Registration Decision RD2019-06

Thiamethoxam and associated seed treatment end-use products

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Conditions of Registration

The conditions of registration previously outlined in section 12 notices for the end-use products listed in Table 1 have been fulfilled. Refer to PRD2017-18, *Thiamethoxam,* for more details on the conditions of registrations.

Registration Decision Statement[1] for Thiamethoxam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting a three-year registration for the sale and use of the end-use products listed in Table 1, containing the technical grade active ingredient thiamethoxam for use as seed treatments. This decision is consistent with the Proposed Registration Decision PRD2017-18, which contains a detailed evaluation of the information submitted in support of this registration. See Appendix I for a summary of comments received during the consultation on PRD2017-18, as well as Health Canada's response to these comments.

An evaluation of available scientific information – as set out in PRD2017-18, in PRVD2017-24, *Thiamethoxam and Its Associated End-Use Products: Pollinator Re-evaluation,* and in RVD2019-04, *Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation* – found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment, provided that labels of registered products are amended as required. Labels will be amended following the re-evaluation implementation schedule described under the next section below.

Table 1 List of End-Use Products Included in This Decision[2]

Product Name	Registration Number
Cruiser Maxx Vibrance Cereals Seed Treatment	30436
Helix Liquid Seed Treatment	26637
Cruiser 5FS Seed Treatment	27045
Cruiser 350FS Seed Treatment Insecticide	27986
Cruiser Maxx Beans Seed Treatment	28821
Cruiser Maxx Cereals Commercial Seed Treatment	29127
Cruiser Maxx Cereals Seed Treatment	29192
A18046A Seed Treatment	30388
Cruiser Maxx Potato Extreme	31024
Cruiser Vibrance Quattro	31453
Helix Vibrance	31454

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[2] Note that the product Helix XTRA Seed Treatment, Reg. No. 26638 was included in Table 1 of the consultation document PRD2017-18. However, this product in no longer registered and is not included in this decision table.

Implementation of Mitigation Measures Required to Protect Pollinators

The additional risk mitigation measures described in the final decision document RVD2019-04 will be implemented over a 24-month period. The risks identified are not considered imminent because they are not expected to cause irreversible harm during this period. Potential effects include sublethal effects on colonies or solitary bees, but affected pollinator populations are expected to recover following implementation of the additional restrictions that will reduce exposure. Moreover, recovery is expected because risks to pollinators are geographically limited to areas where these products are applied and areas adjacent to application sites. The presence of unaffected solitary bees, bumble bees and honey bees in areas where products are not being used will further facilitate recovery since unaffected bees in the environment can move back into areas where effects may have occurred. Overall, risk to pollinators is acceptable during the time period required to implement the mitigation measures.

As a result of this decision, growers will be required to change their pest management practices. Pesticides have extensive and precise instructions and often require specialized application and safety equipment and training. This transition period will allow for an orderly and safe implementation of these new restrictions, and should reduce the risk of product misuse or the improper disposal of products as users switch to alternatives, where required. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses as a result of a re-evaluation (Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*) and with the practice of other international regulators.

A small subset of uses were found to lack alternatives for the management of certain serious pests (the invasive brown marmorated stink bug, and certain weevils) on a very few crops present in limited geographical areas of Canada. As a result, the implementation of the re-evaluation decision for these uses will be delayed for an additional year to allow growers to find pest management solutions. During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing, which will further reduce pollinator exposure. The risks to pollinators are, therefore, considered acceptable for an additional year for this small subset of uses.

The risk-reduction measures and other conditions of registration applicable to the end-use products listed in Table 1 are described in RVD2019-04. For more details, refer to RVD2019-04. After this registration decision is issued, these products will also be subject to the final outcome of the special review currently ongoing.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-18) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

Appendix I Comments and Responses

1. Comments suggesting an immediate phase-out of the products instead of the proposed three-year registration.

Response

Health Canada acknowledges the comments requesting an immediate ban or cancellation of neonicotinoids, and also shares in the concern for pollinator health and agrees with the importance of pollinators to food production.

For the pollinator re-evaluation of thiamethoxam, Health Canada has concluded that continued registration of products containing this active ingredient is acceptable with required amendments; however, certain uses are cancelled to address potential risk of concern to pollinators. The overall exposure to pollinators will be significantly reduced through both removal of many uses that pose a risk to bees and through implementation of additional restrictions in application timing that will further reduce pollinator exposure. As stated earlier, a two-year period to allow for the implementation of the additional risk mitigation measures required to protect pollinators is considered acceptable. The risks identified are not considered imminent because they are not expected to cause irreversible harm over the phase-out period.

The risks to pollinators are also acceptable for one additional year for uses having critical pest management needs (for example, brown marmorated stink bug control). During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing thereby further reducing pollinator exposure.

2. A comment was received disagreeing with the consultation taking place under the authority of subsection 28(1)(*c*) of the *Pest Control Products Act* rather than 28(1)(*a*) "given that data are being evaluated on a prior conditional and thus incomplete registration".

Response

Before any of the conditional registrations were granted, the risk was determined to be acceptable, based on the data evaluated. The conditional registration status of these products was not considered to be an incomplete registration; each conditional registration was a final registration decision based on a finding of acceptable risk made in accordance with section 8 of the *Pest Control Products Act*.

All of the thiamethoxam seed treatment products were initially granted registration before the current *Pest Control Products Act* existed (that is, before 28 June 2006). Given the public interest in all of these neonicotinoid conditional registrations, Health Canada made a decision to consult the public on the most recent proposal in respect of all products in Table 1, and did so under 28(1)(*c*) of the *Pest Control Products Act*.