Re-evaluation Note REV2013-12

Re-evaluation Project Plan for Fomesafen

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In Canada, fomesafen is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrant of fomesafen was notified of the initiation of the re-evaluation of fomesafen. Following this, the registrant of fomesafen technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of fomesafen.

Fomesafen is an herbicide that has been registered in Canada since 1996. Fomesafen is currently registered for early postemergence use for the control of broadleaf weeds in various food and feed crops (Use-Site Categories 13 and 14). Registered fomesafen end-use products are formulated as solutions to be applied by ground equipment only, as an early postemergent spray.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of fomesafen, as well as additional data required. Should additional information become available during the re-evaluation period that affects the regulatory status of fomesafen, the PMRA will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for fomesafen is anticipated to be published in 2015.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for fomesafen was considered adequate for hazard characterization at the time of initial registration. Data generated since the time of the original submission [additional acute toxicity studies], or currently being generated [acute and short term neurotoxicity studies] that may impact the hazard assessment, will be evaluated. Verification of the points of departure used for occupational and dietary risk assessments will be undertaken and areas not addressed in the original evaluation (for example, assessment of acute reference dose requirement, application of the PCPA factor) will be reviewed. Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

Dietary exposure and risk assessments previously conducted to support the registered uses of fomesafen will be re-evaluated to ensure they meet current science standards and policies. In particular, the dietary exposure assessment will be updated to reflect current data including drinking water estimated environmental concentrations (EECs), new food consumption data, and the incorporation of revised toxicological reference doses, if applicable.

Since there are no registered residential uses for fomesafen, a residential risk assessment is not required.

The occupational exposure and risk assessments of fomesafen will be revised to reflect the currently available scientific data and approaches, as well as revised toxicological endpoints and target margins of exposure, if applicable. In the absence of chemical-specific data, standard defaults will be used in the occupational exposure and risk assessments.

Environmental Risk Assessment

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements and with the outcome of the review of recent request for label expansion.

Buffer zones for the protection of sensitive terrestrial and aquatic habitats will be calculated based on current practices and taking into consideration currently registered uses.

The Toxic Substances Management Policy will be taken into consideration.

The environmental fate of fomesafen will be reviewed to determine drinking water and estimated environmental concentrations for risk assessment purposes.

Value

The value of fomesafen will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology and dietary exposure have been identified for fomesafen and were requested from the technical registrant. For details, see Appendix I.

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for fomesafen is anticipated to be published for consultation in 2015.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. 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: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Fomesafen

Toxicology

DACO 4.2.2 Acute Dermal toxicity
DACO 4.2.3 Acute inhalation toxicity
DACO 4.2.4 Primary Eye Irritation
DACO 4.2.5 Primary Dermal irritation
DACO 4.2.6 Dermal sensitization
DACO 4.5.12 Acute Neurotoxicity
DACO 4.5.13 Subchronic Neurotxocity

Food Residue and Dietary Exposure

DACO 7.4.1 Supervised Residue Trials