Point 9

Dossier Sulfoxaflor

Sulfoxaflor is an active substance for use in insecticides.

An application for its approval under Regulation (EC) No 1107/2009 was submitted in 2011. EFSA assessed the active substance and published its conclusion in 2014. EFSA found that there was an acceptable risk to bees under certain use conditions.

Based on the EFSA assessment, the Commission published a Regulation approving its use in plant protection products on 29 July 2015.

Sulfoxaflor is the first pesticide of the chemical class of sulfoximines. It interferes with the signal transmission in the nerval system and its mode of action is the same as the one of the neonicotinoids. However, sulfoxaflor is structurally different from neonicotinoids and there are no known cross-resistances to that substance group.

The EFSA assessment of the dossier of sulfoxaflor has shown that the substance is toxic to bees, but that use conditions can be set where the risk to bees is acceptable.

Sulfoxaflor was approved without special conditions, but the approval Regulation obliges Member States to pay particular attention to the possible risk to bees when authorising plant protection products (e.g. by setting specific conditions of use)..

The approval Regulation furthermore requires the applicant to submit, within two years, confirmatory information to bring the dossier in line with the new data requirements concerning bees which entered into force only after the dossier was submitted.

Point 8

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). 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 (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.

At this stage the Commission is considering if it is needed to further modify the conditions of approval of the three substances.

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

When adopting Regulation (EU) No 485/2013 strictly 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 will publish soon a technical report summarizing the data collected during the open call. As a further step, the Commission mandated EFSA to evaluate those data. Depending on the outcome of this evaluation, the Commission will propose, only if justified, to further modify the conditions of approval of the three neonicotinoids.