NEAR-TOTAL LOSS FOR NEONICOTINOIDS IN EU

Decision based on risk assessments that are outside mainstream science

On April 27, a majority of EU Member States endorsed a Commission proposal to restrict the use of imidacloprid, clothianidin and thiamethoxam to use in greenhouses only. This decision is based on an alleged risk to bees identified by the European Food Safety Authority (EFSA) using a singularly conservative risk assessment approach. This approach is not in line with those used by many other agencies around the world – including the American Environmental Protection Agency and the Canadian Pest Management Regulatory Agency – who hence came to different risk conclusions.

WHAT HAPPENED SO FAR?

2013: The European Commission restricts the use of imidacloprid, clothianidin and thiamethoxam for seed treatment, soil application and foliar treatment in certain bee-attractive crops such as corn and oilseed rape. It also asks EFSA to review additional confirmatory data supplied by the applicants. The crop protection industry questions the legal basis of these restrictions and takes legal action.

MARCH 2017: The Commission unexpectedly proposes to expand the existing restrictions to ban all outdoor uses of the three neonicotinoids, except for use in permanent greenhouses.

FEBRUARY 2018: EFSA publishes the results of its updated risk assessment of the three neonicotinoids.

APRIL 24, 2018: The General Court of the EU announces that it will deliver judgement in the ongoing court cases regarding the 2013 restrictions on May 17.

APRIL 27, 2018: A majority of Member States (16 out of 28) back the Commission's proposal to ban all outdoor uses. The Commission announces it will adopt the regulation in the coming weeks.

WHAT WILL HAPPEN NEXT?

MAY 17, 2018: Delivery of the verdict in the ongoing court cases (scrutinizing the legal basis of the 2013 restrictions), which could have profound implications for the legal justification of the new restrictions.

MAY–JULY 2018: Entry into force 20 days after publication of the implementing regulation in the EU Official Journal, which is expected within weeks, but at most 3 months from now.

SUMMER 2018: Member States are required to amend or withdraw existing authorizations for plant protection products containing the active substances within 3 months of entry into force. **Member States can grant a grace period of up to 6 months** after entry into force for the disposal, storage, placing on the market and use of existing stocks.

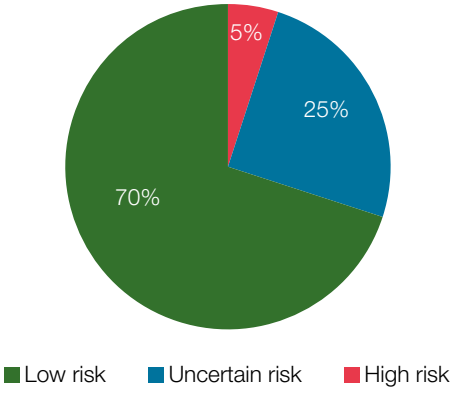
FALL-WINTER 2018: Definitive prohibition of placing on the market and use of treated seeds at the latest 6 months after entry into force unless member states prohibit use earlier.

Take-home messages

// **The EU restrictions are based on a singularly conservative risk assessment approach.**
// The recent risk assessment by **EFSA found a high risk in only very few scenarios** where a final risk conclusion was possible. Introduction of simple mitigation measures, a common practice in the use of crop protection products, could have addressed these.
// **The European restrictions are not in line with the recommendations of other authorities** such as the US EPA or the Canadian PMRA.
// **The verdict in the ongoing court cases regarding the 2013 restrictions is due on May 17**, which could have profound implications for the legal justification of the new restrictions.

RESULTS OF EFSA'S RISK ASSESSMENTS

EFSA final risk conclusions for 513 scenarios[1]



WHAT WAS COMMUNICATED	WHAT THE REPORT SAYS
The press release was titled **"Neonicotinoids: risks to bees confirmed."[2]**	Even when applying its extremely conservative evaluation criteria, EFSA concluded **high risk in only 5 % of the 513 scenarios** taken through the tiered risk assessment process. A low risk was found in 75 % of cases, uncertain risk in 25 %.[3]
EFSA's press release stated that **"most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees."[2]**	A closer look at the report suggests that **relatively few use patterns pose a clear high risk to bees.** No high or uncertain risks were found for honey bees. A high risk was only found in 1 % of cases for solitary bees and 19 % for bumble bees.[3]

IS EFSA'S APPROACH IN LINE WITH OTHER RISK ASSESSMENT APPROACHES?

// **No. Other authorities have followed different risk assessment approaches and principles and have come to different risk conclusions regarding the three neonicotinoids** – for example the American Environmental Protection Agency (EPA) or the Canadian Pest Management Regulatory Agency (PMRA).

// **This difference stems from EFSA's adherence to the "Bee Guidance Document"**, which lays down a highly conservative approach for carrying out a pollinator risk assessment and is not used by authorities elsewhere. The document imposes several study requirements that are not feasible with current study methods. This is why EFSA could come to a final risk conclusion for only 513 out of the 1095 assessed scenarios. Moreover, if no data is available or if a clear low risk cannot be confirmed due to the stringent demands, this approach will always conclude that there is a risk based on the precautionary principle.

CONCLUSIONS FROM (PRELIMINARY) POLLINATOR RISK ASSESSMENTS

EPA[4]
Most approved uses of clothianidin and thiamethoxam pose little risk to honey bee colonies. The major uses of these products (seed treatments in corn, cotton, soybeans and canola) were categorized as low risk. Seed and soil use of imidacloprid show low risks. Foliar application may pose higher risks, but common stewardships can significantly reduce these.

PMRA[5]
Imidacloprid poses minimal to no risk for most uses. The risk from seed treatment uses of clothianidin and thiamethoxam is acceptable, subject to additional mitigation measures in certain crops. The PMRA also proposes risk mitigation measures for certain spray uses.

EFSA[1]
States that "most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees," when the final risk conclusions only come to a high risk in 5 % of the scenarios.

1. CTD: EFSA Journal 2018;16(2):5177; IMD: EFSA Journal 2018;16(2):5178.
2. EFSA (2018) Neonicotinoids: risks to bees confirmed, available from: www.efsa.europa.eu/en/press/news/180228.
3. Making sense of the recent EFSA reports on neonicotinoids: What do they really say?, available from: www.ecpa.eu/sites/default/files/documents/Bayer%20Report%20on%20recent%20Neonic%20conclusions%20April%202018.pdf.
4. EPA: detailed reports available from: www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides.
5. PMRA: detailed reports available from: www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/update-neonicotinoid-pesticides.html.