EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)5470042

Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

20 - 21 May 2019

CIRCABC Link: ***https://circabc.europa.eu/w/browse/b33af22b-7472-4f12-84d4-b00cb6a9c337***

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the meeting in April is published, and that of the meeting in March finalised and to be published in the next days.

A.02 New active substances:

1. New admissible dossiers to be noted:

   a) Inpyrfluxam (S-2399**)**

   The Committee took note of this dossier for a new active substance, a fungicide, where The Netherlands is Rapporteur Member State.

   b) Cinnamaldehyde

   The Committee took note of this dossier for a new active substance, a fungicide where The Netherlands is Rapporteur Member State.

   c) Fluindapyr

   The note taking of this dossier for a new active substance was postponed because the dossier had not yet been distributed to all Member States.

2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:

   There were no new EFSA Conclusions to discuss.

3. Draft Review/Renewal Reports for discussion:

   a) Lavandulyl senecionate

   The Commission informed that EFSA is reconsidering its Conclusion concerning the natural background level of the R isomer. The Commission shared with the Committee the comments from two Member States. The Member States were invited for further comments by 7 June 2019.

b) 1,3 Dichloropropene

The Commission informed about the reactions received from four Member States including the Rapporteur Member State, who sent a comprehensive argumentation. The latter proposed to set provisional ADI and AOEC, which are missing to finalise the (dietary) risk assessment. Six Member States indicated to be inclined to support to the Rapporteur Member State. Member States were invited to inform about their position and send comments about the Rapporteur Member State statement by 7 June 2019.

In parallel one Member State addressed in a letter to the Commission a request for mandating EFSA to assess the potential risks for consumers exposed to commodities having been treated with 1,3-Dichloropropene via emergency use authorisations (see also point A.13). Member States were invited for their comments on this request by 21 June 2019.

c) Napropamid-M

The Commission informed about the reactions received from three Member States and the applicant. Besides the critical area of concern regarding the impurity profile and the remarks on data gaps that need to be clarified by EFSA, the endocrine disrupting (ED) potential needs to be clarified via a specific mandate addressed to EFSA. Member States were invited for their comments by 21 June 2019.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

   No discussion took place.

2. Exchange of view on EFSA conclusions/EFSA scientific reports:

   No discussion took place.

3. Draft Review/Renewal Reports for discussion:

   a) Bromoxynil

   The Commission informed that a meeting took place on 12 April with the Bromoxynil Task Force to discuss the file. The Task Force considers that refinements are possible to address the issues related to non-dietary exposure. The Commission is reflecting on the information submitted by the Task Force. Member States were invited to submit comments on the refinements proposed by 7 June 2019.

   b) Flumioxazin

   No discussion took place.

   c) Clodinafop

   The Commission recalled that a mandate to EFSA was being considered to further investigate whether the non-dietary risks identified following the lowering of the AOEL could be mitigated. Furthermore, the Member States were informed that consideration was being given to comments received by the Member States on the derivation of the AOEL.

d) Fenamiphos

The Commission summarised the positions of Member States received since the March meeting. Several Member States had concerns about the substance and the issues raised in the EFSA Conclusion. Of the Member States expressing a position, a majority were in favour of a non-renewal of approval.

The Commission also explained that following a deeper examination of the EFSA Conclusion, even narrowing use to drip irrigation on non-edible crops in permanent greenhouses only would not be enough to address the issues identified. In particular, an issue for rotational crops was identified and a consumer risk could not be ruled out.

Therefore, doubts remain as to whether an acceptable use can be demonstrated. Member States were asked to provide final comments by 7 June 2019 following which the Commission would proceed to prepare the first draft of the Renewal Report.

e) Metalaxyl-M

The Commission informed that 11 Member States had submitted comments since the March meeting, in addition to further comments from the applicant. In general, Member States were in favour of a renewal of approval and were willing to support restrictions to address the issues identified in the EFSA Conclusion.

The Commission explained that a draft Review Report was under preparation. A restriction to sowing of seeds in greenhouses to address the risk to birds and mammals from consumption of treated seeds would be proposed. However, since no risk was identified for consumption of germinated seedlings, Member States could consider the period needed before plantlets could be moved into open field. The data in the dossier on spinach supported this outcome.

As previously outlined Member States were informed that a limit would also be set for one impurity in the technical material.

f) Fosetyl

The Commission presented a draft Review Report for renewal of approval pending an assessment of endocrine disrupting (ED) properties according to the new criteria. The Commission proposed to mandate the EFSA for an update of the ED assessment in line with the new ED criteria and Guidance Document.

The Commission explained that the use on mandarins is kept as a representative use relied upon. Risk mitigation measures to address the risk for aquatic organisms in pome fruits and grapes will be necessary. Furthermore, the risk from exposure to aluminium from the use of fosetyl was discussed. The Commission proposed to regard this assessment as illustrative, as indicated by EFSA in the conclusion, and not as a decision-making criterion, given that aluminium is not part of any residue definition for this substance.

Member States were invited to send in comments by 21 June 2019.

g) Cypermethrin

The Commission re-iterated its proposal for a renewal with conditions, where the need of drift exposure reduction for off-crop areas (aquatic organisms, off-field arthropods and bees) would be explicitly mentioned as conditions in the implementing Regulation (e.g. to achieve a drift reduction exceeding 95%). In addition, the need to avoid direct contact when bees forage will be mentioned. The toolbox to achieve these conditions will stay at the discretion of the Member States and the Review Report will contain examples of risk reduction measures and their combinations.

The Commission informed the Committee about the comments received from six Member States, which were diverging. The Commission also informed the Committee about the comments received from stakeholders.

The Member States were invited for their comments by 7 June 2019.

h) Beta cyfluthrin

The Commission informed that it seems that the key issues identified in the EFSA Conclusion, i.e. high risk to humans and/or to environment in each representative use, cannot be mitigated. The Commission shared all the related correspondence with the Member States. The Member States were invited for their comments by 7 June 2019.

i) *Pseudomonas chlororaphis MA 342*

The Commission gave an update on the positions of Member States received since the March meeting on the Commission's proposal for non-renewal of approval. One Member State re-iterated the previous support for non-renewal. Another Member State would support the renewal of approval limited to use in seed treatment.

The Rapporteur Member State (RMS) had updated the position paper in which a weight of evidence is used to demonstrate that the approval can be renewed. The applicant submitted recently a new study, which demonstrates that the genotoxic metabolite DDR breaks down rapidly. The renewal dossier for P. chlororaphis included a similar non-GLP compliant degradation study for the metabolite DDR. The RMS accepted this study but during the peer review the study was rejected because it was not carried out under GLP.

A discussion took place on whether it would be justified to consider this degradation information in the decision-making process. The new, GLP-compliant, study simply confirms the findings that were already available. Two Member States expressed support for the position of the RMS. These three Member States also complained about the evident changing of criteria for considering studies reliable. The Commission recallen the legal limitation that new studies cannot be taken into account in the current decision-making.

Member States were invited to submit comments by 7 June 2019.

j) Bifenazate

During the last meeting, Member States were asked to provide comments on the calculations made by the Rapporteur Member State who recalculated the TER values for birds and mammals and non-target arthropods for the minimal use rate.

The Commission gave an update on the positions of Member States received since the March meeting on the Commission's proposal for non-renewal of approval. One Member State supported a renewal of approval for the outdoor uses, with the new data submitted and evaluated at Member State level. One Member State supported non-renewal because the concerns as regards risk to environment are not suited for refinement at Member State level. One Member State expressed support for a renewal with refinement of ecotoxicological risk at Member State or zonal level.

The Commission informed Member States that a meeting took place on 2 May with the applicants Arysta/UPL to discuss the file. The applicants presented deficiencies they perceived in the peer review process as regards lowering of the long-term mammalian endpoint, using a default value for residue decline, and the identification of the data gaps in consumer risk assessment. The applicants also informed of new studies that are currently available.

The Commission is reflecting on the information submitted by the applicants. Member States were invited to submit comments by 7 June 2019.

k) Clopyralid

The Rapporteur Member State confirmed that the completed assessment of the residue trials had been forwarded to EFSA. Once EFSA will have finalised its assessment, the Commisison will be in a position to prepare a Renewal Report.

l) Cyazofamid

The Commission explained that after further discussions with EFSA on the high risk that had been identified for predatory mites and the further information that is needed to address the risk to earthworms, specifically for the representative use of potato, it does not seem that these issues can be resolved.

Member States were asked to provide final comments by 7 June 2019.

m) Etoxazole

The Commission explained that, based on the comments received, most Member States were in favour of a renewal of the substance. In order to solve the ecotoxicology issues, the approval of the active substance would have to be restricted to uses in greenhouses. However, that still leaves open the consumer risk from two metabolites on which toxicological data is missing. Member States were therefore requested to send in their views by 7 June 2019 on three different options: non-renewal, renewal restricted to greenhouses or renewal restricted to non-edible crops in greenhouses.

n) Famoxadone

The Commission presented a short update on the file and explained that for now, a non-renewal is the most likely option. Member States were asked to provide final comments by 7 June.

o) Foramsulfuron

The Commission summarised the comments received so far and explained the proposed way forward based on the draft Review Report already presented in previous meetings. Member states were invited to send comments by 21 June 2019, in particular whether they could agree with the renewal of the active substance.

p) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

No discussion took place.

A.04 Confirmatory Information:

1. General update (no news)

   No discussion took place.

2. Ipconazole (short update)

   No discussion took place.

3. Spiroxamine (review report to take note)

   No discussion took place.

4. Dithianon (short update)

   No discussion took place.

5. Triazole derived metabolites (TDMs) (short update)

   The Commission informed that it was reflecting on how to move forward to finalise the file.

6. Sulfoxaflor

   The Commission summarised shortly the main issues identified in the EFSA Conclusion. Member States were invited to provide comments by 21 June 2019 and, if available, any national risk assessment for bees for authorised outdoor uses.

7. Fenpyrazamine

   The Commission informed that the specification of the technical material as commercially manufactured had been requested as confirmatory data for this active substance, given that the purity information in the approval dossier had been based on a pilot plant production. The Commission informed that EFSA considered that the confirmatory data had been addressed. The Regulation and the Review Report will have to be amended accordingly including hydrazine as relevant impurity in a maximum concentration of (1 mg/kg) and changing from pilot to commercial production.

8. Fluopicolide

   The Commission informed that confirmatory data had been requested as regards the relevance of the metabolite M15 for groundwater. The core assessment identified that the proposed representative uses resulted in an acceptable groundwater assessment when a restriction in the application rate was applied.

   Considering that the approval expires in 2023, there were two proposed ways forward: to amend the review report and leave the application rate refinement for consideration of Member States when performing the exposure assessment from now on plant protection products containing the substance at national level, or to amend the Regulation, including a restriction of the maximum application rate, so that all Member States will have to revise their already granted authorisations. The Commission invited Member states to send comments by 21 June 2019.

9. Isofetamid

   No discussion took place.

10. Benzovindiflupyr

    Confirmatory data had been required to confirm the technical specification of the active substance as manufactured (on commercial scale) including the relevance of impurities and the compliance of the batches with which the (eco)toxicology studies were conducted with the confirmed technical specification. This compliance had been demonstrated. With regard to the mammalian toxicology area, the confirmatory data requirements had been partially addressed; a potential for clastogenicity cannot be excluded for one impurity but the evidence is weak. The Commission informed that further reflections are needed to decide how to proceed.

11. Geraniol

    No discussion took place.

12. Eugenol

    No discussion took place.

13. Thymol

    No discussion took place.

14. Clove oil

    No discussion took place.

15. Gamma-cyhalothrin

    The Commission informed about the outcome of the confirmatory information assessment. Two out of the four issues could not be finalised and a peer review had been proposed for assessing the metabolites PBA and PBA (OH). As those metabolites are in common with other pyrethroids, the Commission is reflecting on the best way forward.

A.05 Article 21 Reviews.

No discussion took place.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

   a) 1-MCP

      The Committee took note of the dossier received for an extension of use.

2. Exchange of view on EFSA conclusions:

   a) Azadirachtin

      No discussion took place.

3. Draft Review/Renewal Reports for discussion:

   No discussion took place.

A.07 Basic substances:

1. New dossiers received (for information)

   a) Calcium hydroxide (extension of use)

      The extension request covers additional uses as a fungicide against Botrytris cinerea in grapevine and Taphrina deformans in peach trees, and as an insecticide against Cacopsylla pruni in plum tree, Psylla pyri and Psylla mali in apple tree, Dysaphis plantaginea in apple tree, leafhopper in grapevine and Eurytoma amygdali in almond-tree.

   b) Carbon dioxide

      The application for approval of carbon dioxide as a basic substance had already been submitted in February 2018. However, carbon dioxide is an approved active substance. The application for renewal as an active substance is currently being assessed. The application for approval as a basic substance has been put on hold because it is necessary to clarify a number of legal questions before proceeding. According to Art. 23 of Regulation (EC) No 1107/2009, only active substances that are not placed on the market as a plant protection product can qualify as basic substances.

2. Exchange of views on EFSA Technical Reports

   a) Propolis extract

      The Commission informed that based on EFSA's Technical Report, the information seems to be insufficient to conclude that the approval criteria for basic substances are satisfied. The applicant had not sent comments on the EFSA Technical Report. The Commission had received two letters of support, which highlight the use of propolis in organic production of bananas.

One Member State was not in favour of an approval as a basic substance because the information submitted is not sufficient to demonstrate the absence of adverse effects. Member States were invited to send comments by 7 June 2019.

b) L-cysteine

The Commission summarised the EFSA Technical Report. L-cysteine fulfils the criteria of a 'foodstuff'. EFSA did not identify any consumer safety concerns. According to EFSA, given the proposed concentration of L-cysteine in the product (8%), no concern would be identified despite the classification of the substance according to Regulation (EC) No 1272/2008 as irritant. EFSA identified data gaps as regards fate and behaviour of L-cysteine in the environment, however no unacceptable effects on the environment are to be expected.

The comments of the applicant to the EFSA report had been made available to Member States. The environmental exposure from the intended use is likely to be negligible compared to background exposure resulting for example from the decomposition of organic matter.

The Commissions preliminary view was that overall there are clear indications that L-cysteine fulfils the criteria of Article 23 and can be approved as a basic substance.

One Member State did not support the approval of L-cysteine as a basic substance due to the proposed classification. Member States were invited to send comments by 7 June 2019.

3. Draft Review Reports for discussion:

a) *Castanea* and *Schinopsis* tannins

The Commission explained that the issues identified in the EFSA Technical reports for Castanea and Schinopsis tannins and Vitis vinefera tannins do not allow for an approval of these substances as basic substances. The Commission therefore intends to prepare proposals for a non-approval of Castanea and Schinopsis tannins and Vitis vinefera tannins as basic substances. Member States were invited to send comments by 21 June 2019.

b) *Vitis vinefera* tannins

Discussed with previous point.

c) Milk

No discussion took place.

A.08 Guidance Documents:

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

   This point was discussed together with agenda point C.01.

   The Commission informed that the EFSA started its work on the review of the Bee Guidance Document by a call for experts.

   One Member State informed about a letter from its Ministers for Agriculture and Ecology to the Commission, a new Citizens Initiative on bees and asked if a Member State can apply uniform principles, which are not listed in Regulation (EU) No 546/2011. The Commission explained that the question cannot be answered in a general way as it depends on the degree of harmonisation or flexibility established in the existing uniform principles.

2. Working Document on emergency authorisations according to Article 53 (discussion)

   Member States were informed that the comments received following previous consultation with Member States were being analysed and that a new version of the draft working document would be made available for the next Committee meeting.

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

   The Commission informed that there is still no significant progress on the file because of other priorities.

   However, the Commission stressed that, the on-going discussions to update the data requirements under the Biocidal Products Regulation (Regulation (EU) No 528/2012), in particular as regards the consideration of the extended one-generation study vs. the two-generation study as well as developmental neurotoxicity studies in view of determining endocrine disrupting properties were rather controversial. An additional expert discussion involving also ECHA and EFSA is planned.

   The Commission intended to ensure coherence among the biocides and the pesticide sector in this regard. Member States were invited to coordinate at national level in order to ensure coherence, as the agreements for the biocides data requirements update will be taken over ultimately for the pesticides sector. Member States were invited to send any comments by 31 May 2019.

4. Guidance Documents for biopesticides and low risk pesticides – update on progress

   The Commission informed the Member States about the progress concerning:

   Draft guidance on Straight Chain Lepidopteran Pheromones, which will be put on hold until the renewal of approval of the group of SCLP has been advanced;

   Draft guidance on the criteria linked to anti-microbial resistance, where the draft is almost finalised for its presentation at the Committee;

   Draft guidance on metabolites of concern, where technical discussions are still on-going due to the complexity of the topic.

A.09 Defining Specific Protection Goals for environmental risk assessment

1. Update and next steps

   The Commission informed that so far 13 Member States had sent nominations of experts to the Workshop, which is planned for 21 June 2019, and asked the other Member States to indicate who will be present. These nominations for two experts per country (experts in risk management, risk assessment, biodiversity, ecosystems, protection goals and who will follow the whole process) should be sent by 24 May 2019 and any comments/questions to be addressed at the workshop by 7 June 2019.

   The Commission re-iterated that the objective of the workshop is to achieve common understanding on the methods that will be used in a later stage to define the specific protection goals for environmental risk assessment for plant protection products.

2. Relevant topics raised by Member States

   a) Biodiversity

   b) Prioritisation of updates and development of Guidance Documents

      The Commission summarised the content of two letters received from Member States addressing biodiversity and prioritisation of guidance documents, and explained that the requests correspond well to the project to define specific protection goals (SPG) for the environmental risk assessment for plant protection products. There are several elements in common, in particular the need of better-defined protection goals, and related ecological considerations like recovery, indirect effects, landscape level effects and multiple stressors. The Commission suggested collaborating on all those issues via the project on SPGs.

A.10 Commission Regulation (EU) No 547/2011 and risk mitigation

1. Feedback about notification of additional phrases by Member States

   No discussion took place.

2. Risk Mitigation / list of risk reduction measures

   The Commission informed that six Member States reacted to the outline presented at earlier meetings and explained that overall the reactions were considered as supportive with some technical questions to be further discussed. The Member States who had not yet reacted were invited to send their comments by 21 June 2019.

A.11 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted)

Eight notifications had been received, affecting the withdrawal of 29 plant protection products. Only one notification of a bentazone-based plant protection product was noted; the other seven notifications were not applicable as they concerned withdrawals of platn protection products where the active substance was expiring.

A.12 Notifications under Article 36(3) of Regulation (EC) No 1107/2009

1. New notifications (to be noted)

Four notifications had been received, three corresponding to rejection of mutual recognition applications and one corresponding to a non-authorisation as concerned Member State. Three were noted, concerning products containing bentazone, deltamethrin and chlorothalonil respectively; for one the Member States involved agreed to open bilateral discussions.

2. Differences in application of Article 36(3) amongst Member States

No discussion took place.

A.13 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009

New notifications (to be noted)

The Committee took note of 62 emergency authorisations received from 15 Member States between 15 March 2019 and 10 May 2019 via the PPPAMS concerning products containing the following substances:

MS	Active substances	Function
AT	Flonicamid (IKI-220)	insecticide
AT	Pelargonic acid (CAS 112-05-0)	herbicide
AT	(EZ)-2 13-Octadecadien-1-yl acetate EZ-3 13-Octadecadienyl Acetate	fungicide
BE	Spirotetramat	herbicide
BE	(Z)-11-Hexadecenal	fungicide
BE	Phosmet	herbicide
BE	Cyantraniliprole	insecticide
BE	Cyantraniliprole	herbicide
BE	Flonicamid (IKI-220)	insecticide
BG	Pyridate	insecticide
DE	Cyantraniliprole	insecticide
EE	lambda-Cyhalothrin	fungicide
ES	Propanil	herbicide
ES	Diflubenzuron	nematicide
FI	Captan	insecticide
FI	tau-Fluvalinate	insecticide
FI	Clomazone	insecticide
FI	*Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660)	fungicide
FR	Florpyrauxifen-benzyl	fungicide
FR	Potassium hydrogen carbonate	herbicide
FR	Dimethyl disulphide	herbicide
FR	Cyantraniliprole	herbicide
FR	Bentazone	herbicide
FR	lambda-Cyhalothrin	herbicide
FR	Spirotetramat	herbicide
FR	*Beauveria bassiana* 203	insecticide

FR	Fosetyl	rodenticide
FR	Sulcotrione	insecticide
FR	Fluopyram	insecticide
FR	Fatty acids C7 to C20	acaricide
FR	Cyantraniliprole	fungicide
FR	Phosmet	insecticide
GR	Acibenzolar-S-methyl (benzothiadiazole)	fungicide
GR	Acibenzolar-S-methyl (benzothiadiazole)	fungicide
GR	Propanil	herbicide
GR	Pyrithiobac sodium	herbicide
GR	Trifloxysulfuron	insecticide
GR	Pretilachlor	insecticide
GR	Florpyrauxifen-benzyl	insecticide
GR	Quinclorac	fungicide
HR	Pyrethrins	herbicide
HR	Zinc phosphide	insecticide
LT	Plant oils/ Rape seed oil Pyrethrins	fungicide
LT	Spirotetramat	fungicide
LT	Fenpyroximate	herbicide
LT	Thiophanate-methyl	insecticide
LT	Chlorantraniliprole	insecticide
LT	Fluopyram Tebuconazole	insecticide
LT	Penthiopyrad	herbicide
LV	Bromoxynil	fungicide
LV	Foramsulfuron Thiencarbazone	herbicide
LV	Thiamethoxam	fungicide
PL	Cypermethrin	herbicide
SI	Spinosad	insecticide
SI	Epoxiconazole Thiophanate-methyl	herbicide
SI	Desmedipham Ethofumesate Lenacil Phenmedipham	insecticide
SI	Alpha-Cypermethrin (aka alphamethrin)	insecticide
SK	Copper hydroxide	insecticide
SK	Copper hydroxide	fungicide
SK	Dimethenamid-P	herbicide
SK	Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1)	nematicide
SK	Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1)	insecticide

The Commission reminded Member States to work in real time to ensure that notifications are recorded and notified as soon as possible to avoid backlogs. The Commission also recalled that there is a need to ensure a full completion of justification information in the authorisations. The Commission highlighted the need for careful selection of the correct EPPO codes and proposed that further guidance could be developed in future in this area.

The Commission informed Member States that there were also approximately 130 additional emergency authorisations added retroactively in PPPAMS (authorised within the period between June 2016 and 31 December 2018 but published in 2019). This input had been triggered by the work related to Harmonised Risk Indicators.

A.14 Plant Protection Products Application Management System (PPPAMS)

The Commission informed Member States that on 20 February 2019, EPPO had held an EPPO Code users meeting. Presentations can be found on the EPPO website. The EPPO Panel of PPP data harmonisation also met on the same date.

The Commission recalled that letters had been sent to all Member States in early April asking for confirmation of the emergency authorisations issued in order to calculate the second Harmonised Risk Indicator introduced in the Sustainable Use Directive, and that many Member States had already reacted to the letter. In some cases, Member States has identified emergency authorisations that were never notified to the Commission (before or after the introduction of PPPAMS).

It was clarified that for authorisations issued before June 2016 these should be submitted using the old style notification form. For those issued from June 2016 onwards, they should be introduced in PPPAMS.

Additionally, some Member States had spotted mistakes in old notifications. However, the Commission explained that it was not currently considered necessary to update old notifications since the harmonised indicator is currently based on numbers, not on the use.

The Commission also updated Member States on the plan to develop a public search facility for emergency authorisations including basic search filters (active substance, Member State and crops) and full notifications (personal contact details removed). The timelines was still to be determined. Updates will follow in subsequent meetings.

A.15 News from European Food Safety Authority (EFSA)

1. General update

   EFSA informed about the acceptance of the mandate to review the bee guidance document and outlined the next steps for the associated works. EFSA also informed about the outcome of the general meeting on physicochemical issues, as well as the progress on the mandate on guidance document on predicting environmental concentrations in soil.

A.16 Improving the efficiency of the process of a.s. approval – update on on-going activities including feedback of Member States

No discussion took place.

A.17 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO)

No discussion took place.

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

The Commission presented a summary of the outcome of SUD audits in Member States, performed in 2018 and 2019. The presentation highlighted weaknesses identified, related to the revised national action plans (NAPs), the inspections of pesticide application equipment (PAE) and the assessment of Integrated Pest Management (IPM) implementation at farm level by Member States' authorities.

With regard to NAPs, 7 out of 10 Member States visited did not review/revise their first NAPs within the five-year period.

Regarding PAE, the most critical findings were related to the fact that two Member States (out of 10) have not yet established and implemented inspection systems, and in another Member State the inspection of PAE was not a legal obligation, although inspections were taking place on a voluntary basis. In the remaining Member States, other issues were identified, such as not having inspected all PAE items in use by the EU deadline, having inspection systems not covering all types of machinery, and having derogations and exemptions allowed, which are not in line with the SUD requirements.

On IPM, although a lot of progress has been made with regard to pest monitoring, early warning systems and IPM Guidelines, the main efforts remain in the area of awareness raising and/or promoting IPM implementation rather than checking compliance and evaluating the implementation of IPM general principles at farm level.

A.19 Minor Uses.

The EU Minor Uses Coordination Facility (MUCF) informed that the MUCF is now fully depending on voluntary assessed contributions from Member States. Although for 2019 the MUCF has received positive responses from 16 countries, the financial situation of the MUCF stays rather critical. On 25 March 2019, Copa-Cogeca circulated a letter on behalf of 11 organisations belonging to the Agri-food Chain Round Table on Plant Protection to DG AGRI, DG SANTE and to all Member States calling upon the Commission to continue the funding of the MUCF.

In June 2019, the Coordination Facility will send out a request to all Member States for contributions for 2020. These letters will be addressed to National Minor Uses Contact Points and Heads of National Plant Protection Organisations as Member States may consider paying alongside their EPPO contribution.

The EU Minor Uses Database (EUMUDA) contains a list of the minor uses needs and priorities of all EU Member States, Norway and Switzerland. The current information is based on a survey conducted in 2018. As it is critical that the information in EUMUDA stays updated, as this is the starting point to solve minor uses issues at European level, the MUCF has launched the 'Survey 2019 on minor uses needs and priorities'. It is envisaged that the updated list of minor uses needs and priorities will be available in EUMUDA in autumn 2019.

A draft Guidance Document on Minor Uses was developed which provides more clarity regarding the rules for authorisation of PPP for minor uses and contributes to further harmonisation between Member States. It will be presented to the Committee for commenting in the next meetings.

A.20 Progress Report on Low Risk Active Substances (update).

The Commission informed Member States about the likely date of presentation of the progress report in the AGRI-FISH Council (subject to confirmation).

A.21 Court cases.

No discussion took place.

A.22 Endocrine Disruptors.

A second Better Training for Safer Food (BTSF) is confirmed for 26-27 November 2019. The format will be the same as for the previous one: up to two experts per Member States (one for the plant protection products sector and one for the biocidal products sector, having not participated to the previous one) will be supported financially. The experts from each Member State should possibly cover both expertise in toxicology and ecotoxicology.

A.23 Maleic hydrazide.

At the last meeting of the Committee, one Member State raised the point that the labelling requirement in the approval for maleic hydrazide, set in 2017 when renewing the approval of this active substance, introduced significant disruption in the potato and feed trade. Similar assessment had been provided by the feed and potatoes industry of one more Member State.

The Commission reminded that this specific labelling requirement was set to address the concern identified by EFSA in relation to the toxicity profile of the metabolite 3-pyridazinone included in the residue definition for risk assessment for animal commodities.

Meanwhile, the Commission had received the re-evaluation of the toxicity profile of 3-pyridazinone and of the consumer risk submitted by one Member State. The conclusion is that there are no safety concerns to consumers from exposure to 3-pyridazinone metabolite. The Commission has contacted the RMS and co-RMS for their opinion.

The Commission further informed that the Maleic Hydrazide Task Force submitted documents which highlight the profound economic and environmental impact of the implementation of labelling restriction. Furthermore, the Task Force had informed Commission that some of the missing studies are now available, which in their view provide evidence that 3-pyridazinone is not a substance of toxicological concern. The Task Force refers to the wording "*as appropriate*" in the text of the Regulation. The Task Force believes that the Member States shall not require the labelling of the treated crops as this cannot be considered to be appropriate nor proportionate.

In the ensuing discussion one Member State generally agreed that there are no safety concerns. Nevertheless, during the peer review, there was a disagreement between RMS, co-RMS and experts as regards whether the reference doses of maleic hydrazide could apply to the metabolite 3-pyridazinone. The final conclusion of the discussion was supported by most EU-experts and was reflected in the EFSA Conclusion and the Commission Review Report. From a procedural point of view, the applicant should apply for an amendment of the approval conditions.

Four Member States shared this opinion. Two of them were, however, concerned that the issue will not be solved in a short term. The Commission view is that the Regulation indeed leaves flexibility for the Member States for the implementation, including that no labelling would be needed if not considered appropriate. Nevertheless, the most appropriate way to solve the problem would be an application for amendment of the approval conditions, by which the applicants could submit the new existing data to support the request to change the conditions of approval.

Member States were invited to submit further comments and ideas on how to proceed by 21 June 2019.

A.24 Interpretation issues:

1. 2,4 D / 2,4 D EHE

No discussion took place.

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

   a) Follow-up in situ generation (update)

      The Commission informed about the three comments received on the discussion paper circulated at a previous meeting that will allow a revision, including a legal check and a re-discussion at a later stage.

      Three cases presented by two Member States will be inserted in the border cases document and presented at a next meeting.

A.25 Classification under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications (summary table for info)

   An updated summary table for info was made available on CIRCABC.

2. General update

   No discussion took place.

A.26 Amendment to General Food Law: presentation and future implementation

The Commission presented the legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain. This proposal amends the General Food Law and - as regards transparency – eight other related sectorial legislative acts including the Regulation (EC) No 1107/2009. The Council and the Parliament had reached agreement on the proposal in February 2019 and the vote took place in the Parliament in April 2019.

The new rules are expected to be published in the Official Journal over summer and they will enter into application early 2021. Follow up work concerning the pesticide sector includes an amendment to Implementing Regulation (EC) No 844/2012 by end 2020 and significant implementation preparations by EFSA and the Commission.

A.27 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 the report and staff working documents are ready at technical level and political validation is on-going.

A.28 Report from working groups, in particular:

1. Working group on Biopesticides

   The Commission informed the Member States about the points discussed at the meeting of the Working Group in May 2019. Progress has been made for drafting guidance documents (see point A.08)

2. Working group on Seed Treatments

   The Commission informed that the draft guidance document (GD) - version 16 was consulted with stakeholders via the Advisory Forum of DG SANTE at the end of 2018. The comments received from stakeholders are currently being sorted and analysed. A meeting of the Working group is planned for October.

   The Commission also mentioned that the current draft GD covers different aspects (e.g. procedural issues, labelling, risk assessment, risk mitigation) and that the part on risk assessment has implications to other GDs focusing on risk assessment being currently worked on by EFSA (e.g. bees, operators, other organisms). The chair of the Working Group and the Commission are currently reflecting how to best organise the work, including involvement of the Committee.

   One Member State asked if the draft guidance document should not be split. The Commission confirmed that this is an option under consideration.

3. Post Approval Issues

   No update was needed (no meeting of the Working Group had taken place since the last meeting of the Committee).

A.29 OECD and EPPO

a) General update

   The Commission informed about the upcoming conferences, seminars, workshops and meetings organised by OECD in the week of 24-28 June and announced a teleconference for agreeing positions in view of the Working Group on Pesticides.

b) Recommendation of the Council on Countering the Illegal Trade of Pesticides

   The Commission informed that the OECD Council has adopted a Recommendation countering the illegal use of pesticides.

This Recommendation and the related guidance documents have been posted on CIRCA-BC and will be discussed with Enforcement authorities during the upcoming meetings in Grange.

A.30 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

No update as regards regulatory decisions taken was needed (no meeting took place since the last committee meeting).

However, on a more general issue the Commission informed that the cumulative risk assessment of triazole derived metabolites currently done by EFSA is progressing and close to finalisation.

A.31 Lists of tests and studies relied upon for active substance assessments.

Member States were reminded about the need to finalise and make available final lists of tests and studies relied upon without delay once the EFSA Conclusion is available i.e. at the end of the peer review process.

Generic companies have repeatedly indicated that they cannot prepare their product renewal dossiers, as the lists are made available too late.

A.32 Scientific publications and information submitted by stakeholders.

The Commission informed the Member States about four new studies submitted by two Member States concerning exposure of residents. The Commission suggests forwarding them to EFSA for consideration in the context of the on-going update of the exposure guidance document.

A.33 Date of next meeting(s).

Next meeting (confirmed) will be on 16 and 17 July 2019.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance 1-methylcyclopropene, 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, and amending the Annex to Commission Implementing Regulation (EU) 2015/408 (Draft Renewal Report SANTE/11631/2018 Rev. 2)

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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/10318/2019 Rev 1).

Vote postponed because the inter service consultation on the draft Regulation was not finalised.

Vote Postponed

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 dimethenamid-P, 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 Renewal Report SANTE/11149/2018 Rev.1).

Vote taken: Favourable opinion.

B.04 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 desmedipham, 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/10556/2018 Rev. 1).

Vote taken: Favourable opinion.

B.05 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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11254/2018 Rev. 3).

Vote postponed following the modification of the classification (confirmed by ECHA's Risk Assessment Committee) as Mutagen Cat. 2 instead of Mutagen Cat. 1B as proposed by EFSA. The dossier has been sent back to EFSA for a re-evaluation accordingly.

Vote Postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance tolclofos- 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 Commisison Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11272/2018 Rev. 3).

Vote taken: Favourable opinion.

B.07 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 dimethoate, 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/11494/2018).

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance florpyrauxifen, 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/10658/2019).

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards bees principles for evaluation and authorisation of plant protection products.

The Commission informed that the interservice consultation on the draft Commission Regulation amending Commission Regulation (EU) No 546/2011 as regards uniform principles in relation to bees for evaluation and authorisation of plant protection products was launched. After closure of this interservice consultation, the draft will be submitted to the public feedback mechanism.

The Commission indicated that it intends to table the draft Regulation for a vote in the meeting of the Committee in July 2019. See also agenda point A 08.01.

C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

The Commission presented the draft Regulation, which had been revised following the comments received from the Member States and from stakeholders. The list of substances had been cross-checked by ECHA as regards substance identity.

The Commission asked whether the Member States could support the proposed general maximum level (0.01%) for the unintentional presence of unacceptable co-formulants as impurities to facilitate enforcement actions, and this proposal was accepted. The proposed transitional period of 2 years for implementing the draft Regulation was also accepted. The suggestion made by some Member States establishing an obligation for the authorisations holders to check whether their plant protection products on the market contain any unacceptable co-formulants was not considered necessary as not all authorisation holders have the full information on the identify of all co-formulants and Member States authorities will have to verify the situation for all products in any case.

A discussion took place concerning the list of substances and the suggestions made by ECHA, mostly related to additional entries for nonylphenols and silica. Member States were invited to comment by 7 June 2019. A new draft of the Regulation, revised according to the progress made so far, will be made available on CIRCA BC soon after the meeting of the Committee.

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 Renewal Report SANTE/10730/2018).

The Commission informed on a mandate sent to EFSA to discuss the risk to mammals and bees in an expert meeting.

One Member State expressed its concerns regarding the current EU MRLs and considered that a revision of these MRLs should be started.

C.04 Exchange of views of the Committee on a draft Commission Implementing Decision concerning the renewal of the approval of the active substance *Verticillium albo-atrum* WCS850 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 Renewal Report SANTE/2019/10198).

The Commission informed about the comments received from four Member States, in general supporting the renewal as low-risk substance. The interservice consultation is on-going. Member States were invited for their comments by 7 June 2019 in view of a possible vote at the meeting of the Committee in July 2019.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance alpha-cypermethrin, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11525/2018).

The Commission informed that the interservice consultation is on-going and the draft review report has been revised for some editorial changes and updates following a comment received from one Member State. The Commission asked for comments by 21 June 2019 in view of a possible vote at the meeting of the Committee in July 2019.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiacloprid, 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/10450/2019).

The Commission informed that the interservice consultation is currently ongoing. After finalisation, the draft Regulation will be notified to the WTO under the TBT agreement. This notification procedure lasts 60 days. Therefore, the vote on the draft Regulation will be taken at the earliest in the meeting of the Committee in October. The Commission asked for comments by 21 June 2019.

C.07 Exchange of views of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Romania for the placing on the market of plant protection product MODESTO 480 FS, containing the active substance clothianidin, and plant protection product NUPRID AL 600 FS, containing the active substance imidacloprid, for use on *Brassica napus* to combat the pests *Phyllotreta* spp. and/or *Psylliodes* spp. in accordance with Article 53 (1) of Regulation (EC) No 1107/2009

Agenda points C.07 and C.08 were discussed together.

The Commission informed the Member States that the interservice consultations on the draft Regulations are not finalised yet. The Commission intended to table both drafts for vote in the meeting of the Committee in July 2019.

One Member State referred to its written comments explaining why they consider the contested emergency authorisations justified. Another Member State indicated supporting the justification provided by the first Member State.

A further Member State inquired why emergency authorisations on neonicotinoids were targeted and no emergency authorisations of other active substances. The Commission referred to the repetition of the emergency authorisations for neonicotinoids together with the authorisations being widespread for the whole territory of the Member States concerned.

One Member State inquired about the consequences if the Decision – when adopted – were not followed by the Member State concerned. The Commission indicated that, in principle, this could lead to an infringement procedure against that Member State.

Some Member States indicated their reservations especially with regard to subsidiarity. One Member State mentioned in this context that Directive 91/414/EEC had been more restrictive on this point and suggested that a wider use of Article 4(7) of Regulation (EU) No 1107/2009 should be envisaged.

Another Member State considered that EFSA should have judged the risk for human health of the emergency authorisations and not the availability of alternatives. The Commission indicated that the Regulation does solely refer to the unavailability of other means of pest control and reminded that stricter rules would only be possible via an amendment of the Regulation (EU) No 1107/2009 (through a full legislative procedure).

Two Member States considered that only national experts within a Member State can judge the necessity of an emergency authorisation and not EFSA and announced that therefore, they will not support the draft Decision.

C.08 Exchange of views of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Lithuania for the placing on the market of plant protection product "CRUISER OSR" containing the active substance thiamethoxam for use on spring rape to combat the plant pests *Phyllotreta* spp. and/or *Psylloides* spp. in accordance with Article 53(1) of Regulation (EC) No 1107/2009

See under previous point (C.07).

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance methiocarb, 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 Renewal Report SANTE/11710/2018).

The Commission recalled that the inter-service consultation was finished and the WTO-TBT notification process was ongoing. The Commission also informed the Committee about the letters received from the applicant.

M.01 Opinion of ANSES

The Commission informed about the Opinion of ANSES as regards the assessment of succinate dehydrogenase inhibitor (SDHI) fungicides. The report indicates that based on the available information there is no indication of a sanitary risk as regards human health or the environment linked to the use of SDHI in agriculture. Consequently, the Committee concluded that no immediate action is needed.

M.02 Draft Regulation not renewing the approval of chlorpropham

The Commission informed that the Appeal Committee had not delivered a favourable opinion on the draft Regulation not renewing the approval of chlorpropham. The Commission will proceed with the adoption and publication of the Regulation.

M.03 EU workshop on product chemistry in November 2019

One Member State informed that they are organising an EU workshop on product chemistry in November 2019. The Commission welcomed the initiative and informed that it intends to support the workshop by covering travel expenses for one expert per Member State.

M.04 Metabolite chlorothalonil-amidosulfonic acid in groundwater

One Member State informed about finding the metabolite chlorothalonil-amidosulfonic acid in groundwater and asked the other Member States about their situation.

M.05 Status of rapporteurship for active substances for which the UK is or was RMS

One Member Sated asked clarification about the status of rapporteurship for active substances for which the UK is or was RMS. The Commission clarified that for the active substances listed in Regulation (EU) 2019/150, which entered into force on 30 March 2019, the reallocation is applicable and the new RMS took over by 1 April 2019.

For all other active substances, the UK remains the RMS until BREXIT occurs. This includes also the dossiers listed in Regulation (EU) 2019/336, for which the entry into force is linked to the end of the period set in accordance with Article 50(3) TEU, currently being set at 31 October 2019, except in case of an earlier ratification of the withdrawal agreement.

M.06 20 May : World bee day

One Member State recalled that 20 May is world bee day.