Re-evaluation Note REV2012-14

Update on the Re-evaluation of Thiophanate-methyl

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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1.0 Background

Thiophanate-methyl is one of the active ingredients under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The purpose of this Re-evaluation Note is to provide an update to registrants, pesticide regulatory officials and the Canadian public on the current status and next steps of the re-evaluation of thiophanate-methyl.

Thiophanate-methyl (TPM) is a broad spectrum, systemic fungicide with both protective and curative action. It is currently registered for use on greenhouse non-food crops, terrestrial food crops, outdoor ornamentals (commercial and domestic class products), turf and seed treatment for food and feed. It is applied by farmers, farm and nursery workers, professional applicators and residential gardeners. Carbendazim is the primary metabolite of thiophanate-methyl and is also considered in this re-evaluation.

2.0 Regulatory Update

The Proposed Re-evaluation Decision Document (PRVD) on thiophanate-methyl was published on 31 January 2011, PRVD2011-07, ***Thiophanate-methyl.*** Extensive comments were received during the consultation period of this document and are currently under review. The following is a summary of the main areas of focus from PRVD2011-07 that will be updated before a final decision can be made on the re-evaluation of thiophanate-methyl.

2.1 Toxicological Assessment

Completion of the mammalian toxicology assessment of thiophanate-methyl is awaiting the submission and review of additional toxicity studies for carbendazim (one-generation reproductive toxicity study) and for thiophanate-methyl (developmental thyroid toxicity study). The study for carbendazim is currently being generated. The requirement for the thiophanate-methyl study is pending completion and review of the carbendazim study.

2.2 Occupational and Non-Occupational Risk Assessment

The risk assessments for occupational and non-occupational scenarios for thiophanate-methyl were presented in PRVD2011-07. Based on available toxicology and exposure information at that time, the PMRA identified potential risks of concern to workers for certain application and postapplication activities. Label changes were proposed to mitigate risk, and further data needs were identified to refine the assessments.

During the consultation period for PRVD2011-07, scientific data, additional information, and recommendations were received. Some of the comments referred to data that is currently being collected and generated.

At this time, finalization of the human occupational and non-occupational risk assessments are on hold, pending the submission and review of the additional mammalian toxicology studies. Once the toxicology review is completed, the exposure and risk assessments will be updated based on the current use profile, available exposure data, comments received, and any additional relevant information related to the exposure assessments. Particular attention will be focused on assessing the dermal absorption of carbendazim, assessing specific use site categories (USCs) including USC 6 (greenhouse uses), USC 10 (seed treatment), and USC 30 (turf), as well as conducting a residential aggregate risk assessment.

2.3 Dietary Risk Assessment

The dietary assessment presented in PRVD2011-07 indicated that the acute and chronic exposures to thiophanate-methyl and carbendazim from food and drinking water sources were not of concern for non-cancer endpoints. However, based on the annual application rate of 3.15 kg a.i./ha (apples, pears and white beans) for cancer risk estimates, the Estimated Environmental Concentration (EEC) was 12.9 µg/L for thiophanate-methyl and carbendazim combined which exceeded the Drinking Water Level of Concern (DWLOC) of 1 µg/L. The cancer risk estimates for drinking water included a number of conservative (health protective) assumptions that may overestimate exposure, and therefore risk. The drinking water modeling presented in PRVD2011-07 used some conservative upper bound assumptions. An updated dietary risk assessment will be conducted and will consider all the thiophanate-methyl labeled use pattern changes and updated toxicology assessment. Where possible, it will take into consideration all use information that was provided during the consultation period of PRVD2011-07 for possible refinements of the drinking water modeling and exposure assessment.

The PMRA is currently working with registrants in obtaining the relevant information required in order to finalize the re-evaluation of thiophanate-methyl, and will communicate the results of the updated assessments in a future document.