



Health
Canada

Santé
Canada

Pest
Management
Regulatory
Agency

Agence de
réglementation
de la lutte
antiparasitaire

OCT 16 2012

Thomas Schmit
Manager of Regulatory Affairs
Liphatech, Inc.
3600 West Elm Street
Milwaukee, WI 53209

Dear Mr. Schmit:

RE: Notice of Objection - Difethialone

Your notice of objection regarding the re-evaluation decision for difethialone (REV2010-17) has now been reviewed and assessed in accordance with the Pest Control Products Act (PCPA). Based on subsection 35(1) of the PCPA, any person may file with the Minister, in the form and manner directed by the Minister, a notice of objection to a decision referred to in paragraph 28(1) (b) within 60 days after the decision statement referred to in subsection 28(5) is made public. The Re-evaluation decision for difethialone (REV2010-17, Risk Mitigation Measures for Eight Rodenticides) was published on November 1st, 2010. Your request, dated April 25, 2012, was made beyond the 60-day period for filing a request for reconsideration. However, the PMRA has reviewed the information provided in support of your objection, the notice of objection letter (Schmit to Law dated April 25, 2012) and the position paper "Difethialone: Justification for Outdoor Use" by A. Goodyear, dated May 2010, and has the following comments.

- Difethialone was first registered in Canada in 2000. The position paper submitted with this notice of objection was reviewed during the initial registration of difethialone.
- Risk assessments conducted during the review of new products containing difethialone, following its initial registration in Canada, raised environmental concerns from its use as a rodenticide.
- Although not included in the initial re-evaluation of the 5 rodenticides (PACR2004-27 and RRD2006-11), subsequent re-evaluations of the rodenticides cluster included difethialone (REV2007-04, REV2009-05 and REV-2010-17). The re-evaluation of this cluster resulted in additional mitigation measures proposed as part of an overall risk-reduction strategy for rodenticides in Canada. These mitigations were mainly based on measures placed on rodenticides in the U.S. in 2008. The proposal for products con-

.../2


taining difethialone to be restricted to "indoor use only" was based on the environmental risk assessments conducted by the Pest Management Regulatory Agency (PMRA) as well as the re-evaluation decisions for rodenticides.

- Issues raised in this notice of objection from Liphatech were discussed and addressed in the decision document (REV-2010-17).

The purpose of a notice of objection is to identify the area of science supporting the registration decision to which objection is taken, to provide the scientific basis of the objection and to request that the area of science in question be referred to a review panel for reconsideration and recommendation. The information provided in your letter and position paper in support of the notice of objection were previously considered during the initial registration of difethialone and during the re-evaluation of the rodenticides. Therefore, a review panel will not be established to reconsider the regulatory decision in response to your request.

Should you have any questions regarding this letter, please contact Bing Dang, at 613-736-3801 or e-mail bing.dang@hc-sc.gc.ca.

Yours truly,



Marion Law

Chief Registrar

PEST MANAGEMENT REGULATORY AGENCY