Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2004-07

Re-evaluation of Niclosamide

The purpose of this document is to notify the registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of niclosamide. The PMRA has determined that niclosamide is acceptable for continued registration.

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1.0 Re-evaluation of niclosamide

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.

Niclosamide was first registered on a temporary basis in 1970 in Canada and is used to control sea lamprey larvae in waters of the Great Lakes basin and the Lake Champlain systems. End-use products containing niclosamide are classified as restricted and can only be applied by certified applicators of the United States Fish and Wildlife Service and the Department of Fisheries and Oceans in Canada, or persons under their direct supervision, in programs approved by the Great Lakes Fisheries Commission. One technical grade active ingredient and three end-use products, Bayluscide 70% Wettable Powder Lampricide Bayluscide, 3.2% Granular Sea Lamprey Larvicide and Bayluscide Emulsifiable Concentrate Lampricide, are registered in Canada by the Department of Fisheries and Oceans.

The registration status of niclosamide and all Canadian registered end-use products containing niclosamide was recently reviewed. The PMRA carried out an assessment of available information and found it sufficient to allow a determination of the safety, merit and value of niclosamide and associated end-use products. The PMRA concluded that the use of niclosamide as per the currently registered label does not result in an unacceptable risk of harm to human health or the environment. Thus, niclosamide and associated end-use products were found acceptable for conversion from temporary to full registration.

The federal Toxic Substances Management Policy (TSMP)[1] and Regulatory Directive DIR99-03[2] were taken into consideration for the purpose of re-evaluation of niclosamide. Niclosamide is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR98-04 or TSMP Track 1 substances as identified in DIR99-03, Appendix II.

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1 The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics.

2 *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy (TSMP),* DIR99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our website at www.hc-sc.gc.ca/pmra-arla.

2.0 Regulatory decision

Data submitted for the registration of the technical active ingredient and end-use products of niclosamide are considered to meet current data requirements. Scientific approaches used to assess the data and draw conclusions on the safety, merit and value of niclosamide are also considered to meet current standards. Based on this and considering that niclosamide is not a TSMP Track 1 substance, niclosamide is considered acceptable for continued registration. No further regulatory action is required at this time.