EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Legislation*
23 - 24 September 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/5a6053c2-525a-4504-98d2-1e207175aece?p=1*

SUMMARY REPORT

A.01 Summary Report of previous meetings:

The Commission informed that the summary reports of all the previous meetings had been published.

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

1. Acetamiprid (amended report to endorse)

This agenda item was discussed together with item B.06 of the agenda of the meeting of Section Pesticide Residues of this Committee which took place simultaneously.

The Commission recalled that this issue had been discussed at the meetings of this Committee in May, June and July 2024.

The draft document presented for endorsement was already presented in the previous meeting of this Committee in July 2024. It included an updated residue definition for risk assessment and updated ADI and ARfD values, which are needed to allow adjustment of MRL values for 38 commodities (see point B.06 mentioned above). The Commission explained that a support of the draft act under point B.06 with qualified majority would at the same time indicate endorsement of the amended renewal report on acetamiprid, as the MRLs are based on the updated TRV and residue definition.

Five Member States expressed concerns about the procedure followed for the evaluation of developmental neurotoxicity properties of acetamiprid and considered that, even though EFSA had held a peer-review panel with external experts, it should also have held a peer-review meeting with Member States' experts before finalising its conclusions. Three of them cited this a reason not to support the endorsement of the amended renewal report.

One Member State also noted that if ADI and ARfD were lowered, they would not be in line with analogous values for acetamiprid under the legislation on biocides, which were set on the basis of the same data. That was cited by this Member State as one of its reasons not to support the amended renewal report.

Two Member States stated that both the dietary (ADI and ARfD) and non-dietary ((A)AOEL) TRVs should have been updated in the amended renewal report, but one of them could endorse it regardless.

One Member State noted that they would endorse the amended renewal report, but expressed concerns that lowering ADI and ARfD would affect reauthorisations of plant protection products under Article 43 of Regulation (EC) No 1107/2009.

Nine Member States stressed that a review of the acetamiprid approval under Article 21 of Regulation (EC) No 1107/2009 due to suspected developmental neurotoxicity properties should be launched without delay. One of them indicated that the review should also cover assessment in accordance with current criteria for identification of the endocrine disrupting properties.

The Commission informed that it was already taking the steps needed to launch an Article 21 review procedure, however, it stressed that this assessment is expected to require time as generation of new data would be necessary.

One Member State requested that minor editorial change is introduced in the draft amendment of the Renew Report. As no other Member State opposed that request, a revised document was presented to the Standing Committee for endorsement.

The Committee endorsed the amended review report.

The following protocol declarations were made:

Austria:

Austria agrees with the endorsement of the amended Review Report for Acetamiprid including lowered values for the ADI and ARfD. As the additional safety factor applied for the lowering of the dietary toxicological reference values (TRVs) would be also applicable to non-dietary TRVs as stated in the report, a further discussion to clarify the identified uncertainties (e.g. by Art. 21) and to amend the (A)AOEL as well, if necessary, should be initiated as soon as possible.

Germany:

From a German perspective, comprehensive, precautionary consumer protection is a top priority.

In case of acetamiprid, however, from a risk assessment point of view, the precautionary lowering of the toxicological reference values (TRVs) while introducing an additional safety factor of 5 is not considered to be scientifically justified on the basis of uncertainty of the relevant developmental neurotoxicity (DNT) study quoted by EFSA, as there are no new findings in this regard. In fact, this study has already been the subject of extensive discussions in the re-approval procedure and at international level. In addition, 17 further in vitro tests (tests according to the OECD-IATA protocol) are now available. In these assays, acetamiprid apparently was proven negative, rather providing evidence supporting the absence of a potential for developmental neurotoxicity.

Furthermore, it is questionable why – if indeed any safety factor was required – this safety factor would not be applied to the AOEL and AAOEL, since the experimental basis for the derivation of ADI, ARfD and A(AOEL) is the same.

Germany instead supports the preparation of a new DNT study to conclusively assess the TRVs in a subsequent evaluation under Article 21 of Regulation (EC) No

1107/2009. We consider it necessary to involve the Member States in the peer review process to base any decision on sound scientific process.

Accordingly, Germany can support neither the new TRVs nor the resulting MRLs for acetamiprid.

We would also like to reiterate our concern regarding the Commission's on the spot approach of linking the vote on the draft regulation to amend / lower MRLs - automatically to an acceptance of the TRVs, without the underlying TRVs having been taken note of beforehand, which would be a precondition to amending the MRLs. Thus far, there has been no agreement between the Member States in this regard. We would very much welcome it if the agreed order of procedural steps, i.e. a) note taking of the TRVs b) amending respective MRLs, were to be adhered to again in the future.

Spain:

In the evaluation of the new acetamiprid ADI and ARfD values, a new, unvalidated methodology was used, neither endorsed by the OECD nor by the SCoPAFF Legislation Section, and unrelated to the relevant data requirements of Regulation (EC) No 1107/2009. Although a peer review process without Member State experts was presented as a valid option, we still believe that a proper peer review involving those experts would be necessary. The findings raised unresolved issues that required additional data from the applicant, who should have been given a reasonable timeframe to submit studies and confirm the need to lower the MRLs.

A.03 Date of next meeting(s):

The Commission confirmed that the next meeting of this Committee would take place on 2-3 October 2024.

A.04 AoB:

No additional points were discussed.