

## Evaluation Report for Category B, Subcategory 4.2 Application

**Application Number:** 2013-5134  
**Application:** Renewal without consultation  
**Product:** Thiamethoxam Technical  
**Registration Number:** 26665  
**Active ingredients (a.i.):** Thiamethoxam  
**PMRA Document Number :** 2481930

### Background

Thiamethoxam Technical (Registration Number 26665) was first registered for use in Canada in 2000. During the original review, thiamethoxam was conditionally registered based on data requirements for the technical grade active ingredient. A subsequent application (2008-0617) for conversion from conditional to full registration addressed all of the original conditions of registration. While the evaluation of the pollinator data did not indicate any risks of concern, additional confirmatory environmental data were required for the end-use products.

Thiamethoxam is currently conditionally registered for use on greenhouse non-food crops (Use Site Category 6), seed treatments food and feed (USC 10), terrestrial feed crops (USC 13), terrestrial food crops (USC 14) and turf (USC 30), pending a fully registered end-use product for the associated USCs. The required environmental data for all the outdoor end-use products consists of data on the residues of thiamethoxam and its major metabolite clothianidin in pollen and nectar of terrestrial plants, and a new hive study for USC 13/14.

During the course of the pollinator study reviews for thiamethoxam, a new harmonized pollinator risk assessment framework was under development. This new framework is a more scientifically robust framework that is designed to address impacts on pollinators (adult, larvae and hive health) from multiple exposure pathways. The new framework includes a tiered approach to pollinator risk assessment (Tier I (laboratory studies), Tier II (semi-field and residue studies), and Tier III (field studies)), and is now being used by both the PMRA and US EPA for all new chemicals. The new guidance for the harmonized pollinator risk assessment was posted on the Health Canada Website in June 2014.

In order to conduct pollinator assessments according to the new framework, the PMRA and US EPA announced the re-evaluation of clothianidin and thiamethoxam in June 2012 (REV2012-02, *Re-evaluation of Neonicotinoid Insecticides*) and requested additional studies. A status update was provided in REV2013-15, *Re-evaluation Update for Neonicotinoid Insecticides*.

### Purpose of Application

The purpose of this application was to extend Thiamethoxam Technical's registration validity period in order to allow time for the registrant to generate the data to address the remaining

conditions of registration for the associated end-use products.

### **Chemistry, Health and Value Assessments**

Chemistry, health and value assessments were not required for this application.

### **Environmental Assessment**

A number of residue and toxicity studies have been submitted, while others are ongoing, and will be submitted to the PMRA upon completion. The registrant continues to work cooperatively with the PMRA, the US EPA and the California Department of Pesticide Regulation to develop study protocols that will best address the remaining data requirements.

To date, none of the submitted studies that have been reviewed have indicated any areas of risk concern that would trigger additional regulatory action beyond a requirement to submit additional studies.

To facilitate the PMRA conducting a more comprehensive environmental review, the PMRA supports the extension of registration of Thiamethoxam Technical.

### **Conclusion**

The PMRA granted an extension to the conditional registration of Thiamethoxam Technical to December 31, 2016. The timeline has been amended to be aligned with all of the thiamethoxam containing end-use products.

### **References**

None

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2015

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.