Registration Decision RD2019-07

Thiamethoxam, Actara 25WG Insecticide, Actara 240SC Insecticide, and other related end-use products

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Conditions of Registration

The conditions of registration outlined in the section 12 notices for the end-use products listed in Table 1 have been fulfilled. Refer to PRD2018-14, *Thiamethoxam, Actara 25WG Insecticide, Actara 240SC Insecticide, and other related end-use products*, for more details on the conditions of registrations.

Special Review of Thiamethoxam

The PMRA announced in 2016 the initiation of a special review to evaluate the impact of thiamethoxam on aquatic invertebrates (Re-evaluation Note REV2016-17, *Initiation of Special Reviews: Potential Environmental Risk to Aquatic Invertebrates Related to the Use of Clothianidin and Thiamethoxam*).

Since that time, Health Canada has published a Proposed Special Review Decision for public consultation, PSRD2018-02, *Special Review of Thiamethoxam Risk to Aquatic Invertebrates: Proposed Decision for Consultation*. This proposal summarized the science evaluation with regards to the potential risks posed by thiamethoxam to aquatic invertebrates in Canada, as well as proposed strategies to reduce the risks to these organisms. The PMRA is currently reviewing all of the information received during the consultation and working on completing its risk assessment and risk management conclusions in respect of aquatic invertebrates.

The continued registration of the products in Table 1 and the use of thiamethoxam technical active ingredient in USCs 5, 13, 14, and 27 will be subject to the outcomes of the final decision pertaining to the special review of thiamethoxam.

Registration Decision Statement[1] for Thiamethoxam

As the conditions of registrations have been fulfilled, 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. These products contain the technical grade active ingredient thiamethoxam for use as foliar and soil applications to terrestrial food and feed crops, ornamentals and greenhouse food crops. This decision is consistent with the science review in Sections 1.0, 2.0, 3.0, 4.0 (except 4.2.2) and 5.0 of the Proposed Registration Decision, PRD2018-14, which contains a detailed evaluation of the information submitted in support of this registration. It is also consistent with the information outlined 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*. See Appendix I for a summary of comments received during the consultation on PRD2018-14, as well as Health Canada's response to these comments.

It should be noted that the final decision on aquatic invertebrates, detailed in Section 4.2.2 of PRD2018-14, is pending. This final decision will be applied to the products in Table 1.

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

An evaluation of available scientific information, as set out in PRD2018-14, PRVD2017-24, and RVD2019-04, 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. Labels will be amended following the re-evaluation implementation schedule described under the next section.

Table 1 List of end-use products included in this decision.

Product Name	Registration Number
Thiamethoxam Technical USCs 5, 13, 14, 27	26665
Actara 240SC Insecticide	28407
Actara 25WG Insecticide	28408
Endigo Insecticide	30404
Flagship Insecticide	30723
Minecto Duo 40WG	30900

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 over 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 which 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 over 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 PRD2018-14) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa) with the exception of the references to PSRD2018-02. The references included in PSRD2018-02 will be available upon the release of the final decision on aquatic invertebrates. 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).

Any person may file a notice of objection[2] regarding the registration decisions for Actara 25WG Insecticide and Actara 240SC Insecticide within 60 days from the date of publication of these Registration Decisions. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[2] As per subsection 35(1) of the *Pest Control Products Act.*

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 outlining the need for immediate implementation of decisions made under section 8 of the *Pest Control Products Act*. The commenter indicated that the PMRA must base its decisions under section 8 on the risk assessments completed at the time and that there is no jurisdiction to phase out products where the risk is unacceptable under section 8 of the *Pest Control Products Act*.**

A three-year registration has been granted for these products under section 8 of the *Pest Control Products Act*. Use restrictions are to be implemented over two years, with an additional year for a small subset of uses where there are no registered suitable alternatives. This allows for an orderly and safe transition over the course of the implementation period, and reduces the risk of product misuse or the improper disposal of products. 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 or special review (Regulatory Directive DIR2018-01). This approach is also consistent with how other international regulators address the implementation of new restrictions when risks are not imminent because they are not expected to cause irreversible harm.

The time period of the registration, as well as other factors such as the geographical area over which the product is expected to be applied during the phase outs of those uses, are valid considerations when considering the level of acceptable risk, as factors such as length and breadth of exposure to bee population levels can affect the overall scientific conclusion of risk.

Health Canada has determined that while the risks to pollinators are unacceptable for some uses in the long-term, over the short term the risks are acceptable because they are not imminent, that is, they are not expected to cause irreversible harm over the implementation period. Accordingly, the decisions made under section 8 of the *Pest Control Products Act* align with those made under section 21 of the *Pest Control Products Act* and the risks are considered acceptable over the three-year period of the registration.

Health Canada did not include the proposed decision under the special review concerning aquatic invertebrates because the information received during the public consultation is still being reviewed to determine whether the outcome of the risk assessment published in the PSRD2018-02 will change. Once any necessary revisions are made to the risk assessment, the appropriate risk mitigation measures can be determined and implemented as part of the final special review decision.