Proposed Acceptability for Continuing Registration

PACR2005-07

Re-evaluation of Metribuzin

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated metribuzin. The PMRA has determined that metribuzin is acceptable for continued registration with the implementation of additional mitigation measures to further protect workers and the environment. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing metribuzin with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration document provides a rationale for the proposed regulatory decision for metribuzin. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Section at the address below.

(publié aussi en français)

30 August 2005

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca

www.pmra-arla.gc.ca

 ${\bf Information\ Service:}$

1 800 267-6315 or (613) 736-3799

Facsimile: (613) 736-3798



ISBN: 0-662-41397-0 (0-662-41398-9)

Catalogue number: H113-18/2005-7E (H113-18/2005-7E-PDF)

\circledcirc Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2005

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.

1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, PMRA Re-evaluation Program, presents the details of the re-evaluation activities and program structure.

Metribuzin has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of metribuzin and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1998 RED document for metribuzin. In its re-evaluation of metribuzin, the PMRA based its conclusions on this 1998 RED document, taking into account the Canadian use pattern and issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Metribuzin

Active substance: metribuzin

Function: herbicide

Chemical names:

IUPAC: 4-amino-6-*tert*-butyl-4,5-dihydro-3-methylthio-1,2,4-triazin-5-one CAS: 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4*H*)-

one

Chemical class: triazinone

CAS number: 21087-64-9

Molecular formula: $C_8H_{14}N_4OS$

Molecular weight: 214.3

Structural formula: $(CH_3)_3C - \bigvee_{N=N}^{N-N} - SCH_3$

NH₂

In Canada, metribuzin was first registered in 1971. According to current end-use product labels, this active ingredient is registered in Canada for use on alfalfa, asparagus, barley, carrots, chick peas, fababean, field corn, lentils, peas, potatoes, soybean, sweet white lupin, tomatoes, wheat, fruit trees (apple, apricot, cherry, peach, pear and plum) and shelterbelts to control annual grasses and broadleaved weeds. Canadian products containing metribuzin are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for metribuzin is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the RED for metribuzin.

The federal TSMP and Regulatory Directive <u>DIR99-03</u> were taken into consideration during the review of metribuzin, and it was concluded that metribuzin is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive <u>DIR98-04</u> or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for metribuzin addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of metribuzin that are also registered in Canada. The PMRA has determined that metribuzin is acceptable for continued registration with the implementation of additional mitigation measures specified in Section 4.0. Registrants will be required to submit the confirmatory data identified in Section 5.0.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision. Registrants of products containing metribuzin should not apply for label amendments or submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

For all commercial end-use products containing metribuzin, the following statements must be included in a section entitled "**PRECAUTIONS**":

- "Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."
- "Wear long pants, a long-sleeved shirt and chemical-resistant gloves during mixing/loading, clean-up and repair activities."
- "If this pest control product is to be used on a commodity that may be exported to the U.S. and if you require information on acceptable residue levels in the U.S., contact 1-866-375-4648 or www.cropro.org/."

For all commercial end-use products containing metribuzin, the following statements must be included in a section entitled "**DIRECTIONS FOR USE**":

- "Do not re-enter or allow re-entry into treated areas until 12 hours after application."
- "It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application."
- "For all uses, **DO NOT** apply with low-pressure and high volume hand wand equipment."
- "<u>Field sprayer application</u>: **DO NOT** apply during periods of dead calm or when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

DO NOT apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangelands, and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands) and estuarine/marine habitats.

Method of Application	Buffer zones (m) for protection of:					
	Terrestrial habitats	Aquatic habitats of water depth:				
		<1 m	1–3 m	>3 m		
Field sprayer	20	10	4	2		
Field sprayer with shrouds	6	3	1	0		
Field sprayer with cones	15	5	3	1		

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture."

For commercial end-use products containing more than one active ingredient (e.g., registration no. 26233 containing metribuzin and flufenacet), the largest (most restrictive) buffer zone(s) of the active ingredients involved should appear on the label.

For all commercial end-use products containing metribuzin the following statements must be included in a section entitled "ENVIRONMENTAL HAZARD":

- "The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow."
- "To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted, fine textured, or low in organic matter such as clay).

Avoid application of this product when heavy rain is forecast."

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

4.1 Maximum Residue Limits

There are no dietary concerns regarding use of metribuzin on food crops reported in the USEPA RED. In addition, all Canadian uses, including the ones not considered in the USEPA assessment, were recently evaluated by the PMRA and found to be acceptable in terms of dietary exposure. Metribuzin is currently registered in Canada for use on alfalfa, apple, apricot, asparagus, barley, carrot, cherry, chickpea, corn, fababean, lentil, lupin, pea, peach, pear, plum, potato, soybean, tomato and wheat. Metribuzin may be used on other crops in other countries. Currently, maximum residue limits (MRLs) of metribuzin and its metabolites are specified in Table II, Division 15 of the Canadian Food and Drug Regulations for potatoes. Residues in other commodities must not exceed 0.1 ppm, a general MRL specified in Regulation B.15.002(1) of the Canadian Food and Drug Regulations. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2003-01, Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002 (1)].

5.0 Additional Data Requirements

Based on the USEPA review of their environmental fate data, metribuzin has a potential to leach into groundwater and can runoff or drift into surface water. The USEPA monitoring data indicated that levels of metribuzin and its metabolites do not exceed USEPA's drinking water standards for human health in the United States. Data are required to confirm that acceptable levels are not exceeded in Canada. A scientifically based rationale to show relevance of existing American monitoring data to Canada may be acceptable. This rationale should include information on metribuzin use in Canada (e.g., areas of use, quantity used, typical application rates, etc.) and establish the vulnerability of areas of use to groundwater contamination (i.e., provide information on soil type and groundwater depth in areas of use). Any existing Canadian water monitoring data is also required. The above data and/or scientific rationale are required within 24 months of finalization of the re-evaluation decision.

The technical registrant of metribuzin will be required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);
- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of metribuzin;
- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO) tables for Use-site Category #7 (Industrial Oil Seed Crops and Fibre Crops), #13 (Terrestrial Feed Crops), #14 (Terrestrial Food Crops) and #27 (Ornamentals Outdoor). The following sections of the DACO tables must be addressed:
 - for the technical grade active ingredient: DACOs 2 through 9, inclusive; and
 - for the end-use product: DACOs 5 through 9, inclusive.

6.0 Supporting Documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. 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.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document <u>Metribuzin</u> is available on the Office of Pesticide Programs' website at <u>www.epa.gov/pesticides/reregistration</u> under Chemical Status.

Appendix I Products Containing Metribuzin Registered in Canada as of January 2005

Product Name	Registrant	Registration Number	Guarantee	Class
Sencor Metribuzin Technical	Bayer CropScience Inc.	20537	93.8%	Technical
Metribuzin 75 DF Manufacturing Concentrate	E.I. Du Pont Canada Company	25443	75%	Manufacturing concentrate
Sencor 75 DF Sprayule	Bayer CropScience Inc.	17242	75%	Commercial
Sencor Solupak 75 DF	Bayer CropScience Inc.	20968	75%	Commercial
Conquest Herbicide Tankmix	Bayer CropScience Inc.	24406	75%	Commercial
Sencor 75 DF Peas Sprayule	Bayer CropScience Inc.	25840	75%	Commercial
Axiom DF Herbicide ¹	Bayer CropScience Inc.	26233	13.6%	Commercial
Sencor DF Soybean	Bayer CropScience Inc.	27362	75%	Commercial
Sencor 500F Flowable Herbicide	Bayer CropScience Inc.	14867	500 g/L	Commercial
Sencor 480F Flowable Herbicide	Bayer CropScience Inc.	26280	480 g/L	Commercial
Sencor Soybean Flowable Herbicide ²	Bayer CropScience Inc.	26717	500 g/L	Commercial
Sencor 480 Flowable Soybean Herbicide	Bayer CropScience Inc.	27091	480 g/L	Commercial
Lexone DF Herbicide Dispersable Granule	E.I. Du Pont Canada Company	15959	75%	Commercial
Lexone DF Herbicide Toss-n-Go Bags	E.I. Du Pont Canada Company	21077	75%	Commercial
Fire Toss-n-Go ³	E.I. Du Pont Canada Company	24462	75%	Commercial

Product Name	Registrant	Registration Number	Guarantee	Class
Lexone 75 DF Sprayule	E.I. Du Pont Canada Company	25770	75%	Commercial
Evict 75 DF Herbicide	United Agri Products Canada Inc.	26843	75%	Commercial

- 1. With flufenacet at 54.4%. Flufenacet is not subject to re-evaluation (first registered after 31 December 1994).
- 2. Product 26717 was discontinued on 30 April 2003. Although the product is no longer produced by the registrant, it may remain for sale until stock depletion or expiration date, whichever comes first. This product was not included in the re-evaluation of metribuzin.
- 3. Product 24462 was discontinued on 31 July 2004. Although the product is no longer produced by the registrant, it may remain for sale until stock depletion or expiration date, whichever comes first. This product was not included in the re-evaluation of metribuzin.