UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Joint PMRA / USEPA Re-evaluation Update for the Pollinator Risk Assessment of the Neonicotinoid Insecticides

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Introduction

In May 2015, Health Canada's Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency's Office of Pesticide Programs (USEPA OPP) (Agencies) announced, as an initiative of the Regulatory Cooperation Council, that they would be collaborating on a bilateral pesticide re-evaluation process for the pollinator assessment of three neonicotinoid pesticides (clothianidin, imidacloprid, and thiamethoxam), based on the jointly developed harmonized Pollinator Risk Assessment Framework.[1] The Agencies have been working closely with the California Department of Pesticide Regulation (CDPR). In addition, USEPA OPP and CDPR are using the same framework to conduct a co-operative re-evaluation of dinotefuran, a neonicotinoid pesticide which is registered in the United States but not in Canada.

These pesticides are nitroguanidine neonicotinoids, a group of insecticides that have been approved for use in the United States and Canada for a number of years. In recent years, there have been reports in scientific literature suggesting that exposure to neonicotinoids may impact pollinator health; however, these studies have generally been conducted under laboratory situations, or in the field with exposure to doses that are higher than would normally be encountered in the environment.

In support of science-based risk management decisions, the Agencies are relying on the harmonized Pollinator Risk Assessment Framework methodology to conduct the pollinator risk assessment for the neonicotinoids. The Framework relies on a tiered approach which begins with conservative exposure assumptions and laboratory toxicity data conducted with individual bees, then progresses to more realistic exposure measurements in nectar and pollen, as well as colony level bee studies conducted in the field.

Data required under the Framework has been divided into three tiers. Tier 1 consists of laboratory toxicity studies with both adult and larval honey bees exposed for acute and chronic durations. Tier 2 effects studies include feeding and tunnel studies in which honey bee hives are exposed to neonicotinoids in a more realistic setting than the laboratory. Tier 2 residue studies measure exposure based on pollen and nectar residue data from neonicotinoid products applied to crops using different application methods. Tier 3 studies are generally large-scale field studies that most closely resemble an in-field exposure scenario for honey bees.

Neonicotinoid registrants have submitted, or are in the process of conducting, a number of studies to support their chemical-specific pollinator risk assessments. The Agencies will use these studies as well as information from published literature in the tiered risk assessment approach. All relevant scientific information will be considered alongside incident data in a weight-of-evidence approach, which considers if the information is robust and consistent, for the risk characterization.

This document provides a status update on the pollinator risk assessments of clothianidin, imidacloprid, thiamethoxam, and dinotefuran.

[1] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Status of Registrant Data Submission and Review by the Agencies

Over 350 pollinator studies have been submitted by the neonicotinoid registrants and are currently undergoing a cooperative review by all three agencies. To date, over 300 of the studies received have been reviewed by at least one agency. While progress is being made with the study reviews, there are additional studies that are currently being conducted which are required for the completion of the re-evaluations.

Status of Open Literature Review

The Agencies will incorporate information from the body of peer-reviewed scientific literature into the pollinator risk assessments. Studies may include information about neonicotinoid residues in pollen/nectar as well as lethal and sublethal effects (foraging behavior, etc.) to different life stages (larvae, adults) in honey bee hives, and overall colony health. Studies on different types of bees (for example bumble bees and solitary bees) will also be included.

The Agencies have conducted a number of literature searches which have identified hundreds of peer reviewed scientific studies. After a screen of the results, the Agencies prioritized about 250 open literature studies for further evaluation based on whether they assessed the residues or effects described above. Studies which are considered to be informative will be incorporated into the pollinator risk assessment. The Agencies continue to monitor current research findings and will incorporate more recent information as it becomes available.

Next Steps

Since the Agencies began the imidacloprid review about a year before the other neonicotinoids, imidacloprid is further along in the review process and initial findings have been presented in preliminary pollinator risk assessment documents:

- Health Canada's PMRA – Re-evaluation of Imidacloprid – Preliminary Pollinator Assessment
- USEPA – Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid

See table below for anticipated milestones for the pollinator assessments. The publication of each document will be followed by a public consultation period.

Neonicotinoid	Assessment	PMRA / USEPA/ CDPR[1]
Imidacloprid	Preliminary	Jan. 2016
	Final	Dec. 2016
Clothianidin	Preliminary	Dec. 2016
	Final	Dec. 2017
Thiamethoxam	Preliminary	Dec. 2016
	Final	Dec. 2017

Neonicotinoid	Assessment	PMRA / USEPA/ CDPR[1]
Dinotefuran	Preliminary	Dec. 2016[2]
	Final	Dec. 2017[2]

[1] CDPR plans to issue its determination with respect to its reevaluation of neonicotinoids (clothianidin, dinotefuran, imidacloprid, and thiamethoxam) on or before 1 July 2018.

[2] Not Applicable to PMRA.

Additional Information

The issue of pollinator health is complex, and is likely influenced by a number of factors including pests, pathogens and viruses, nutrition, pesticide exposure, bee management practices, and lack of genetic diversity. The PMRA and USEPA OPP, as the federal regulators of pesticides in Canada and the United States, respectively, are working together to protect bees and other pollinators from pesticide exposure.

Information regarding PMRA's and USEPA OPP's actions to protect pollinators and additional resources can be found at:

Health Canada's PMRA - www.healthcanada.gc.ca/pollinators

USEPA - http://www2.epa.gov/pollinator-protection