



## Category C Submission Efficacy Reviews

In March 1999, the Pest Management Regulatory Agency released Regulatory Note REG99-01, *Category C Submission Efficacy Reviews*. The purpose of this Regulatory Note is to clarify the eligibility, criteria and procedures for acceptance of submissions as “fast track” efficacy reviews for registrants, applicants and other interested parties. This Regulatory Note replaces REG99-01.

*(publié aussi en français)*

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## Introduction

In March 1999, the Pest Management Regulatory Agency (PMRA) released Regulatory Note REG99-01, *Category C Submission Efficacy Reviews*. The purpose of this new Regulatory Note is to clarify the eligibility, criteria and procedures for acceptance of submissions as “fast track” efficacy reviews for registrants, applicants and other interested parties.

## Background

The PMRA was encouraged by the Economic Management Advisory Committee and other parties to shorten Category B timelines as originally set out in Regulatory Proposal PRO96-01, *Management of Submissions Policy*. The PMRA agreed to recategorize the Category B submissions that required only efficacy data (REG99-01).

Based on experience gained with submissions following the introduction of this approach in 1999, the following clarifications are intended to further facilitate the fast track Category C approach.

## Eligibility

**Category B submissions that require only efficacy or value (Part 10) data are eligible to be reclassified as Category C “fast track” submissions, provided that the request concerns:**

- a decrease in the use rate, where the requested decrease in rate does not apply to more than three pests;
- a change in the level of control (e.g., going from suppression to control);
- tank-mixes:
  - (a) non-food uses,
  - (b) food uses where the product is not intended for application to a transgenic crop; or
- the addition of pest(s) to a maximum of two (2), provided the total amount of active ingredient applied to the crop in a season does not change as a result of the new pest addition. (Registrants will need to express the allowable maximum seasonal rate of active ingredient on the product label.)

**The following clarifications are applicable to all tank-mixes:**

- (1) products proposed for use in tank-mixes must each be registered for the specific use and the specific crop(s) when applied individually;

- (2) a maximum of two (2) label amendments are allowed under one submission, e.g., two tank-mixes, one tank-mix and decreased rate, one tank-mix and change affecting one pest;
- (3) all tank-mix partners must already be registered for the timing and method(s) of application proposed in the tank-mix directions, e.g., if the tank-mix is proposed for aerial application, all the tank-mix partners must already be registered for aerial application; and
- (4) the application rate for all tank-mix partners cannot exceed the registered rate when products are used individually, i.e., same rate or less.

## Criteria

The following criteria must be met to qualify as Category C “fast track” submissions:

- Submissions can be made for registered products or uses for which a certificate of registration has been issued under Section 13 of the *Pest Control Products (PCP) Act* and Regulations.
- Submissions can be made, on a case-by-case basis, for temporary registered products or uses that have been issued a certificate of registration under Section 17 of the PCP Act and Regulations. Because of the short timelines for review of the Category C “fast track” submissions, it is recommended that a presubmission consultation with the PMRA take place before submissions that involve temporary registrations are made.

## Procedures for submission

All submissions must be organized and formatted according to the provisions of PRO98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*. The efficacy and crop tolerance data should be organized as per Appendix VII of the above document. The elements of a complete submission for the cases being described in this document are listed under the section entitled “Elements of a Complete Fast Track Category C Submission for Efficacy Evaluation Only.”

The procedure for managing these submissions is as outlined in PRO96-01 for Category C submissions, i.e., receipt and log-in, screening, letter of deficiencies at screening (if deficient) and review. After completion of review, if the submission is deemed unacceptable, it will be withdrawn and the applicant will be advised of this decision.

**Please note that submissions made as Category C “fast track”, if determined to require review of any data components other than efficacy, e.g., review of residue data for tank-mixes, will be recategorized as Category B submissions. As a result of this, both the timeline and the fees will be adjusted.**

The PMRA's performance standard for Category C "fast track" submissions is 150 days (verification, screening and review) as opposed to the normal Category B performance standard of 417 days. This meets the key industry request for a PMRA response on current year efficacy data prior to the upcoming use season.

**Elements of a complete fast track Category C submission for efficacy evaluation only**

- Covering letter outlining the purpose and contents of the submission, including an explanation of how this application is eligible and meets the criteria outlined in this Regulatory Note for processing as a Category C "fast track" submission
- Application form completed, dated and signed
- Fee form indicating Parts 1*b* and 10
- Payment of CAN \$1168
- Draft supplemental label in paper (four copies) and electronic (PDF) formats
- Index of supporting data and reports (two copies) and electronic (PDF) formats
- Efficacy and value data and summaries (Part 10) in paper and in electronic spreadsheet (e.g., Excel, Lotus 123) formats