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SANTE E4-Plant protection products

Point 5

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.

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 of 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 preform 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>

At this stage the Commission is considering if it is needed to further modify the conditions of approval for thiamethoxam, clothianidin and imidacloprid. For all three substances a draft proposal will be presented to the Member States for commenting during the next Standing Committee Plants, Animals, Food and Feed of 22-23 March 2017.

Dossier implementation of the methodology for the evaluation of pesticides on bees and on uniform principles

The discussion on both the proposal for the implementation of the methodology for the evaluation of pesticides on bees and on the amendment of the uniform principles regarding the risk to honeybees is still ongoing. For both proposals an amended draft will be presented to the Member States during a next Standing Committee Plants, Animals, Food and Feed.