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Re-evaluation Note

REV2017-24

Re-evaluation Project Plan for Tebuconazole

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Background

In Canada, tebuconazole is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Tebuconazole is registered as fungicide used on agricultural crops and on turf. Agricultural uses of tebuconazole include seed treatments and foliar applications. Tebuconazole is also registered for use as a wood preservative. As of 13 June 2017, there are two technical grade products and twenty-six end-use products containing tebuconazole registered for use in Canada. All tebuconazole uses other than antispasmodics are included in this re-evaluation.

Under the authority of section 16 of the *Pest Control Products Act*, all registrants of tebuconazole were notified of the initiation of the re-evaluation of tebuconazole. Following this, the registrants of tebuconazole technical grade active ingredients in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of tebuconazole.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of tebuconazole is defined as a Category 2, as described in Regulatory Directive DIR2016-04: *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for tebuconazole is anticipated to be published for consultation by November 2018. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, occupational exposure (for seed treatments), and dietary exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of tebuconazole for the other aspects of the human health assessment.

Environmental Risk Assessment

A new assessment will be conducted for the heavy duty wood preservative use. For uses as an agricultural fungicide, some aspects of the existing assessments will be updated including risks to terrestrial non-target organisms.

Value

The value of tebuconazole will be considered. The viability of alternatives will be examined for certain uses if risks of concern which require mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrants to provide data for tebuconazole related to chemistry, toxicology and the environment. Relevant data/studies have been requested from the technical registrants. A summary of the data call-in is found in PMRA's Public Registry, found online at <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html>. For a list of data categories that have been required, see Appendix I.

Additional Information

The PMRA documents can be found in the Pesticides and Pest Management portion of the Canada.ca website at <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html>. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	pmra.infoserv@hc-sc.gc.ca	

Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Tebuconazole

I. Chemistry Data

DACO 2.13.4 Impurities of Toxicological Concern

II. Toxicology Data

DACO 4.8 Other Studies: Endocrine Effects

III. Environmental Fate Data

DACO 8.3.4 Laboratory Study of the Leaching Potential from Treated Wood

IV. Pollinator Data

DACO 9.2.4.2 Bee Adult Acute Oral Toxicity (required)

DACO 9.2.4.3 Bee Larvae Toxicity (required)

DACO 9.2.4.4 Bee Adult Chronic Toxicity (required)

DACO 9.2.4.5 Bee Toxicity of Residues on Foliage (may be required)*

DACO 9.2.4.6 Semi-Field Studies for Pollinators (may be required)*

DACO 9.2.4.7 Field Studies for Pollinators (may be required)*

DACO 9.2.4.8 Residue Studies for Pollinators (may be required)*

* Depending on the outcome of the screening level risk assessment

V. Environmental Toxicology Data Other than for Pollinators

DACO 9.5.3.1 Fish, Early Life Cycle Toxicity Test

DACO 9.9 Other Studies: Effects on Amphibians