Proposed Re-evaluation Decision PRVD2018-12, Imidacloprid and its Associated End-use Products: Pollinator Re-evaluation

Health Canada

Pest Management Regulatory Agency
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Proposed Re-evaluation Decision

Under the authority of the Pest Control Products Act, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a re-evaluation of all agricultural, turf and ornamental uses for imidacloprid and its associated end-use products, specifically to assess the risk to pollinators. This re-evaluation assessed the potential risk to pollinators in light of international updates to the pollinator risk assessment framework, including information requirements. Extensive information obtained from published literature was considered, as well as data received from registrants. In 2016, the PMRA published a preliminary pollinator risk assessment, Re-evaluation of Imidacloprid - Preliminary Pollinator Assessment (REV2016-05) based on available data at that time. Since then, the PMRA has received additional data from the registrants, and considered more studies available from the open literature resources. This update of the pollinator risk assessment considers all the available data to date. Health Canada applied internationally accepted risk assessment methods as well as current risk management approaches and policies. In addition to the pollinator risk assessment, the value of the active ingredient to the use sector was considered.

Health Canada and the United States Environmental Protection Agency (USEPA) collaborated on this pollinator assessment, based on the jointly developed harmonized Guidance for Assessing Pesticide Risks to Bees. The Agencies have also been working closely with the California Department of Pesticide Regulation (CDPR).

This document (Proposed Re-evaluation Decision PRVD2018-12, Imidacloprid and its Associated End-use Products: Pollinator Re-evaluation) presents the proposed

regulatory decision for the pollinator re-evaluation of imidacloprid, including proposed risk mitigation measures to further protect pollinators, as well as the science evaluation on which the proposed decision was based. PRVD2018-12 is subject to a 90-day public consultation period, during which the public, including manufacturers and stakeholders, may submit written comments and additional information to Health Canada's PMRA Publications Section. The final re-evaluation decision will be published taking into consideration any comments and information received.

Prior to the publication of this proposed regulatory decision (PRVD2018-12) for the pollinator re-evaluation of imidacloprid, the PMRA published the proposed decision for the re-evaluation of imidacloprid in November 2016, which presented the risk assessments for both health and environment (excluding pollinators), as well as value (Proposed Re-evaluation Decision PRVD2016-20, Imidacloprid). While PRVD2016-20 proposed to phase-out all the agricultural and a majority of other outdoor uses of imidacloprid over three to five years for the protection of the environment, the current proposed regulatory decision is based solely on the pollinator risk assessment for imidacloprid. A final decision that integrates both imidacloprid re-evaluations is anticipated in December 2018 and will be published taking into consideration any comments and information received during the respective consultation periods. Additional reviews related to re-evaluations and special reviews previously announced in respect of other neonicotinoids are ongoing. Anticipated time frames for decisions related to these activities are outlined in: Update on the Neonicotinoid Pesticides (December 2017).

Outcome of Science Evaluation

Imidacloprid is an insecticide that is widely used in Canada on a variety of crops. PRVD2018-12 summarizes the potential risks posed by imidacloprid to insect pollinators, such as honey bees, bumble bees, and solitary bees in Canada, as well as proposed strategies to reduce the risks to these pollinators. With over 700 native species in Canada, bees are the most common pollinators. Bees and other insect pollinators are critical to the production of many crops and play an essential ecological role.

Products containing imidacloprid are sold as sprays to be applied to plants and to bare soil. Imidacloprid is also used as a coating on crop seeds to prevent insects from eating the seeds when they are planted in the ground and to protect the plants grown from treated seeds. Some uses result in imidacloprid being taken up by the plants from the soil or through their leaves, where it then moves into parts of the flower where nectar and pollen are produced. As a result of bees using nectar and pollen as their primary sources of food, bees may be exposed to imidacloprid (and its breakdown products) when they visit certain flowers to collect pollen and nectar. Bees may also be accidentally sprayed or collect water containing imidacloprid. Imidacloprid can also be injected into the trunk of deciduous and coniferous trees for the control of insect pests. Assessment for imidacloprid tree injection has recently been published separately (Proposed Registration Decision PRD2016-16, Imidacloprid) and is not included in this re-evaluation for pollinators.

Health Canada examined hundreds of laboratory and outdoor field studies with bees from research conducted around the world. These studies examined possible effects on bees from a wide range of situations including:

- bees contacting imidacloprid while visiting flowers;
- bees consuming imidacloprid in the pollen and nectar of flowers;
- bees exposed to imidacloprid for a short period of time (acute exposure) and for a long period of time (chronic exposure);
- bees exposed to imidacloprid in water;
- bees exposed to dust that may be generated while planting seeds that were coated with imidacloprid;
- adult bees, developing bees and the whole colony exposed within bee hives; and
- exposure of different species of bees including honey bees (also called Apis bees) and other species of bees, such as bumble bees and solitary bees (also called non-Apis bees).

This risk assessment, conducted according to the Guidance for Assessing Pesticide Risks to Bees, has determined that there are varying degrees of effects on bees. Some current uses of imidacloprid are not expected to affect bees; however, there are some uses of imidacloprid that may pose a risk of concern to bees. Therefore, mitigation measures are proposed to minimize potential exposure to bees, where necessary. Mitigation measures include cancellation of some uses, changes to the use pattern, and label improvements. When imidacloprid is used in accordance with these new proposed risk reduction measures, the reduced environmental exposure is deemed adequate and risks are considered to be acceptable. Label statements informing users of the potential for toxicity to pollinators will be required on product labels.

Bees may be exposed to dust produced during planting of treated seed for certain cereal and legume crops. There are already label statements in place to reduce exposure to dust produced during planting of treated corn and soybean seed; these label statements include best management practices, as well as mandatory use of dust-reducing fluency agents in certain types of planters. Details can be found on Health Canada's Pollinator Protection webpage. In addition, Health Canada will require the addition of label statements for all cereal and legume crops to minimize exposure to dust during planting of treated seed; these statements would include general best management practices, but would not include use of a dust-reducing fluency agent.

Health Canada also assessed the risks to bees posed by water sources that may be used by pollinators for water collection (for example, water from puddles, streams and plants) in areas where imidacloprid is applied, and determined that water sources do not pose risks of concern to bees.

Proposed Regulatory Decision for Imidacloprid

Under the authority of the Pest Control Products Act and based on the evaluation of currently available scientific information related to pollinators, products containing imidacloprid are being proposed for continued registration in Canada, and risk mitigation measures are required to be in place to further protect pollinators.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures that must be followed by law. As a result of this re-evaluation of imidacloprid, further risk mitigation measures for product labels are being proposed.

Measures to Protect Pollinators

Due to the attractiveness of some crops to bees when their flowers are in bloom, and based on an assessment of the risks to bees, the application of pesticides containing imidacloprid can lead to effects that may impact the survival of bee colonies or solitary bee species.

In order to protect pollinators, Health Canada is proposing to phase out the following uses of imidacloprid:

- Foliar application to pome fruit, stone fruit, certain tree nuts with high pollinator attractiveness, small fruit and berries (caneberry; bushberry; low-growing berry excluding strawberry and excluding lowbush blueberry followed by renovation; berry and small fruit vine excluding grape);
- Soil application on legume vegetables, fruiting vegetables, cucurbit vegetables, herbs (excluding herbs that are harvested before bloom), small fruit and berries (caneberry; bushberry; low-growing berry; berry and small fruit vine excluding grapes);
- Soil application to ornamentals that will result in pollinator exposure.

In order to protect pollinators, **Health Canada is proposing that the following crops cannot be sprayed before or during bloom:**

- Foliar application to fruiting vegetables, herbs (excluding herbs that are harvested before bloom), legume vegetables (broad beans/fava beans/Vicia faba only), strawberry, lowbush blueberry if followed by renovation after harvest, tree nuts excluding those with high pollinator attractiveness.

In order to protect pollinators, **Health Canada is proposing that the following crops cannot be sprayed during bloom:**

- Foliar application to potato, sweet potato, grapes, legume vegetables (excluding broad beans/fava beans/Vicia faba), hops, peanut, tobacco.

To minimize bee exposure to dust during planting of treated seed, **additional label statements are proposed for the following use**:

- Seed treatment of cereal and legume crops.

International Regulatory Context

Imidacloprid is under registration review by the United States Environmental Protection Agency (USEPA). The PMRA conducted the pollinator risk assessment according to the Guidance for Assessing Pesticide Risks to Bees in collaboration with the USEPA.

The European Food Safety Authority (EFSA) published updated risk assessments for seed treatments and granules in February 2018 and concluded that overall, neonicotinoids represent a risk to bees. In April 2018, based on EFSA's risk assessments, Member States endorsed the European Commission's proposals to ban the outdoor uses of imidacloprid, thiamethoxam, and clothianidin.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit

additional information that could be used to refine risk assessments during the 90-day public consultation period upon publication of this proposed re-evaluation decision (PRVD2018-12).

All comments received during the 90-day public consultation period will be considered in the preparation of the re-evaluation decision document, which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with the PMRA's responses.