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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
05 - 06 December 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/464af872-3138-4681-b28a-2929453eaa28*

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**

   No new admissible dossiers received.

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

   a) Napropamid-M

   The Commission informed about the comments received from four Member States. Based on the support of the majority of Member States, the Commission will mandate EFSA to clarify if the active substance has endocrine disrupting properties according to the new criteria. Clarifications will also be requested as regards soil degradation (anaerobic conditions) and its possible consequences for the risk assessment for soil and aquatic organisms, as well as for groundwater exposure for transformation products.

   b) Pydiflumetofen

   The Commission summarised the EFSA Conclusion. This new active substance shows very high persistence in soil (laboratory and field studies) and in water/sediment studies. Some Member States considered these results of high concern but mentioned that the standard risk assessment methodologies are not sufficient for extremely persistent compounds. Furthermore, the available evidence was not considered sufficient to draw a conclusion on endocrine disrupting properties for non target organisms other than mammals. Member States were requested to send comments and positions by 13 January 2020 in particular whether they agree about the methods used for the determination of persistence.

   c) 1,3-Dichloropropene

The Commission informed that one Member State had accepted to submit a proposal for a revised harmonised classification under the CLP Regulation to exclude possible genotoxic properties of 1,3-D and that reflections are on-going as regards the next steps.

d) Ethamethsulfuron-methyl

The Commission explained that following the Opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) in September 2019, which concluded that ethamethsulfuron-methyl should not be classified as toxic for reproduction, which has removed the critical concern about the relevance of groundwater metabolites.

The Commission explained that it was now examining the EFSA Conclusion so that all issues were considered, in particular it was necessary to also examine if the endocrine disrupting properties of the substance had been fully assessed. A meeting had taken place with the applicant in October 2019, who intended to submit further comments in due course which will be made available to Member States via CIRCABC.

Member States were invited to provide comments on the substance by 13 January 2020, also taking into account comments of the applicant once made available.

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

No discussion took place.

A.03 Renewal of approval:

1. **General topics:**

a) Access to original dossiers

Further to the discussion at the last meeting of the Committee on the repeated requests received from potential applicants regarding access to studies submitted as part of approval dossiers and for which data protection had expired, the Commission informed that it received comments and letters from one Member State and two stakeholder associations where internal reflections were ongoing.

The Commission reminded that access to these studies cannot be denied to the requestors, and stressed the importance of carrying out comprehensive and robust risk assessments in the context of renewal applications, ensuring that all information, including older studies are taken into account.

b) 6th renewal programme

The Commission informed that it has started to work on the 6th renewal programme identifying the active substances that would be included in it, also taking into consideration the recent amendment to the General Fool Law and ensuing changes in deadlines and procedures.

As first approximation, active substances expiring between 31 March 2025 and 27 December 2028 (a total of 24 substances) would be included. The criteria to be followed to assign the Rapporteur Member States would be:

- There are less active substances to allocate than the number of Member States, therefore the smallest Member States would not be included in this allocation round unless they volunteer for an active substance.
- If a Member State has experience with the zonal assessments of plant protection products, it would be allocated to the corresponding active substance.
- In principle and according to the recommendations from the European Parliament, the former Rapporteur Member State should not be appointed again as Rapporteur of an active substance, either if it was for a first renewal or already renewed.

The Commission also reminded Member States about the need to consider and where appropriate hold pre-submission meetings with applicants.

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

a) Phlebiopsis gigantea VRA 1835, VRA 1984 and FOC PG 410.3

The Commission informed Member States that in case of applications for microbial active substances involving different strains of the same species (e.g. the case of *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3), the different strains eventually approved will be listed in different entries of the Annex to the Implementing Regulations (i.e. in different rows). The same approach will be applied for the public EU pesticides database. Review/renewal reports concerning applications of different strains belonging to the same species will be handled based on a case-by-case approach, depending on the level of similarity of different strains and biological properties. This approach ensures compliance to the Uniform Principles which state that identity of the micro-organism shall be established at strain level and consistency as regards the number of active substances actually approved (i.e. microorganisms at strain level).

The Commission also indicated that it will prepare a draft Regulation for the renewal of *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3, which are expected to be proposed for an opinion in the meeting of the Committee in March.

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

a) Flumioxazin

The Commission informed that a mandate had been sent to EFSA with regards to the evaluation of whether flumioxazin has endocrine disrupting properties according to the new criteria.

b) Clopyralid

No discussion took place.

c) Cyazofamid

The Commission summarised the comments received so far from Member States.

The Commission informed about a meeting with the applicant and that the applicant had sent a new set of substantial comments, which had been made available on CIRCABC.

Member States were invited again to clearly indicate their positions by 13 January 2020, with respect to a support for non-renewal, restricted renewal to greenhouses, or renewal.

d) Famoxadone

The Commission resumed discussions on this dossier and explained it has contacted EFSA to clarify some aspects. The Commission invited the Member States to send preliminary views on a proposal of renewal of approval by 13 January 2020. One Membe State commented the this substance will be included in the annex of Directive 2008/105/EC and that it will send written comments.

e) Etoxazole

The Commission summarised the comments received so far from Member States and invited the Member States to clearly express their positions by 13 January 2020, in particular whether they can support restricted approval to greenhouses or if they consider a further restriction to ornamentals is needed due to the non-finalised consumer dietary risk assessment.

f) Indoxacarb

The Commission summarised the recent EFSA statement on the updated peer review concerning the risk to mammals and bees for the active substance indoxacarb and of recent comments sent by the applicant. Member States were invited to send their views by 7 February 2020.

A.04 Confirmatory Information:

1. Spiroxamine

The Commission indicated that based on the feedback received from Member States, the review report is going to be amended to reflect the closure of the assessment of the confirmatory information related to the groundwater assessment, which had come to a positive conclusion. The Commission will send a mandate to EFSA to update the consumer risk assessment and the risk assessment for fish. The potential stereo-selective degradation of each isomer in plants, animals and the environment will be addressed during the renewal process.

2. Triazole derived metabolites (TDMs) (general appendix which will be added to each concerned review report to take note)

The Commission recalled the approach that was proposed to finalise the confirmatory information process for the triazole substances in relation to the Triazole Derived Metabolites (TDMs) and the consumer assessments: each Review Report would be updated to reflect the specific confirmatory information point (where relevant) and in all these cases an Appendix would be added to the Review Report to establish the toxicological reference values and residue definitions that apply to the TDMs.

The Commission explained some amendments to the draft Appendix made since the previous meeting. No Member State expressed any objection to the Appendix and it was thus endorsed by the Committee.

The Commission explained that it would start working on the individual updates to Review Reports and attach the Appendix to each report during that process. It was

anticipated that some reports could already be noted in the meeting of the Committee in March 2020.

3. Sulfoxaflor

   The Commission informed that it had sent a mandate to the EFSA with regard to the risk to bees from consumption of puddle water and the risk to bumble bees and solitary bees in field margins.

4. Isofetamid

   No discussion took place.

5. Terbuthylazine

   The Commission informed that following a call for comments on the updated EFSA Conclusion in the meeting of the Committee in October 2019, five Member States had reacted and all had expressed concerns about the substance based on groundwater contamination and consumer exposure and had indicated that a withdrawal of the approval would be the most appropriate measure.

   Member States who had not expressed a position were invited to provide comments by 13 January 2020.

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 mentioned that it would propose to extend the representative uses to acaracide for ornamentals in permanent greenhouse as no issues had been identified during the peer review.

      As to the confirmatory information, there are remaining uncertainties although not raising critical concerns as to the consumer risk assessment. Therefore, taking into consideration that the supplementary dossier for the renewal of approval has to be submitted by 30 of November 2021, the Commission proposed that these issues are addressed during the renewal process. Member States did not raise objections to the proposed approach.

A.07 Basic substances:

1. **New dossiers received (for information)**

   The Commission informed that the following dossiers had been received: chitosan hydrochloride (extension) and two applications for the approval of ozone as a basic substance.

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

   No news to discuss.

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

   a) Sucrose

      No discussion took place.

   b) Fructose

      No discussion took place.

   c) Lecithins (extension)

      The Commission explained that it did not intend to mandate the EFSA for an updated technical report for this extension given the nature of the substances and their uses. The Commission presented the amendment to the review report for approval of lecithins as basic substance to include the new use in carrots. Member States were invited to send comments by 13 January 2020.

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 of the objection by the European Parliament to the draft Regulation modifying the Uniform Principles for bees, which had received a favourable opinion of the Committee in its meeting in July 2019. The Commission can therefore not adopt the Regulation and consequently no part of the 2013 EFSA Bee Guidance Document can currently be implemented.

   The Commission explained that this objection does not impact the ongoing review of the Bee Guidance Document. EFSA will continue to work on this mandate with a finalisation in March 2021.

   The Commission also informed that it is reflecting on possible the next steps.

   One Member State stated that it would be more effective to wait with any new proposal until the finalisation of the review by the EFSA. Another Member State underlined that the finalisation of the review in March 2021 can only be seen as the starting date of a new procedure to endorse this Guidance Document.

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

   The Commission gave an update on the state of play of the draft document, explaining that previous comments had been taken into account in a new version. The Commission invited Member States to provide final comments and explained that it would then consult stakeholders before finalising this document.

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 gave an update on the state of play of the draft Guidance Document which will be discussed again by the Working Group Biopesticides later in December 2019. Latest amendments concern the list of antimicrobials to be tested. A new version will be distributed by e-mail to Member States with an invitation to comment by 13 January 2020.

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

   The Commission updated on the state of play of the draft Guidance Document which will be discussed again by the Working Group Biopesticides later in December 2019.

6. **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 table containing all comments will be forwarded to the Post Approval Issues Working Group to update the guidance.

7. **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 table containing all comments from Member States and the main stakeholder associations (ECPA, ECCA, IBMA) consulted will be forwarded to the Post Approval Issues Working Group to update the guidance.

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

   The Commission informed that a commenting table containing all comments from Member States and the main stakeholder associations (ECPA, ECCA, IBMA) consulted will be forwarded to the Post Approval Issues Working Group to update the guidance.

A.09 Defining Specific Protection Goals for environmental risk assessment.

The Commission informed that the joint report of the workshops which took place in June (Member States) and September (stakeholders) is finalised. The next workshop is planned for 3 and 4 February 2020 with the joint participation of experts from the Member States and stakeholders.

Member States who have not yet nominated experts for the project were invited to send their nominations as soon as possible, by 13 January 2020 at the latest. The Commission also invited Member States' representatives in this Committee to get in contact with the national authorities in charge of nature and biodiversity protection.

The Commission informed about the interest of some stakeholders oi this project demonstrated by letters sent to the Commission and e-mails sent to some members of this Committee.

One Member Stated commented that it is still a question if biodiversity is covered by the ecosystem services approach. The Commission acknowledged this question and recalled that the framework proposed by EFSA was initiated in order to better consider impacts on biodiversity and on ecosystems into the risk assessment for pesticides. So far no alternative method has been proposed by any participants of the two workshops in 2019.

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

1. **Feedback about notification of additional phrases by Member States (no update)**

   No news to discuss.

2. **Risk Mitigation / list of risk reduction measures: outline of Workshop on 17 January 2020**

   The Commission presented the draft agenda of the workshop on reduction of exposure to pesticides which will take place on 17 January 2020 in Brussels. The Commission invited Member States to appoint up to two experts who could be reimbursed by 17 December 2019.

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

No news to discuss.

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

No news to discuss.

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

No news to discuss.

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

The Commission informed about the public database of notifications of emergency authorisations and the planned further development work on PPPAMS. The public database was expected to go live early in 2020.

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

EFSA gave an overview of progress in the peer-review process for some active substances and explained the editorial change foreseen in the EFSA Conclusions, in order to have a stand-alone section on endocrine disrupting properties.

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

The Commission welcomed the new stand-alone section on endocrine disruption proposed by EFSA (See previous point). It also stressed the importance of addressing issues early in the risk assessment process, as late changes are causing delays in finalising the risk assessment and ultimately the regulatory decision-making. Therefore, the presubmission meetings among Rapporteur Member States, EFSA and the applicants are important in order to clarify the data needs.

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:

The Minor use coordinator informed that Finland, which has currently the presidency of the Council of the EU, has taken the initiative to discuss the long-term funding of the MUCF as AOB point in the meeting of the AGRIFISH Council the 16-17 December 2019. Several Member States and the Commission had indicated to support the Finnish initiative. For 2020 the EU Minor Uses Coordination (MUCF) will be fully depending on voluntary assessed contributions from Member States. Although the MUCF has already received positive responses from 13 Member States, funds for 2020 are not yet secured. As actions/initiatives to raise funding for 2020 are still ongoing, the Minor Uses Steering Group decided to postpone a decision on the 2020 budget for the MUCF to early February 2020.

A representative from the Slovak Republic had been nominated to represent the Central and Eastern European Countries in the Minor Uses Steering Group. This nomination will be forwarded to the Annual General Meeting for a final decision in February 2020.

In October 2019 the MUCF had published the results of the '2019 survey' on the minor uses database EUMUDA. In total, more than 6 000 minor use needs and priorities from 28 EU Member States are now available. Details can be found at: http://www.eumuda.eu/database/table_minor_uses.

On 30-31 October/1 November 2019, minor uses meetings of 7 different Commodity Expert Groups and of the Horizontal Expert Group were held in Dublin with more than 90 minor uses experts from 25 different countries participating. More details can be found in the Minor Uses Newsletter: https://www.minoruses.eu/mucf/newsletters

The MUCF is organising a Workshop on "Minor Uses and Speciality Crops: The way forward in Europe" on 18-20 February 2020 in Paris. The French Ministry of Agriculture and Food is hosting this event. The two pillars of the workshop are (i) enhancing harmonisation and (ii) moving towards a European wide coordination of minor uses work. The Workshop will be structured in plenary and break-out group sessions. More information will be placed on https://www.minoruses.eu/

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

   The Guidance Document on Minor Uses will provide more clarity regarding the rules for authorisation of minor uses and contributes to further harmonisation between Member States. The Commission informed that based on recent comments received an updated revision of the Guidance Document will be prepared.

A.20 Court cases.

The Commission provided a short overview on the judgment of the European Court of Justice in case C-445/18 Vaselife International BV and Chrysal International BV v CTGB (Preliminary ruling on the interpretation of Article 52 of Regulation (EC) No 1107/2009). It also informed that the President of the General Court had dismissed the application for interim measure, seeking suspension of the operation of Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 concerning the non-renewal of approval of the active substance ethoprophos (T-317/19 R).

A.21 Ombudsman cases.

The Commission informed that on 3 December 2019 the Ombudsman had taken a decision on the complaint of the NGO Pollinis concerning the Commission's refusal to grant access to the positions of Member States in this Committee on the implementation of the EFSA 2013 Bee Guidance Document. The Commission had refused to give access invoking the confidentiality according to comitology rules and arguing that public disclosure of Member State positions would undermine the ongoing decision-making process. However the Ombudsman had confirmed the conclusions of her recommendation of December 2018 and found maladministration of the Commission in such refusal of access to documents.

Two Member States stressed that they considered the position of the Commission correct, and that discussions in the Committee should not be disclosed in order to allow for comprehensive and frank discussions during decision making.

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

The Commission presented the main amendments introduced by Regulation (EU) No 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain and in particular those relevant for Regulation (EC) No 1107/2009. This Regulation was published on 6 September 2019 in the Official Journal and it will apply as of 27 March 2021.

The Commission informed that these amendments will require considerable amendments to Implementing Regulation No 844/2012 before the end of 2020 and significant implementation preparations by EFSA and the Commission. Work has started at both, the Commission and EFSA, and this Committee will be informed and consulted regularly.

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

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

   Due to the late availability of the revised document, one Member State commented that they would not be able to take note of this point. As a consequence, the point was postponed until the next meeting of this Committee.

2. **Chlorotalonil monitoring data**

   The Commission presented the feedback received from Member States on chlorothalonil monitoring data. One Member State asked which procedure needs to be followed to evaluate data which becomes available after a substance is no longer approved, which could nevertheless still be relevant given for instance in cases of past contamination of groundwater with metabolites when the active substance was approved.

   Member States were invited to provide their comments by 7 February 2020.

3. **Candidates for substitution**

   The Commission informed about its intention to amend Implementing Regulation (EU) 2015/408, which established the first list of active substances identified as candidates for substitution. The objective of the amendment is twofold: 1) include the active substances that fulfil any of the criteria of a candidate for substitution which were approved or renewed after 31 January 2013 under the transitional

provision of Article 80(1) of Regulation (EC) No 1107/2009. 2) include the active substances that fulfil any of the criteria of a candidate for substitution which were approved or renewed before 31 January 2013 under the transitional provision of Article 80(1) of Regulation (EC) No 1107/2009 but their classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixture had changed following RAC opinions during the last years.

Member States were requested to bring to the attention of the Commission by 13 January 2020 any active substance that in their view should be considered for the amendment of Implementing Regulation (EU) 2015/408.

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

The Commission informed that the draft act correcting the CAS number of the substance is expected to be presented at the next meeting of this Committee.

5. **Maleic hydrazide labelling provisions**

The Commission informed that no further views of Member States had been received and considered the point now closed.

A.24 Interpretation issues:

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

The Commission informed that several Member States had raised comments on the issue whether the renewal of approval of 2,4 D also covered 2,4 D EHE and that a meeting with the applicant had taken place.

The situation is that the dossier submitted for the renewal of approval of 2,4 D (acid) did not include any data on 2,4 D EHE (which is an ester of the acid), although such data had been part of the original approval. A "bridging dossier" providing the data on 2,4 D EHE had already been evaluated by the Rapporteur Member State to be available for product authorisations.

The Commission confirmed its view that the ester is to be considered being a different substance. As a consequence no use of a "bridging dossier" at Member State level during authorisation is possible as the concept of "bridging dossier" does not exist under Regulation (EC) No 1107/2009.

The Commission had advised the applicant to apply for amendment of the conditions of approval (Art 7) to specify that the relevant listing in the Annex to Regulation 540/2011 should be amended to cover the acid and the ester. As the assessment of the data for the ester had already been made by the Rapporteur Member State, and there are indications that the risk profile for the ester would be more favourable than for the acid, the process for the amendment of the approval could be expected to proceed rather quickly.

Member States are requested to send comments and positions by 13 January 2020.

2. **Nitrophenolates salts (Na/K; CHAP)**

The Commission informed about the fact that two Member States delivered authorisations for the placing on the market of national fertilisers containing potassium salts of nitrophenolates. Member States were invited to send by 13 January 2020 their opinion and position about the equivalence of the two salts, potassium and sodium, the latter being approved as active substances for plant protection products.

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

a) Scope Document rev. 58 (previous border cases – confirmation)

As a follow-up of the publication of the Fertilising Products Regulation No 1009/2019 the Commission presented amendments to several entries of the scope document, which concerned the new category of fertilising products called plant biostimulants as they were overlapping with some categories covered by the scope of Regulation (EC) No 1107/2009. Member States were invited to send comments by 13 January 2020.

b) Ongoing cases:

b.1. Irradiated pollen

b.2. Ozone as soil fumigant and seed disinfectant

b.3. Water conditioner

b.4. Eruca (*Bacillus megaterium* and *B. mycoides*)

b.5. Wildfire fighting product

The Commission presented the new border cases listed above with proposals for interpretation. Member States were invited to send comments by 13 January 2020.

c) Follow-up in situ generation (update)

The Commission presented a draft discussion paper on a way forward to address the different scenarios corresponding to in situ generation of active substances. Member States were invited to send comments by 31 January 2020.

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

This point was discussed together with point A.03.1.

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

No news to discuss. The point is considered closed.

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

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

The Commission made an updated table available to the Member States.

The Commission also recalled that these summary tables were provided over the last years in order to support timely submission of CLP dossiers. However, these tables are now in a way superseded by the vote taken under agenda item B.01. As a consequence, they will no longer be provided and this standing point of the Committee meetings is deleted.

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 Reports from Working Groups, in particular:

1. **Working Group Biopesticides**

The Commission reported about the activities of the Working Group Biopesticides which, besides the finalisation of the two guidance documents referred to under point A.08 of the agenda, has also worked on data requirements for microorganisms and viruses. A planning of meetings of the Working Group was presented by the Commission which considers this activity as priority aiming at adapting the data requirements in a proportionate way for these non-chemical active substances and products.

2. **Working Group Seed Treatments**

   No news to discuss.

3. **Post Approval Issues** Working Group

   No news to discuss.

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:

The Commission informed of the call for comments on the OECD working paper on Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-Based Pesticides and the Empirical Testing Decision Tree for External dsRNA. Member States are invited to send any comments to the OECD secretariat with a copy to the Commission by 30 January 2020.

1. **Expert Group on Drones**

   The Commission informed about the ongoing work of the ad-hoc expert group aiming at checking whether the application of plant protection products by unmanned aerial vehicles (e.g. drones) would require specific data. A questionnaire addressed to competent authorities will be distributed to this Committee with a view to gather available information by 14 February 2020.

A.30 Scientific publications and information submitted by stakeholders:

- FAO/WHO report on Foodborne Antimicrobial Resistance

The Commission informed about this report which has a special focus on the role of fungicidal plant protection products in the emergence of antimicrobial resistance.

A.31 Date of next meeting(s).

The next meeting (subject to confirmation) is planned for 23 and 24 January 2020.

B.01 Exchange of views and possible opinion 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 recalled that the approach and preliminary drafts had been presented at several meetings of this Committee in the course of 2019 and that information had also been provided to the meeting of the Competent Authorities for REACH and CLP in 2019.

The Commission informed that, after the meeting of this Committee in October, one Member State had raised a question on the transition period (Article 2) regarding dossiers for which the application (but not the supplementary dossiers) had already been received. The Commission also informed that one Member State had signalled its support to the draft Regulation in writing.

The Commission further explained that the draft Regulation had been subject to a public consultation via the feedback mechanism on the Better Regulation portal of the European Commission from 24 October until 21 November 2019. During the commenting period, one contribution from ECPA had been received.[1] The Commission informed the Committee about the comments raised and the Commission's view on them as follows:

- ECPA voiced general concern about the too short stop-the-clock period of 30 days foreseen in Article 13 of Regulation 844/2012 and therefore suggested prolongation of this period during adaptation of pesticides implementing rules to recent General Food Law changes.
- ECPA suggested an additional recital regarding the submission of a notification of intention to submit a CLH dossier to ECHA. The Commission underlined that the recital will not become part of the amended Regulation. Moreover, the submission of an intention is systematically encouraged already today – it is a practice, but not enshrined in the legal text of Regulation (EC) No 1272/2008 (CLP).
- ECPA suggested the insertion of new text for Rapporteur Member State's reaction to accordance check issues at ECHA level. The Commission explained that it considered that the accordance check is not a legal concept but part of the CLP practice, to ensure that ECHA has all relevant information at its disposal (see Article 37(1) of the CLP Regulation). The timelines had been thoroughly discussed with ECHA and appear feasible, also in the light of the already existing coordination between ECHA and EFSA in relation with submissions using the combined/joined template for draft renewal assessment reports and CLH dossiers.
- ECPA requested clarification as to the entry into force. The Commission considered no redrafting necessary in the light of the legal text which provides that the amendments enter into force in accordance with standard rules, i.e. 20 days after the publication in the Official Journal. Application of the new measure is deferred to allow for adaptation by dossier submitters. The Commission, in its revised draft, proposes a new phrasing of the transitional period, to clarify that the date of expiry of approval is the relevant moment in time. This means that all dossiers are captured after a transitional period and removes doubts as to dossiers for which the application but not the supplementary dossiers were already received (i.e. to clarify the situation for all cases where the expiry of approval was modified to spread the workload of the renewal programme more evenly).
- ECPA enquired about plans of the Commission to create a level playing field between substances as to their CLH coverage. The Commission considered that it is precisely the purpose of the proposal to achieve gradually such a level playing field, given that the legislator's intention (in CLP) that all active substances in biocidal

[1] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-6571120_en#isc-2019-05598

and plant protection products should normally be subject to harmonised classification & labelling is not fully realised yet.

- A transitional period of 2 years was suggested by ECPA. The Commission considered that the issue should be addressed as soon as possible. Discussions on the amendment started in 2016, the joint template became operational in 2017. Moreover, the proposal relates to a change of a procedure and not material rules-classification aspects are part of the data requirements already today where relevant.
- ECPA enquired about a revision of AIR 4 and AIR 5 programmes. The Commission informed that this was not intended.

No Member State had further comments.

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 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. 1).

The Commission informed Member States on the documents for vote and explained that there had not been any significant developments on chlorpyrifos since the previous meeting of this Committee. A brief summary of the comments received from Member States was given. Furthermore, Member States were informed that a number of third countries had provided comments on the TBT notification which would be responded to in due course. The comments primarily related to the impact of lowering the Maximum Residue Levels (not directly impacted by the non-renewal decision).

Several Member States asked for protocol declarations to be included in the summary of the meeting:

Poland supports the Commission draft on non-renewal of active substances chlorpyrifos and chlorpyrifos-methyl. However, we find the deadline for Member States for withdrawal of authorisation unrealistic and very difficult to be met mainly because of national procedural regulations, setting deadlines and obligations for competent authority to inform the authorizations holders and their right to appeal at every stage of the procedure which results from the Act " the Code of Administrative Procedure".

The Portuguese authorities wish to state that legal measures provided in articles 3 and 4 of the proposed Regulation are considered disproportionate, ineffective and will represent an administrative and enforcement burden for competent authorities. Foreseen grace period duration will not allow proper disposal and use of plant protection products as expected time frame for using up stocks will not match normal agricultural use for this active substance. This inconsistency may represent an unforeseen and uncontrollable risk for the environment as existing stocks will not have the opportunity to be legally sold and / or used. This legal measure is expected to create an unnecessary economic burden both for SMEs and farmers.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance 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. 2).

The Commission informed Member States on the documents for vote and presented a brief summary of the comments received from Member States.

Member States were reminded that EFSA had provided a full and detailed explanation of the scientific outcomes for chlorpyrifos-methyl (and chlorpyrifos) in the last meeting of the Committee.

The Commission also presented the developments since the October meeting of the Committee:

- EFSA had made its updated statement on chlorpyrifos-methyl available to Member States and the Applicant on 11 November 2019 and published it on 26 November 2019. The statement confirmed the concerns for human health raised in the earlier version and concluded that the approval criteria for human health are not fulfilled. Further rationale for the conclusions reached was provided.
- The Renewal Report was updated to reflect the updated statement and circulated for comments to the applicants. The applicants' comments had been considered by the Commission and shared with Member States.
- The applicants considered the conclusions reached not acceptable and that there is no concern for genotoxicity or developmental neuorotoxicity.
- Several Member States had expressed concerns about the conclusion reached and the read across approach used for the assessment of genotoxicity.
- One Member State had submitted a paper on the importance of chlorpyrifos-methyl to control the Asian stink bug.
- Member States were informed that a number of third countries had provided comments on the TBT notification which would be responded to in due course. The comments primarily related to the impact of lowering the Maximum Residue Levels (not directly impacted by the non-renewal decision).

Several Member States asked for protocol declarations to be included in the summary of the meeting:

Poland supports the Commission draft on non-renewal of active substances chlorpyrifos and chlorpyrifos-methyl. However, we find the deadline for Member States for withdrawal of authorisation unrealistic and very difficult to be met mainly because of national procedural regulations, setting deadlines and obligations for competent authority to inform the authorizations holders and their right to appeal at every stage of the procedure which results from the Act " the Code of Administrative Procedure".

The Portuguese authorities wish to state that legal measures provided in articles 3 and 4 of the proposed Regulation are considered disproportionate, ineffective and will represent an administrative and enforcement burden for competent authorities. Foreseen grace period duration will not allow proper disposal and use of plant protection products as expected time frame for using up stocks will not match normal

agricultural use for this active substance. This inconsistency may represent an unforeseen and uncontrollable risk for the environment as existing stocks will not have the opportunity to be legally sold and or used. This legal measure is expected to create an unnecessary economic burden both for SME and farmers.

Italy notes that the draft on chlorpyrifos methyl does not duly takes into account the results, all negative, of the toxicological dossier submitted for its renewal and a crossover methodology has been used from chlorpyrifos based on poor quality literature studies whereas the complete set of negative results from the GLP studies conducted on chlorpyrifos methyl could have reversely been used to demonstrate the absence of genotoxicity also for chlorpyrifos. Furthermore, chlorpyrifos methyl represents the only effective mean to fight the brown marmorated stink bug. Finally it is underlined that a decision is taken without a complete final opinion from EFSA. For the above reasons, Italy abstains.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion 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 presented the final legal text and Review Report following the interservice consultation and informed that the TBT process had been initiated.

The Commission also provided a summary of comments received. Several Member States did not consider the restriction to use of treated seeds warranted and consider that mitigation measures could be used at national level. On the other hand several Member States had indicated that they would prefer further restrictions (to limit also foliar uses to greenhouses also).

Member States were also informed about a letter from Copa Cogeca which expressed concerns about the restriction.

The Commission recalled the need to ensure consistency and compliance with the regulatory framework and reminded Member States that the applicant could submit an application after renewal to amend the conditions of approval if it could provide further information or mitigation measures to address the concern identified for birds and mammals. The rapporteur Member State indicated that the applicant had already made contact about such an application. The Commission stated that this approach would be the best as it would ensure a robust consideration of new information and harmonisation between Member States. It would also be an opportunity for Member States to discuss mitigation approaches during the peer review.

A tour de table was carried out to establish the views of Member States. Given that the TBT notification period was still running, the vote was postponed.

Vote postponed.

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

The Commission informed that the inter services consultation was still not closed.

Some Member States (3) requested again to align the concentration limit for unintentional presence as impurity of the co-formulants listed in the Annex (0.01 %) to the limit in the CLP Regulation for the classification of a mixture containing a classified substance (0.1%). The Commission recalled that there was no link between the limit for the presence of a substance as unintentional impurity (which is primarily determined by the performance of analytical methods) and the classification of a mixture containing the substance intentionally.

C.02 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. 2).

The Commission summarised the comments received from Member States. Three Member States supported and one Member State did not support the approval of L-cysteine as a basic substance. Two Member States expressed the opinion that the restriction to professional users is inconsistent with the concept of basic substances. One Member State was of the opinion that the substance shall be regarded as of no concern only when it is offered to the user in a product with the concentration low enough to regard it as no longer dangerous.

The Commission presented the revised draft review report and draft Regulation. The Commission recalled Article 23(5) of Regulation (EC) No 1107/2009 which says that Article 6 and 13 apply also to basic substances. Article 6(g) stipulates that approval may be subject to conditions and restrictions including "designation of categories of users, such as professional and non-professional". Nevertheless, based on the comments received from Member States in writing and during the last meeting of this Committee, the Commission proposed not to include the restriction to professional users.

The Commission recalled Article 3 of Regulation 1107/2009 which in the definition of a substance of concern makes a clear link with the concentration of the substance in plant protection products. As regards the risk to operators, basic substances are put on the market for purposes other than plant protection, therefore L-cysteine should be packaged and labelled in accordance with the CLP Regulation including information to enable users to take the necessary measures as regards the protection of human health, safety and the environment.

One Member State indicated that it would support the proposal if L-cysteine would be available on the market in a product mixed with flower at a concentration that would allow to regard it as of no concern. Two Member States shared concerns as regards the identity of a substance to be approved: pure L-cysteine or its mixture with wheat flour. Two Member States supported the proposal. One Member State commented that, as a general rule, if a substance is a foodstuff, it shall be approved as a basic substance.

Member States were invited to comment by 13 January 2020.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of Milk as a basic substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12816/2019 Rev. 2).

The Commission summarised the comments received from four Member States on the draft review report which had been amended accordingly and distributed in advance of the meeting together with the draft Commission Implementing Regulation. In view of launching the inter-services consultation Member States were invited to send their comments and suggestions by 13 January 2020.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of propolis 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/11782/2019 Rev. 0).

The Commission summarised the comments received from Member States and the applicant. One Member State supported the non-approval of propolis as a basic substance. The applicant did not agree with the proposal for non-approval of propolis extract as a basic substance. All the comments had been made available to Member States.

The Commission presented the draft Review Report and draft Regulation in view of a non-approval of propolis extract as a basic substance. The information available on the toxicological profile of propolis extract is incomplete. Additionally, propolis is a skin sensitizer. The allergen labelling suggested by the applicant is not implementable as products such as bananas are not labelled. The approach proposed is consistent with the conditions of approval of other basic substances which can cause allergies.

One Member State concerns related to the non-approval of substances as basic substances based on incompleteness of the dossiers. The Commission recalled that the applicants may submit new applications with improved dossiers at any time in the future. The applicants are always consulted on the technical report of EFSA and on the draft Review Reports. They are also informed on the possibility to withdraw the application at any stage of the procedure prior to the vote at this Committee. The reasons for non-approvals are outlined in the Review Reports and/or recitals to the Regulations.

The Member States were invited to comment by 13 January 2020.

C.05 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 informed that comments had been received from some Member States and the applicant supporting in general the proposal of the Commission. The

Commission presented the revised draft Review Report and the draft Regulation proposing the renewal of the approval.

Member States were invited to comment by 13 January 2020.

M.01 Miscellaneous:

- The BTSF Training Course on the Application of the "EFSA/ECHA Guidance to identify Endocrine Disruptors" performed on 27-28 October had seen wide interest of Member States. Member States were invited to indicate by 13 January 2020 interest in a similar additional training in 2020.
- As the first EU-Workshop "Product chemistry of plant protection products– Harmonisation of the assessment with regard to the zonal authorisation" has been performed on 19-20 November, Member States were requested express their position by 13 January 2020 as regards whether they would like to have an additional Workshop on the same topic in 2020.
- The Commission informed that on 11 November 2019 a call for tender had been published for a new BTSF (Better Training for Safer Food) training called "Organisation and Implementation of Training Activities on the Risk Assessment of Microorganisms used as Pesticides or Biocides". Deadline for application is 12 February 2020.
- The contractor will organise and implement a three-day training course focussed on the risk assessment for microorganisms used as plant protection products and biocidal products. The course should start in 2020 and be performed 6 times in a period of 24 months, and it is addressed to risk assessors from Member States. The training programme could possibly be renewed for two more years.
- The Commission briefly updated on the outcome of the votes in the Appeal Committee on the draft Decisions requiring Romania and Lithuania not to grant emergency authorisation in accordance with Article 53(3) for the uses of neonicotinoids for future seasons, which had been considered not justified and the draft objection by the European Parliament against the extensions of approval of mancozeb and dimoxystrobin, which will be voted on at the next Plenary session of the European Parliament.
- The Commission also informed about an exchange of letters with one Member State concerning the ban of use and sale of treated seeds, adopted on the legal basis of Article 49 as a Union-wide measure. The Commission informed that there is no possibility to continue using seeds treated before the date when the restriction for seed treatment became applicable. It is not possible that a Member State reverts (where a union-wide measure on the basis of Article 49(2) has been adopted) back to the conditions underlying Article 49 (2) and declares that they would have been fulfilled in the light of the EFSA opinion. Therefore there is no other possibility for the continued use of treated seeds (and the necessary treatment) than by analogous application of Article 53. The exchange of letters had been made available via CIRCABC to Member States.