



Label Process Changes Part 2: Guidance for Industry

The purpose of this document is to provide guidance to industry on the implementation of the label process changes described in the companion document *LPS2003-01, Label Process Changes Part 1: Overview*. This document provides direction to applicants concerning label requirements and process for new submissions and submissions in progress.

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Foreword

The purpose of this document is to provide guidance to industry on the implementation of the label process changes described in the companion document *LPS2003-01, Label Process Changes Part 1: Overview*. This document provides direction to applicants concerning label requirements and process for new submissions and submissions in progress.

New submissions received on or after January 1, 2003, and submissions in progress for which a *registration eligibility letter* has not yet been issued as of January 1, 2003 will all benefit from the elimination of the requirement for a “final printed label” prior to issuance of a certificate of registration. These submissions will receive a certificate of registration on the basis of an *approved label*.

Those submissions in progress for which a *registration eligibility letter* has been issued before January 1, 2003 with a request for a “final printed label” will be completed on the basis of an *approved label*, as will submissions participating in the label pilot project. A separate submission for approval of a “final printed label” will no longer be required. A period of transition is required to deal with these submissions in progress and the PMRA will communicate individually with registrants to assist them in completing their submission labelling requirements.

The requirement for a bilingual label for issuance of a certificate of registration, as of January 1, 2003, will impact both new submissions and submissions in progress. This document augments the previously published guidance in the July 5, 2002 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*, by providing additional details and instructions concerning process changes resulting from the bilingual labelling requirement.

Electronic label format and specification requirements will change on July 1, 2003, as outlined in this document. The change allows the Agency to optimize the use of the electronic label, and will result in a discontinuation of the requirement for hard copy labels. The lead time, from the date of publication of this guidance document to July 1, 2003, will allow a transition period in which applicants and registrants are encouraged to voluntarily submit electronic labels according to the new format requirements.

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

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1.0 Purpose

This document provides consolidated guidance for industry in determining the impact of the various label process changes for new applications as well as submissions in progress as of January 1, 2003.

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, i.e., 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 which 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 New submissions

3.1 General process

3.1.1 Application requirements

Applications for new or amended registrations received by the PMRA on or after January 1, 2003 must be accompanied by a *proposed label* in only one of the two official languages.

- The language of the *proposed label* must be the same as the principal language of the submission components, i.e., French labels should accompany submissions where the application, cover letter, and supporting documents are submitted in French. This will determine the language of screening and review.
- From January 1, 2003 to June 30, 2003, an electronic *proposed label*, in the principal language of the submission, must be submitted in PDF normal format and must be accompanied by four (4) hard copies.
- As of July 1, 2003, an electronic *proposed label*, in the principal language of the submission, must be submitted in PDF normal format and must be in accordance with the specifications detailed in Appendix I. Applicants are strongly encouraged to begin submitting electronic labels according to these specifications prior to July 1, 2003.

3.1.2 Screening and submission review

Label revisions required by the PMRA will be communicated to the applicant in the principal language of the submission components, i.e., the same language as the application, cover letter and supporting documents.

Upon completion of the submission review, the *registration eligibility decision letter* will be sent to the applicant, by the PMRA, accompanied by an *annotated label* reflecting the conditions of registration, and the requirement for submission of a *corrected label*.

3.1.3 Applicant submission of *corrected label*

The applicant will have 45 days in which to submit a *corrected label* in bilingual format.

- From January 1, 2003 to June 30, 2003 an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be accompanied by four (4) hard copies.
- As of July 1, 2003, an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be in accordance with the specifications detailed in Appendix I. Applicants are strongly encouraged to begin submitting electronic labels according to these specifications prior to July 1, 2003.

3.1.4 PMRA label verification and issuance of a certificate of registration

The PMRA will verify the *corrected label* to ensure that the required label changes have been incorporated and that the English and French portions of the bilingual label are consistent in meaning and reflect the terms of the regulatory decision. To avoid delays in the issuance of a certificate of registration, it is important that the applicant submit a good quality label translation. Poor quality translation will result in the label being returned to the applicant with 45 days in which to correct translation errors and return the bilingual *corrected label* to the PMRA for verification. A certificate of registration will be issued when the PMRA is satisfied that **all changes** have been incorporated by the applicant. This is considered the *approved label* and is the label version that provides the content for the registrant to print the *marketplace label*, and will be posted to the PMRA Web label collection.

3.2 Exceptions to the general process for new submissions

There are certain submission subcategories for which the applicant must submit a bilingual label as part of their application. These submission categories include:

- 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.

4.0 Submissions in progress on January 1, 2003

The PMRA recognizes that on January 1, 2003, current submissions will be at varying stages of completion. Guidance will be provided by PMRA in submission related correspondence to assist registrants in determining the process for completing individual submissions. The following information will form the basis for that guidance.

4.1 *Registration eligibility decision letter has not been issued as of January 1, 2003 (i.e., a regulatory decision is pending)*

Submissions for which a decision regarding eligibility for registration has not yet been communicated to the applicant will follow a similar process to that described above for new submissions.

- the *proposed label* that was submitted with the application will be screened and reviewed in one language only which will be the principal language of the submission components, i.e., English labels should accompany submissions where the application, cover letter and supporting documents are submitted in English.
- Any label revisions deemed necessary by the PMRA will be annotated to the *proposed label* in this language.

Upon completion of the submission review, a *registration eligibility decision letter* will be sent to the applicant, by the PMRA, accompanied by an *annotated label*. The applicant will have 45 days in which to submit a *corrected label*.

- From January 1, 2003 to June 30, 2003 an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be accompanied by four (4) hard copies.
- As of July 1, 2003, an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be in accordance with the specifications detailed in Appendix I. Applicants are strongly encouraged to begin submitting electronic labels according to these specifications prior to July 1, 2003.

The PMRA will verify the *corrected label* to ensure that the required label changes have been incorporated and that the English and French portions of the bilingual label are consistent in meaning and reflect the terms of the regulatory decision. To avoid delays in the issuance of a certificate of registration, it is important that the applicant submit a good quality label translation. Poor quality translation will result in the label being returned to the applicant with 45 days in which to correct translation errors and return the bilingual *corrected label* to the PMRA for verification. A certificate of registration will be issued when the PMRA is satisfied that **all changes** have been incorporated by the applicant. This is considered the *approved label* and is the label version that provides the content for the *marketplace label*, and will be posted to the PMRA Web label collection.

4.2 *Registration eligibility decision letter* has been issued by the PMRA and submission of label is pending

Applicants in receipt of a letter outlining the conditions of registration prior to January 1, 2003 may no longer submit a printer's proof or a "final printed label" in order to receive a certificate of registration. A bilingual *corrected label* is now required to complete the registration process. The bilingual *corrected label* must be submitted to the PMRA in accordance with the time lines communicated in the *registration eligibility decision letter* and in the following format:

- From January 1, 2003 to June 30, 2003 an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be accompanied by four (4) hard copies.
- As of July 1, 2003, an electronic *corrected label*, consisting of an English electronic file and a French electronic file, must be submitted in PDF normal format and must be in accordance with the specifications detailed in Appendix I. Applicants are strongly encouraged to begin submitting electronic labels according to these specifications prior to January 1, 2003.

The PMRA will verify the *corrected label* to ensure that the required label changes have been incorporated and that the English and French portions of the bilingual label are consistent in meaning and reflect the terms of the regulatory decision. To avoid delays in the issuance of a certificate of registration, it is important that the applicant submit a good quality label translation. Poor quality translation will result in the label being returned to the applicant with 45 days in which to correct translation errors and return the bilingual *corrected label* to the PMRA for verification. A certificate of registration will be issued when the PMRA is satisfied that **all changes** have been incorporated by the applicant. This is considered the *approved label* and is the label version that provides the content for the *marketplace label* and will be posted to the PMRA Web label collection.

4.3 Category specific exceptions for submissions in progress on January 1, 2003 (e.g., where issuance of a *registration eligibility decision letter* is not part of the approval process)

There are certain submission subcategories for which the issuance of a *registration eligibility decision letter* is not part of the approval process. These submissions only require a label comparison against a previously approved label which allows the second language verification to be conducted as part of this comparison. These submission categories include:

- 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

As of January 1, 2003, all certificates of registration issued must be based on a bilingual product label therefore all labels submitted after the date of issuance of this document must be in bilingual format.

Any submissions in progress on January 1, 2003, for the categories listed above, for which a bilingual product label has not been filed with the application, will be placed on hold. The applicant will be given 45 days in which to submit a bilingual product label for verification and certificate issuance. Following receipt by the PMRA of the bilingual product label, the label comparison, against the previously approved label wording, and second language verification will be conducted as a single step.

The above transition clause does not apply to the two other categories for which the issuance of a registration eligibility decision letter is not part of the approval process, namely:

- Category B.4.2—Extension of temporary registration, or
- Category D.6—Product registration renewal

Extension and renewal processes for the year 2002 incorporated bilingual labelling and so a transition phase is not required.

4.4 Certificate of registration has been issued on the basis of the pilot project

For cases in which a company has participated in the label pilot project and received a certificate of registration, based on either label text or a printer's proof with the requirement that the final printed label be submitted within 45 days of printing, the final printed label requirement will be waived and the certificate of registration previously issued remains valid up to the expiry date.

Submissions will be withdrawn for those cases in which a company has submitted final printed labels before January 1, 2003. The certificate of registration previously issued remains valid up to the expiry date.

5.0 Registration renewal date

The implementation of these process changes has a direct impact on product registration expiry dates. As of January 1, 2003, all product registration expiry dates will only be advanced through product registration renewal or extension of temporary registration and not through amendments. For example, a product with an expiry date of December 31, 2005 will now be required to apply for a product registration renewal in the year 2005 regardless of any submission amendments that may be approved between January 1, 2003 and December 31, 2005.

6.0 Terms and conditions

With the changes to the processes outlined above, it should be noted that the registrant of the product continues to be 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 is 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.

Appendix I Guidance for formatting electronic labels

Electronic *label text* file(s) must be submitted according to the following specifications:

- 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).

Additional guidance on the preparation of electronic labels may be obtained by contacting the PMRA Information Service at 1-800-267-6315 or (613) 736-3799.

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