

Re-evaluation Decision Document

3-Trifluoromethyl-4-nitrophenol

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 3-trifluoromethyl-4-nitrophenol (TFM) is now complete.

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

This RRD presents the regulatory decisions resulting from the re-evaluation of TFM as published in the Proposed Acceptability for Continuing Registration (PACR) document, <u>PACR2004-11</u> on 14 May 2004.

(publié aussi en français)

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1.0 Introduction

The re-evaluation of the available information for the active ingredient TFM and its associated uses to control sea lamprey larvae in waters of the Great Lake basin and the Lake Champlain systems has been completed by the PMRA.

2.0 Background

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

On 14 May 2004, the PMRA published PACR2004-11, *Re-evaluation of 3-trifluoromethyl-4-nitrophenol*, for consultation on the proposed regulatory decision for TFM. Comments concerning this PACR were received by the PMRA from interested parties. The PMRA has consolidated and summarized the comments received, and provides responses in Appendix I.

This RRD also presents the regulatory decisions resulting from the re-evaluation of TFM.

3.0 Regulatory decision

The PMRA has determined that TFM is acceptable for continuing registration provided that the mitigation measures specified in the PACR are implemented.

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

Appendix I Comments and responses:

The PMRA received comments in response to PACR2004-11, from registrants of TFM products. The PMRA has consolidated and summarized the comments received, and provides responses below.

1.0 Chemistry

1.1 Comment pertaining to additional data requirements

In Section 5.0, additional chemistry data is required to review the current levels of microcontaminants in the technical grade active ingredient (TGAI) and one formulated product. However, there is no list of microcontaminants for which data has to be provided. Could the PMRA provide such a list?

PMRA response

Section 2.0 of the PACR identified low levels of polychlorinated biphenyls (PCBs) and octachlorodibenzofuran as the Track 1 substances reported in the technical product. The additional chemistry data in Section 5.0 are required to confirm current levels of these chemicals.

1.2 Comment pertaining to analysis of the TGAI and formulated product for microcontaminants

The formulation process does not allow for the introduction of microcontaminants into the formulated product. As such, is it necessary to do an analysis of the formulated product? Would analysis of the TGAI not be sufficient?

PMRA response

The results from the analysis of the TGAI would be sufficient to determine the levels of microcontaminants that would occur in formulated products. Section 5.0 of the PACR specifies that chemistry data are required to review current levels of microcontaminants in the technical source of TFM.