Point 7

Dossier neonicotinoids

a. EFSA Conclusions on the pesticide risk assessment for bees for the active substance thiamethoxam, clothianidin and imidacloprid.

The Commission when adopting the restrictions on the three neonicotinoids (Regulation (EU) No 485/2013), based its decision on the EFSA evaluation for the seed treatment and granular uses (as described in recital 7 of that Regulation). Moreover, the restrictions covered also the foliar uses before flowering for all the crops attractive to bees (listed in the Regulation mentioned above). For the restrictions on foliar applications, the Commission based mainly its decision on the precautionary principle, pending the evaluation of foliar uses (recital 7).

In this framework, in 2013 the Commission mandated EFSA to perform the risk assessment for bees for the three neonicotinoids considering all uses other than seed treatment and granules. This assessment included e.g. foliar uses. EFSA published 3 Conclusions on the pesticide risk assessment for bees for the active substance thiamethoxam, clothianidin and imidacloprid. The documents are public available at the following address:

Thiamethoxam:
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4212.pdf

Clothianidin
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4210.pdf

Imidacloprid
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4211.pdf

In those conclusions, overall the **risk is confirmed** for the majority of scenarios for foliar/spray application before and during flowering. Risks are also identified for scenarios when the application takes place after flowering.

All potentially necessary modifications of the approvals of the substances will be included in the decision following the assessment of confirmatory information (see below).

b. EFSA open call for data and review of new scientific information

When adopting Regulation (EU) No 485/2013 restricting the use of neonicotinoids, the Commission committed to initiate a review of the new scientific information within 2 years from the entry into force.

The restrictions are **not**, as is often misunderstood, limited in time. As laid down in the Regulation 485/2013, the restrictions on the use of neonicotinoids remain in place while this review is carried out.

The Commission has mandated the European Safety Authority (EFSA) to carry out an open call for data. The call was closed on 30 September 2015. [Additional information is available on the EFSA website: http://www.efsa.europa.eu/en/data/call/150522]. Based on the data received, EFSA published a technical report summarizing the data collected during the open call (http://www.efsa.europa.eu/en/supporting/pub/903e). As a further step, the Commission mandated EFSA to evaluate those data. Depending on the outcome of this evaluation, which is expected to be available on 30 November 2017 the Commission will propose, if justified, to further modify the conditions of approval of the three neonicotinoids.

c. EFSA conclusions on the peer review of the pesticide risk assessment for the active substances thiamethoxam, imidacloprid and clothianidin in light of confirmatory data submitted

When adopting Regulation (EU) No 485/2013 restricting the use of neonicotinoids, the applicants were requested to submit confirmatory data in order to maintain the approval of the remaining non-protected uses.

In a first step the EFSA coordinated a consultation with EU Member States regarding the confirmatory data received for all three neonicotinoids. The documents are public available at the following address:

Thiamethoxam:
https://www.efsa.europa.eu/en/supporting/pub/1020e

Clothianidin
http://www.efsa.europa.eu/en/supporting/pub/925e

Imidacloprid
http://www.efsa.europa.eu/en/supporting/pub/1038e

Based on these outcomes, the Commission mandated the EFSA to peer review the pesticide risk assessment for the active substances imidacloprid and clothianidin in light of confirmatory data submitted. The data submitted for thiamethoxam was considered insufficient to perform such a review.

The EFSA conclusions on the peer review of the pesticide risk assessment for the active substances imidacloprid and clothianidin in light of confirmatory data submitted were published by the EFSA on 8 November 2016 and are publically available at the following addresses:

Clothianidin
http://www.efsa.europa.eu/en/efsajournal/pub/4606

Imidacloprid
http://www.efsa.europa.eu/en/efsajournal/pub/4607

The conclusions of the European Food Safety Authority (EFSA) for the active substances clothianidin and imidacloprid were finalised in October 2016 and identified further risks for bees related to the use of these substances. Therefore, for all three substances, working documents, suggesting to further restrict the conditions of approval, are currently being discussed with the Member States. The Commission inter-service consultation was finalised and the proposals were notified to the World Trade Organisation, under the TBT notification procedure, allowing trading partners a commenting period of 60 days which will end on 3 October 2017. After that, the measure will be submitted to the Standing Committee on Plants, Animals, Food and Feed for discussion and a possible opinion.

Dossier Maleic hydrazide

The approval of maleic hydrazide has been recently renewed till 31 October 2032 by the Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017.

The maximum level for the toxicologically relevant impurity hydrazine in the active substance as manufactured was set at the level considered safe in the risk assessment performed by the European Food Safety Authority.

The renewal Regulation shall apply from 1 November 2017. Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material. From 1 November 2018, the impurity hydrazine shall not exceed 0.028 mg/kg in the technical material.

Dossier Diquat

The expiry date for diquat has been extended until 30 June 2018 in order to allow for the renewal procedure to be finalised.

Based on the EFSA conclusion the approval criteria do not seem to be satisfied for:

- The estimated operator, worker, bystander and resident exposure to diquat in 'Diquat 20% SL' exceed the AOEL even when the use of PPE is considered. The estimated worker, bystander and resident exposure to diquat in 'A14142A' exceed the AOEL even when the use of PPE is considered.

- The risk to birds

Available data is insufficient to satisfy the requirements with regard to:

- A proper identification/characterisation of the unidentified material in the SPE eluate in one soil photolysis study.

- Potential long term consequences of the use of diquat regarding groundwater exposure.

- The aquatic risk assessment for the metabolite AQ1

Based on the EFSA conclusion, the Commission proposed a non-renewal of approval for diquat. The Commission inter-service consultation was finalised as well as TBT procedure in front of the World Trade Organisation. Given an ongoing technical discussion between the applicant for diquat and the EFSA, it was decided to postpone submission of the measure to the Standing Committee on Plants, Animals, Food and Feed for discussion and a possible opinion. The Commission can currently not indicate by when the draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance diquat will be presented to the Standing Committee Plants, Animals, Food and Feed for an opinion.