EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)4499724

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
18 - 19 May 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/f8942369-3a8a-4eef-a521-e50fadb4f1d0*

SUMMARY REPORT

The meeting took place via videoconference 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 previous meeting is published.

A.02 New dossiers:

New active substances

This point was postponed.

Basic substances applications received

The Commission informed that the following applications for basic substances had been received:

a) Sodium chloride (extension of use)

The application for extension of use of sodium chloride as a basic substance against the invasive alien plant species *Baccharis halimfolia* only concerned its use in coastal areas flooded periodically with sea water.

Member States were asked to send comments by 18 June as regards (a) the need for a full risk assessment by EFSA or whether they consider that the decision can be taken based on the risk assessment already performed by EFSA for the original approval of sodium chloride as a basic substance; (b) their positions on approval of this extension of use of sodium chloride and (c) restriction of use to areas which are flooded with sea water.

b) Mycosubtilin

Mycosubtilin is a natural lipopeptide produced by Bacillus bacteria that has antifungal properties. The application concerns uses as field spray application for antifungal protection (rust, apple scab, grey mould) of apple, vegetables and grape wine.

c) Water extract tannins from Castanea sp and Schinopsis sp

The water extract contains a mixture of tannins from the chestnut tree and from quebracho trees. It is proposed to be used as a nematicide, in field, applied on soil as a spray or via drip irrigation, for protection of vegetables.

d) Black soap

Black soap is a complex mixture of natural compounds which are saponified. It is also known as insecticidal soap. It is proposed to be used as an insecticide, in a spray on all crops, trees and ornamentals.

e) Pepper dust

The substance is intended for home garden uses. After application on the plants and surrounding soil, it acts as a repellent against cats and dogs.

f) Calcium propionate

The application is for a use of calcium propionate as a fungicide (against Botrytis ssp) in spray application on turfgrass and other grasses.

Amendment of conditions of approval

No news to discuss.

Article 21 Reviews

No news to discuss.

A.03 Renewal of approval and general issues:

a) **Withdrawals**

The Commission informed that the applications for haloxyfop-P and Ca-phosphide had been withdrawn and that it will proceed preparing a draft Regulation retracting the earlier extensions of approvals according to the foreseen procedures.

b) **Potential resistance to azoles with demethylase inhibitor as mode of action and epidemiological data**

The Commission informed the Committee about a letter from the Netherlands raising concerns about potential resistance to medical azoles caused by the use of demethylase inhibitor azoles used in plant protection products, and about the impact of pesticide exposure on neurological disorders, including Parkinson's disease. The Netherlands called for studies investigating neurotoxic effects to become standard requirements for all dossiers.

The Commission informed the Committee about a letter from Denmark also outlining concerns about cross-resistance to medical azoles of *Aspergillus fumigatus,* and calling on amending the data requirements, a coordinated review of existing knowledge and a testing strategy.

With regard to Parkinson's disease the Commission highlighted work already performed or on-going at EFSA, in particular the new project on NAMs (New Approach Methodologies) and several pilot cases studies with Member States, including one where NAMs will be used to address the data gap related to possible Parkinsonian effects.

With regard to the need to update data requirements, it was recalled that currently studies on DNT are required if there is evidence from other studies or from the mode of action that such investigations are needed, and that further work on DNT is ongoing at EFSA level.

The Commission recalled that-up-to-date knowledge and concerns could already be considered as part of the renewal reviews of azole substances (all concerned substances are either under review or will be reviewed in the next few years). The need to impose restrictions or for other measures will be considered as part of the renewal process.

The Commission welcomed the initiatives of the Netherlands and Denmark and asked all Member States to provide comments and additional input to move forward.

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

New active substances:

a) Chloropicrin

The Commission informed that the EFSA conclusion had been received on 30 January 2020 but due to the COVID-19 restrictions, the first discussion could not be held during the meeting in March.

The Commission summarised the concerns identified for this active substance used for soil fumigation. The critical areas of concern are the suspected genotoxicity of the metabolite dichloronitromethane DCNM, the mutagenic potential (in vivo) of chloropicrin that prevents conclusions on the potential risks to consumers, operators, workers, bystanders and residents, the potential groundwater contamination at levels above the parametric drinking water limit of 0.1 µg/L for all the representative uses and considering all the FOCUS scenarios/crops (monitoring data submitted by the applicant were so far not considered), and effects on soil macro- and micro-organisms, non-target arthropods and soil organisms for all representative uses.

The function and the mode of application of the substance (soil injection or dripping with an additional plastic coverage), the proposed risk mitigation measures to minimise the exposure of humans and non-target organisms (lower proposed application rate, strip application, tractor fan, removal of beehives during application and until removal of the plastic covers), detailed by the applicant were made available to the Committee.

The Commission requested Member States to comment on the EFSA conclusions and the applicant's comments by 18 June 2020.

Renewal of approval

b) Blood meal

The Commission informed that the EFSA conclusion had been received on 31 January and that the first version of the Renewal Report is drafted.

The only data gap identified by EFSA concerns the risk for fish and aquatic invertebrates when spraying techniques are used. No critical areas of concern were identified.

The Commission requested Member States to comment on the EFSA conclusion and the applicant's comments by 5 June 2020.

Basic substances

c) Capsicum annuum annuum, longum group, cayenne, ext

The Commission informed that the extract is intended to be used as a repellent to seed eating mammals and birds. In the EFSA technical report, many questions were raised 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.

Member States were requested to comment by 18 June 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 referred to the soil sterilisation use of this active substance as nematicide, fungicide and herbicide on carrots (field use) and on tomatoes (greenhouse application) as representative uses, by injection in 20 cm soil and then covering by plastic film. The active substance is naturally present in food and used as a flavouring agent. It is irritating and sensitising.

EFSA could not derive toxicological reference values for the consumer risk assessment due to lack of testing by oral route and for the metabolite MSA, in particular because of the genotoxicity potential of this metabolite which cannot be excluded. Neither acceptable exposure scenario nor safe conditions of use have been identified for the potentially exposed populations (operators, workers and bystanders). DMDS is unlikely to be an endocrine disruptor for humans. A critical area of concern has been identified with respect to potential groundwater contamination by dimethyl disulfide. Critical areas of concern have been identified for birds and mammals (acute risk), aquatic organisms (acute risk) and earthworms.

The applicant informed about stewardship programmes and suggested a reduced rate of application of 200 kg/ha, limit the use to greenhouses, apply once every 2 years from May to October to limit the release into the environment during rainy periods. He also suggested to limit use only by professional applicators duly trained. The applicant also mentioned that the plant protection product would be marketed as a “package” solution with the approved barrier film (DAF) and the training / certification of the professional user.

Member States were invited to comment on the EFSA conclusion and the applicant’s comments by 18 June 2020.

b) Ethamethsulfuron-methyl

The Commission informed that the application for approval had been withdrawn and that an administrative non-approval Regulation would be prepared, with a vote foreseen in the meetingof the Committee in July 2020.

Renewal of approval

c) Etoxazole (detailed discussion, tour de table)

The Commission summarised its proposal for renewal as candidate for substitution with restriction to non-edible crops in permanent greenhouses. The Commission informed on the comments received so far from Member States and the comments of the applicant on the draft renewal report as well as the supportive letter from a consultant company.

No discussion took place. The Commission invited each Member State to clearly express their position by 5 June 2010.

d) Clopyralid

This point was postponed.

e) Famoxadone

The Commission recalled that the earlier proposal for non-renewal had not reached support of the majority of Member States. As a consequence, in February 2020 a revised proposal for renewal of approval as a candidate for substitution with risk mitigation measures was made available to the Member States via written procedure. This proposal considered re-calculations made by the former RMS (UK) as well as new RMM. So far six Member States reacted: one supporting, one not supporting because of risk to human health and the environment (birds and aquatic organisms), two raising concerns on the environment without having a definitive position yet, and two Member States suggesting recalculations as regards consumer exposure and the risk for workers.

The Commission understands that the situation remains unclear and also reminded that the former Rapporteur Member State (UK) is not anymore present in the Committee for clarifying. In addition, as some of the Members States who replied indicated that some aspects of the evaluation would need to be revised, a detailed discussion seems sensible 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. A first discussion took place during this meeting, together with the measures how to potentially address them.

Two Member States stated during the meeting that they agreed with the evaluation of the Rapporteur Member State of the worker exposure or the rationale of the applicant to support the submitted study on the long term risk for birds and mammals. EFSA commented that it would check again the worker exposure estimates and the long term reproduction study, which was rejected by EFSA during the review of the renewal dossier. The Commission indicated that it will reflect on the way forward and consider whether to give a formal mandate to EFSA.

f) Cypermethrin (detailed discussion, tour de table)

The Commission summarised its proposal for renewal as candidate for substitution with several restrictions and conditions in line with Art. 6 (i) of Regulation (EC) 1107/2009. A draft renewal report and a draft of the specific conditions had been made available for comments of the Member States.

A total of 18 Member States indicated their potential support of the renewal under the conditions set out by the Commission, 2 Member States still did not have a position and 7 Member States did not support renewal.

Member States were invited for further comments by 5 June 2020.

g) Indoxacarb

The Commission informed on the updated peer review by EFSA, on the basis of which the Commission intends to maintain its proposal to non-renew the approval of indoxacarb based on the risk to bees and mammals for the representative use in maize and the risk for consumers, workers, mammals and bees for the representative use in lettuce. Furthermore, several open points remain regarding human metabolism, the consumer dietary risk assessment and the risk for leaching to groundwater for one soil metabolite.

Comments from the applicant and Member States on the updated EFSA peer review had been made available to the Committee.

Member States were requested to comment by 18 June 2020.

h) Bifenazate (detailed discussion, tour de table)

The Commission summarised the reasons for the proposal for non-renewal: two critical areas of concern (high risk to birds and mammals and to non-target arthropods); risk to operator and workers in case of in-door uses, and to residents in outdoor uses if the EFSA method is applied; the risk assessment could not be finalised due to some important data gaps. The assessment of aquatic risk could not be finalised also due to several data gaps.

The Commission informed on the overall situation of the feedback received from the Member States (6 Member States indicated their potential support for non-renewal, while 7 Member States would support renewal). The Commission shared the applicant's comment received since the last meeting.

No discussion took place. The Member States were invited to provide their comments by 5 June 2020.

i) Kieselgur

The Commission informed that it had received EFSA's conclusion on 27 February 2020. EFSA had not identified any critical areas of concern. A draft review report for a renewal had been made available to the Committee, as well as the comments of the applicant. The Commission considered that kieselgur does not qualify as low risk substance, due to concerns about limited local effects of kieselgur in the lungs and the associated recommendation that operators wear respiratory protective equipment.

Member States were invited to provide their comments by 5 June 2020.

Basic substances

j) Lecithins (extension of use) – amended review report to take note

The Committee took note of the amended review report.

k) Sucrose (extension of use)

See point below.

l) Fructose (extension of use)

The Commission discussed fructose and sucrose together. The applications for extension of use concern the alignment of the conditions of use for apples of both already approved basic substances as an elicitor of the plant defence mechanism, extension to the use as fungicide and insecticide on grapevine, and extension of use as insecticide on maize (grain corn).

After consultation of the Member States, the Commission did not seek the assistance of EFSA due to the nature of the substances and the nature of the request. As explained in more detail in the respective draft review reports, the Commission believes that it can be assumed that the additional uses of both substances also fulfil the criteria of Article 23 and can therefore be approved. The draft review reports had been sent to the applicants and some minor comments had been received.

Member States were requested to comment by 18 June 2020.

m) Comfrey steeping

The application for approval of comfrey steeping as a basic substance concerns the use of an extract from the plant *Symphytum officinale* as insect repellent and plant elicitor in fruit trees, grass and vegetables, to be applied as a spray and via watering of seedlings. The Commission proposed to precise the name of the basic substance to "fermented extract from leaves of *Symphytum officinale* L. (comfrey)" for reflecting the difference between the process of preparation of the extract from comfrey for uses as a basic substance, compared to extracts intended for human consumption or as a traditional medicine.

The EFSA Technical Report was published in November 2019. This report identified a large number of data gaps in all areas of the risk assessment. The application had not demonstrated that the use of fermented extract from leaves of comfrey for purposes of plant protection would be safe. In particular, the EFSA report indicates that comfrey is known to contain genotoxic and carcinogenic components, such as pyrrolizidine alkaloids.

As regards compliance with the criteria of Art 23 of Regulation (EC) No 1107/2009, the fermented extract from leaves of comfrey does not fulfil the criteria of a "foodstuff", a relevant evaluation of its safety, performed in accordance with EU legislation, is not available, it cannot be concluded that it is not a substance of concern, and the provided information was insufficient to finalise the risk assessment in all the areas. Therefore, the Commission considered that the fermented extract from leaves of comfrey cannot be approved as a basic substance. A draft review report had been made available.

Member States were asked to send comments and positions by 18 June 2020.

n) Clayed charcoal

The application for an extension of use of clayed charcoal as a basic substance covers a formulation as a wettable powder to be sprayed on vine trunks after mixing with water. The Technical Report of EFSA was published in November 2019. The major concern identified by EFSA is the presence of dust of crystalline silica - carcinogenic to humans by inhalation if its concentration in bentonite (ingredient of clayed charcoal) exceeds 0.1%. The information available in the application was not sufficient to demonstrate that clayed charcoal under evaluation meets the requirement that the level of respirable crystalline silica in bentonite, and in the clayed charcoal, does not exceed 0.1%. Therefore, the Commission proposed to not approve the extension of use of clayed charcoal as a basic substance in a form of wettable powder in spray application.

Furthermore, it is difficult to identify the predominant use of clayed charcoal with specifications as approved as a basic substance for purposes other than plant protection, and the preparation of clayed charcoal for use from the individual

ingredients is not detailed in the application. Lastly, clayed charcoal is in fact a mixture of two substances (charcoal and bentonite) and, therefore, does not fulfil the definition of substance in Regulation (EC) No 1107/2009. These elements are described in more detail in an information note made available to the Committee.

Member States were asked to send by 18 June 2020 their comments and positions as regards (a) the draft Review Report and proposal for non-approval of extension of use of clayed charcoal as a basic substance; (b) issues raised in the information note made available on CIRCABC.

o) Allium cepa (extract)

The Commission informed about the application for approval of this new basic substance: a water extract of onion bulbs to be used to control fungi in potatoes, tomatoes and cucumbers. Considering the nature of the substance, the relatively low application rates, and the conditions of use proposed, it is concluded that the use of extracts from *Allium cepa* L. bulbs, would fulfil the criteria of Article 23 and thus can be approved as a basic substance.

The review report had been made available to Member States and sent to the applicant (no comments received yet).

Member States were requested to comment by 18 June 2020.

p) Vinegar (extension of use)

The Commission explained that this application concerned a second extension of use of vinegar, for being used as an herbicide on non-agricultural areas. The inhalation and ecotoxicological risks that were identified by EFSA in the previous applications, still stand. The proposed application rate is much higher than the accepted application rate for medicinal, aromatic and perfume crops. Therefore, the commission proposed not to approve the extension of use.

Member States were requested to comment by 18 June 2020.

Amendment of conditions of approval

No news to discuss.

A.06 Confirmatory Information:

1) Spiroxamine (amended review report to take note)

The Committee took note of the amended review report.

2) Azadirachtin (amended review report to take note)

The Committee took note of the amended review report.

However, one Member State stated that it supported the conclusion by EFSA, that there is not sufficient information on the relative toxicity profile of the different components of the extracts and that the lead active compound approach cannot be used.

3) Triazole derived metabolites (TDMs)

– *Paclobutrazole (amended review report to take note)*

The Committee took note of the amended review report.

– *Difenoconazole (amended review report to take note)*

The Committee took note of the amended review report.

– *Bromuconazole*

Member States were informed that a draft revised Review Report had been prepared to further reflect the conclusion of the assessment of the TDMs, in particular to add an additional Appendix outlining the reference values and residue definitions.

Member States were asked to provide their comments on the updated report by 18 June 2020.

4) Terbuthylazine

The Commission recalled its request to Member States to consider if a restriction to use once every second year at a maximum of 850 g/ha would address the concerns identified by EFSA with regard to the potential contamination of groundwater and consumer risk. The Commission explained that based on comments and views received so far, a clear direction was not identified.

Several Member States indicated concerns about that approach since the calculations provided by the applicant had not been peer reviewed and the consumer assessment would still remain open since no reference values can be set for LM 3 and LM6, and these remain above 0.75 ug/L even when used biannually.

Other Member States were inclined to support such an approach, considering that the restriction would result in lower levels of metabolites in groundwater and no risk for consumers.

The Commission recalled that the renewal evaluation is scheduled to begin in 2022.

In order to move forward, the Commission asked Member States who did not react so far to submit their views by 5 June on the proposal for a restriction to biannual use at a maximum of 850 g/ha.

5) Ipconazole

The Commission explained that in addition to its proposal to identify ipconazole as a candidate for substitution due to the classification of the substance as toxic for reproduction category 1B (see point B.10), a review of the approval in accordance with Article 21 of Regulation (EC) No 1107/2009 may also be initiated.

Member States were asked for their views on such a review by 5 June 2020.

6) Triazine amine (relevant for metsulfuron-methyl, prosulfuron, thifensulfuron-methyl and iodosulfuron)

Following the publication of the EFSA Opinion on triazine amine, the Commission suggested to address these confirmatory information processes in two steps.

Firstly, to close the confirmatory information process for metsulfuron-methyl, noting in the review report that the Opinion of the EFSA Panel and its recommendation to carry out an *in vitro* micronucleus study to complete the data package for aneugenicity. The EFSA Opinion did not indicate a specific concern for aneugenicity but rather indicated that according to the latest scientific knowledge, an *in vitro* micronucleus study should be provided. Since the renewal dossier for metsulfuron-methyl is due in September 2020, the study would need to

be provided in the context of the renewal assessment. Once the study has been evaluated any further necessary actions would be considered.

In a second step, if the submitted study confirms that triazine amine does not present a concern for aneugenicity, the confirmatory information processes would then be also closed for the other concerned active substances. Conversely, if a concern is identified further action would be considered, e.g. review under Article 21 of Regulation (EC) No 1107/2009.

Member States were asked to provide comments on the suggested way forward by 18 June 2020.

7) Sulfoxaflor

The Commission informed about the findings in the EFSA statement of 27 February 2020. Comments from Member States and the applicant had been made available on CIRCABC as well as a support letter from a stakeholder.

The Commission informed that the risk to honeybees from puddle water is now clarified by EFSA. Based on the screening assessment for the risk to bumblebees and solitary bees in field margins, up to 99.5% drift reduction is needed.

The Commission informed that, based on previous comments received from Member States, it was reflecting on amending the approval conditions, in particular as regards the acceptability of risk mitigation measures.

8) Gamma-cyhalothrin

This point was postponed.

9) Lamda-cyhalothrin

This point was postponed.

10) Pyrethrins

This point was postponed.

11) L-ascorbic acid

This point was postponed.

12) Benzovindiflupyr

This point was postponed.

13) Isoxaben

This point was postponed.

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)

Member States were informed about the outcome of the workshop on the first consultation of risk managers on the review of the Bee Guidance Document, held in Brussels on 6 March 2020. Experts from 21 Member States (1 risk manager and 1 risk assessor per Member State) had intended to participate. Due to travel restrictions following the COVID-19 outbreak, experts from only 17 Member States were present physically during the workshop. EFSA and ECHA were connected via

a video link. The report of the workshop, which includes the presentations of EFSA, had been made available on CIRCABC.

The Commisison also informed that different scientific approaches to be used as basis for the review of the EFSA 2013 Bee Guidance Document were currently being developed by EFSA considering the feedback received during the workshop on the 6 of March.

The Commission announced a follow-up online meeting on this subject in June 2020; invitation and background documents will be made available before that meeting.

2) Brief procedural updates:

a) Draft update of Guidance on emergency authorisations according to Article 53

The Commission informed that the Member State comments submitted since March had been considered. A new version of the draft had been prepared and made available. The Commision explained some of the main changes, including the inclusion of a new subsection specifically on seed treatment and use and marketing of treated seeds. This consolidated the various pieces of information on seeds that were in the earlier versions.

Member States were informed that a stakeholder consultation would be launched via the Advisory Group on the Food Chain and Animal and Plant Health later in May.

b) Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance

The Commission informed that the last Member State comments received had been considered in the revised version made available.

Member States were informed that a stakeholder consultation would be launched via the Advisory Group on the Food Chain and Animal and Plant Health later in May.

c) Draft Guidance document on the risk assessment of metabolites produced by micro-organisms

The Commission informed that the last Member State comments received (in particular on Stage 4) had been considered in the revised version made available.

Member States were informed that a stakeholder consultation would be launched via the Advisory Group on the Food Chain and Animal and Plant Health later in May.

3) Review of Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011)

The Commission recalled that Member States had been invited to submit comments by 8 May 2020. A separate commenting period for stakeholders (applicants) ran in parallel, in order to involve all concerned parties.

4) Draft Guidance Document for the Generation and Evaluation of Data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No 1107/2009

The Commission recalled that Member States had been invited to submit comments by 8 May 2020. A separate commenting period for stakeholders (applicants) ran in parallel, in order to involve all concerned parties.

5) EFSA Guidance on the risk assessment of PPP active substances and their transformation products that have stereoisomers

The Commission informed that this Guidance had been adopted by EFSA in July 2019 and presented to this Committee in its meeting in October 2019. Member States had not sent any comments. The Guidance had also been discussed at the meeting of the residues section of this Committee. The Commission had received a letter from ECPA requesting a transition period before the adoption of the Guidance.

The Commission announced that it intends to take note of the Guidance during the meeting of this Committee in July, and proposed as application date 1 August 2021, which is one year after the intended endorsing (note taking) of the Committee, and two years after the adoption by EFSA. This implies that the Guidance would apply to all the new dossiers submitted after this date.

Member States were invited to send their comments as regards the Guidance and the proposed application date by 5 June 2020.

6) Additional data for review of EFSA Exposure Guidance Document– for information

This point was postponed.

7) Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02 (no news)

No news to discuss.

A.08 Defining Specific Protection Goals for Environmental Risk Assessment, in particular Report on the Workshop on 3-4 February 2020 and way forward:

The Commission informed on the main outcomes of the workshop "Specific Protection Goals for the Environmental Risk Assessment of PPP – moving on with the EFSA method (3 - 4 February 2020, Brussels) "and made available to Member States the report of the workshop.

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

The Commission informed on the main outcomes of the workshop "Reducing exposure to pesticides – experience so far and next steps towards more sustainable plant protection" (17 January 2020, Brussels) dedicated to the risk mitigation measures and made available to Member States the report of the workshop.

Member States were invited to submit suggestions as regards the proposed way forward presented by the Commission by 18 June 2020.

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

Article 44(4) (<u>to take note</u>)

A total of 28 notifications had been received from December 2019 until May 2020 and the Committee took note of them.

This includes notifications on withdrawal of authorisations due to analysis and inspections and non-compliance with the specifications, notifications on withdrawal of authorisations for glyphosate based products due to Governmental decision, notification on withdrawal of an authorisation for an indoxacarb product due to risk for bees, notifications of modification of the authorisations of folpet product due to new classification, among others. Due to the transitional period on Brexit, the Commission also informed the Member States about the action taken by the United Kingdom so that the Member States can decide to take action and revise their national authorisations accordingly.

Article 36(3) (to take note)

A total of 24 notifications had been received from December 2019 until May 2020 and the Committee took note of them.

A total of 10 notifications concerned rejections of mutual recognition applications and 14 concerned rejections of authorisation under the zonal system.

Poland commented on a notification refusing the mutual recognition on the product Metax 500 SC providing the following protocol declaration:

The application for granting authorisation for the product Mezotop 500 SC (Metazachlor-chem) which is reference product for Metax 500 SC (second name) was submitted on 7th May 2014 so before the entry into force of the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products and "EFSA model". That is why the assessment has been carried out in line with approach applied at the time of submission of the application. Therefore, we find authorizing the product Metax 500 SC fully justified.

What is more, Poland has a different approach than Spain as regards mutual recognition. In our view, the Member State where mutual recognition is sought shall accept the assessment carried out in line with regulations and guidance documents binding at the day of submission an application in reference Member State. That is why in similar situation Poland would probably authorise the product based on art 40 of the Regulation.

Article 53 (for information and discussion)

Member States were reminded to ensure that notifications of authorisations are processed and submitted to the Commission without delay and that backlogs are avoided. Notifications should be complete and contain the relevant information to justify the emergency use.

The Commission recalled that all emergency authorisations are published since February 2020 on https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home, therefore note taking of these kind of notifications will no longer take place in future Committee meetings. Instead, Commission intends in regular intervals to discuss particular aspects, and invites Member States to also increase their scrutiny on this topic.

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

This point was postponed.

A.12 News from European Food Safety Authority (EFSA).

EFSA gave an overview of progress in the peer-review process for some active substances and informed that some formatting changes in the EFSA Conclusions will be implemented. These editorial changes aim at better explaining the rationale and consequence of data gaps for the risk assessment, introduce and/or reformat Appendices A and C, and add a summary table on the potential risk mitigation measures assessed.

EFSA also mentioend that a re-prioritisation of activities might be needed under the current Covid-19 related situation.

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

No news to report and no discussion took place.

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

1) **Update on Regulation for renewals of approval of active substances**

The Commission had provided an outline and a working document of a future Implementing Regulation on CIRCA BC and addressed some of the comments received form the Member States following the written consultation. The Commission intends to submit a draft legal text for discussion at the next meeting of this Committee.

2) **Update on IT tools for notification and submission of applications**

The Commission presented the intention to use IUCLID as IT tool for notification and submission of pesticide applications for applications after March 2021 – all necessary software elements are expected to be ready for the IUCLID update due by October 2020. The Commission explained the reasons to choose IUCLID as submission format for active substances (chemicals and microorganisms) and basic substances. The functionalities of IUCLID will allow follow-up actions which would cover for instance confidentiality checks, disseminations, comparison with notified studied, and automatic generation of assessment reports, which would not be possible with other formats.

One Member State commented on the complexity of the project and the short and challenging deadlines. EFSA replied that it aims to achieve the project's objective in time for March 2021.

Member States were asked to communicate to the Commission the future IUCLID contact points for pesticides in their administrations.

3) **Update on 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)**

The Member States were updated on the revision of the Working Document SANCO/10363/2012 that is planned in the context of implementation of new transparency rules. The update will include discussions and suggestions held within the respective Working Group in 2017.

The changes to the current procedure for approval of basic substances that will be required by the new transparency rules cover an optional pre-submission advice on the applicant's request, and the notification of the studies in case the applicant carries out or commissions new studies in support of his application. It will be also

proposed that the applications for approval as a basic substance are submitted using the IUCLID software. The relevant interface of IUCLID will be simplified and adapted to the needs of applicants for basic substances.

The applications will also be made public by EFSA and subject to public consultation immediately after the acceptance of the application by the Commission. This public consultation will also allow third parties to submit proposals for additional uses of the basic substance which are not covered in the initial application (the approach is consistent with suggestions given by the Member States who were active in the Working Group in 2017). The new proposed uses would be evaluated together with all the comments received in the context of public consultation, and could be included in the risk assessment by Member States and EFSA from the beginning.

After taking on board comments from the public consultation, the regulatory procedure will continue following the usual steps: commenting by Member States and EFSA, update of application by the applicant, publication of the Technical Report by EFSA, and decision making in this Committee.

Member States were asked to send comments and suggestions to the proposed amendments to the Working Document SANCO/10363/2012 by 18 June 2020.

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

1) **Acibenzolar-S-methyl – updated review report (<u>to take note</u>)**

The Committee took note of the amended review report.

2) **Chlorotalonil monitoring data**

This point was postponed.

A.16 General issues for information / discussion:

1) BREXIT

The Commission informed that an updated notice for stakeholders, replacing the former notice and the questions and answers will be published shortly. The link will be communicated to Member States and be included in SANTE's webpage (published on 25 May at: https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/plant_protection_products_en.pdf) Attention was drawn to the rules for free circulation of goods between the two markets (EU and UK) that have been placed on the market before the end of the transition period.

2) COVID-19

The Commission informed that a multitude of actors is affected by delays caused by the Corona Virus (Member States, EFSA, Commission). However, legal deadlines cannot be derogated ex ante. While the concept of force majeure applies to exceptional situations, its application needs to reply on a case-by-case consideration, especially as not all applicants and Member States are equally affected and tasks carried out by applicants or Member States differ in nature and are differently affected by absenteeism or confinement measures. Stakeholders had been advised to carefully document delays, their reasons, and the efforts to contain the delays, as this will also allow the Commission to assess whether extension of

approval deadlines are justified under Article 17 of Regulation (EC) No 1107/2009. The Commission invited the Member States to inform about those dossiers evaluated by them for which they expect that delays set by the Regulation are likely not to be met.

3) **2,4 D / 2,4 D EHE**

The Commission recalled that this point had been discussed in the meeting of this Committee in December 2019, where the process of amending the condition of approval of the active substance 2,4 D in order to include other forms (ester) had been suggested as the best way forward. No additional comments had been received from Member States which would lead to a better solution. Therefore, the discussion is considered closed and an amendment of conditions of approval agreed at the best way forward.

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

The point was postponed.

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

The point was postponed.

6) **Scope of Regulation (EC) No 1107/2009**

The point was postponed.

A.17 Safeners and Synergists.

The Commission informed that it had initiated work to implement Article 26 of Regulation (EC) No 1107/2009, aiming at the adoption of a Regulation establishing a work programme for the gradual review of synergists and safeners on the EU market.

The Commission was currently analysing the list of substances identified as synergists and safeners by Member States following a survey initiated in the autumn of 2019. The Commission thanked the 19 Member States which had replied to the survey. ECPA had also sent the list of safeners and synergists placed on the market by their members.

Member States who had not yet replied to the survey were invited to react by 18 June 2020. The Commission intended to present a first outline for the next meeting of this Committee.

A.18 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

The Commission informed that publication of the REFIT evaluation report, accompanied by a Staff Working Document is scheduled for publication on 20 May 2020, together with the Farm to Fork Strategy and the Biodiversity Strategy.

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

The Commission informed on issues relating to data collection on microbial plant protection products under Regulation (EC) No 1185/2009. The legal obligation on Member States is to report this data in kg, but the active substances in these plant protection products are not quantified in kg.

The Commission will launch a short survey to gather information on how Member States report this data now, and to determine if Member States would support the development of a guidance document by ESTAT to establish conversion factors for each microbial plant protection products (to convert cfu or I.U. to kg), which all Member States could then use when reporting data on the sales and use of microbial plant protection products to the Commission.

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

No news to report and no discussion took place.

A.21 Report from working groups, in particular:

1) Working group on Biopesticides

This point was postponed.

2) Working group on Seed Treatments

The Commission informed that the Draft Guidance Document on seed treatment, risk management part, was finalised by the Working Group and submitted to the Commission. The Commission will review it internally and present it to this Committee.

The risk assessment part of this guidance document is intended to be finalised by EFSA following a mandate from the Commission on the basis of an updated draft (still in progress).

3) Working group Post Approval Issues

This point was postponed.

A.22 Minor Uses.

The Commission informed that the annual general meeting of the Minor Use Coordination Facility (MUCF) had been held in February 2020. Slovakia was elected as a member of the Steering Group. The financing of the MUCF for 2020 is secured. A workshop had been organised in February 2020 with representatives of the Member States, the Commission, industry, stakeholders, and its summary is available on the website of the MUCF. The meeting of the horizontal expert groups in March 2020 had been cancelled due to Covid-19.

The Commission also informed that the coordinator and the technical expert had left the MUCF. There are two vacancies open. More information is available on the website of the MUCF and had been made available to this Committee.

A.23 Court cases.

No news to report and no discussion took place.

A.24 Ombudsman cases.

No news to report and no discussion took place.

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

The Commission presented the mandate to EFSA on the joint review of MRLs for fosetyl and phosphonates, which includes references to both the current acceptable

daily intake (ADI) for phosphonic acid and the new, lower ADI derived in the peer review for fosetyl. The Commission indicated its intention, upon receipt of the reasoned opinion, to prepare a draft Regulation modifying MRLs on the basis of EFSA's recommendation in the scenario with the new, lower ADI. It asked Member States to raise any concerns they may have in writing by 5 June 2020, as it would otherwise assume tacit agreement.

The Commission presented the draft mandate to EFSA on the updated exposure assessment for spinosad considering the acute reference dose (ARfD) of 0.1 mg/kg body weight (BW) proposed by EFSA in the framework of the peer-review of the assessment conducted in the context of the renewal of the active substance (EFSA, 2018). The Commission clarified that new endpoints had not yet been endorsed by risk managers, since a decision on the renewal of the active substance was not yet taken. When considering the proposed ARfD, a risk to consumers cannot be excluded for several food products. EFSA will consult Member States to identify fall-back GAPs that would lead to a safe scenario. The Commission asked Member States to raise any concerns they may have in writing by 5 June 2020, as it would otherwise assume tacit agreement.

The Commission presented the draft mandates to EFSA on toxicology and MRLs for propoxur, and on MRLs for methoxyfenozide, for information only.

Post-meeting note: The Commission did not receive any concerns raised by Member States on the mandates for fosetyl/phosphonates or spinosad by the timeline indicated.

A.26 OECD and EPPO activities, in particular:

- *Report of the OECD Risk Reduction Seminar on Evolving Digital and Mechanical Technologies*
- *WG on Drones*
- *Invitation Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD)*
- *Guidance Document on the Exchange and Use of International Efficacy and Crop Safety Data for Minor Uses*
- *Preparation of OECD WG on Pesticides (Virtual meeting)*

The Commission highlighted briefly the various activities and invitations sent by the OECD. In June 2020 the traditional meetings will be replaced by virtual ones, namely the meeting of the expert group on biopesticides (9-10 June), and the Working Group on Pesticides (11-12 June) for which the Commission will organise coordination meetings with participating Member States in the first week of June.

A.27 Scientific publications and information submitted by stakeholders.

The Commission raised the attention of Member States to the information available on CIRCABC for this point, which includes letters from PAN and ECPA concerning several relevant points on the agenda of the current meeting.

A.28 Date of next meeting(s).

The next meeting is scheduled for 16 and 17 July 2020, subject to confirmation.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) modifying Annex III of 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 summarised the modifications since the last version, which had been made in the light of the comments from the Member States: raising of the concentration limit for the unintentional presence as impurities from 0.01% to 0.1%, deletion of minerals, inclusion of additional octylphenols ethoxylated, deletion of a repetition (entries 82 and 85).

One Member States raised the possibility of applying SCL (Specific Concentration Limits for Classification) if existing, instead of using the concentration on 0.1% for determining the unintentional presence of the substances as impurities.

Two Member States did not support the proposal as the underlying criteria to identify unacceptable co-formulants should be part of the proposal.

One Member State inquired about the time for actual implementation. The Commission explained that if the vote is taken, the Parliament and the Council will have 3 months for scrutiny and if none of them objects, the Commission could adopt the Regulation in December 2020.

One Member Sate informed that it supports in principle the rationale for including substances in Annex III. However, given the impact on authorised products and sequentially its impact on the agricultural sector, a grace period defined at the discretion of the Member State should be set. The Commission recalled that the draft Regulation foresee a considerable time period for Member States to review existing authorisations.

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

Outcome: the written procedure was terminated without result on request of one Member State.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-methyl, 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/11254/2018 Rev 4/).

The Commission recalled that several discussions had already taken place since 2018 and that the rationale of the draft was among others based on the properties of the main metabolite carbendazim – an active substance non-renewed on its own – and on the endocrine disrupting properties of the active substance. The Commission also recalled that the same draft Regulation had been subjected to vote via written procedure following the meeting in March, which had been terminated without result on request of one Member State.

One Member State expressed its disagreement with the EFSA Conclusion and asked the Commission to send a mandate to EFSA to review its assessment. Another Member State supported the draft Regulation recalling the endocrine disrupting properties of the substance. A third Member State informed that it will abstain in a vote. Some Member States requested to postpone the vote. The Commission recalled the possibility of abstaining or voting against a draft Regulation in a written procedure instead of stopping the vote – as would also be the case in a vote during the meeting – in particular for votes on draft Regulations for which there is support with qualified majority as was the case here.

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

Outcome: the written procedure was terminated without result on request of two Member States.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance pyriproxifen, 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/(Draft Review Report SANTE/11426/2019 / Rev.1).

The Commission summarised the modification inserted in the updated review report, which had been made following the requests of some Member States: the inclusion of the structural formula and addition of the words "flowering weeds" in the text.

Two Member States had requested modification of the text for giving enough time to applicants for product authorisation to modify the new content of one impurity (toluene). The text had been modified accordingly.

Two Member States indicated that they did not support the proposal because they considered the risk assessment for bees not finalised or they would have preferred a restriction to greenhouses only.

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

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance beta-cyfluthrin, 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/12798/2019 Rev 1).

The Commission recalled the rationale for its proposal of non-renewal and summarised the earlier discussions in the Committee. The Commission informed that EFSA had updated its Conclusion in particular the list of endpoints (published 1 April 2020), and shared the comments received from three Member States, and the applicant(s). The Commission informed on the comments of third countries received during the WTO TBT/SPS procedures.

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

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance fenamiphos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11402/2019 Rev. 1).

The Commission summarised the main issues related to this active substance, which led to the proposal not to renew the approval.

The consumer risk assessment could not be finalised due to several data gaps in the residue section (agreed at unanimity during the EFSA expert meeting). Moreover, there is also an acute exceedance for dietary exposure and the residue definitions for primary and rotational crops are provisional also for the lack of information on the genotoxicity of metabolites potentially present.

As regards the use on ornamentals and nursery stock that could be grown in rotation with food crops, the submitted study shows that the residues of fenamiphos, its sulfone and sulfoxide metabolites are present at relevant levels in succeeding crops. Moreover, for the metabolite M09 more data is required to exclude a genotoxic potential.

The Rapporteur Member State did not share the EFSA position on the provisional consumer risk assessment. Other Member States commented on the importance of these active substance in Southern Member States. Three Member States informed that they would vote against the Commission proposal.

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

Outcome: the written procedure was terminated without result on request of one Member State.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the low risk active substance ferric pyrophosphate, 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/10230/2020 Rev. 0).

The Commission summarised the main points of the EFSA conclusions and highlighted the general low toxicity of the substance. Data gaps on sediment-dwelling organisms, sub lethal effects to honeybee and the chronic risk to honeybee adult and larvae were discussed. The Commission reasoned that the iron and phosphate levels that occur naturally in sediment are expected to be many orders of magnitude higher than those that result from application of the representative product in the field. The exposure of these non-target organisms to ferric pyrophosphate as a consequence of the use as plant protection product is not expected to the be significantly higher than the already occurring levels, and thus not expected to have a negative impact. Furthermore, ferric pyrophosphate does not present insecticidal activity.

Additionally, residues of ferric pyrophosphate are expected to be negligible in nectar and pollen (because of its very poor solubility in water). Taking into account the natural occurrence of iron and phosphate in the environment, including plants, it is not expected that the representative product will lead to sub lethal or toxic effects to honeybee (larvae and adults).

Professional operators, when applying manually the product, are exposed to 15.31% of the AOEL when wearing adequate personal protective equipment (gloves). The Commission argued that generic personal protective equipment should not be, per se, considered as "specific", and that the active substances would therefore qualify as low risk.

Two Member States expressed some concerns about considering the active substance as low risk but eventually agreed to consider the low risk issue for professional operators at product authorisation level.

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

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance sodium hydrogen carbonate 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/11724/2018 Rev. 2).

The Commission introduced the draft Regulation and recalled that the measure had been discussed at earlier meetings of this Committee. It explained that once first authorisations of plant protection products consisting of or containing the substance would be issued by one or more Member States, the Commission will propose to withdraw the approval of the substance as a basic substance by amendment of Regulation (EU) 540/2011. The Commission took the view that the rationale of the Regulation that basic substances cannot be placed on the market as plant protection products (as stated in Article 23(1)(d) would be no longer fulfilled where a substance was approved as a regular active substance and plant protection products containing it authorised by Member States.

One Member State considered that the condition of Article 23(1)(d) did not apply for substances that are foodstuff as was the case here. It furthermore argued that in accordance with the 3rd subparagraph of Article 23 (1), such substances must be approved as basic substance.

Several Member States opposed the approval if that would result in the removal of the status of the substance as a basic substance.

One Member State argued for an inclusion of the substance in the list of approved substances both as a low risk regular active substance and as a basic substance.

The Commission recalled that there is no legal basis to reject the approval: all conditions and procedures as set out in Articles 7 to 13 of the PPP Regulation had been followed and the approval criteria were clearly met. Member States wishing to maintain

the approval as basic substance could later on oppose a Commission proposal to withdraw that approval.

The Commission also highlighted that the approval as a regular substance allowed the application of plant protection and labelling rules, which was in the interest of consumers and users such as the possibility of the substance to be used together with other substances (i.e. coformulants). On request of one Member State, the Commission also confirmed that the approval as a regular active substance and the possible delisting as a basic substance would not affect the possibility of the substance to be used in organic farming.

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

Outcome: the written procedure was terminated without result on request of one Member State.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval the active substances *Phlebiopsis gigantea* VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12900/2019 Rev. 1).

The Commission explained the modifications introduced in the draft Regulation and the review report in order to address the comments received since the last meeting. Firstly, the date of application was postponed from 1 July 2020 to 1 September 2020 due to the voting date. A new table was added in the Annex to the renewal Regulation, in order to specify that the *P.gigantea* strains for which renewal was not submitted, included in the same entry of the Commission Implementing Regulation 540/2011, will still be kept in Part A. The three strains under renewal will be moved to part D (low-risk).

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

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of Milk 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/12816/2019 Rev.3).

The Commission summarised the modification inserted in the new versions of the draft Regulation and review report in order to address the comments of some Member States and those resulting from the consultation of all Commission services concerned: in particular a reference to the animal by-products Regulation had been added.

One Member State informed that despite these modifications it did not support the proposal.

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

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron methyl, ipconazole and tembotrione in the list of candidates for substitution.

The Commission informed on the rationale of adding the seven active substances to the list of candidates for substitution, and shared the comments of the applicants. One Member State mentioned that they would not be ready to vote.

The vote was postponed, as the consultation of the Commission services concerned had not yet been finalised. Member States were invited to submit their comments by 5 June 2020.

Vote postponed.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and s-metolachlor.

The Commission presented the draft Regulation which was required for administrative reasons based on Article 17 of the Plant Protection Products Regulation.

Three Member States expressed their concerns and opposition because they considered that the approvals of active substances with EFSA conclusions already available, especially those active substances meeting a cut-off criterion, should not be prolonged. They opposed in particular extension of the approvals of bifenazate, bromoxynil and cyazofamid.

One Member State did not agree with the extension of the approval of bromoxynil. Nevertheless, because the draft Regulation covered a package of substances, they expressed their intention to vote in favour of the entire package.

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

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances.

The Commission informed that the 6th renewal programme allocates Rapporteur Member States for active substances for which approval expires between 31 March 2025 and 27 December 2028 after consultation with Member States, taking into consideration the recent amendment to the General Food Law and ensuring changes in deadlines and procedures. The draft Regulation will be submitted as soon as possible for vote, to ensure that Member States can already consider where appropriate to hold pre-submission meetings with applicants.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance azadirachtin (Amended Review Report SANCO/10311/2011 Rev. 1).

The Commission explained that the EFSA Conclusions did not identify any concerns for the extension of the use as acaricide on ornamentals on artificial soil in green house. Therefore, the Commission proposed to change the conditions of approval and to lift the restriction as insecticide only and extend the use as acaricide with no conditions.

The draft addendum to the review report will be sent to the applicant after this meeting for review and comments. Member States were invited to provide comments by 18 June 2020.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance bromoxynil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/10156/2020 Rev. 1).

The Commission provided an update on the ongoing procedure and informed about some changes to the draft Regulation and draft Renewal Report compared with the previous versions. The Commission summarised comments and positions received since March which indicated broad support for the non-renewal of approval. The Commission also informed that a vote is intended for the next meeting of the Committee in July.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of 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/10326/2019 / Rev. 0).

The Commission informed that the new Rapporteur Member State requested to review some studies that in its view were not fully considered by the former Rapporteur Member State (UK), and committed to provide this revised risk assessment evaluation

no later than early July, i.e. ahead of the next meeting of this Committee. The Commission recalled that an opinion of the Risk Assessment Committee of the European Chemicals Agency (ECHA) had been published in March 2019 recommending classification as toxic to reproduction Category 1B, and that an intention to submit a dossier proposing to revise this classification according to new studies on vertebrates had recently been submitted by Malta (possible date of dossier submission is December 2020).

Two Member States requested to send written comments on the proposal. Three Member States requested to proceed with no delay to a vote on the draft Regulation. Three Member States requested a longer grace period. One Member State raised the possibility to restrict the use to a single application per crop as this might lead to an acceptable outcome of the risk assessment. One Member State recalled the endocrine disrupting properties of the substance.

The Commission stated its intention to propose a vote on the draft Regulation at the next meeting of this Committee in July.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020 Rev. 0).

The Commission summarised the main issues in the EFSA conclusions, which had been published on 23 September 2019 and on which the proposal for a non-renewal is based.

The risk assessment identified concerns with regards to the long-term risk to birds and mammals including the risk from secondary poisoning, the long-term risk to aquatic organisms even when applying mitigation measures, long-term risk to aquatic organisms from metabolites 371R and 372R. The technical specification was not supported by the toxicological assessment, including the level of a genotoxic impurity (EBNA), however this can be potentially solved by lowering the concentration of the impurity to 0.085 mg/kg. It appears that the long-term risk to aquatic organisms from metabolites 371R and 372R may be overestimated since a 10-fold level of toxicity of the parent compound was assumed for the metabolites even if evidence of lower level of toxicity was available during the peer-review. However, the long-term risk to birds and mammals could not be excluded within the representative uses identified.

A number of data gaps were also identified as regards the risk assessment to unique human metabolites (i.e. significantly increased in comparison with other tested species) which could not be finalised. Additionally, the consumer risk assessment could not be finalised.

Furthermore, the evaluation of the persistent, bio accumulative and toxic (PBT) properties according to point 3.7.2 of Annex II of Regulation (EC) No 1107/2009 may be considered fulfilled for soil. Although evidence for persistency is from just one of a number of available soil studies at 20°C and of three soils when the half-lives are normalised to 12°C, the T criterion is fulfilled (NOEC = 0.0019 mg a.s./L) and the B criterion could not be evaluated since no valid BCF study was available.

Three Member States commented that the Commission proposal seemed to be too conservative and that they could solve the outstanding issue at Member States level during product authorisation.

The Commission invited Member States to propose practical examples of risk mitigation measures for birds and mammals. Depending on these Member States comments, the Commission may reflect on its approach.

C.06 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, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020 Rev. 0).

The Commission informed that pydiflumetofen is a new active substance, used as a fungicide on field application for pome fruits, grapes, potato, fruiting vegetables, cucurbits and *Brassicae.* Pydiflumetofen exhibited very high persistence in soil both in laboratory and in field studies, and in water/sediment studies: EFSA and some Member States had raised the need of residue studies for rotational crops. In addition the available evidence was not considered sufficient to draw a conclusion on the endocrine disrupting properties for non-target organisms. In any case, if approved, this active substance would be a candidate for substitution (persistent and toxic).

The applicant had informed the Commision that the studies for persistency are not reflecting realistic field conditions, and that more realistic new studies on dissipation are available which could however not be submitted during the evaluation of the active substance. The Commission had suggested to the applicant to consider withdrawal of the application followed by a resubmission which could include the studies not submitted so far and all necessary data to complete the evaluation of endocrine disruption properties.

One Member State proposed a restricted approval for one application per growing season. Four Member States requested to wait with decision-making and to conduct further assessments (i.e. submission of further studies and a mandate to EFSA to evaluate them), or to consider a restricted approval and the setting of a requirement for confirmatory information. Two Member States requested to perform the assessment of endocrine disrupting properties in conjunction with the studies not submitted during the peer review. One Member State did not support the proposal of the Commission.

Member States were requested to comment by 18 June 2020.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the amendment of the conditions of approval of the active substance fenpyrazamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10690/2012 Rev. 3).

The Commission informed that, given that the confirmatory data had been addressed and evaluated, the approval conditions and the review report could be amended, by including a maximum concentration for hydrazine as relevant impurity, which reflects the change in production from pilot to commercial scale. The Commission will proceed

with submitting a notification under the WTO-TBT agreement and prepare the draft Regulation amending the approval conditions.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benalaxyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10240/2020 Rev. 0).

The Commission summarised the main issues identified in the EFSA conclusions published on 16 December 2019.

Concerns were identified with regard to the potential groundwater contamination by relevant metabolites, the long-term risk to birds and earthworm-eating birds from secondary poisoning and the long-term risk to in-field and off-field non-target arthropods for all representative uses. Furthermore, a number of data gaps was also identified to conclude as regards endocrine disrupting properties according to the new scientific criteria.

Additionally, the risk assessment residue definition for fruit crops could not be finalised, the residue definitions for root crops and rotational crops remained open, the livestock exposure assessment could not be conducted, the consumer risk assessment through drinking water with regard to groundwater metabolites M2, F4-acetyl, F7 and F8 is unknown, and the nature of the residues consequent to water treatment following abstraction of surface water is unknown as well.

Moreover, because no valid BCF estimate was available, it was impossible to finalise the risk from secondary poisoning of fish-eating birds and mammals and the assessment of the PBT criteria could not be completed.

The Commission also informed the Member States that the applicant had neither presented new studies to assess the endocrine disruption potential when so requested nor commented on the draft review report when given the opportunity.

One Member State declared that it would abstain from the vote and 15 Member States indicated that they would support the Commission proposal.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of carbon dioxide as a basic substance in accordance with Article 23 of 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 Regulation, which is still under consultation of all Commission services concerned. The rationale for proposing a non-approval of carbon dioxide as a basic substance is the fact that carbon dioxide is currently approved as an active substance, included in Part A of the Annex to Regulation (EC) No 540/2011, and authorised as a plant protection product in two Member States. The procedure for the renewal of approval is currently ongoing. Therefore, in accordance with point (d) in the 2nd subparagraph in Article 23(1) of the Regulation (EC) No 1107/2009, approval as basic substance is not possible.

The Commission invited Member States for comments on the draft in writing by 18 June 2020.

M.01 Miscellaneous:

- The Commission informed about the invitation of Pesticide Action Network (PAN) to its online conference 'Vision for Transition: How Agriculture and Cities of the Future can save Biodiversity' on 11 and 12 May 2020. This invitation had been made available to Member States via CIRCA BC on 8 May 2020. PAN had also informed of the European Citizen Initiative "Save Bees and Farmers".

- One Member Stated informed about the draft guidance on time dependent sorption of pesticides to soil (aged sorption for groundwater leaching assessments), which was discussed in the Pesticide Steering Network and which in its opinion is finalised from a technical point of view as it considers already the relevant EFSA Opinion. This Member State suggested a final commenting round of Member States at this Committee and invited comments to be sent by 18 June 2020, which will be considered for a final revised draft version. This draft version will then be sent to EFSA for finalisation of this guidance document.

- The same Member State also informed about the Generic FOCUS kinetics guidance, which was prepared by the UK but on which further technical work is necessary. This Member State volunteered to take over the lead for this draft guidance. A technical commenting round is foreseen later in the process.

- The same Member State also informed about the availability of a publication (*Gimsing, et al., 2019, Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009, Journal of Consumer Protection and Food Safety (2019) 14 (Suppl 1):S1–S93*), which could serve as a basis for further work on a harmonised use of groundwater monitoring data in EU regulatory pesticide risk assessment. This Member State reported of previous discussions at the Pesticide Steering Network (PSN) and suggested – in line with the discussions at the PSN - that the Commission mandates EFSA covering, for instance a public consultation on this SETAC publication with the aim to deliver an applicable Guidance Document for the use of monitoring data in ground water risk assessment and to start a discussion on specific protection goals for ground water.