Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Pro96-01

Regulatory Proposal

Management of Submissions Policy

This document introduces new performance standards and describes the process for managing submissions.

The new process is being implemented for all Submission Categories. Applicants will be kept informed about this and related initiatives such as data requirements for screening, Comprehensive Summaries for Category A submissions and international harmonization.

Interim performance standards for Category A submissions are effective for submissions received after July 1, 1996. Performance standards for other submission Categories and biopesticides (e.g., microbials, pheromones) will be introduced by April 1, 1997.

Interested parties have 30 days to provide comments about this proposed Policy. Comments may be sent to the Publications Coordinator, Pest Management Regulatory Agency, Health Canada, 2250 Riverside Drive, Nepean, Ontario, K1A 0K9 or by electronic mail to Grace_Lewis@hc-sc.gc.ca.

(publié aussi en français)

June 7, 1996

This document is published by the Submission Management and Information Division, Pest Management Regulatory Agency. For further information, please contact:

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Canada

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1.0 Purpose

The purpose of this policy is to outline the method by which the Pest Management Regulatory Agency (PMRA) manages applications and material submitted for the notification, research, registration and amendment of pest control products.

2.0 Implementation

The process described in this policy applies to all submission categories.

A phased approach with respect to performance standards is being implemented for all submission categories, as detailed in Appendix I. The timeframes are PMRA Interim Performance Standards, and will be reviewed during the implementation phase.

Effective July 1, 1996, Category A submission performance standards (with the exception of biopesticides) will apply. Once screening criteria has been developed for biopesticides, Category A performance standards will apply. Applicants will be advised of the implementation schedule for all other submission types as they become available.

Reviews will be conducted in chronological order within each category, based on the date the submission is accepted for review.

The submissions are grouped into the following categories.

Category A submissions include new active ingredients and major new uses and have either full or substantial data packages that may include mammalian toxicology, exposure, residue, chemistry, environmental chemistry and fate, and environmental toxicology and value data. User Requested Minor Use Registrations (URMUR) may have reduced data requirements.

Category B submissions include new formulations, changes in current formulations, new hosts and/or pests added to existing products, renewal or conversion of temporary registration, new source of currently registered active ingredient, and changes in rates and methods of application.

Category C submissions include product registrations and amendments which may have reduced data requirements.

Category D submissions include Import for Manufacture and Export Program (IMEP), Own Use Import (OUI), Master Copy, Private Label and User Requested Minor Use Label Expansion (URMULE).

Category E submissions include Research Permits for new actives, new use of registered actives, and notifications that are required for field research carried out in Canada. Exemptions from data requirements are based on the size and location of treated areas.

3.0 Instructions for Submitting the Application

Submissions must be addressed to:

Submission Management and Information Division
Pest Management Regulatory Agency
2250 Riverside Drive
A.L. 6605E1
Ottawa ON K1A 0K9

Direct delivery of data to the individual divisions will no longer be accepted. Instructions regarding applying for registration can be found in Part 5.0 of the *Registration Handbook* and other documents pertaining to the specific types of submissions.

4.0 Submission Content

A submission consists of:

- a covering letter stating the purpose and contents of the submission;
- completed forms such as application for registration, specification, application for research permit, Own Use Import;
- a fee which is indicated on the application form;
- documentation such as letters of confirmation, support, agent;
- an index in electronic format;
- draft labels according to Canadian format, as outlined in the *Registration Handbook*;
- data according to the use-site category in the proper format;
- where available, foreign regulatory agency reviews for individual studies; and
- where available, Comprehensive Summaries according the European Union Directive, Annex II, Tiers I to IV.

A future Regulatory Directive will require applicants to include Comprehensive Summaries for Category A submissions.

5.0 Submission Management Process

The Submission Flow Diagram in Appendix II outlines the submission process. Interim performance standards are in calendar days.

5.1 Verification

Within seven days of receipt, all submissions are verified to ensure that fees, forms, labels and required information have been provided according to the *Registration Handbook*. Deficiencies will result in the submission being returned to the applicant at the applicant's expense.

Applicants whose submissions are accepted are provided a submission number acknowledging receipt of the submission. This number should appear on all correspondence to the Agency.

Once accepted, submissions are forwarded for screening.

5.2 Screening

Submissions are screened for acceptability. Screening documents for new active ingredients (conventional chemicals) are provided to applicants on request. Screening documents for other submission categories will be provided to applicants as they become available.

Screening is based on current data requirements. Data requirements may be amended and updated through the development of guidelines and international harmonization activities.

Submissions are screened within 45 days of receipt. If no deficiencies are identified, the submission is accepted and forwarded to the appropriate science divisions for review. If deficiencies are identified, the applicant has 45 days to submit all of the requested information. There are no reminders. If there is no response or if the response is incomplete or inadequate, the submission is withdrawn and returned to the applicant at the applicant's expense. The submission number is no longer valid. A submission that has been withdrawn may be submitted as a new submission.

5.3 Submission Review

All submission types are considered workload from the date of acceptance for review.

The interim performance standards for submission categories are detailed in Appendix I.

The review of the submission is coordinated to ensure that performance standards are met. The coordinated review of data is conducted by the appropriate science divisions and includes the preparation of a Proposed Regulatory Decision Document (PRDD) when required.

If no deficiencies are identified in any of the review streams, it is determined whether a PRDD is required. If a PRDD is required, the applicant is notified and the consultation period begins. If a PRDD is not required, the applicant is notified.

During the review, evaluators may request clarification of minor points on submitted data; this is done by facsimile. Clarifications do not contain requests for new data elements. To facilitate clarification, it is recommended that the applicant identify the appropriate contact person for each study or part of the submission. The applicant has 10 days to respond to the request; the review continues during this time. If the response to the request for clarification is not provided within 10 days, the review ceases, and the submission is withdrawn and returned at the applicant's expense.

If major deficiencies are identified during one or more of the review streams of Category A, B and C submissions at any time during review, the review of all streams stops. The applicant is sent a letter of preliminary deficiency which states the data requirements, and is given 90 days to fulfil the requirements. There are no reminders. If the requested data are submitted, they are screened within 45 days and the full time for completing the review is applied. Lack of, or an inadequate response within 90 days results in the submission being withdrawn and returned to the applicant at the applicant's expense. If the response is adequate, the review continues.

If all review streams are complete for Category A, B and C submissions and the results of one or more reviews indicate that further data are required, or if other issues are identified, the applicant is informed in a letter of evaluation deficiency and has 90 days to respond. There are no reminders. The submitted data are screened within 45 days and the review completed within 180 days.

5.4 Proposed Regulatory Decision Document (PRDD)

Bilingual PRDDs are produced for all new active ingredients and some major new uses of presently registered pesticides.

The consultation period for all PRDDs is up to 45 days from the date of publication. The comments received during the consultation period are assessed and the final decision is made within 45 days from the end of the comment period.

5.5 Decision

The applicant receives a consolidated letter of intent to register from the Chief Registrar outlining the regulatory decision.

5.6 Final Label Review

The applicant has 30 days to submit a final label in response to the letter of intent to register. Approval of the final label and issuance of the certificate of registration takes place within 45 days of the receipt of the final label. If the final label has errors which could compromise human and environmental health or safety, or product performance, the applicant is asked to change it and is given a further 30 days. The Agency has 30 days to complete the label review and issue the registration certificate.

The certificate of registration is issued and the product register updated.

6.0 Temporary Registration

Temporary registrations are permitted for a period of less than one year in an emergency, or when the registrant agrees to produce supplementary information related to the registered product. Renewal of the product registration requires a complete submission containing the information specified in the temporary registration decision. It is treated as a Category B submission and is subject to the same acceptance criteria and timelines.

APPENDIX I

PEST MANAGEMENT REGULATORY AGENCY
INTERIM PERFORMANCE STANDARDS for REVIEW of PEST CONTROL PRODUCTS
for SUBMISSIONS RECEIVED AFTER JULY 1, 1996

CATEGORY A[1]

Target = 90% of submissions in all Categories to be processed within the time shown.

CATEGORY A SUBMISSION	**PERFORMANCE STANDARDS (in calendar days)**							
Submission Type	**Class**	**Verifi-cation**	**Scre e-ning**	**Review**	**2nd Screen**[2]	**2nd Review**[2]	**Consultation / Comments PRDD**	**Verification of Final Label**
New Active Ingredient	**Priority**	7	45	365	45	180	90	45
	Standard	7	45	550	45	180	90 as required	45
Major New Use	**Priority**	7	45	365	45	180	90 as required	45
	Standard	7	45	550	45	180	90 as required	45
URMUR	**Priority**	7	45	365	45	180	90 as required	45

1 Biopesticides, e.g., pheromones, microbials, will be included once procedures and screening criteria have been developed.
2 If required for response to evaluation deficiency.

PEST MANAGEMENT REGULATORY AGENCY
INTERIM PERFORMANCE STANDARDS for REVIEW of PEST CONTROL PRODUCTS
for SUBMISSIONS RECEIVED AFTER APRIL 1, 1997

CATEGORY B

Target = 90% of submissions in all Categories to be processed within the time shown.

CATEGORY B SUBMISSION	PERFORMANCE STANDARDS (in calendar days)							
Submission Type	**Class**	**Verifi-cation**	**Scree-ning**	**Review**	**2nd Screen[1]**	**2nd Review[1]**	**Consultation / Comments PRDD**	**Verification of Final Label**
New Formulation / Change in Formulation / New Hosts / New Pests / New Source / Changes in Rate / Methods of Application	**Standard**	7	45	365	45	180	n/a	45

1 If required for response to evaluation deficiency.

PEST MANAGEMENT REGULATORY AGENCY
INTERIM PERFORMANCE STANDARDS for REVIEW of PEST CONTROL PRODUCTS
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CATEGORY C

Target = 90% of submissions in all Categories to be processed within the time shown.

CATEGORY C SUBMISSION	**PERFORMANCE STANDARDS (in calendar days)**							
Submission Type	**Class**	**Verifi-cation**	**Screening**	**Review**	**2nd Screen[1]**	**2nd Review[1]**	**Consultation / Comments PRDD**	**Verification of Final Label**
Product Registrations / Amendments	**Standard**	7	45	90 - 180[2]	45	90 - 120[2]	n/a	45

1 If required for response to evaluation deficiency.
2 Performance standard linked to size of supporting database: to be determined.

PEST MANAGEMENT REGULATORY AGENCY
INTERIM PERFORMANCE STANDARDS for REVIEW of PEST CONTROL PRODUCTS
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CATEGORY D

Target = 90% of submissions in all Categories to be processed within the time shown.

CATEGORY D SUBMISSION	**PERFORMANCE STANDARDS (in calendar days)**							
Submission Type - *Special Programs*	**Class**	**Verifi-cation**	**Screening**	**Review**	**2nd Screen[1]**	**2nd Review[1]**	**Consultation / Comments PRDD**	**Verification of Final Label**
IMEP[2]	**Standard**	7	14	32	14 - as required	32 - as required	n/a	14
OUI[2]	**Standard**	7	14[3]	56	n/a	n/a	n/a	14
Master Copy	**Standard**	7	21		n/a	n/a	n/a	21
Private Label	**Standard**	7	n/a	n/a	n/a	n/a	n/a	14
URMULE[2,4]	**Standard**	7	30	60[4]	n/a	60 - 180[5]	n/a	n/a

1 If required for response to evaluation deficiency.
2 Specialized review streams.
3 Includes label review.
4 URMULE may require a preliminary review to determine data requirements.
5 Performance standard linked to size of supporting database: to be determined.

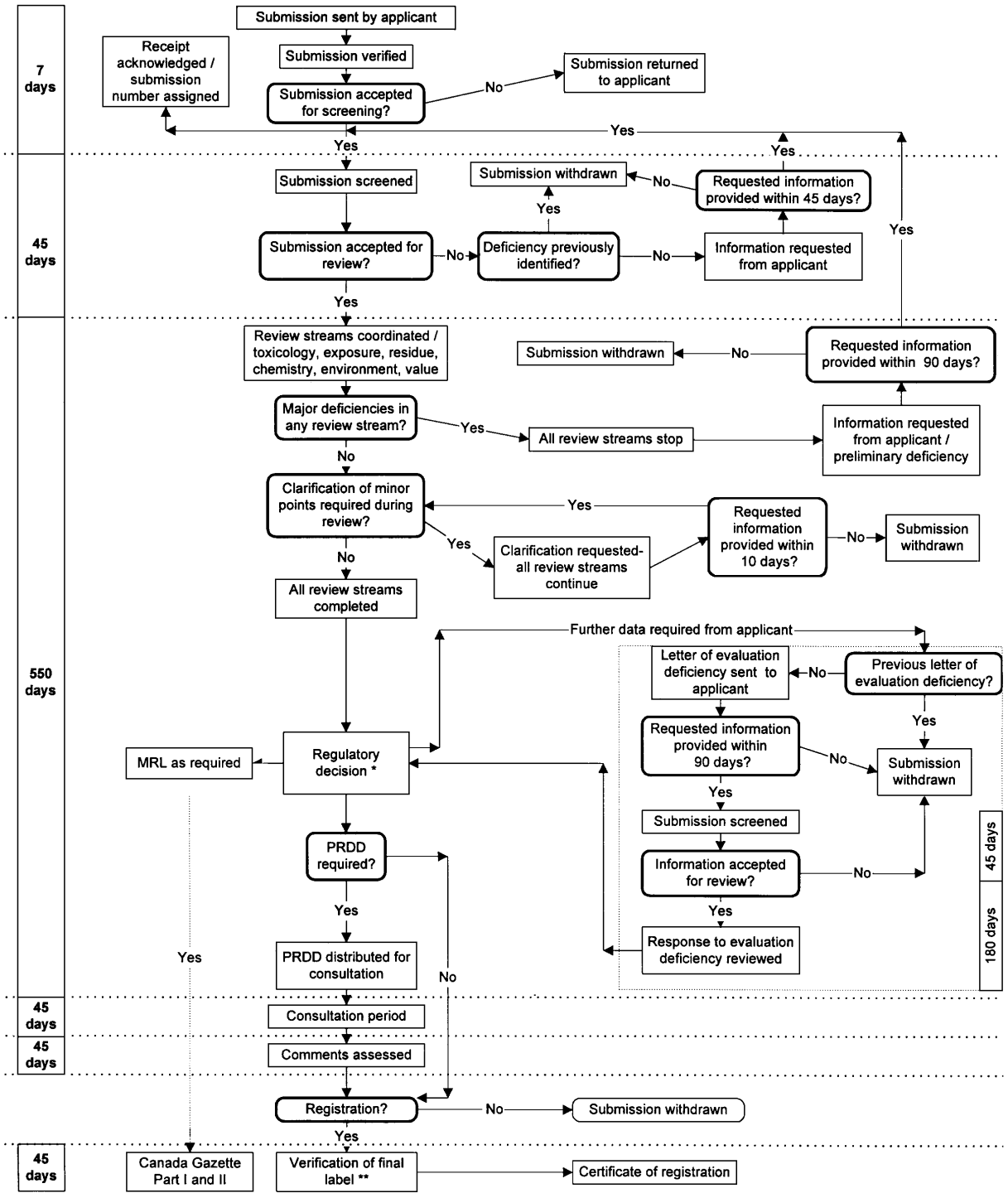
PEST MANAGEMENT REGULATORY AGENCY
INTERIM PERFORMANCE STANDARDS for REVIEW of PEST CONTROL PRODUCTS
for SUBMISSIONS RECEIVED AFTER APRIL 1, 1997

CATEGORY E

Target = 90% of submissions in all Categories to be processed within the time shown.

CATEGORY E SUBMISSION	**PERFORMANCE STANDARDS (in calendar days)**							
Submission Type - *Research Permits*	**Class**	**Verifi-cation**	**Scree-ning**	**Review**	**2nd Screen**	**2nd Review**	**Consultation / Comments PRDD**	**Verification of Final Label**
New Active, Food	**Standard**	7	45	365	n/a	n/a	n/a	part of review
New Active, Non-Food / Crop Destruct	**Standard**	7	45	165	n/a	n/a	n/a	part of review
Other	**Standard**	7	14	86	n/a	n/a	n/a	part of review
Notification	**Standard**	7	30 default		n/a	n/a	n/a	part of review

Proposed Category A Submission Process



* *Includes decision about whether a PRDD is required - company is notified*

** *Options to be assessed with PMRA-industry working group*