Re-evaluation Decision Document

RRD2004-30

Capsaicin

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of capsaicin is now complete.

The Pest Management Regulatory Agency (PMRA) has determined that capsaicin is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified.

This RRD includes the comments made to the PMRA in response to the Proposed Acceptability for Continuing Registration (PACR) document, <u>PACR2004-08</u>, *Re-evaluation of Capsaicin*, published on 21 April 2004. This document also presents the PMRA's response to the comments and the regulatory decisions resulting from the re-evaluation of capsaicin.

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1.0 Introduction

The re-evaluation of the available information for the active ingredient capsaicin and its associated uses has been completed by the PMRA.

2.0 Background

The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of capsaicin is now complete.

On 21 April 2004, the PMRA published PACR2004-08, *Re-evaluation of Capsaicin*, for consultation on the proposed regulatory decision for capsaicin. Comments were received from a registrant concerning this PACR.

This RRD summarizes these comments and the PMRA's response as well as outlines the regulatory decision resulting from the re-evaluation of capsaicin.

3.0 Regulatory decision

The PMRA has reviewed the comments received in response to the proposed regulatory decision for capsaicin (Appendix I) and has concluded that these comments did not result in substantive changes to the regulatory decision as described in PACR2004-08.

The PMRA has determined that capsaicin is acceptable for continuing registration provided that the mitigation measures specified in the PACR are implemented. In addition to changes to the proposed label statements resulting from external comments, the PMRA has further refined certain label statements found in Appendix I of the PACR. The revised label amendments are outlined in Appendix II of this RRD.

Section 5.0 of the PACR outlined additional requirements for continued registration of capsaicin. The registrants will be informed by letter of the specific requirements affecting their product registrations and the regulatory options available to comply with this decision.

Appendix I Comments and responses to PACR2004-08

The PMRA received one comment in response to PACR2004-08. The PMRA has summarized the comment received and provides a response below.

Comment on proposed label changes for domestic products

The additional proposed requirement for the use of gloves is too extreme for domestic products with a small percentage of capsaicin (< 1%). The PMRA should exempt domestic products containing less than 1% capsaicin from requiring gloves for the following reasons:

- 1. these products contain less capsaicin than found in some consumer products such as barbeque sauce; and
- 2. the precautionary wording does not take into consideration that seed and suet products are packed in a manner that does not allow the consumer to come in direct contact with the product.

Response

The PMRA has found the above rationale submitted by the registrant to be acceptable and has removed the requirement for rubber gloves when using domestic products with $\leq 1\%$ capsaicin. Nevertheless, precaution should be taken to avoid touching eyes or face or using the washroom until after washing hands.

Appendix II Label amendments for capsaicin

(NOTE:

The label amendments presented below 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 following label statements.)

- (i) In the "Precautions" section of all end-use products, the following statement must appear:
- "Wash hands before touching eyes or face and prior to using the washroom."
- (ii) In the "Precautions" section of all pressurized spray bear repellent products, the following statements must appear:
- "This product is for spraying the face of aggressive bears only and is not to be used against domestic animals or human beings."
- "Capsaicin sprays will not repel bears from treated objects or areas. Do not spray objects (e.g., tents, clothing) or areas with this product."