EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
24 June 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/58196a86-0bc6-4afb-a382-47954c01ca89?p=1&n=10&sort=modified_DESC*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary report of the meeting in January 2024 is published, and the ones of the meetings in March and May are in preparation.

A.02 Updates, clarifications & questions on specific active substances:

1. Acetamiprid (amended report to endorse)

The Commission recalled that acetamiprid was renewed in 2018 (expiring in 2033) and that EFSA concluded in a statement published 2022 that there was no conclusive evidence of higher hazards compared to previous renewal assessment.

However, a recent statement of EFSA adopted in March 2024 suggested to change the residue definition for risk assessment of leafy and fruit crops and to lower the toxicological reference values (TRV) on the basis of uncertainties related to DNT potential of acetamiprid, with the consequence to adjust (lower) the MRL values for commodities in a next step. The Commission suggested to endorse these updated ADI and ARfD values via the updated amended report made available to the Committee on 18 June 2024.

The Commission also suggested initiating an Article 21 procedure under Regulation (EC) No 1107/2009 that would address the uncertainties on DNT and also confirm the non-dietary TRV. Such an Article 21 review could also cover the assessment under the new ED criteria, which although from a scientific point of view not urgent, could be covered for procedural reasons.

The Commission informed of the recent discussions on the topic at the Post-approval Issues (PAI) Working Group, where some Member States indicated the high impact on the completed and on-going authorisations of PPPs containing acetamiprid that might result in loss of harmonisation between Member States. This impact would also duplicate work and overload the national competent authorities. Similar concerns were expressed by the applicant, as indicted in their written comments made available to the Committee. The applicant also questioned the procedural and scientific aspects of the evaluation conducted by EFSA and that they had not been given opportunity to submit studies which might have resolved the identified uncertainties.

Sixteen Member States stated that they have no mandate to endorse the draft amended Report and asked for postponing the endorsement.

Three Member States wondered why only the dietary TRV would be lowered. The Commission explained that the lowering of ADI and ARfD is a precautionary measure that would allow quick subsequent measures to be taken on the residues side (i.e., 38 MRLs were of concern for consumers and would be lowered), while all TRVs would be addressed in a comprehensive way in the course of the proposed Article 21, which would allow for consideration of additional data and their peer review.

Five Member States stressed the high importance of acetamiprid and the need of carefully considering consequences of the decisions taken. At least two Member States also expressed concern that EFSA proposal had not been subjected to proper peer-review by them. The Commission stressed again that it believed that its proposal was the best possible compromise between the necessity to act quickly to protect the consumers' health and the need to ensure legal and regulatory certainty. It also clarified that for most crops for which MRLs would be lowered, fall-back GAPs were available, leading to lower MRLs still allowing certain field uses.

Member States were invited to comment by 28 June 2024 on the draft amended report and indicate their reasons in the case they would not be in condition to endorse it. Member States were also invited to comment on the scope of a potential Article 21 procedure.

A.03 Scientific publications and information submitted by stakeholders:

There was no news to discuss.

A.04 Date of next meeting(s):

The Commission confirmed that the next meeting of this Committee will take place on 10 and 11 July 2024.

A.05 AoB.

One Member State wondered how a restriction of approval for captan would impact the MRLs (see point B.01).

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance captan 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/12270/2020)

(SANTE/12268/2020)

The Commission presented the same draft renewal of approval restricted to greenhouses that was shared in the previous meeting of this Committee and verified the positions of Member States. Only 12 Member States (representing less than 35 % of the population) supported the draft, while fifteen indicated that they do not support it.

Considering this strong opposition, the Commission suggested an alternative draft renewal of approval that would allow certain field uses with conditions and restrictions which would reduce the exposure of the environment using pesticide application technology (e.g., via precision agriculture). The submission of information to confirm the level of reduction of the exposure, in line with the recently adopted Compendium of conditions of use to reduce exposure and risk from plant protection products of the environment, would be required from the applicant.

The alternative proposed by the Commission was welcomed by 17 Member States, regardless of whether they initially favoured, opposed, or abstained to the draft initially tabled. Several Member States indicated that they have no mandate to discuss on the new alternative. Those who intervened welcomed the Commission attempt to offer a pragmatic solution and the consideration of modern agriculture practice. Some practical implementation aspects were raised.

Member States were invited to comment by 26 June 2024 on the new draft documents.

Vote postponed.