.

Member States were invited to comment by 23 November 2020.

Renewal of approval

e. Clopyralid

The Commission reiterated that the EFSA Conclusion identifies uncertainty with regards to the risk to consumers, due to the presence of an unknown plant metabolite and to the fact that the studies on grass and cereals (the supported uses) were not presented transparently. Since there is an ongoing application under Regulation (EC) No 396/2005 (Article 10) from the same applicant to increase, among others, MRLs on grass and cereals, the Commission proposed to wait for the outcome of that procedure, which may solve the identified consumer issues, before deciding on the renewal of the approval of clopyralid. Member States were invited to comment on this overview and the points discussed by 9 November 2020.

f. Famoxadone

The Commission recalled that the current proposal for a renewal of the approval had not received support from the required majority of Member States. Some of the Members States had indicated in previous meetings that some aspects of the evaluation would need to be revised and that a detailed discussion on the issues identified by EFSA (the long term risk for bird and mammals, the risk for workers, the risk to aquatic organisms and the consumer exposure) is still needed. Therefore, given the complex scientific discussion, the diverging positions of Member States and given that the former Rapporteur Member State (UK) cannot share anymore its views, the Commission indicated that further discussion with EFSA is needed to clarify the main controversial areas of the dossier. No comments were requested st this stage.

g. Bifenazate

The Commission reiterated the reasons for the proposal for non-renewal: two critical area of concern (high risk to birds and mammals and to non-target

arthropods) for all the representative uses and the non-finalised risk assessment for consumers and aquatic organisms.

The Commission informed that 18 Member States had commented until now: 5 Member States indicated their potential support of non-renewal, while 13 Member States would support renewal. The Commission shared the comments from the Member States and from the applicant received since the last meeting. The Commission informed that it is currently discussing a mandate with EFSA to complete and peer review the risk assessment.

Member States were invited to send any additional comments by 23 November 2020.

h. Cyazofamid

The Commission informed that EFSA had updated its Conclusion on 28 July 2020 following a mandate from the Commission. The Commission internal procedure on the next step had not yet been finalised, and the revised renewal report will be available as soon as possible. The Commission shared the comments from the Member States and from the applicant received since the last meeting.

The Member States were invited to send any additional comments by 9 November 2020.

i. Flumioxazin

The Commission presented the updated EFSA Conclusion and referred to comments from the applicant on this Conclusion that had been made available to all Member States. Member States were invited to comment by 23 November 2020.

j. *Akanthomyces muscarius* Ve6

The Commission recalled that the EFSA Conclusion identified no areas of concern, but several data gaps and issues that could not be finalised. The Commission informed that comments had been received from two Member States and that the renewal report is available. Based on the elements provided in the dossier and the fact that the product has been used for more than 10 years in several Member State without occurrence of adverse effects, the Commission intended to propose to renew the approval of the substance. The substance would qualify as a low risk substance. Member States were invited to comment by 9 November 2020.

k. Clodinafop

The Commission recalled that the critical concern related to non-dietary exposure had been solved following the finalisation by EFSA of the mandate on the topic, as reported in the updated EFSA Conclusion.

The Commission explained that a draft renewal report had been prepared and sent to the applicant for comments. The draft report would support a proposal for renewal of approval, dependent on the further assessment of endocrine disrupting (ED) properties of clodinafop for which the Commission would send a mandate to EFSA.

Member States were invited to consider the draft renewal report and provide any comments or views on the proposal (except for the ED assessment) by 9 November 2020.

l. *Streptomyces* K61

The Commission presented the EFSA Conclusion. EFSA identified one critical area of concern, several data gaps and issues that could not be finalised, which in essence are related to three aspects:

- High toxicity (mortality) following intratracheal administration of the viable micro-organisms in test animals. The lack of reference values was an impediment to conclude on the risk for operators and workers with regard to the representative uses of Streptomyces K61 and residents and bystanders in case of walk-in tunnels.
- The identification of secondary metabolites/toxins produced by Streptomyces K61 potentially present after application of the product,
- The unfinished assessments of infectivity/pathogenicity.

The Commission informed the Committee that comments had been received from two Member States who shared the concerns and data gaps identified. Furthermore the Commission informed that the applicant had provided extensive comments on the EFSA Conclusion and that the Commission had requested EFSA to review these comments.

Member States were invited to send further comments by 23 November 2020. Based on them and further exploration of the dossier the Commission will decide on the way forward.

Basic substances

m. Vinegar (extension of use)

The Commission informed that four Member States had commented. The applicant had sent an updated version of the application, lowering the application rate and restricting the application to spot applications on paths, borders, sidewalks and terraces. Some Member State also requested to look at the approval of acetic acid and comparing the amounts of acetic acid to be used in the proposed extension and the amounts of acetic acid to be used according to the approval as a regular active substance. The Commission is looking into these elements.

Member States were invited to comment by 9 November 2020.

n. Clayed charcoal (amended review report to be noted)

The Commission informed that since the last meeting of this Committee, three Member States had provided comments indicating support for the non-approval. Member States were invited to send any additional comments by 9 November 2020.

o. Sodium chloride (extension of use)

The Commission informed that since the last meeting of this Committee, one Member State had provided comments indicating support for the approval. The applicant had withdrawn support for the use in combination with plastic. The Member States were invited to send any additional comments by 9 November 2020.

p. Comfrey steeping

Since the last meeting of this Committee, three Member States had provided comments. Two Member States supported the Commission proposal for non-approval. One Member State indicated that it would be appropriate to consider the

additional data submitted by another Member State in July. EFSA had provided feedback on the additional data. Given the expected genotoxic (and carcinogenic) potential of components of Comfrey extract, the provided references seem not to be sufficient to dismiss the concerns raised in the EFSA Technical Report.

Member States were invited to send positions and comments on the additional data by 9 November 2020.

q. *Capsicum annuum, longum group, cayenne* (extract)

This point was a duplicate of point C.06.

r. Whey (extension)

The Commission informed that comments on the EFSA conclusion had been received from two Member States as well as the applicant. Issues were raised for the use on grapevines and the consumption of grape-leaves since the whey residues might provoke an allergic reaction. The Commission informed that it is still reflecting on how to proceed.

Member States were invited to comment by 9 November 2020.

s. *Equisetum avense* (extension)

The Commission informed that comments had been received from two Member States as well as the applicant on the EFSA Technical Report and the draft review report. Based on the comments received regarding the data gap that EFSA had identified for the composition of the extract and all the uncertainties following this, the Commission informed that it is reconsidering the original dossier as well as this request for extension.

Member States were invited to comment by 9 November 2020.

Amendment of conditions of approval

t. Prosulfuron

The Commission informed that a draft addendum to the renewal report and a draft Regulation and Annex had been prepared to amend the conditions of approval, removing the restriction of use. The applicant had been consulted on the addendum to the renewal report

The Commission provided a summary of comments received since the meeting of this Committee in July. Several Member States had expressed concerns about metabolites leaching into groundwater whereas others considered that the issue that led to the restriction in 2017 had been addressed satisfactorily.

Member States were asked to provide comments on the draft texts by 9 November 2020 after which the amendment procedure would progress.

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs)

The Commission informed Member States that there is one further substance for which a confirmatory information requirement was set concerning TDMs for which the review report had not yet been updated but would be in due course.

The Commission also recalled that there are other substances for which no confirmatory requirement had been set in the approval but where TDMs are relevant

and where the new endpoints agreed by Member States in December 2019 apply. Member States were asked to consider if the review reports for those substances should be updated to include an Appendix listing the endpoints, as done for other substance already.

Member States were reminded to take into account the conclusion and endpoints on the TDMs in their evaluations (active substances and plant protection products).

Member States were also informed that the applicant taskforce on TDMs (TDMG) had recently submitted information about new studies that it is generating on the TDMs, and had asked how this data can be evaluated in a coordinated way at EU level, rather than being fragmented as part of individual substance evaluations.

It was noted that previously the UK had acted as Rapporteur Member State for the evaluation of the data on TDMs but that now another Member State would need to do the work, if agreed to proceed at EU level. Member States were asked for their views on how to manage the evaluation of new data, also in view of the need to ensure harmonisation in the assessment of TDM substances and the best use of resources.

Member States were invited to comment by 23 November 2020.

2. Gamma-cyhalothrin (amended report to take note)

   The Commission explained that it is preparing a mandate to EFSA to review the common metabolites of several pyrethroids to address one of the two non-finalised issues of the confirmatory information process. As regards the other issue i.e. high risk to wild mammals, the Commission asked the Member States, in particular those who have national authorisations for products containing gamma-cyhalothrin (according to the pesticide database AT, BE, BG, CZ, DE, DK, FR, HR, HU, IE, LT, PL, RO, SK), to indicate the details of those authorisations, especially the rate of application, frequency of application and BBCH stage.

   The note taking of an amendment review report did not take place. The Member States were invited to comment by 9 November 2020.

3. L-ascorbic acid (amended report to take note)

   The Committee took note of the amendment review report which addressed the confirmatory information.

4. Fluometuron (amended report to take note)

   The Committee took note of the amendment review report which addressed the confirmatory information.

5. Terbuthylazine

   The Commission recalled that comments and reactions from Member States over the past meetings had in general been more in favour of introducing restrictions to the approval, therefore the Commission had prepared a proposal for amending the approval. The Commission provided a brief explanation of the elements taken into account and asked Member States to consider the updated review report and provide comments by 9 November 2020.

6. Ipconazole

   Member States were informed that a review of the approval in accordance with Article 21 had been launched in August in line with requests by some Member States. The letter sent to the applicant has been made available to Member States via CIRCABC. The applicant must provide information to show a safe use by 30 November 2020, taking into account the concerns raised for birds and the classification of the substance as toxic for reproduction, category 1B. After that an assessment will take place in view of a regulatory decision on whether to amend or withdraw the approval.

7. Tri-allate

   Following the process to review the confirmatory information EFSA had published its Conclusion in September 2020. Member States were invited to consider the comments of the applicant who is dissatisfied with the Conclusion, since it raises issues which were not directly part of the confirmatory information assessment, in particular as regards the data package for genotoxicity of the parent substance.

   In addition, critical concerns are identified about contamination of groundwater by metabolites of tri-allate, for one metabolite (DIPA) above 10 ug/L in all scenarios, significant exposure from DIPA in groundwater is expected and the consumer assessment remains unfinalised.

   The Commission recalled that the renewal process had already commenced. The rapporteur Member States, the Netherlands, was invited to provide an update on the finalisation of the RAR and to indicate if the issues identified in the EFSA Conclusion on the confirmatory information have been addressed or not.

   The Commission would then reflect on the next steps. Member States were invited to comment by 23 November 2020.

8. Sulfoxaflor

   The Commission presented comments from Member States received since the last meeting of this Committee and mentioned that it had made letters of support from growers associations available to the Member States.

   The Commission informed of its intention to restrict the approval of sulfoxaflor to uses in permanent greenhouses only.

   One Member State informed of the recent authorisation by its competent authority of the use of sulfoxaflor in winter cereals and wondered about the justification for a restriction to protected crops only. Another Member State considered that risk mitigation measures are possible. Although most Member States did not have final positions yet, eight Member States indicated that they will probably not support a proposal to restrict the uses to permanent greenhouses. Two Member States indicated that they might be able to support the Commission's proposal. Five Member States indicated not having a position yet.

   Member States were invited to send their position on restricting the approval to permanent greenhouses by 9 November 2020.

9. Pyrethrins

   Member States were invited to comment by 23 November 2020 on the amended review report, which considers the on-going renewal process and indicates that the

Rapporteur Member State would inform the Commission with no delay if it considers that the consumer risk assessment is causing concerns. A review of the approval in accordance with Article 21 could be considered in such a case.

10. Benzovindiflupyr

    Member States were invited to comment by 23 November 2020 the amended review report, which considers the on-going renewal process and will also assess an in-vitro micronucleus test already submitted in the dossier for the renewal, to elucidate the clastogenicity potential of one the impurity.

11. Dithianon

    The Commission informed that the TTC approach used by the rapporteur Member State to perform a consumer risk assessment related to the residues in processed products was considered inappropriate by EFSA as the EFSA PPR Guidance on the Residue Definition for risk assessment has not yet been endorsed by the Commission and the Member States. This is highlighted in the updated Conclusion on the peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data, published by EFSA in June 2020. Therefore, as the confirmatory data point remains open, the Commission informed that it is considering a withdrawal of the approval of the active substance and invited Member States to comment on this way forward by 23 November 2020.

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

    The point was postponed.

13. Amilsubron

    The Commission reminded that the applicant submitted confirmatory information within the deadline for which a technical report of EFSA is available. However, one point (endocrine disruption) remains open due to procedural issues: in light of the implemenation of the new scientific criteria to identify endocrine disruptors, the Commission had sent a letter to the applicant in December 2018, informing that a full assessment according to the new criteria should be submitted as confirmatory information by November 2020.

14. Tebufenozide

    The Commission recalled that the first approval of tebufenozide (1 June 2011) obliged the applicant to submit further data on the relevance of metabolites RH-6595, RH-2651 and M2 and the degradation of tebufenozide in anaerobic soils and soils of alkaline pH. The required data were submitted within the prescribed period of two years, evaluated by the Rapporteur Member State, and peer-reviewed as reflected in the EFSA Technical Report.

    The degradation of tebufenozide in anaerobic soils and soils of alkaline pH was addressed successfully. The metabolite RH-2651 is predicted to occur above 0.1 µg/L in all FOCUS scenarios for the representative uses considered and based on the data available a genotoxic potential could not be excluded during the assessment of the confirmatory information. The applicant, in 2018, after EFSA finalised its Technical Report, provided a new study aiming at demonstrating the non-relevance of the aforementioned metabolite. Given the upcoming start of the renewal procedure (November 2021), the Commission proposed two ways forward to the Member States: 1) amend the review report considering the latest information

(without peer-reviewing it) or 2) start an Article 21 procedure with a following mandate to EFSA to review the new information. The Member States were invited to comment by 9 November 2020.

15. Isofetamid

The Commission mentioned that based on the EFSA Technical Report and comments received from Member States, it proposed to update the specifications with respect to the content of impurities and acceptable limits. Only the review report would be amended but not the approval as the minimum purity remains the same as for the original approval.

The Commission supported EFSA's view to take the specifications of the batches produced at the current production site as reference specifications (and not those from the pilot scale batches). The current minimum purity would cover the the commercial scale production batches.

Member States were invited to comment on the draft amended review report by 9 November 2020.

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 positions of three additional Member States on the approach to decide on the specific protection goals for the risk assessment for bees, which had been made available since the last meeting of this Committee. One of this Member States supported approach 2 as proposed by the EFSA and the the other two Member States opted for a combination of the proposed approaches 2 and 3.

The Commission recalled that the current discussions focus on honeybees given that data are available but emphasised the need to also set specific protection goals for bumble bees and solitary bees. Given that data are scarce for wild bees, the way forward might be an 'a priori' decision as suggested by several Member States. Member States were therefore invited to send proposals on the setting of a specific protection goal for bumble bees and/or solitary bees (either an approach or an 'a priori' value) by 23 November 2020.

The Commission also informed the Member States of the discussion on 1 October 2020 on the review of the Bee Guidance in the ENVI Committee of the European Parliament. EFSA had informed the Parliament that the specific protection goal in 2013 was based on limited scientific data and provided further explanations as regards the different approaches that could be used for determining the protection goals. The Commission informed that EFSA is currently working on a document that should address all concerns and questions raised by the Parliament and would provide the necessary scientific data to risk managers to set a specific protection goal for honeybees. This document will be published on the website of the EFSA. A next meeting with Member States will only be organised once this document is finalised; the Commission is considering organising this as a joined event with stakeholders.

One Member State inquired about the timing of a next workshop. One Member State mentioned that the choice of the approach for setting the protection goals also

got attention from national NGOs. One Member State repeated its comments on the 2013 Bee Guidance Document. One Member State wondered if the deadline to finalise the review will be challenged given the ongoing discussions.

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

   The Commission informed Member States that stakeholder comments had been analysed and a revised version of the document was available. No significant changes had been introduced compared with the version last reviewed by Member States, rather certain points had been clarified and improved.

   Several Member States expressed concerns about various aspects in the draft document and made suggestions for final changes. Therefore, note-taking was postponed and Member States were invited to provide further comments by 9 November 2020 in view of finalising the document.

3. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance (to take note)

   The Commission informed that very few comments had been received since the last meeting of this Committee.

   The Standing Committee took note of the document with an implementation date of 1 May 2021 (approximately 6 months after note taking).

4. Draft Guidance document on the risk assessment of metabolites produced by microorganisms (to take note)

   The Commission explained that the document had been reviewed by the Working Group Biopesticides following the comments received by several Member States. The restructuring of the stepwise approach proposed by one Member State was eventually considered as not entirely justified at this stage. One Member State stated that an evaluation of the guidance document would be needed once experience is available with first cases – the Commission noted that such a continuous evaluation is already foreseen in the document.

   The Standing Committee took note of the document with an implementation date of 1 November 2021 (approximately 12 months following the note taking).

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

   The Commission gave an update on the issues under discussion. Since the meeting of this Committee in July 2020, the Commission had received comments from two Member States and EFSA. Further discussion is required on the timelines and some other practicalities of the process of approval of basic substances. It is also necessary to align the procedures and wording between the Working Document on basic substances and related Guidance Documents of EFSA which are not yet finalised. The comments submitted to sections other than Section 2 of the Working Document will be taken into account at a later stage, as the current revision concerns only Section 2 and the changes required by the new Transparency Regulation.

   The note taking of the revised Working Document was postponed as several points in the draft are still under discussion. Member States were invited to send any additional comments by 9 November 2020.

6. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers

   The Commission gave an update on the issues related to adoption of the EFSA Guidance on the risk assessment of active substances and their transformation products that have stereoisomers. Since the meeting of this Committee in July 2020, the Commission did not receive new comments from Member States. The Commission informed on the letter of ECPA requesting the delay of the implementation date till end of 2022.

   The Commission informed about the discussion during the meeting of the Standing Committee Section Phytopharmaceuticals - Residues. The issues related to the specificities of MRL timelines were solved. The Commission presented an implementation plan, with a proposed implementation date 1 August 2021. The note taking of the guidance is envisaged at the next meeting of this Committee. Member States were invited to send any additional comments by 23 November 2020.

7. Additional data for review of EFSA Exposure Guidance Document – for information

   The Commission informed that EFSA had recently sent a letter, informing that not enough data are available to address some aspects of the update requested in the mandate received by EFSA in 2017. As a consequence, EFSA suggested to either update the guidance document by November 2021, including a scenario for greenhouses, the revision of several crop parameters, and the implementation of an on-line user-friendly calculator, leaving the other aspects for a later point in time once the data would be available, or alternatively stop the mandate until it would be possible to address all aspects. EFSA indicated a preference for the first option. The Commission also indicated its preference of this option. No other views were presented by a Member State in the Committee.

   The Commission will ask EFSA to proceed with the update of the guidance document by November 2021 on the aspects for which this is possible as stated before.

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

   The Commission informed the Committee that the analyses of the 600 comments received on the draft updates is still ongoing.

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

   The Commission informed that only two Member States had raised comments, which could be sorted out at technical level but were not yet implemented as the drafts are intended to be forwarded to EFSA for finalisation. The Commission noted that the EFSA PPR Panel was involved twice during the drafting of the draft, and informed it will get in contact with EFSA in order to find the most pragmatic way to endorse this draft guidance document with no undue delay.

10. 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 there were no news to report, and that internal consultation on some legal interpretations were still ongoing.

11. 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 informed that as announced in the report on the REFIT evaluation of the pesticides legislation it intended to resume the work initiated in 2014-15 leading to the development of a draft Technical Guidance document on points 3.6.3 to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular concerning negligible exposure to active substances used in plant protection products. No guidance on negligible exposure in the environment was included in this draft document – it focussed on human health only (dietary and non-dietary exposure). Thresholds for non-dietary exposure were not yet agreed (for the first tier assessment 10% of the AOEL had been suggested, and for the second tier a margin of exposure of 1000 was suggested). At the time, Member States could not agree to endorse the Technical Guidance. Since 2015, negligible exposure has been assessed in several cases, and as no alternative exists, the draft Technical Guidance has actually been used by applicants, Member States and EFSA.

    In order to steer the next steps, Member States were asked whether they would be in a position to finalise the document as it was left in 2015, perhaps with some small amendments, and whether they would support a threshold for non-dietary exposure of 10% of the AOEL and 1000 for margin of exposure, or to indicate an alternative approach they think would be better.

    Member States were invited to submit comments by 23 November 2020.

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

    After the consultation of Member States and stakeholders (associations of applicants) last year, an updated version derived from the outcome of the comments received and aiming to improve the operation of the zonal system, had been agreed in the Post Approval Issues Working Group of this Committee.

    Member States were invited to comment the new version of the Guidance Document by 23 November 2020.

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

The Commission informed on the developments since the last meeting of this Committee in July, in particular the nomination of the members of the Working Group and its first two meetings. The Working Group discussed the planning of the next steps including a draft working document on generic pesticide scenarios and the governance. The Commission had shared the comments from the Member State on the outline of the next steps. The Commission informed that the planned meeting to update stakeholders was postponed.

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

The Commission informed on the drafting of the future guidance document on risk mitigation measures, which will also be discussed by the Working Group mentioned under A.08.

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

– Article 44(4) (to take note)

Two notifications had been received and the Committee took note of them. The notifications concerned the withdrawal of authorisations of penflufen based products, as the substance had been classified by ECHA's Committee for Risk Assessment (RAC) as carcinogenic, category 2, which gives rise to the obligation to submit confirmatory information as regards the relevance of the metabolite M01 (penflufen-3-hydroxy-butyl) for groundwater. Since the Rapporteur Member State informed that this data had not been submitted, the Commission announced that the approval will be withdrawn and invited Member States to comment by 9 of November 2020.

– Article 36(3) (to take note)

A total of 15 notifications had been received and the Committee took note of them.

11 notifications concerned rejections of mutual recognition applications and 2 concerned rejections of authorisation under the zonal system.

Additionally, the UK notified a rejection of authorisation under the zonal system of a folpet and difenoconazole containing plant protection product.

– Article 53

The Commission informed that since 15 May 2020 a total of 127 Article 53 notifications from Member States had been received and are publicly available, for which the 120-day authorisation period starts after this date and ends before 16 October 2020. A further 98 notifications had been received for which the 120 day period started after 15 May 2020 but did not yet end by 16 October 2020.

The Commission informed that at regular intervals (approximately yearly), a detailed analysis will be provided as regards all the notifications received for a more detailed discussion.

The Commission noted that 10 Member States granted repeatedly emergency authorisations for the use of the neonicotinoids imidacloprid, thiamethoxam, clothianidin in sugar beets following the prohibition of all their outdoor uses in May 2018 and also for thiacloprid following the non-renewal of approval on 3 February 2020. The Commission informed of its intention to mandate EFSA in accordance with Article 53(2) of Regulation (EC) No 1107/2009 to assess whether these emergency authorisations granted for the 2020 sugar beet growing season fulfil the conditions set out in Article 53(1) of the Regulation.

A.11 Plant Protection Products Application Management System (PPPAMS):

Member States were informed that a new release of PPPAMS (version 1.30) had been made available and that an email was under preparation to be sent to Lead Users in Member States to outline the changes and provide the necessary information.

A.12 News from European Food Safety Authority (EFSA), in particular;

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

   EFSA informed about the planned written consultation of the Member States on its draft Practical Arrangements concerning confidentiality in accordance with the

empowerment set out in Articles 7 and 16 of Regulation EC No 1107/2009 which will be initiated in November. Comments of Member States will be summarised at the next meeting of this Committee and the practical arrangements are intended to be signed before the end of the year.

2. Update on EFSA practical arrangements on Transparency/confidentiality (Art. 38/39 GFL Regulation); Pre-submission phase (Art. 32a/32b/32c GFL Regulation)

   EFSA provided an overview of the draft Practical Arrangements for the pre-submission phase and public consultations, focusing on how the new proposed provisions laid down in the Practical Arrangements will apply in the field of pesticides under Regulation (EC) No 1107/2009. The planned written consultation with the Member States will be initiated in November and channelled through the experts of the General Food Law. The practical arrangements are intended to be signed before the end of the year.

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

   EFSA presented an update on the development of IUCLID as IT tool for the pesticide dossier submission and indicated that IUCLID was to be released in the next few days. EFSA also introduced the Hypercare programme for the first dossier submissions, which will provide targeted support to Member States and applicants for early submitters of dossiers for the renewal of approval of active substances and a few MRL submissions. Around 15 substances with deadlines for dossier submission in July-August 2021 will be included.

   The Commission thanked EFSA, ECHA and all the participants of the IUCLID technical group for the efforts made to achieve the first version of IUCLID for pesticides and encouraged the Member States to participate in the upcoming training and hyper-care programme.

A.13 Improving the efficiency of the process of a.s. approval / renewal:

No news to discuss.

A.14 New Transparency rules: General Food Law amendment and implementation.

1. Data format for submissions of applications of approval/amendment of approval

   The Commission presented a working document setting out principles to implement the new submission format for approval or amendment of approval dossiers, and indicated that the internal consultation still needs to be initiated. The Commission announced that it intends to submit a draft implementing Regulation for discussion at the next meeting of this Committee and invited Member States to submit any comment on the working document by 9 November 2020.

A.15 Farm to Fork Strategy and REFIT evaluation – update and follow up actions, in particular:

1. Microorganism Active Substances – update of data requirements

   The Commission informed on progress of the work related to the revision of the data requirements and Uniform Principles for the placing on the market and the evaluation of micro-organisms and plant protection products containing them (Regulations (EU) No 283/2013, No 284/2013, and No 546/2011). The

Commission thanked Member States experts involved in these activities. The Commission highlighted that this work is part of the implementation of the Farm to Fork strategy and the follow-up to the report on the REFIT evaluation of the pesticides legislation, and that the revisions of these Regulations is expected to foster access to the market of non-chemical alternatives and to provide more tools for organic farming. The Commission also indicated its intention to set in a clear and transparent way approval criteria for micro-organisms by amending Annex II of Reg. (EC) 1107/2009. The Commission informed that it planned to present first drafts of the amended Regulations to this Committee in December 2020. Member States were invited to comment by 9 November 2020.

2. Low risk plant protection products

   The Commission presented a state of play of approved low-risk active substances, the number of which is steadily increasing. The Commission reminded that low-risk products benefit from an accelerated review process and a longer authorisation period. However, it seems that at national level, the uptake of the possibilities offered by Regulation (EC) No 1107/2009 is limited as plant protection products containing active substance approved with the status of low-risk are no necessarily authorised with low-risk status in the Member States. The Commission indicated that it is analysing the reasons for this and that clarification of the criteria for low-risk products may be needed.

3. Comparative risk assessment

   The report on the REFIT evaluation of the pesticides legislation found that the rules for active substances that are candidates for substitution are ineffective and inefficient. According to the feedback received, the comparative assessments carried out by Member States are complex and require resources, but so far did not lead to any substitution of plant protection products, mainly due to the lack of alternatives at national level with proven better risk profiles. As one of the Commission's commitments is to simplify the comparative assessment of products containing candidates for substitution, the Commission will, in close collaboration with Member States, consider to amend Annex IV of the PPP Regulation to improve the effectiveness of comparative assessments. Discussions will be initiated in the PAI WG for this purpose.

A.16 Clarifications & questions related to specific active substance:

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

   The Commission informed that reports received from Member States on this topic had been translated and that it was reflecting on how to further investigate this issue. A discussion with EFSA was envisaged. As an immediate action, the Commission reminded rapporteur Member States for azole substances to ensure that the issue is taken on board during the assessment, as far as possible.

   The Commission also informed Member States that industry was carrying out various activities on the topic and that further information may also become available from that work.

2. SDHI active substances

   The Commission informed of a petition submitted to the European Parliament on SDHI active substances and that it had made relevant documents available. At the

meeting of the Petition Committee (PETI) on 22 September 2020 it was decided to keep the petition open.

The Commission recalled that many of the SDHI substances are currently either under renewal or the renewal procedure will be started soon. Rapporteur Member States of SDHI substances were requested to consider if the scientific articles mentioned in the petition are applicable.

One Member State confirmed that it will keep this Committee informed about a review of its national opinion on the "assessment of a warning signal regarding the toxicity of succinate dehydrogenase inhibitor (SDHI) fungicides" and that it will perform an assessment of cumulative dietary exposure. Another Member State supported this activity and provided a link to a FAQ page regarding this subject on their website.

The Commission announced that it will included this point again on the agenda of a forthcoming meeting of this Committee when new data becomes available.

3. Residues in ornamental cut flowers

The Commission recalled the discussions in this Committee between March and October 2017 on residues in cut flowers and potential exposure of florists, and informed that discussions will be resumed, in particular also in the Post Approval Issues Working Group because the topic is related to authorised products on ornamentals and potential residues on cut flowers. The Commission indicated that it is in particular interested to know how this topic is handled at national level, and informed that it had contacted EFSA for technical information, in particular the potential extrapolation of exposure scenarios to florists..

One Member Stated informed that it provided additional information in March 2019 and will send it again. The Commission thanked this Member State and invited all Member States to submit any further relevant information by 9 November 2020.

4. Flupyradifurone

The Commission informed the Committee on the feedback received from three Member States on the notification received from one Member State which was presented in the previous meeting of this committee. The Commission invited Member States to send their positions by 23 November 2020.

A.17 General issues for information / discussion

1. Brexit preparedness

No new information was reported, nor were any questions raised.

2. Illegal plant protection product use

The Commission informed that during the past months it had received numerous signals, complaints, information from media, and parliamentary questions concerning cases of illegal use of pesticides in several Member States.

In particular, the Commission received information about residues above the authorised limits for dimethoate, omethoate, chlorpyrifos in products coming from Bulgaria, outdoor uses of clothianidin, thiamethoxam, chlorpyrifos, fenvalerate, and DTT in Bulgaria; residues of linuron in products originating from Poland, and plant protection products containing acetochlor found in Slovakia. The

Commission also reported on cases of sale of illegal pesticides in Poland and in Italy. The products concerned contained dimethoate, chlorpyrifos and iprodione.

The Commission reminded Member States of their duty to enforce the Plant Protection Products Regulation and conduct controls at national level – in the field and in shops where the products are sold or on online platforms where unauthorised products are offered. It highly recommended to conduct broad controls cooperating also with third-countries as it seems that many of the unauthorised plant protection products were actually imported illicitly.

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

   This point was postponed.

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

   This point was postponed.

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

   This points was postponed.

6. BTSF – trainings

   The Commission informed on the planned training programme on the risk assessment for micro-organisms used as pesticides or biocides. The kick-off meeting with the contractor took place in June this year. Training activities are planned to start in January 2021 and, due to the on-going pandemic, the first sessions will be remote.

   The Commission informed that a kick off meeting with the contractor for the BTSF training on the criteria to identify endocrine disrupting properties had occurred in July. However, the actual training activities, which had been planned for November 2020, will be postponed due to the ongoing pandemic.

A.18 Safeners and Synergists:

The Commission presented an outline for the process to set up a work programme for the review of synergists and safeners on the market as foreseen in Article 26 of Regulation (EC) No 1107/2009 and invited Member States to submit comments, in particular those Member States which so far had not replied to earlier invitations for commenting.

A.19 News from Sustainable Use Directive (Directive 2009/128/EC):

The Commission provided an update on the progress with the evaluation of the Directive on the sustainable use of pesticides and the impact assessment of its planned revision.

Member States asked for relevant publications from the European Institutions, which were provided:

- European Parliament study concerning implementation of the SUD (https://www.europarl.europa.eu/RegData/etudes/STUD/2018/627113/EPRS_STU(2018)627113_EN.pdf),
- European Parliament resolution on implementation of the SUD (https://www.europarl.europa.eu/doceo/document/TA-8-2019-0082_EN.html, https://www.europarl.europa.eu/news/en/headlines/society/20190117STO23722/pesticides-in-food-what-is-the-european-parliament-doing-to-help).
- European Court of Auditors report (https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=53001).

A.20 News from Health and Food Audits and Analysis (SANTE, Directorate F):

No news to discuss.

A.21 Report from working groups, in particular:

1. Working group on Biopesticides

   No news to discuss.

2. Working group on Seed Treatments

   No news to discuss.

3. Working Group on Post Approval Issues

   a) Updated Terms of Reference rev.3 (to take note)

   The Committee took note of a revision of the terms of reference, by which the minutes of the Working group will be made publicly available.

A.22 Minor Uses:

No news to discuss.

A.23 Court cases:

The Commission reported on developments since the meeting of the Committee in July: two recent judgments (in cases C-514/19, C-784/18 P) and two opinions delivered by the respective advocate-general (cases C-352/19 P, C-499/18 P).

The Commission informed that two new court cases were registered, involving access to documents requests:

Case T-371/20 Pollinis France c/Commission: The NGO Pollinis was refused access under Regulation 1049/2001 to several documents containing Member States' positions on the Bee Guidance Document expressed in the framework of the comitology procedure. Pollinis contests the refusal before the ECJ.

Case T-554/20 Pollinis France c/Commission : Similar to T-371/20, the NGO Pollinis was refused access under Regulation 1049/2001 to documents containing Member States' positions on the Bee Guidance Document. Pollinis contests the decision of the Commission before the ECJ.

A.24 Ombudsman cases:

The Commission informed about two new cases:

2020/1239 ECCA – complaint from ECCA for maladministration against the Commission. ECCA presented a new legal interpretation of the data protection provisions of Regulation (EC) No 1107/2009 in May 2019. The Commission took more than the usual time to examine the position and provide a reply as extensive consultations with the Legal Service and the Member States in the framework of the Post Approval Issues Working Group were held.

2020/1402- PAN Europe – complaint from PAN against the Commission related to the ongoing project for determining specific protection goals for the assessment of environmental risks of pesticides. The Ombudsman opened an inquiry into one part of the complaint.

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

The Commission informed that the following outcomes of the Residues Section of the Committee held on 28-29 September 2020 have possible impacts on authorisations of plant protection products:

Substance	Type of change (see above)	Agenda item	SANTE doc number
Diclofop	MRLs were lowered and residue definition amended.	B 02	SANTE/10044/2020
Fluopyram	MRLs were lowered.	B 02	SANTE/10044/2020
Ipconazole	MRLs were lowered.	B 02	SANTE/10044/2020
Terbuthylazine	MRLs were lowered and residue definition amended.	B 02	SANTE/10044/2020
Fluxapyroxad	MRLs were lowered.	B 03	SANTE/10032/2020
Hymexazol	MRLs were lowered.	B 03	SANTE/10032/2020
Metamitron	MRLs were lowered.	B 03	SANTE/10032/2020
Penflufen	MRLs were lowered.	B 03	SANTE/10032/2020
Spirotetramat	MRLs were lowered and residue definition amended.	B 03	SANTE/10032/2020
Benalaxyl	MRLs were lowered.	B 04	SANTE/10034/2020
Benalaxyl-M	MRLs were lowered.	B 04	SANTE/10034/2020
Dichlobenil	MRLs were lowered.	B 04	SANTE/10034/2020
Fluopicolide	MRLs were lowered.	B 04	SANTE/10034/2020
Proquinazid	MRLs were lowered and residue definition amended.	B 04	SANTE/10034/2020
Pyridalyl	MRLs were lowered.	B 04	SANTE/10034/2020
Carbon tetrachloride	MRLs were lowered.	B 05	SANTE/10482/2020
Chlorothalonil	MRLs were lowered.	B 05	SANTE/10482/2020
Chlorpropham	MRLs were lowered.	B 05	SANTE/10482/2020
Dimethoate	MRLs were lowered.	B 05	SANTE/10482/2020
Ethoprophos	MRLs were lowered.	B 05	SANTE/10482/2020

Fenamidone	MRLs were lowered.	B 05	SANTE/10482/2020
Methiocarb	MRLs were lowered.	B 05	SANTE/10482/2020
Propiconazole	MRLs were lowered.	B 05	SANTE/10482/2020
Pymetrozine	MRLs were lowered.	B 05	SANTE/10482/2020
Chlordecone	MRLs were lowered.	B 06	SANTE/12510/2019

The Commission also informed that EFSA indicated in the Conclusions of the peer review for abamectin that there might be an acute risks in relation to some commodities and that a review of the MRLs is necessary in view of the lowered toxicological reference values. The Commission suggested to mandate EFSA with no delay, in order to assess the safety of the existing MRLs also considering the ones that were proposed in a recent Reasoned Opinion, which were not yet implemented in the MRL Regulation. A Member State indicated that it has some reservations in relation to the acute reference doce (ARfD) proposed by EFSA and believes that the ARfD of 0.0025 mg/kg bw, which is based on neurotoxic effects in dogs, would be relevant for acute exposure assessments.

Member States were invited to provide comments by 9 November 2020.

A.26 OECD and EPPO activities:

This point was postponed.

A.27 Scientific publications and information submitted by stakeholders:

The Commission informed that a letter of PAN and a letter of ECPA had been received and made available to Member States.

A.28 Date of next meeting(s):

The Commission informed that the next meeting of this Committee is confirmed for 3 - 4 December and is likely to take place virtually due to COVID 19. The Commission will circulate the tentative dates for the meetings in 2021 as soon as they are available.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012.

The Commission reiterated the reasoning for the draft Regulation and explained the changes made compared to the draft previously seen by Member States.

The Commission informed about the comments received via the feedback mechanism. In total 18 comments had been submitted, among which 6 anonymous, 1 from a citizen, 2 from NGOs, 1 from a trade union and 8 from business operators and business associations. One comment had been submitted from the USA. All the comments were supporting the proposal.

Some of the changes introduced and illustrated during the meeting by the Commission were based on comments received via the feedback mechanism; in particular a specific reference to Article 17 of Regulation (EC) No 1107/2009 had been added in Article 2 and Article 17 of the draft Regulation in other to improve the clarity of these provisions. In addition, other small changes had been introduced.

The vote on the draft Regulation took place during the meeting.

Outcome of the vote: Favourable opinion.

The following protocol declarations were made:

The Netherlands welcomes the proposal because of the improvements in the renewal procedure and its transparency and will therefore support it. However, the proposal also means extra work for Member States without allocating any extra time in the procedure while the current legal timelines for Member states are already unrealistic in view of the work required. This also leads to the extension of the approval period for almost every active substance in the renewal process. We therefore ask the Commission to acknowledge this problem and to come with additional actions in order to reduce the pressure on the renewal process at Member State level, and by doing so to prevent further delays.

Germany took note of the explanations from the Commission according to which it is for legal reasons not possible to insert in Art.11 (4) of the draft proposal the following wording "Irrespective of the assessment mentioned above an assessment of the toxicological endpoints needed for risk assessment for consumer intake as well as of the analytical methods for residues in products of plant and animal origin should always be conducted".

Germany shares the view of the Commission that this might concern only a few substances. However, Germany regrets that - irrespective of the current import tolerance approach regarding the so called "cut-off" substances - it is not foreseen to conduct an assessment leading to the derivation of reference values, of residue definitions and of analytical methods.

Especially for enforcement this information is needed in case of possible residue findings with a view to decide on appropriate enforcement measures.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EC) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 1,4-Dimethylnaphthalene, 6-Benzyladenine, acequinocyl, *Adoxophyes orana granulovirus*, aluminium sulfate, amisulbrom, *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), azadirachtin, *Bacillus pumilus* QST 2808, benalaxyl-M, bixafen, bupirimate, *Candida oleophila* strain O, chlorantraniliprole, disodium phosphonate, dithianon, dodine, emamectin, flubendiamide, fluometuron, fluxapyroxad, flutriafol, hexythiazox, imazamox, ipconazole, isoxaben, L-ascorbic acid, lime sulphur, orange oil, *Paecilomyces fumosoroseus* strain Fe9901, pencycuron, pendimethalin, penflufen, penthiopyrad, potassium phosphonates, prosulfuron, *Pseudomonas sp*. Strain DSMZ 13134, pyridalyl, pyriofenone, pyroxsulam, quinmerac, S-abscisic acid, sedaxane, sintofen, Sodium silver thiosulphate, spinetoram, spiromesifen, spirotetramat, *Streptomyces lydicus* WYEC 108, tau-Fluvalinate, tebufenozide, tembotrione, thiencarbazone, valifenalate, zinc phosphide.

The Commission reiterated the reasoning for the draft Regulation and explained the changes made compared to the draft previously seen by Member States.

The vote on the draft Regulation took place during the meeting.

Outcome of the vote: Favourable opinion.

The following protocol declaration was made:

Germany supports the extensions of the approval periods.

However, we are in favour of an additional 3 months for all the active substances in the proposal.

An even distribution of the workload in the programme can thus be achieved again.

We are convinced that a period of 6 months would help both, MS and applicants, in preparing high quality dossiers in the new IUCLID format.

It should also be taken into account that the introduction of a new data format requires not only technical but also administrative adjustments of the procedures.

In addition, we are afraid that the approval of low risk substances and micro-organisms might be hampered since many of these substances are applied for by SMEs (small and medium enterprises), which might not have the resources/the experience to prepare dossiers in IUCLID.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance mancozeb, 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/10326/2020 / Rev. 1).

The Commission recalled that at the last meeting of this Committee in July 2020, the Committee had agreed to vote on a draft Regulation not renewing the approval of mancozeb by written procedure as a qualified majority was expected. However, the procedure was stopped with no result on request of three Member States.

In addition, on 2 September 2020, the new Rapporteur Member State submitted an updated assessment including studies that in its view had not been fully considered by the former Rapporteur Member State UK. The updated assessment confirmed to a large extent the earlier findings. Comments on this updated evaluation had been sent by the applicant to the Commission on 16 October 2020 and they had been made available to Member States. EFSA had confirmed that also with the new evaluation, the active substance is fulfilling the criteria to be identified as having endocrine disrupting properties (T modality confirmed). In conclusion, neither the applicant's argumentation nor the updated assessment of the new Rapporteur Member State provided indications to change the outcome of the EFSA conclusion.

Furthermore, the submission of new studies by the applicant to change the classification of mancozeb recommended by ECHA's RAC Committee (toxic to reproduction, category 1B) is delayed and hence the Member State who had indicated its intention to submit a new proposal to modify the harmonised classification had not yet done so. Therefore, a potentially different new RAC recommendation would not be available before the second half of 2022. The legally binding requirement for classification of mancozeb as toxic to reproduction, Category 1B, is expected to be published in the next adaptation to technical progress of the CLP Regulation.

Therefore, the Commission considered that there was no reason to modify the draft Regulation substantially. However, explanations the recitals of the legal act had been amended to reflect the latest developments.

One Member State requested to extend the deadline by which Member States have to withdraw authorisations and the length of the grace periods that Member States may grant for placing on the market and use of existing stocks of products. This request was supported by several other Member States. The Commission agreed to modify the draft Regulation accordingly, while emphasising that the periods set are the maximum possible, while Member States who wish to do so can withdraw authorisations earlier and set shorter grace periods.

The vote on the draft Regulation took place during the meeting.

Outcome of the vote: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance etoxazole 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/2020/10320 Rev. 2).

The Commission reiterated its proposal for renewal as candidate for substitution with restriction to non-edible crops in permanent greenhouses (as defined in the PPP Regulation) and had shared the comments of the Member States, the reply to comments from the US in the TBT procedure, the applicant's letter and the answer of the Commission as well as a supportive letter from a stakeholder received since the last meeting of this Committee.

As a reply to comments from one Member State, the Commission clarified that its proposal is to restrict the use on ornamentals to permanent greenhouse to mitigate the

risk to non-target arthropods and aquatic organisms. This is found to be a viable and real solution given that product authorisations exist for such a use in Europe.

The Commission summarised the reactions of Member States received, two of which would abstain as their opinion is that the restriction to non-edible crops is not required, and two would vote against.

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

Outcome of the vote: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of carbon dioxide 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.

The Commission introduced the draft, which remained unchanged since the previous meeting of this Committee and recalled that a broader discussion on the interpretation of the rules on basic substances under Regulation (EC) No 1107/2009 was foreseen under agenda point A.02.

The Commission recalled the reasons for the proposal not to approve the substance as basic substance, i.e. the fact that carbon dioxide is currently approved as regular active substance for use in plant protection product under Regulation (EC) No 1107/2009, which precludes the (additional) approval of the same substance as a basic substance. The Commission summarised the reactions of Member States received, two of which had signalled support for the draft Regulation, one its indicative support. Two Member States had informed not to support the draft Regulation.

During the ensuing discussion, five Member States informed that they consider that an approval as a basic substance, was possible, which, contrary to the rationale put forward by the Commission, is not precluded by an existing approval as regular active substance followed by product authorisations for substances that fulfil the criteria as foodstuff and could therefore not support the draft Regulation.

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

Outcome of the vote: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance topramezone, 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.

The Commission recalled the reason for the non-approval i.e. the applicant had withdrawn its application.

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

Outcome of the vote: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance blood meal as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11236/2020).

The Commission informed that after the meeting of this Committee in July comments from Member States had been received, and the consultation of all Commission services concerned was launched, but not terminated yet. Consequently, voting was postponed.

Vote postponed.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance extracts from *Allium cepa* L. bulbs 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/10842/2020 Rev. 1).

The Commission explained some minor modifications introduced in the draft Regulation and the renewal report after consultation of the other Commission services concerned.

The Commission briefly explained the comments received from four Member States since the last meeting of this Committee. One Member State could not agree with the proposal to approve the extract as a basic substance based on the outcome of the assessment. This Member State explained that the applicant has not updated the application significantly based on Member States' comments. Despite the fact that the substance is likely to fulfil the basic substance criteria in Article 23 of Regulation (EC) No 1107/2009 with regard to inherent properties, the applicant had not shown safety for the proposed uses of *Allium cepa* extract. Therefore, based on the current application, the Member State was of the opinion that safe use has not been demonstrated.

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

Outcome of the vote: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance Kieselgur (Diatomaceous earth) 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/10898/2020).

The Commission informed about a few minor modifications introduced in the draft Regulation and the renewal report after consultation of the Commission services concerned. The Commission thanked for the comments received from five Member States that were mostly included in the documents presented for vote. The Commission

reminded that the proposed renewal is not for a low risk substance, as there is a need for a specific risk mitigation measure for operators.

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

Outcome of the vote: Favourable opinion.

B.10 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 calcium phosphide, denathonium benzoate, haloxyfop-P, imidacloprid, pencycuron and zeta-cypermethrin.

The Commission recalled that this draft Regulation had already been submitted to a vote via written procedure on 30 September 2020, but that the procedure was stopped with no result on request of one Member State.

A revised draft Regulation was introduced in this meeting of the Committee, where the active substances plant oils/citronella and tebufenpyrad had been removed, as the Commission had been informed by the respective Rapporteur Member States that the renewal procedures were on-going for both and admissibility of the dossiers is expected.

The vote on the draft Regulation took place during the meeting.

Outcome of the vote: Favourable opinion.

Section C Draft(s) presented for discussion

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).

Following a request from the Commission to Member States in May 2020 to indicate practical risk mitigation measures to reduce the risk to the environment for this active substance, a few Member States had sent their proposals. As requested by Member States during the meeting of this Committee in July 2020, the Commission had asked EFSA and the Rapporteur Member State (RMS) to review those proposed measures and the views of EFSA and the RMS had been made available to Member States. Neither EFSA nor the RMS did agree that the proposed measures would mitigate the risks to acceptable levels.

The Commission invited Member States to send their position on the proposed risk mitigation under consideration of the views of EFSA and the RMS by 9 November 2020.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non- approval of the active substance pydiflumetofen 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/10300/2020 Rev. 1).

The Commission informed that at the last meeting of this Committee, the Rapporteur Member State expressed his willingness to consider additional studies on persistence submitted by the applicant. While three Member States had indicated they would support a non-approval, comments had been received by several Member States which support the consideration of additional ad-hoc persistence studies as the current assessment is not fully suitable for volatile substances. The Rapporteur Member State will revise the assessment in order to finalise the evaluation. As a consequence, the dossier of this substance which is not yet on the market, will be put on hold until the re-evaluation is available.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10730/2018 Rev. 2).

The Commission informed about comments received from four Member States since the proposal was presented in the meeting of this Committee in July 2020. Also comments from the applicant on the proposal had been made available to the Member States.

One of the comments from the applicant indicates that it does not agree that indoxacarb could be regarded as persistent given that the DT50 in field is lower than 10 days. With regard to persistence, the Commission considered the laboratory DT50 of 230 days, however overall the persistency of indoxacarb is not decisive given that the proposal is to not renew the approval. The applicant agrees that the toxicity criterion (for PBT criteria) is met.

One Member State indicated the importance of this substance for IPM given its high specificity for Lepidoptera and expects an impact on its local agriculture if this substance is no longer available.

Member States were invited to send comments by 23 November 2020.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11527/2018 Rev 1).

The Commission recalled that at the meeting of this Committee in May, a proposal for renewal of cypermethrin as candidate for substitution with stringent risk mitigation targets to address high risk to aquatic organisms, non-target organisms (off-field) and bees (in field) identified in the EFSA Conclusion of 2018 had not received a qualified majority support from Member States at an indicative ‘tour de table’. Following a

Statement from EFSA, this proposal would have set out the levels of the necessary drift reduction and some additional risk mitigation measures (expressed as restrictions and conditions in line with Article 6 (i) of Regulation (EC) 1107/2009). However, a group of Member States found the required risk mitigation unrealistic and not achievable in practice.

At the meeting of this Committee in October 2020, several Member States reiterated that risk mitigation measures as required in the light of the EFSA Statement exist and that they are realistic under their national conditions. The Commission confirmed that one safe use in one Member States is enough to renew a substance. The Commission explained that the previous proposal allowed flexibility to implement the obligation not to grant authorisation in case alternative plant protection methods are available or if the conditions to ensure the required level of risk mitigation are not given. Nevertheless, given the lack of sufficient support for renewal under these conditions, the Commission now proposed non-renewal of approval.

The Commission shared the draft review report and the draft Regulation as well as the comments from the Member States and a supportive letter from a stakeholder received since the last meeting. The Member States were invited to confirm their positions and/or send their comments by 9 November 2020.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of *Bacillus amyloliquefaciens* AH2 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11938/2020).

The Commission informed of the comments received from the Member States and the applicant on the EFSA Conclusion and presented the draft Regulation to approve *Bacillus amyloliquefaciens* strain AH2 as low-risk active substance, as *Bacillus amyloliquefaciens* strain AH2 meets the criteria for low-risk substances of point 5 of Annex II to Regulation (EC) No 1107/2009. Member States were invited to submit comments by 23 November 2020.

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

The Commission presented the main issues regarding the application. The extract is to be used as a repellent against seed eating mammals and birds. Even though the applicant argues that this extract is used for food and feed purposes, there are many data gaps in the application. There are many questions from Member States and EFSA regarding the genotoxic properties of the active component of the extract, capsaicin. Many data gaps remain for the fate and behaviour section and on the effects on non-target species. Several Member States concluded that due to the toxicity issues and the fact that harmful effects on animal health or unacceptable effects on the environment cannot be excluded, it would not be appropriate to consider the substance as a basic substance or to approve it.

On 12 October 2020, the applicant sent the Commission a declaration that the substance was now an approved feed additive and that he does not understand why it can be approved as a feed additive and not be used for plant protection. However, when comparing the application and the EFSA assessments for food and feed uses, it emerged that the substances concerned are different. The main component in the feed additive is capsanthin which is manufactured by saponifying sweet peppers or paprika. The main component in the basic substance application is, as far as could be ascertained, capsaicin from 'chili peppers'.

The basic substance application mentions a content of 6% capsaicin, while for the feed additive, tests have shown the absence of capsaicin or very low concentrations. So the manufacturing process is different as well as the final composition.

In the light of the many remaining concerns, the Commission will maintain the proposal for non-approval. Member States were invited to comment by 9 November 2020.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation on the approval of the active substance 24-epibrassinolide as low risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11348/2020).

The Commission summarised the findings of the EFSA Conclusion on the new active substance 24-epibrassinolide. The Commission informed about the comments of 3 Member States that had been integrated where possible. In the Conclusion, no critical areas of concern or issues that could not be finalised were identified. The Commission reminded, that the new active substance 24-epibrassinolide fulfils all criteria for the approval as a low risk substance.

Member States were invited to provide their comments by 9 November 2020.

C.08 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 fenpyrazamine (Draft Review Report SANTE/10690/2012 Rev. 3).

Pro memoria – no news - TBT notification process ongoing .

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance Garlic extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11050/2020).

The Commission informed that since the last meeting of this Committee only three Member States reacted, being in general in agreement with the way forward proposed by the Commission (i.e. approval with restrictions to only granular formulation for potatoes and parsnips). Member States were invited to send further comments by 9 November 2020.