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Streamlined Category B Submissions

PMRA Guidance Document



*Protecting human health
and the environment*

*Protéger la santé humaine
et l'environnement*



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March 2023	Original document, published pursuant to consultation document PRO2020-01, and replacing regulatory document REG2002-04.

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This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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1.0 Introduction

The purpose of this new guidance document is to clarify the eligibility and conditions for acceptance of Streamlined Category B Submissions.

2.0 Background

With the publication of Regulatory Directive DIR2017-01, Management of Submissions Policy (8 March 2017), new terminology was introduced for submissions with a limited number of amendments, and requiring only a value assessment: Streamlined Category B Submissions. These types of submissions were formerly termed Category C Efficacy Reviews (REG2002-04). On 3 July 2020, in Regulatory Proposal PRO2020-01, the PMRA proposed to increase the number of label amendments permitted within one of these submissions to six (6).

This guidance document is published pursuant to PRO2020-01 and replaces REG2002-04.

3.0 Eligibility

Category B submissions that require only value (Part 10) information are eligible for review as Category B Streamlined submissions, provided that the request concerns:

- a decrease in the use rate;
- an increase in the level of control (for example, upgrading to control from suppression);
- the addition of a pest;
- the addition of a tank-mix; or
- the addition of the general label statement related to tank mixing found in the PMRA Guidance Document, Tank Mix Labelling.

4.0 Conditions

In order to qualify as a Streamlined Category B submission, the following conditions must be met.

- The total amount of product applied to the crop does not increase as a result of the amendments (for example, no increase in application rate and/or number of applications per year).
- Products proposed for use in tank-mixes must each be registered for the specific use site/crop when applied individually; the application rate when applied as a tank mix partner cannot exceed the application rate when the product is used alone.
- All tank-mix partners must already be registered for the timing (for example, pre-emergent, post-bloom) and method of application (for example, soil drench, foliar, aerial) proposed in the tank-mix directions.

- A maximum of six (6) label amendments are allowed within one submission. For example:
 - The addition of six (6) new pests; or
 - a decrease in the application rate for three (3) pests already on the label and the addition of three (3) new pests; or
 - the addition of one (1) tank mix that is proposed to control five (5) pests that do not already appear on either tank mix partner label, etc.