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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

21 - 22 October 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/878ad6f8-bcc2-40e9-8494-47b1d8665808*

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the last meeting is to be published in the next days.

A.02 New active substances:

1. ***New admissible dossiers to be noted:***

The Committee took note of three new admissible dossiers for the following substances: limestone (Rapporteur Member State Czech Republic), as well as *Bacillus subtilis* strain FMCH002, *Bacillus licheniformis* strain FMCH001 (Rapporteur Member State: the Netherlands).

The Committee also took note of the withdrawal of an application for approval for *Chromobacterium subtsugae* PRAA4-1.

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

a) Napropamid-M

The Commission informed that EFSA could not examine the questions of the applicant about the data gaps identified after the peer-review. The Commission suggested to proceed with a mandate to EFSA to clarify the open issue as regards the new criteria to identify endocrine disrupting properties, since this is not available in the EFSA Conclusion. Once this assessment is available, discussions would resume considering also the suggestions of one Member State as regards the impurity profile and the reference values, the soil metabolites, the effects on non-target organisms and the analytical methods. Member States were invited to comment on this way forward by 6 November 2019.

b) Pydiflumetofen

The Commission informed that the applicant was consulted on the EFSA Conclusion and its comments are available to Member States on CIRCABC.

The Commission invited Member States to send any comment on the EFSA Conclusion by 6 November 2019, in particular as regards a potential approval.

3. ***Draft Review/Renewal Reports for discussion:***

a) Lavandulyl senecionate

The Commission informed that the applicant is expected to comment on the draft renewal report as soon as the revised EFSA conclusion is available.

As several Member States indicated their potential support for an approval of lavandulyl as low-risk substance during and after the last meeting, the Commission intends to move forward on the file after having received the comments of the applicant, aiming to vote on the decision concerning this substance as soon as possible.

In parallel, the Commission is considering a horizontal mandate on the natural background levels of arthropod pheromones.

b) 1,3-Dichloropropene

The Commission informed that eight Member States had reacted to the non-paper presented at the last meeting of this Committee to accommodate the views of some Member States; this non-paper being an alternative to a non-approval as initially considered by the Commission. These eight Member States overall supported the stepwise approach (assessment of endocrine disruption potential in line with the new criteria and genotoxicity clearance by EFSA and ECHA, respectively).

The Commission had updated the non-paper with the comments received; the non-paper presented possible ways suggested by the Rapporteur Member State to address concerns related to technical specifications, suspected mutagenic potential, consumer dietary risk assessment, risks to non-target arthropods and soil organisms, risks to groundwater contamination, risks to operators and birds and mammals and is available on CIRCABC. A restricted approval would only be possible if these aspects are clarified.

One Member State had indicated that it would volunteer for preparing the dossier to propose harmonised classification under the CLP Regulation as regards mutagenicity/ genotoxicity. In parallel to this the Commission will reflect on whether to mandate EFSA as regards the new criteria to identify endocrine disruptors, which have not yet been formally addressed by EFSA.

A.03 Renewal of approval:

1. ***General topics:***

a) Access to original dossiers

The Commission informed Member States about repeated requests received from potential applicants regarding access to studies submitted as part of registration dossiers. One Member State had submitted a discussion paper on this.

The Commission invited Member States to share their experiences and views on enabling applicants to have access to the required information for renewal assessments (when the applicant does not have access to the dossier submitted for the first EU approval). Member States indicated a number of different

practices in handling requests for studies and some Member States expressed concerns about giving out full studies to applicants, as the Member States are not the owner of the GLP-studies.

The Commission stressed that access to these studies cannot be denied to the requestors, and recalled that there had been several Court judgements on the issue of accessing information related to active substances. Furthermore, the Commission reminded Member States about the importance of carrying out comprehensive and robust risk assessments, ensuring that all information, including older studies are taken into account.

The Commission also explained that in the future (from March 2021), all studies supporting the approval or renewal of approval of active substances will be published in full as a consequence of the recent amendment to the General Food Law, and therefore the situation that studies are not available to applicants will phase out with time.

b) 6th renewal programme

Considering the recent amendment to the General Fool Law and ensuing changes in deadlines and procedures, the Commission has started to work on the 6th renewal programme and to identify the active substances that would need to be included in it. It needs to be considered that at least 60 months before the expiry of the approval of a substance the pre-submission meetings with Rapporteur Member State and EFSA need to take place, and that at least 54 months before the expiry of approval the list of intended studies to be performed for the renewal needs to be submitted. The Committee will be kept updated and consulted on the draft renewal programme.

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

a) Mancozeb

The applicant was consulted on the EFSA Conclusion and raised concerns about the assessment carried out by the rapporteur Member State, UK, claiming that due to Brexit the UK did not appropriately updated parts of the assessment after the expert meeting leading to an unfavourable EFSA Conclusion. The comments of the applicant had been made available to Member States via CIRCABC.

An opinion of the Risk Assessment Committee of the European Chemicals Agency (ECHA), adopted on 15 March 2019, recommended to classify mancozeb as toxic for reproduction Cat. 1B and carcinogen Cat. 2, meaning that the substance would meet one of the cut-off criteria. The applicant would like to perform an additional study on vertebrates in order to allow for the submission of a new proposal for harmonised classification to reassess the reproductive toxicity of the substance. Furthermore, the applicant complained that not enough time had been given to the assessment of endocrine disrupting properties during the peer review.

Member States were invited to send comments by 6 November 2019 on the EFSA Conclusion and on their views on the request of the applicant to conduct new vertebrate studies in view of submitting a new proposal for harmonised classification as regards toxicity to reproduction.

b) *Phlebiopsis gigantea* VRA 1835, VRA 1984 and FOC PG 410.3

The Commission informed that the EFSA conclusion had been published on 9 October 2019, the applicant had been consulted on 20 September 2019, and its comments received on 11 October 2019. No critical areas of concern and only two data gaps had been identified by EFSA. Member States were invited to provide comments on the EFSA conclusion by 6 November 2019.

3. ***Draft Review/Renewal Reports for discussion:***

a) Bromoxynil

The Commission summarised the reactions from Member States received since the last meeting of the Committee, in particular concerning whether it would be feasible to mandate EFSA to consider new data related to refining the risk assessment for residents.

The Commission explained that all avenues had been explored and that a proposal on bromoxynil would be presented as soon as possible. One Member State indicated that a decision for non-renewal should be presented.

b) Flumioxazin

The Commission summarised the reactions from Member States received since the last meeting of the Committee. The Commission informed of its intention to mandate the EFSA for an updated assessment of the endocrine disrupting properties of flumioxazin on the basis of the new criteria.

c) Fenamiphos

The Commission informed that two Member States had reviewed the applicant's comments on the EFSA Conclusion and were not convinced by the arguments put forward and therefore supported non-renewal of approval.

The Commission also informed that the applicant had submitted further comments on the consumer risk assessment (genotoxicity assessment of metabolites and the use of residue trials). The Commission had asked EFSA to check the comments and EFSA had confirmed the position in its Conclusion.

The Commission asked for final comments from Member States by 6 November 2019 and highlighted that given the issues identified by EFSA and the comments received so far, the proposal for non-renewal will be maintained.

d) Cypermethrin

The Commission summarised the EFSA Statement on risk mitigation measures for cypermethrin. A draft renewal report had been made available for the comments of the Member States. It proposed to restrict the use of plant protection products containing this active substance to professional users provided strict risk mitigation measures are used in order to achieve safe use via at least 95% exposure reduction to ensure low risk to non-target arthropods and aquatic organisms, and the restriction to use the substance outside flowering of the crop and when less than 10% of the field is covered by bee-attractive, flowering weeds to ensure low risk to bees. The Commission will consider a decision along this line only if Member States signal sufficient support. Member States were invited for their comments by 6 November 2019.

One Member State mentioned that cypermethrin has been included in the list of priority substances under the Water Framework Directive since 22 December 2018. The Commission will consider this together with the comments from Member States to define the further steps.

e) Beta cyfluthrin

The Commission informed that in addition to six Member States who had reacted earlier, one more Member State had indicated its support for non-renewal of approval since the last meeting of the Committee. The Commission informed the Committee about the applicants' comments received since the last meeting, and also that EFSA and the Rapporteur Member State will update the List of endpoints with the outcome of the respective peer review meeting on ecotoxicological issues.

The Member States were invited for their comments by 6 November 2019.

f) *Pseudomonas chlororaphis MA 342*

No news to discuss.

g) Bifenazate

The Commission informed on a comment received from one Member State supporting the proposal for non-renewal of approval. The Commission also informed on a meeting with the applicant, who had presented scientific concerns about the procedure followed for the risk assessment and its outcome. The documents summarising the key issues in the risk assessment submitted by the applicant had been made available to Member States. Member States were invited to send comments.

h) Clopyralid

No news to discuss.

i) Cyazofamid

The Commission summarised the comments received so far from Member States. The Commission informed that the applicant had sent a new set of substantial comments, which had been made available on CIRCABC, together with the related feedback from EFSA.

Member States were invited again to clearly indicate their positions by 6 November 2019, in particular under consideration of the comments from the applicant and with respect to a support for non-renewal, restricted renewal to greenhouses, or renewal of approval.

j) Famoxadone

No news to discuss.

k) Etoxazole

The Commission summarised the comments received so far from Member States and invited the Member States to clearly express their positions by 6 November 2019, in particular with respect to a support for restricted renewal of approval to non-edible crops in greenhouses.

l) Fosethyl

The Commission informed about a mandate sent to EFSA to assess if fosethyl is to be considered to have endocrine disruption properties according to the new scientific criteria.

m) Pyriproxyfen

A draft renewal report had been prepared and the applicant had been consulted on it. Both the draft report and these comments are available to Member States on CIRCABC. Some Member States had already expressed their views, which are also on CIRCABC. The Commission invited the Member States to clearly express their positions on the draft renewal report by 6 November 2019.

A.04 Confirmatory information:

1. ***Fluopicolide***

The Committee took note of a revised review report. One Member State had general concerns about the potential for leaching of metabolites of fluopicolide into groundwater.

2. ***Spiroxamine***

The Commission informed that out of the four areas identified for confirmatory information, only one has been closed: the groundwater exposure assessment for metabolite M03, for which there is no further concern and no regulatory action needs to be triggered.

The requirement for confirmatory data on potential stereo-selective degradation of each isomer remains open due to the lack of guidance. Hence, it should be considered during the upcoming renewal process.

As to the confirmatory information regarding the toxicity of potential plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities, the consumer risk assessment for grapes should be updated with revised toxicological reference values. As regards the confirmatory information on the risk to aquatic organisms an updated assessment is needed. The Commission informed that it intends to mandate to EFSA to finalise these assessments of confirmatory information.

In summary, the Commission proposed to maintain the approval for the current use in cereals and - once EFSA will have delivered on the mandate mentioned above - to update the review report and, if needed, initiate regulatory action. Member States were invited to comment on this approach by 6 November 2019.

3. Dithianon

The Commission informed that the Rapporteur Member State had evaluated the new submitted data and issued an Addendum 2 to the DAR in September 2018 and a more recent update in August 2019, which was shared on CIRCABC. With this new document, the Commission will mandate EFSA to review the assessment and to revise its conclusions (dated 2015), with the aim to clarify the data gaps on residues and the acute intake concern.

4. Triazole derived metabolites (TDMs)

   The Commission recalled its intention to update the review report for each concerned active substance in order to finalise the confirmatory information process and provide clarity for ongoing and future regulatory processes (approval, authorisation and MRLs).

   Member States were asked to consider and provide feedback on a first example updated review report. The Commission explained that, after one example update is agreed, the intention is to update each specific substance review report with elements related to the assessment of that substance, plus a generic conclusion on the outcome of the consumer risk assessment for the TDMs and to also include an Appendix to each review report that confirms the agreed reference values and residue definitions for the TDMs.

   Member States were invited to send comments by 6 November 2019.

5. Sulfoxaflor

   The Commission summarised the risk to bees as assessed by EFSA and pointed to two open points in this risk assessment, namely the risk from exposure to puddle water and calculations of the risk to bumblebees and solitary bees in field borders. The Commission informed that it intends to mandate EFSA for these calculations as all the necessary data is available in the dossier. The outcome of these calculations will enable to determine the extent of the necessary restrictions to the approval conditions for sulfoxaflor.

6. Fenpyrazamine

   The Commission informed that, given that the confirmatory data had been delivered and assessed, the approval conditions and the review report should be amended accordingly, by including a maximum concentration for hydrazine as relevant impurity, which reflects the change in production from pilot to commercial scale. It will be necessary to launch a WTO-TBT notification for the draft Regulation amending the approval conditions.

7. Isofetamid

   No news to discuss.

8. Benzovindiflupyr

   The Commission recalled that 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 which were conducted with the confirmed technical specification. This compliance had been demonstrated. With regards to mammalian toxicology, the assessment of the confirmatory data led EFSA to consider that the evidence for clastogenicity is weak.

   The Commission suggested to amend the approval conditions and the review report under consideration of the precautionary principle, by including a maximum concentration for the new relevant impurity. It will be necessary to launch a WTO-TBT notification for the draft Regulation amending the approval conditions.

9. Geraniol

   No news to discuss.

10. Eugenol

    No news to discuss.

11. Thymol

    No news to discuss.

12. Clove oil

    No news to discuss.

13. Gamma-cyhalothrin

    The Commission shared the comments of the applicant and informed that three Member States had expressed their support for the proposed way forward i.e. to launch a peer-review with regards to the metabolites PBA, PBA(OH) and long-term risk to wild mammals following the evaluation on the confirmatory information on lambda-cyhalothrin by the Rapporteur Member State. Member States were invited for their comments by 6 November 2019.

14. Ipconazole

    The Commission updated Member States following discussions in previous meetings, in particular as regards the request from a few Member States to launch an Article 21 review of the approval of ipconazole due to the recommendation by the Risk Assessment Committee of the European Chemicals Agency to classify ipconazole as toxic for reproduction, Category 1B.

    The Commission explained that it was reflecting on various options and will inform the Member States without delay when a decision on the way forward will have been taken.

15. Terbuthylazine

    The Commission recalled the history of the assessment of confirmatory information leading to the updated EFSA Conclusion, published in September 2019. Member States were invited to provide their comments and views on the way forward, taking into account the EFSA Conclusion and the comments of the applicant, by 6 November 2019.

A.05 Article 21 Reviews.

No news to discuss.

A.06 Amendment of the conditions of approval:

1. ***New admissible dossiers to be noted:***

   No news to discuss.

2. ***Exchange of view on EFSA conclusions***:

   No news to discuss.

3. ***Draft Review/Renewal Reports for discussion***:

   a) Azadirachtin

The Commission informed that on the five issues identified by EFSA, uncertainty remains on some, deserving further review. Member States had provided mixed feedback on the acceptance of the lead substance approach for consumer risk assessment, which should be looked at in more detail.

Also it appeared that the concern over the nature of residue could be eventually overcome as residue trials demonstrated that the translocation of Azadirachtin A from leaves to tuber was below the Limit of Quantification. On the matter of residue behaviour for unknown metabolites or degradation products, considering the toxicological properties of Azadirachtin A, the Rapporteur Member State had concluded that the exposure estimate would be below the accepted daily intake (ADI) and the acute reference dose (ARfD). Altogether, taking into consideration that operator and worker exposure does not exceed the AOEL, even without wearing protective equipment, the risk could be considered as acceptable.

The Commission informed that it plans to present a draft review report for taking note once the assessment for the remaining confirmatory data if concluded, and invited Member States to send their views and comments by 6 November 2019.

A.07 Basic substances:

1. ***New dossiers received***

   The Commission informed about the following dossiers received: *Equisetum arvense* extension, E235 natamycin, Tribasic, Sodium hypochlorite, *Urtica spp.* extension.

   The Commission also informed on a letter received from an applicant for carbon dioxide as a basic substance requesting clarification on the status of the application submitted some time ago. Carbon dioxide is currently approved as a regular active substance. The application for renewal is under evaluation. The application for approval as a basic substance had been put on hold because it had triggered a number of legal questions that needed to be clarified before the application could be processed. The following documents had been made available to Member States: application for approval of carbon dioxide as a basic substance, the cover letter in which the applicant explains why he believes that carbon dioxide should be approved as a basic substance, and the letter with request for clarification mentioned above. The Member States were invited to send comments by 6 November, which the Commission will take into consideration for its reflections before responding to the applicant.

2. ***Exchange of views on EFSA Technical Reports***

   No news to discuss.

3. ***Draft Review Reports for discussion:***

   a) Milk

      The Commission presented the draft Review Report in view of the approval of raw cow milk as fungicide according to a similar use pattern as for the basic substance whey approved previously.

      One Member State pointed to the additional use of milk as disinfectant of automatic cutting machinery which will be added in a revised version of the report. The Member States were invited to comment by 6 November 2019.

b) Propolis extract

The Commission presented the draft Review Report in view of a non-approval of propolis extract as a basic substance. The Member States were invited to comment by 6 November 2019.

c) Saponaria

The Commission informed that this substance has been on hold for some time and reopened the discussion by presenting again the review report from 2017. The Commission does not intend to change this review report. The Member States were invited to comment by 6 November 2019.

d) Sucrose

Points A 07.03.d and A 07.03.e were discussed together.

The Commission informed about the application to extend and align the use conditions for both substances.

The Commission explained that it does not intend to mandate the EFSA for an updated technical report given the nature of both substances. The Member States were invited to comment by 25 November 2019.

e) Fructose

See points A 07.03.d.

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)***

The Commission informed about the discussion in the ENVI Committee of the European Parliament on 21 October 2019. The Committee had adopted a draft Resolution objecting to the draft Regulation amending the uniform principles that would have allowed implementation of the part of the EFSA 2013 Guidance Document related to acute toxicity for honey bees, which had received a favourable opinion in this Committee in July 2019. The ENVI Committee considers that more action should be taken to protect pollinators and therefore considered that additional parts of the 2013 EFSA Bee Guidance Document should be implemented without delay, in particular those related to chronic toxicity for honey bees and acute toxicity for bumblebees. If adopted in the plenary of the European Parliament (vote foreseen on 23 October 2019), the Commission will be prevented from adopting the draft Regulation.

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

The Commission informed that a new version of the guidance was available, taking into account most of the additional comments received since the meeting of this Committee in July. The comments related to treated seeds still remained to be addressed and further discussion is needed, also in light of the other aspects related to seeds. A final version of the updated draft guidance documents will be prepared to be presented at a forthcoming meeting of this Committee and then a stakeholder consultation will be initiated.

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

   No news to discuss.

4. ***Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance***

   The Commission informed that six Member States had commented on the version presented at the meeting of this Committee in July. Consequently, the Biopesticides Working Group (WG) has rediscussed the document and seemed to agree on the main principles for approval and low-risk criteria. The discussion of the WG also influenced the ongoing review of the data requirements for microorganisms as new techniques such as the (relatively) new whole genome sequencing technique may be considered. Three Member States stated that further discussion on this issue seems necessary.

   The Commission indicated that the draft guidance document would be re-discussed at the Biopesticides Working Group of 6 November 2019, and this Committee will be updated thereafter.

5. ***Draft Guidance document on the risk assessment of metabolites produced by micro-organisms***

   The Commission informed that two Member States had reacted to the decision scheme presented at the meeting of this Committee in July. The Commission indicated that the draft guidance document will be re-discussed at the meeting of the Biopesticides Working Group on 6 November 2019, and this Committee will be updated thereafter.

6. ***Guidance on the impact of water treatment processes on the nature of residues in drinking water***

   The Commission informed that following the update provided to Member States at the meeting of this Committee in July a mandate to EFSA and ECHA to develop a joint guidance on impact of water treatment processes on residues in drinking water will be issued by the end of October. The mandate will be shared with Member States for information and will be made publicly available via EFSA's Register of Questions.

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

   The Commission informed that a commenting period had been opened during the summer, involving all interested parties. A commenting table containing all comments will be forwarded to the PAI WG to update the guidance.

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

   The Commission informed that a commenting period had been opened during the summer in parallel with the guidance document referred to under the previous agenda item, involving all interested parties. A commenting table containing all comments will be forwarded to the PAI WG to update the guidance.

9. ***Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43***

   The Commission informed that a commenting period will be opened involving all interested parties.

A.09 Defining specific protection goals for environmental risk assessment.

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

1. ***Feedback about notification of additional phrases by MS***

   The Commission informed that one Member State had informed about one additional precautionary sentence concerning protection of bees.

2. ***Risk Mitigation / list of risk reduction measures***

   The Commission presented the comments several Member States had made on the outline paper. Member States were invited to nominate by 6 November 2019 two experts to attend a workshop that the Commission will organise on 17 January 2020 on the topic.

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

1. ***New notifications (to be noted)***

   Two notifications had been received and were noted.

   One notification was about the withdrawal of the authorisation for a PPP containing epoxiconazole, due to the recent classification of the active substance as toxic for reproduction, Cat 1B, and considered by the Member State as fulfilling the criteria to be identified as endocrine disruptor. The other notification was about the amendment of the authorisation conditions for four PPP containing prosulfocarb to include use restrictions.

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

1. ***New notifications (to be noted)***

   Eight notifications had been received and were noted.

   Five concerned rejections of mutual recognition applications for a plant protection product containing mancozeb, a plant protection product containing a mixture of mancozeb and amisulbrom, a plant protection product containing metamitron, and two plant protection product containing paraffin oil.

   Three concerned rejections of authorisation under the zonal system for a plant protection product containing alpha-cypermethrin, a plant protection product containing a mixture of fluopyram and Fosetyl-Al, and a plant protection product containing 1-methyl-cyclopropene.

   Additionally, postponed from the previous meeting, the notification concerning the rejection of the mutual recognition for a plant protection product containing a mixture of copper and cymoxanil was also noted after bilateral discussions between the two Member States concerned.

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

   Postponed.

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

1. ***New notifications (to be noted)***

In the period from 5 July to 9 October 2019 a total of 53 emergency authorisations were granted by Member States for a range of active substances (mostly approved active substances) and uses. No Member States raised any particular observations and the Committee took note of the 53 emergency authorisations.

The Commission reminded Member States of the importance of completing the notifications timely, accurately and fully in PPPAMS, especially in light of the imminent publication of notifications received (see point A.14).

Member State	Active Substances	Function
BE	Sulfuryl fluoride	insecticide
BE	Imidacloprid	insecticide
CZ	Zinc phosphide	rodenticide
CZ	Zinc phosphide	rodenticide
DE	Plant oils/ Rape seed oil	insecticide
	Pyrethrins	
DE	Asulam	herbicide
DE	Azadirachtin (Margosa extract)	Acaricide insecticide
DE	Cyantraniliprole	insecticide
DE	Lime sulphur (calcium polysulphid)	fungicide
DE	Beauveria brongniartii	insecticide
DK	Imidacloprid	insecticide
ES	Thidiazuron	plant growth regulator
ES	lambda-Cyhalothrin	insecticide
ES	Spinetoram	insecticide
ES	Dichlorvos	attractant
ES	Azoxystrobin	fungicide
ES	Gibberellic acid	plant growth regulator
FR	Spinosad	insecticide
FR	Eugenol	fungicide
	Geraniol	
	Thymol	
FR	Pyridalyl	insecticide
FR	Spinosad	insecticide
FR	Spinosad	insecticide
FR	Chlorantraniliprole	insecticide
FR	Dimethenamid-P	herbicide
	Metazachlor	
FR	Paraffin oil/(CAS 64742-46-7)	fungicide
FR	Cyantraniliprole	insecticide
FR	Dichlorprop-P	plant growth regulator
FR	Spinosad	insecticide
FR	Beauveria bassiana 203	insecticide
FR	Potassium hydrogen carbonate	fungicide
FR	Fludioxonil	fungicide
FR	lambda-Cyhalothrin	insecticide
FR	Sodium hypochlorite	bactericide
FR	Boscalid (formerly nicobifen)	fungicide
	Pyraclostrobin	

Member State	Active Substances	Function
GR	Potassium phosphonates (formerly potassium phosphite)	fungicide
GR	Fosetyl	fungicide
IE	Cyantraniliprole	insecticide
IT	Mancozeb	fungicide
IT	Flonicamid (IKI-220)	insecticide
IT	Boscalid (formerly nicobifen)	fungicide
	Pyraclostrobin	
IT	Dimethomorph	fungicide
IT	Acetamiprid	insecticide
IT	Acetamiprid	insecticide
IT	Metarhizium anisopliae var. anisopliae strain BIPESCO 5/F52	insecticide
LV	Ethametsulfuron	herbicide
LV	2-Methyl-3-buten-2-ol 2-Methyl-6-methylene-2 7-octadien-4-ol (ipsdienol) 466-Trimethyl-bicyclo[3.1.1]hept-3-en-ol ((S)-cis-verbenol)	attractant
LV	266-Trimethylbicyclo[3.1.1]hept-2-ene (alpha-Pinen) 2-Methyl-6-methylene-2 7-octadien-4-ol (ipsdienol) 466-Trimethyl-bicyclo[3.1.1]hept-3-en-ol ((S)-cis-verbenol)	attractant
LV	Sodium silver thiosulphate	plant growth regulator
LV	Acetamiprid	insecticide
SE	Plant oils/ Rape seed oil	Acaricide
	Pyrethrins	insecticide
SI	Sulfuryl fluoride	insecticide
SK	Fenpyroximate	insecticide
UK	Cyantraniliprole	insecticide

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

The Commission gave a demonstration of the new database of emergency authorisations that was due to go live soon, explaining the features and search options available. The Commission explained that the database would complement the existing EU Pesticides Database and increase transparency.

Several Member States thanked the Commission for the work to develop the database, especially in view of improving transparency.

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

EFSA presented the newly adopted Guidance Document on the risk assessment of active substances and their transformation products that have stereoisomers.

EFSA also informed about the on-going pilot project to develop a harmonised GAP table. The pilot is running in the context of the MRL assessment. After consultation of Member States, eventually a new GAP table format to be used for both MRL and active substances peer-reviews will be adopted.

EFSA also gave an overview of progress in the peer-review process for some active substances.

A.16 Improving the efficiency of the process of a.s. approval.

No news to discuss.

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

No news to discuss.

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

No news to discuss.

A.19 Minor Uses:

1. ***Draft guidance document on minor uses according to Regulation (EC) No 1107/2009***

   The discussion was postponed.

A.20 Court cases.

The Commission informed on the judgment in case T-476/17 and on the preliminary ruling of the European Court of Justice in case C-616/17 (Blaise and others). As regards the latter, the Commission informed of the letter sent on 6 October 2019 by Pesticide Action Network Europe and Generations Futures on the follow-up to this judgment as regards testing of plant protection products for long-term toxicity and carcinogenicity. The two associations had requested the Commission to bring this letter to the Committee's attention. Upon request of a Member State, the Commission confirmed that the reply to this letter will also be made available to the Committee.

A.21 Ombudsman cases.

No news to discuss.

A.22 New Transparency rules: General Food Law amendment and implementation.

The Commission informed about the adoption of Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. This Regulation was published on 6 September 2019 in the Official Journal and it will apply as of 27 March 2021.

Follow-up work concerning the pesticide sector includes an amendment to Implementing Regulation No 844/2012 by the end of 2020 and significant implementation preparations by EFSA and the Commission.

A.23 Clarifications & questions related to specific active substance:

1. ***Chlorotalonil monitoring data***

   The discussion was postponed.

2. ***Candidates for substitution***

   The discussion was postponed.

3. ***Carvone: correcting act to the Implementing Regulation***

The approval of carvone was renewed in May 2019 by Commission Implementing Regulation (EU) No. 2019/706. Unfortunately it appeared that due to a typographical error in the EFSA Conclusions in the CAS number (Chemical Abstracts Number of the Americal Chemical Society) in the Annex to the Implementing Regulation is incorrect. Because the CAS number is a key identifier for an active substance and, if not corrected, can be misleading for further regulatory or commercial activities, the Commission informed that it considers it necessary to prepare a correcting act which has to follow the full adoption procedure and needs to be presented to this Committee for a vote.

4. ***Maleic hydrazide labelling provisions***

The Commission informed on a comment received from one Member State supporting the position of the Commission and from another Member State mentioning that the approval conditions should be amended based on new data available for the metabolite 3-pyridazinone. The Commission informed about a message received from the applicants on their intention to submit an Article 7 application for amendment of the conditions of approval and that Belgium has agreed to act as the Rapporteur Member State for the evaluation of the new data on 3-pyridazinone.

A.24 Interpretation issues:

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

The discussion was postponed.

2. ***Nitrophenolates salts***

The discussion was postponed.

3. ***Scope of Regulation (EC) No 1107/2009***

a) Scope Document rev.56 (previous border cases – confirmation)

The Commission presented the latest version of the border cases document outlining the cases presented below with a proposal for each entry. Member States shall send their comments about the proposed conclusion by 20th November 2019.

The Commission presented the request introduced by one Member State for a use of ozone as fumigating and seed disinfecting agent. This Member State considered that ozone could fulfil the criterion for basic substance. The Commission invited Member States to comment by 20 November 2019.

b) Kaolin as sunscreen

The discussion was postponed.

c) New cases:
c.1. Fescues seeds infected with endophytic fungus (FR)
c.2. Banana latex removers
c.3. Potassium permanganate sachets
c.4. Cis-jasmone
c.5. Irradiated pollen
c.6. Ozone

d) Follow-up in situ generation (update)

The discussion was postponed.

4. ***Data protection – access to old studies during the renewal process***

The Commission informed that it has received several questions concerning the access to "old" studies by a subsequent applicant who is not the owner of the studies.

The Commission explained its current interpretation. If the requested studies benefit from data protection under Chapter V of Regulation 1107/2009, the subsequent applicants (who are not the owners of the data) shall provide a letter of access in order to be able to use the studies. There is no other option but to reach agreement with the owner of the data (besides for test and studies involving vertebrate animals where the studies could be used even without letter of access – in accordance with Article 62(4)).

However, if the requested studies do not benefit from data protection anymore, then these studies could be used for the benefit of a subsequent applicant - per argumentum a contrario of Article 59(1) and Article 61 interpreted in the light of recital 39 of Regulation 1107/2009. The re-evaluation of studies should be done only when it is necessary, for example, when new criteria should be applied for the renewal. The competent authority can use the studies of the original applicant for the evaluation in view of establishing the RAR. Moreover, if a re-evaluation of the original study is indeed necessary, then the competent authority shall grant the subsequent applicant access to the full study (except for confidential parts) for the purpose of preparing its dossier and answering enquiries during the peer review process.

The Commission also stressed that the adopted amendment of the General Food Law Regulation aims at increasing the transparency and sustainability of the EU risk assessment in the food chain. The amendment foresees the proactive publication of all full study reports very early in the risk assessment process except for duly justified confidential information.

5. ***Article 32(1) vs. Article 44(3(a) and Article 46 of Regulation 1107/2009***

The Commission informed that it considers that the Member States cannot apply Article 32(1) together with Article 46 and grant a grace period after the expiry of the additional one-year period foreseen under Article 32(1) in cases where the approval of an active substance expired due to the withdrawal of application/non submission of an application for renewal. In such cases the Member States shall proceed without delay after the expiry of approval of the active substance to the withdrawal of the national authorisation under Article 44(3)(a) and may then grant a grace period under Article 46, if considered appropriate and in line with the conditions set in that Article.

The Commission summarised the state of play for the AIR4 programme. A document with a list of the active substances for which no application had been received or the dossier had been withdrawn, was available on CIRCABC, stating also the expiry date of the active substances concerned. The ultimate use date may vary depending on the decision taken in each Member State as regards grace periods, following the interpretation above.

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

1. ***Status of notifications for harmonised classification (summary table for info)***

   The discussion was postponed.

A.26 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

No news to discuss.

A.27 Report from working groups, in particular:

1. ***Working Group on Biopesticides***

   The Commission provided an overview of the on-going work related to the revision of data requirements for microorganisms, the grounds supporting the revision, the process, the principles applied for the revision process and the ways of working. As a tentative timeline, a first draft of the revised data requirements could be presented to this Committee by the end of 2020. The work is currently supported by the BioPesticides Working Group and Member States who are not yet represented were invited to consider appointing a representative.

2. ***Working Group on Seed Treatments***

   The Commission informed that following previous discussions in this Committee, the draft Seed Treatment Guidance Document had been split into two parts related to risk assessment and risk management, respectively. EFSA will be mandated to finalise the part related to risk assessment. The next meeting of the working group on the risk management part is scheduled for January 2020.

3. ***Working Group on Post Approval Issues***

   The Committee took note of updated Terms of Reference for the Working Group.

   In addition, the Commission informed about recent developments in the Post Approval Issues Working Group, which had its last meeting on 24 and 25 September 2019:

   – Update of the overview table on confirmatory data, paying particular attention to the fact of the re-allocation of Rapporteur Member States as a consequence of Brexit.

   – Call for the importance of communicating the list of studies relied upon during the renewal process. The studies in the list should be matched later on during the process of product authorisation.

   – A new interpretation of the data protection provisions in Regulation 1107/2009 had been brought forward by one stakeholder association. The Working Group considered it appropriate to assess the legal merits of this new interpretation. Meanwhile, the Commission Notice on guidance related to data protection had been published in the Official Journal on 8 July 2019.

   – The EU Minor Uses Coordination Facility had developed together with a drafting group a ‘Guidance Document on Minor Uses’. Although in general the application for an extension for minor uses according to Article 51 follows the same (zonal) procedure as other applications, there are currently differences in the implementation of the minor use provisions of Regulation

(EC) No 1107/2009. This document was presented to the PAI Working Group, which seemed to prefer a standalone document rather than integrating it in the Zonal Evaluation and Mutual Recognition Guidance Document, as had been the Commission's proposal.

- Following a question on implementation of the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey brought up in a recent meeting of the Inter-Zonal Steering Committee, the Commission clarified that residue trials would not be needed in all cases and that a pragmatic approach should be followed as set out in the decision tree of the guidelines. The Commission acknowledged that monitoring data could be used in addition to other relevant information.
- Grouping of metabolites is a key issue in the establishment of the residue definition for dietary risk assessment. The EFSA guidance document does not give advice on grouping metabolites and it makes reference to OECD guidance and other tools. Therefore, the PAI Working Group suggests to request EFSA to create a working group to elaborate principles and give advice to applicants and Member States.

A.28 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

No news to discuss.

A.29 OECD and EPPO activities, in particular:

1. Report of last WG Pesticides + Seminar on Digital and Mechanical Technologies (+ Expert group on drones)
2. Expert group on biopesticides: call for comments

The discussion was postponed.

A.30 Scientific publications and information submitted by stakeholders.

The Commission informed about the letters from stakeholder associations sent for the purpose of the discussions at this meeting.

A.31 Date of next meeting(s).

The Commission informed that the next meeting of the Committee of 5 and 6 December is confirmed. The following dates are planned for the meetings of this Committee in 2020: 23-24 March, 18-19 May, 16-17 July, 22-23 October, and 3-4 December.

B.01 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 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 Rev. 1).

The Commission recalled that thiacloprid has a harmonised classification as toxic for reproduction, Category 1B. Furthermore, it is classified as carcinogen, Category 2 and metabolites which are predicted to leach into groundwater in all scenarios are considered relevant since no evidence had been provided to show that they are not carcinogenic. The risk assessment for aquatic organisms, bees and non-target plants could not be finalised and many data gaps were identified.

The Commission informed that many insecticides are still approved in the EU although a full analysis of alternatives is not available to the Commission. Given the risks and concerns identified for thiacloprid, the approval of thiacloprid cannot be renewed.

Member States have the option to consider if the use of thiacloprid is indispensable for certain uses, and if so, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be fully justified.

Several Member States indicated that they would like a longer grace period than 12 months. Several Member States agreed with Denmark (see below) that it would be preferable to include a provisions related specifically to marketing and use of treated seeds in order to ensure a harmonised approach throughout the EU. These Member States called on the Commission to consider the approach for future cases. The Commission recalled that in the absence of harmonised provisions, Member States have the possibility to take all measures that they consider necessary at national level.

Outcome of the vote: favourable opinion.

Denmark asked for the following protocol declaration to be added to the summary report:

As risk assessment shows that sowing of seeds treated with thiacloprid poses unacceptable risk to human health, groundwater and the environment, we would urge the Commission to present a correcting act for the implementing regulation of the non-renewal for thiacloprid, as soon as possible. Denmark would like to see the implementing regulation for thiacloprid amended so that fixed grace periods are set for placing on the market and sowing of seeds treated with thiacloprid.

Vote taken: Favourable opinion.

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

The Commission informed that it had prepared a draft Regulation not renewing the approval and that the TBT notification procedure was concluded. However significant changes related to the harmonised classification had triggered the need for reconsideration of the dossier: the Risk Assessment Committee of the European Chemicals Agency had recommended classification as mutagenic, Category 2 (opinion adopted in March 2019), whilst EFSA had considered mutagenic, Category 1 appropriate in its Conclusion. In addition, the applicant had raised that as regards the potential genotoxicity of thiophanate-methyl, the RAC opinion considered the substance "non clastogenic", while EFSA in its conclusion had considered it "weakly clastogenic", thus leading to the impossibility to derive reference values and consequently no identification of a possible safe use by EFSA.

The Commission is currently reflecting if, provided these issues are solved, a restricted renewal on tomato/aubergines in permanent closed structures could be possible. A reference value derivation according to RAC values seems possible, however it is still necessary to exclude endocrine disrupting effects (thyroid) for which a mandate to EFSA would be needed.

Information provided by the applicant had been made available to Member States via CIRCABC for their consideration.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Vitis vinifera* cane tannins as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/11448/2019 Rev. 1)

One Member State mentioned that these tannins are natural substances and the treatment of data gaps for basic substances needs to be revised.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion 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.

Several Member States considered that granting Art. 53 authorisations is a Member States competence and indicated that therefore they would not vote in favour of the draft Decision. Three Member States mentioned the absence of clear criteria for

mandating the EFSA to evaluate the granted emergency authorisations, and two Member States added that EFSA does not have the right expertise to assess Art. 53 applications.

One Member State considered that granting emergency authorisations is a prerogative of Member States and that Commission Decisions as the one proposed are perceived as limiting this Member States prerogative; furthermore, some doubts remain on the effectiveness of the proposed measures.

Two Member States made reference to the subsidiarity principle and another Member State considered punishment of individual Member States not appropriate as many Member States grant emergency authorisations.

One Member State considered an EU measure against emergency authorisations only appropriate in case the products authorised cause a risk to consumers which is not the case for the products concerned by the draft Decision.

One Member State said it had no alternatives authorised for seed treatment.

Vote taken: No opinion.

B.05 Exchange of views and possible opinion 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.

Several Member States considered that granting Art. 53 authorisations is a Member States competence and indicated that therefore they would not vote in favour of the draft Decision. Three Member States mentioned the absence of clear criteria for mandating the EFSA to evaluate the granted emergency authorisations, and two Member States added that EFSA does not have the right expertise to assess Art. 53 applications.

One Member State considered that granting emergency authorisations is a prerogative of Member States and that Commission Decisions as the one proposed are perceived as limiting this Member States prerogative; furthermore, some doubts remain on the effectiveness of the proposed measures.

Two Member States made reference to the subsidiarity principle and another Member State considered punishment of individual Member States not appropriate as many Member States grant emergency authorisations.

One Member State considered an EU measure against emergency authorisations only appropriate in case the products authorised cause a risk to consumers which is not the case for the product concerned by the draft Decision.

One Member State said it had no effective alternatives, in particular as a vote on the non-renewal of the approval of the available alternative identified by EFSA (the active substance thiacloprid) had taken place on the same day as the vote on this draft Decision. Therefore, this Member State considers the draft Commission Decision not justified.

Vote taken: No opinion.

B.06 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 benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin.

Three Member States opposed the draft Regulation because they considered that the approvals of active substances causing concern, especially those active substances meeting a cut-off criterion, should not be prolonged. They indicated to be in particular against extension of the approvals of mancozeb and mecoprop-P.

One Member State did not agree with the extension of the approval of mancozeb. Nevertheless, because the draft Regulation covered a package of substances, they will vote in favour of the entire package.

Vote taken: Favourable opinion.

C.01 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 informed that the interservice consultation was not yet finalised and therefore no updated draft had been made available.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances.

The Commission presented the latest version of the draft Regulation, following conclusion of the inter-service consultation, and explained the limited number of changes compared to the version presented to this Committee in its meeting in July 2019. Member States had no comments on the new draft.

The Commission shared the indicative time table, including the imminent launch of the public feedback mechanism (4 weeks duration). The final draft is expected to be presented for the opinion of this Committee in December 2019.

Member States were invited to share any additional comments as soon as possible and before 6 November 2019.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance metalaxyl-M, 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/11112/2019 Rev.2).

The Commission informed that the interservice consultation was ongoing; a final text would be made available once completed and a WTO TBT notification would then also be launched since the renewal includes restrictions. A vote is foreseen in March 2020.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance chlorpyrifos, 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/11938/2019 Rev. 0).

See Point C.05 for the joint discussion of both agenda items.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance chlorpyrifos-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/11942/2019 Rev. 1).

The Commission started by underlining that chlorpyrifos and chlorpyrifos-methyl were subject to two separate renewal processes based on separate applications, dossiers and assessments. However, points C.04 and C.05 were discussed together for efficiency purposes.

The Commission recalled that given the concerns identified during peer review expert discussions in April for human health, the Commission had mandated EFSA to provide statements on the available outcomes related to human health for chlorpyrifos and chlorpyrifos-methyl, indicating whether the approval criteria laid down in Article 4 of Regulation 1107/2009 are fulfilled. On 2 August 2019, EFSA had published statements for both substances, confirming that concerns for human health exist and that the approval criteria for active substances are not fulfilled. For both substances concerns were identified, in particular in relation to the potential of the substances to cause damage to DNA and to adversely impact the development of children's brains (developmental neurotoxicity). Experts concluded that toxicological reference values cannot be determined for both substances and therefore the dietary and non-dietary risk assessments cannot be conducted. In the case of chlorpyrifos-methyl, the conclusions were, in part, reached based on read-across with chlorpyrifos. In its statement, EFSA had advised that a follow up expert discussion was needed to further discuss the read-across approach and whether reference values could be established for chlorpyrifos-methyl.

Draft renewal reports had been sent to the applicants and to Member States in mid-August with a request for comments. The applicants had also been invited to provide comments on technical aspects of chlorpyrifos-methyl to be taken into account in the second expert discussion. The applicants' comments had been made available to Member States. Several Member States had provided written comments supporting the proposal for non-renewal of approval of chlorpyrifos and reserving a final position on chlorpyrifos-methyl until the second expert meeting would be completed.

The Commission informed that in early September, EFSA had held a second expert discussion on chlorpyrifos-methyl in which experts had confirmed their earlier conclusion that genotoxicity cannot be ruled out and that reference values cannot be established. The Commission confirmed that it had asked EFSA to update its statement on chlorpyrifos-methyl.

The Commission further informed that one of the applicants supporting renewal of chlorpyrifos-methyl had requested a meeting with the Commission, which had taken place in early October to express its disagreement on the process followed and the outcome described in EFSA's statement for the substance. The applicant did not consider read-across a valid approach, nor did it consider that there was any evidence of genotoxicity or developmental neurotoxicity for chlorpyrifos-methyl. Further comments had been received on 18 October and had been made available to Member States.

EFSA gave a detailed presentation on the findings for chlorpyrifos and chlorpyrifos-methyl, in particular to explain the approach taken for chlorpyrifos-methyl in light of the criticism of the applicants.

The Commission informed Member States about a number of letters received, in particular:

– An applicant for the renewal of chlorpyrifos and chlorpyrifos-methyl submitted a position paper to Member States disagreeing with the conclusion in the EFSA Statements.

– A growers' organisation had also sent a letter to the Commission expressing concern about the loss of the substances and the process followed.

The Commission informed the Member States that the interservice consultations had been finalised and the WTO TBT notifications had been launched for both substances. The Commission highlighted that the transitional and grace periods had been shortened; Member States would have 1 month to withdraw authorisations and could grant a further 2 months for grace periods for sale and use of existing stocks (i.e. a total period of 3 months grace period from the date of entry into force of the non-renewal Regulations). The Commission also indicated that it will initiate action without delay to reduce the MRLs for the substances.

Finally the Commission explained that the intention is to vote on the draft Regulations not renewing the approvals of chlorpyrifos and chlorpyrifos-methyl in the next meeting of this Committee (scheduled for 5-6 December 2019).

Several Member States took the floor expressing agreement that non-renewal of approval of chlorpyrifos is fully justified based on the concerns identified for human health. Several Member States also expressed support for the non-renewal of chlorpyrifos-methyl based on the outcome of the two expert discussions. Some Member States wanted to have further time to reflect on chlorpyrifos-methyl, in order to be able to take into account the forthcoming updated statement of EFSA.

There were diverging views among Member States on the appropriate grace period; some supported the 3-month period proposed (a few even calling for a shorter one) while others asked for a longer period, particularly for chlorpyrifos-methyl.

One Member State expressed doubts about the assessment approach taken for chlorpyrifos-methyl while another asked for clarity about developmental neurotoxicity, to which EFSA responded in detail.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of L-cysteine 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/11056/2019 Rev.0).

The Commission presented the revised draft review report and draft Regulation. Based on the comments from Member States, the section on the identity of the substance and GAP table had been revised. Additionally, the Commission proposed to restrict the approval to professional users due to the classification of the undiluted substance.

Three Member States commented that the proposed restriction would be difficult to enforce, whereas one Member State supported the proposal. Another Member State expressed concerns as regards risk to operators.

Member States were invited to comment by 6 November 2019.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Castanea* and *Schinopsis* tannins 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/11444/2019 Rev.0).

The Commission informed that the applicant had withdrawn its application for the approval of *Castanea* and *Schinopsis* tannins as a basic substance. The Commission considered the procedure as closed and no legal act will be prepared.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance foramsulfuron, 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/11214/2016 rev.1).

The Commission presented the revised draft review report and the draft Regulation renewing the approval. Comments had been received from Member States and the applicant. The rapporteur Member State informed that it had submitted the classification proposal to ECHA on 30 September 2019 for accordance check.

Member States were invited to comment by 6 November 2019.

M.01 Information from the Commission:

The Commission informed about:

- A call for candidates for Joint Meeting on Pesticide Residues (JMPR) experts, for which the information is on CIRCABC;

- A vacant position for a seconded national expert, for which a vacancy notice had been sent to the Permanent Representations with a deadline for applications by 25 October 2019;
- The organisation of the first annual Endocrine Disruptors Forum (announced in the Commission's Communication setting out an Endocrine Disruptors Strategy) in Brussels on 8 November 2019. Registration is open and information had been circulated;
- The organisation of a Better Training for Safer Food workshop on endocrine disruptors for Member States experts on 27-28 November 2019 in Brussels;
- A PPPs chemistry workshop for Member States experts on 19-20 November in Brussels, organised with Germany.

The Commission also announced that it would request Member States by letter to send information about the safeners and synergists currently authorised in their territories, as well as to inform about updated information on the time they take for authorisation of plant protection products in accordance with the different procedures foreseen in Regulation 1107/2009.