



Label Process Changes Part 1: Overview

The purpose of this document is to provide guidance to industry and other interested parties on the label process changes being implemented within the Pest Management Regulatory Agency (PMRA) as part of the ongoing efforts to streamline the registration process. The process changes include elimination of the requirement for submission of a printed label prior to issuance of a certificate of registration, implementation of the bilingual labelling regulations and a modification of the electronic label requirement.

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Foreword

The purpose of this document is to communicate to industry and other interested parties, the label process changes being implemented within the Pest Management Regulatory Agency (PMRA) as part of the ongoing efforts to streamline the registration process. The process changes include elimination of the requirement to submit a printed label prior to issuance of a certificate of registration, implementation of the bilingual labelling regulations and a modification of the electronic label requirement.

The elimination of the requirement for a printed label prior to issuance of a certificate of registration represents a positive step in streamlining the label review process for both industry and the PMRA. This process change will result in the issuance of a certificate of registration up to one year earlier. As of January 1, 2003, certificates of registration will be issued on the basis of approved label text with no requirement for follow-up submission of a printed label. Printed labels will only be required with registration renewal applications.

Commencing January 1, 2003, when the regulation for bilingual labels takes effect, all certificates for new, amended or renewed registration will be issued on the basis of a bilingual text label. This requirement represents additional workload for both industry and the Agency. The elimination of the printed label requirement simplifies the label approval process and allows for a more manageable workflow for the bilingual label review.

The label component of a submission package is currently required in both hard copy and electronic format. Beginning July 1, 2003, new specifications will be introduced for the electronic label, and a hard copy label will no longer be required. These electronic label specifications will allow the Agency to optimize the use of the electronic label throughout the submission review process. The lead time from now to July 1, 2003 will allow a period for industry to become familiar with the new electronic label specifications. Applicants are strongly encouraged to begin submitting electronic labels according to these specifications prior to July 1, 2003.

The Agency recognizes that the implementation of the process changes described in this document will evolve, and welcomes comments for consideration in further streamlining of the overall registration process. Comments should be submitted to the Publications Coordinator at PMRA.

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1.0 Purpose

The purpose of this document is to communicate changes to the processes for submission and review of pesticide labels as the PMRA moves forward to streamline registration processes. The goal is to simplify the process and advance the use of electronic labels while implementing the mandatory approval of label content in both official languages under the recent amendment to the Pest Control Products Regulations (PCPR).

This document is one of two companion documents on label process changes:

- a. *LPS2003-01, Label Process Changes Part 1: Overview*
- b. *LPS2003-02, Label Process Changes Part 2: Guidance for Industry*

2.0 Definitions

The following label terminology has been adopted:

<i>PDF normal</i>	is a file type that is created through word processing software (e.g., Word Perfect, Microsoft Word) as a print file rather than a scanned image.
<i>Label text</i>	is the text content only of the label. The <i>label text</i> has no graphic images, no colour and no publishing layout, e.g., precautionary symbols are replaced with the appropriate symbol signal words. It is not the marketplace or the printer's proof label. Refer to Appendices F to I of the Registration Handbook for examples of text only labels.
<i>Proposed label</i>	is the <i>label text</i> version that accompanies the application to register or amend the registration of a pest control product.
<i>Annotated label</i>	is the <i>label text</i> version which is marked up (annotated) by the PMRA to communicate to the applicant the terms of the regulatory review and therefore the label corrections required.
<i>Corrected label</i>	is the <i>label text</i> version submitted by the applicant after incorporating changes requested by the PMRA.
<i>Approved label</i>	is the <i>label text</i> version verified by the PMRA for consistency with the <i>annotated label</i> and upon which the Certificate of Registration is issued. The <i>approved label</i> is electronically posted to the PMRA Web label collection.

Marketplace label is the label found on the actual product container in the marketplace. This label may contain graphics, logos, etc., which are deemed acceptable under the *Pest Control Products Act* and Regulations. Previously this was commonly referred to as the “final printed label”.

Registration eligibility decision letter

is a letter issued at the end of the review process that communicates to the applicant the conditions of registration, and provides a consolidation of the changes that must be made by the registrant to the *proposed label*.

3.0 Background

Over the last few years, the PMRA has been working with the Canadian pesticide industry registrants and other agencies to improve the efficiency of the registration process. There is recognition that one way to improve efficiency involves the use of electronic technology. It is anticipated that full implementation of an electronic submission and evaluation capability for the pesticide label will improve efficiency for both the Agency and registrants.

The PMRA has initiated several joint industry-agency pilot projects using current Internet technology and incorporating the federal government’s comprehensive Government On-line initiatives. These initiatives were designed to support the ongoing development of electronic submission processes. In addition, a joint industry-PMRA label working group recommended other means of improving efficiency and simplifying processes through earlier issuance of a certificate of registration.

The initiatives already undertaken as a result of the joint efforts of industry and the PMRA are outlined below.

Progress summary: Electronic tools and processes

- Electronic Dossier, Delivery and Evaluation (EDDE) system. EDDE is the cornerstone for achieving efficiency gains for all regulatory partners in providing a standard electronic format to handle industry submissions. Details on the EDDE system are available in the following documents: REG2001-06, *Guidance to Applicants for Preparing Electronic Submissions Part I: An Overview*; EDDE2001-01, *Guidance to Applicants for Preparing Electronic Submissions: Part II, Guidance for Industry During Pilot Stage*; EDDE2001-02, *Guidance to Applicants for Preparing Electronic Submissions: Part III, Guidance of Evaluator Functional Requirements for Electronic Evaluation*; and EDDE2001-03, *Guidance to Applicants for Preparing Electronic submissions: Part IV, Guidance on the Preparation of Documents for Electronic Exchange*.

- EDDENET, the PMRA electronic registration site, provides electronic tools to facilitate submission assembly and to support the exchange of submission components in an electronic format through a secure channel. General use of EDDENET will be announced at a later date.
- Electronic fill and print forms, available in PDF format on the PMRA Web site, also contribute to improved efficiency for both industry and the PMRA with respect to submission processing (REG2001-01, *Electronic Forms*).
- Electronic evaluation templates used by PMRA evaluators are available on the PMRA Web site for use by applicants when preparing their submissions. These templates capture the specific data components for each data set. Their early use by industry, as well as PMRA evaluators, provides for consistency of submission content and format and facilitates the evaluation process.
- The PMRA provides the complete pesticide label collection of currently registered products on its Web site in PDF format. Label searches, including full text or product information searches can be conducted through ELSE (Electronic Label: Search and Evaluation). ELSE can be accessed via the PMRA Website search button (<http://www.hc-sc.gc.ca/pmra-arla/>).
- Submission of an electronic label in addition to paper copies has been a PMRA requirement for some time (PRO98-02: *Organizing and Formatting a Complete Submission for Pest Control Products*). This facilitates the maintenance of the PMRA Web label collection mentioned above and has permitted testing of electronic label review processes within the PMRA.

Progress summary: Issuance of a certificate of registration and process simplification

- The PMRA responded to a recommendation of a 1997 joint industry-PMRA label working group by implementing a voluntary pilot project to assess the feasibility of issuing a certificate of registration based on the version of the label presented by the company at the final step of the registration process (see R98-01, *Implementation of the Label Working Group Recommendations*). This allowed the applicant to request that a certificate of registration be issued on the basis of a PMRA approved *corrected label* or a printer's proof label. Under the terms of the voluntary pilot project, the *marketplace label* still has to be submitted to the PMRA as a separate application within 45 days of its printing. The applicant can begin selling the product as soon as the final printed label (*marketplace label*) submission has been filed. Prior to providing the option of joining this pilot project, the final step of the registration process required the submission of the *marketplace label*. Applicants were allowed 365 days after issuance of the registration eligibility decision letter to submit the *marketplace label* for issuance of a certificate of registration.

- In 2001, the PMRA expanded the scope of notifiable label changes to include additional minor label changes (DIR2001-04, *Notification/Non-notification*). As part of this directive, labels are required with the notified label change.

4.0 Moving forward

4.1 Points to consider in moving forward

- Although the submission of an electronic label has been a PMRA requirement for some time, these are received in a variety of software formats, such as Microsoft Word, Word Perfect, PageMaker and PDF image format. The data corruption difficulties associated with converting electronic documents from one type of word processing software to another are widely recognized and are addressed in EDDE2001-03, *Guidance to Applicants for Preparing Electronic Submissions, Part IV: Guidance on the Preparation of Documents for Electronic Exchange*.
- The EDDE document series, previously referenced, established PDF normal as the preferred format for filing electronic submissions since it retains the integrity of the original document upon conversion, and supports the functional requirements of submission review.
- The ability to conduct an effective comparison of electronic labels during the label review and verification processes is dependent on the label content being presented in a consistent order from one label version to the next, both within and between submissions for the same product. The receipt of various types of labels such as printer's proof labels, *marketplace labels*, scanned label images and varying order of label information within text-based files, do not support an effective electronic comparison.
- The manner in which PDF is captured can impact the accuracy of the web label collection search results. For example, a scanned PDF file does not permit effective searching because it is an image.
- Effective January 1, 2003, the PMRA must issue all certificates of registration on the basis of a bilingual label. This requirement was detailed in the *Canada Gazette* Part II on December 19, 2001. Changes to the label submission and review procedures to accommodate this requirement were communicated in part in the Memorandum to Registrants, Applicants and Agents on the subject *Procedures for the Implementation of Bilingual Labelling Requirements for Submission Categories A, B and C under the Pest Control Products Act* which was issued on July 5, 2002. The bilingual labelling requirement results in added workload and increases the complexity of the label verification process.

- With implementation of mandatory bilingual labelling, the PMRA must work towards posting both the English and the French text portion of *approved labels* on the PMRA Web label collection. In order to avoid the return of duplicate or erroneous search results, the framework will require a separate posting of the English and French *label text*.

4.2 Approach

The PMRA is currently managing multiple and complex label processes. We recognize that all parties would benefit from streamlining these processes and, to assist with this, we have already committed to increasing the use of electronic tools. We also realize that the new bilingual labelling requirements must be incorporated into the submission approval process in as efficient a manner as possible, in order to minimize the impact of the additional workload and cost to industry and the PMRA.

The strategy for moving forward is to build on what has already been achieved and to focus on streamlining current processes while implementing new ones. The label process improvements described in this document are designed to:

- standardize the label submission and review process by improving upon the voluntary label pilot project initiated through R98-01, *Implementation of the Label Working Group Recommendations*;
- simplify the processes by eliminating some of the current process requirements;
- minimize the impact of the new bilingual label requirement by conducting the English and French language verification at a single step of the submission process, i.e., the final step before the certificate of registration is issued; and
- promote the use of electronic labels during the submission review process by requesting that they be submitted in a standard software format and with a standardized structure in the order of label information to:
 - avoid software incompatibility and conversion issues;
 - support an effective electronic comparison of successive label versions; and
 - facilitate electronic annotation of label changes.

The process changes required to support the implementation of these streamlining efforts, and their specific benefits, are outlined in Section 5.

5.0 Implementation

5.1 Notification labels

Effective January 1, 2003, label changes made under DIR2001-04, *Notification/Non-notification* will no longer require submission of a label; PMRA will continue to reflect notifiable changes on the PMRA Web label collection.

5.2 Discontinuation of the voluntary label pilot project

Effective January 1, 2003, the voluntary label pilot project is replaced by the process outlined below.

- A certificate of registration will be issued based on an *approved label* (for details see section 2.0 Definitions) for all submissions to register or amend the registration of a pest control product (where a label is required as part of the submission). All other versions of labels will no longer be accepted (e.g., printer's proof, final printed label). Upon issuance of the PMRA *registration eligibility decision letter* and accompanying *annotated label*, the applicant/registrant will have 45 days to submit the *corrected label*. It is the PMRA's intent to issue a certificate of registration based on the *approved label* within a further 45 days, according to PRO96-01, *Management of Submissions Policy*, providing all requested label corrections have been incorporated.

NOTE: there will be no requirement for a separate follow-up submission of a *marketplace label* upon printing.

- A copy of the *marketplace label* will continue to be required to accompany submissions for product registration renewal and extension of temporary registration where the product is marketed in Canada.
- To ensure registration renewal occurs at least every five years, registration expiry dates will no longer be extended upon issuance of a certificate to amend a product registration.

These changes build upon the success of the voluntary label pilot project and standardize and streamline the label approval process to accommodate the earliest possible issuance of a certificate of registration for all submissions to register a product or amend a registration. The removal of the requirement to submit a follow-up submission of a *marketplace label* following early certificate issuance, and the elimination of the requirement for submission of a label with notification reduces industry's paper and financial burden as well as the workload for the PMRA. These changes also represent a further step towards implementation of a fully electronic label submission and review process (see Section 5.4).

NOTE: The registrant of a product is responsible for ensuring that the *marketplace label* matches the *approved label*. It is an offence according to the PCPA to distribute a product with a *marketplace label* that does not conform to the *approved label* for which a certificate of registration has been issued. Presentation, symbols and graphics associated with the *marketplace label* must all be consistent with, and in compliance with, regulatory requirements including the approved claims and uses.

5.3 Bilingual labelling

Effective January 1, 2003, all certificates issued for new, amended or renewed registration must be based on a bilingual product label, with minor exceptions as detailed in Appendix I.

5.3.1 Bilingual labelling process

The process changes required to accommodate bilingual labelling for the majority of submissions categories are outlined below.

- The PMRA screening and review of the *proposed label* will be conducted in one official language only, as determined by the principal language of the submission components. (Exceptions to this are detailed in Section 5.3.2). Consequently the applicant is required to submit a *proposed label* in the principal language of the submission (i.e., English labels should accompany submissions containing the principal components in English). Refer to the document *LPS2003-02, Label Process Changes Part 2: Guidance to Industry* for details.
- Label changes deemed necessary by the PMRA will be communicated to the applicant in the principal language as determined above.
- Following communication of the conditions of registration, the applicant will be required to submit a *corrected label* incorporating all changes reflected in the *annotated label* that accompanies the *registration eligibility decision letter*. A translation of the *corrected label*, in the second language, must be provided at this point.
- The PMRA will verify that the English and French portions of the bilingual *corrected label* are consistent in meaning and reflect the conditions of registration. Poor quality translations will result in a delay in the issuance of a certificate of registration.

The changes described above are aimed at simplifying a potentially complex process due to the now mandatory bilingual labelling requirement and related increased PMRA workload associated with dual language verification. The rationale for requiring submission of a *proposed label* in one official language at the beginning of the review process is to avoid the extra workload of screening and reviewing the *proposed label* in both official languages at every step of the registration process.

Appendix I contains information regarding the interpretation of the amendment to the PCPR on bilingual labelling.

5.3.2 Bilingual Labelling Process Exceptions

There are certain submission subcategories which are exempted from the process described in Section 5.3.1. For the following submission types, the applicant must submit a bilingual label as part of their application:

- Category B.4.2—Extension of temporary registration
- Category C.6.3—User Requested Minor Use Label Expansion (URMULE) supplemental labels
- Category D.1— Importation for Manufacturing and Export Program (IMEP)
- Category D.4—Master copy
- Category D.5—Private label
- Category D.6—Product registration renewal

The content of the labels filed with submission types B.4.2, C.6.3, D.5 and D.6 should not differ from the previously approved label, except for changes that have been reported according to DIR2001-04, *Notification/Non-notification*. Consequently, for these submission types, the label comparison, against the previously approved label wording, and second language verification will be conducted as a single step.

In the case of Category D.1 submissions, the label text is prescribed by and will be compared to the label format given in DIR95-05, *Importation for Manufacturing and Export Program (IMEP)*. The label for a Category D.4 must be identical to, or form a subset of the label uses of the Master Product registration on which the Master Copy is based.

5.4 Electronic labels

Effective January 1, 2003, all electronic *label text* files must be submitted in PDF normal format and must be accompanied by four (4) hard copies.

Effective July 1, 2003, all electronic *label text* files must be submitted in PDF normal format and must adhere to the specifications detailed below. As of this date, a hard copy label will no longer be required. This advance notice gives adequate time for registrants to prepare for the new electronic label file specifications. The full Adobe Acrobat software (version 4 or higher) is required to comply with this requirement.

Electronic *label text* file(s), with the following specifications, must be submitted for all applications that require a label.

- Spell check—ensure that the label text has been edited for spelling errors prior to conversion to PDF, e.g., use the spell check tool in the authoring software;
- File type: PDF normal (refer to Section 2.0 Definitions);
- Text order in the file
 - must reflect the standard label format identified in Appendices F to I of the Registration Handbook
 - must contain generous spacing between sections (to allow for annotations to be incorporated into the body of the text during the label review process, rather than as attachments), and
 - must remain consistent throughout successive submissions for a product;
- Separate electronic files for English and French *label text* for *corrected labels*;
- File naming: should include a language indicator for English or French, product registration number (where one exists), a label component indicator (e.g., sleeve, booklet, etc.), and file date, e.g., E-12345-booklet-12oct2002.pdf;
- Method of submission: diskette or CD-ROM; and
- Virus check: the applicant must scan the files for viruses and provide the PMRA with details of the software used (name, version, date of virus signature update file and company).

Prior to July 1, 2003, registrants and applicants are strongly encouraged to begin submitting electronic labels according to these specifications.

The changes described above will enable the PMRA to further refine and integrate electronic tools and processes, developed in consultation with industry, into existing operational activities. Meeting all of the specifications outlined above will provide the momentum for progressing toward the full implementation of an electronic label screening and review process. Submission of the English and French portions of the *label text* in separate files will greatly assist with the posting of separate English and French text on the PMRA Web label collection which, in turn, will facilitate accurate and reliable label searches.

5.5 Ongoing activities

As the process changes described in this document are implemented, the PMRA will develop standards (e.g., for annotations) and training plans to enable staff and registrants to use electronic labels effectively. Following implementation of the changes described in this document, the PMRA will focus first on Category A and C submissions and begin to issue *registration eligibility decision letters*, accompanied by an electronically annotated *label text*. This process will be applied to the remaining submission categories once the process standards and training has been completed. The PMRA will endeavour to complete the transition in as efficient a manner as possible.

6.0 Implementation schedule summary

For consolidated guidance regarding the implementation of the label process changes described below, refer to the partner document *LPS2003-02, Label Process Changes Part 2: Guidance for Industry*.

January 1, 2003

- Replacement of the voluntary label pilot project—A certificate of registration will be issued on the basis of an *approved label*. A separate submission for approval of a *marketplace label* will no longer be required. Submission of the *marketplace label* will be required at registration renewal only.
- Bilingual labels required for issuance of certificate of registration—all certificates for new, amended or renewed registration must be issued on the basis of a bilingual product label with exemptions as detailed in Appendix I.
- Submission of electronic labels—registrants are encouraged to submit electronic labels prepared according to the specifications detailed in Section 5.4.

July 1, 2003

- Submission of electronic labels—submission of electronic *label text*, prepared according to the specifications outlined in Section 5.4, will become a requirement for all submissions. Hard copy *label text* will no longer be required to accompany a submission application.
- The PMRA will continue to refine the electronic label process through development of annotation standards and training plans to enable effective use of electronic labels by both the Agency and industry.
- With a focus on Categories A and C, the Agency will begin to issue *registration eligibility decision letters* accompanied by electronically annotated *label text*.

7.0 Implications for industry

The PMRA is committed to meeting its performance targets, however this becomes challenging with the increasing complexity of product labels and the implementation of the mandatory bilingual labelling requirements. The process changes described in this document are essential to meeting these challenges and maintaining acceptable turnaround times.

The PMRA will provide a timely label review for submissions accompanied by labels which meet the requirements outlined in this document. The review of labels which do not meet the specifications detailed in this document will not be completed in the 45-day time frame for label verification. The additional time required to review such labels will result in a significant delay in the issuance of a certificate of registration.

8.0 Guidance

For consolidated guidance on the process changes described in this document, and their impact on submissions received prior to January 1, 2003, refer to *LPS2003-02, Label Process Changes Part 2: Guidance for Industry*.

The label process changes and requirements described in this document, and the companion document *LPS2003-02, Label Process Changes Part 2: Guidance for Industry*, supercede information previously published by the PMRA with respect to label requirements and processing.

Appendix I Summary of the bilingual labelling regulatory amendment

The implications of the Amendment to the Pest Control Products Regulations requiring bilingual labelling on all pest control products regulated under the PCPA is summarized in the following:

- All new product registration, amendment or product renewal which takes effect on or after January 1, 2003 is subject to the bilingual labelling requirement.
- An amendment for an emergency registration approved after January 1, 2003 will not trigger the bilingual labelling requirement unless the registered product label is already bilingual in which case the label directions for the emergency amendment must also be bilingual. This exemption is in effect until January 1, 2008 by which time all registered product labels will be bilingual.
- Products which are not manufactured, imported, sold or used in Canada are exempt from the bilingual labelling requirement.
- Pest control products which are subject to regulation under the PCPA, but which are exempt from the registration requirement, e.g., products regulated under Schedule 1 of the PCPA, Own Use Import (OUI) Program, and experimental uses (i.e. research permits and research notifications), will not be required to have bilingual labels until January 1, 2008.