

Regulatory Directive

Initial Product/Private Label Registration Process

The Private Label Registration Process has been put in place to streamline product registration procedures in the interests of improving operating efficiency and service to clients. Once a registered product is granted Initial Product status, it may be used as a precedent for the registration of subsequent Private label Products. Initial Product status may be requested in the original submission for registration or, through amending a currently registered product. Private Label products will be processed on a priority basis.

This Regulatory Directive replaces Memorandum to Registrants R-1-247, dated September 14, 1987.

(publié aussi en français)

October 28, 1993

This document is published by the Submission Management and Information Division,
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1.0 Registration of an Initial Product

The Initial Product application package **must** contain the following:

- An *Application for New or Amended Registration* (AGR 1170) (complete Box 13);
- A *Product Specification* form (AGR 1168);
- Five (5) copies of the draft Initial Product label;
- A letter of Confirmation of Source of supply from the manufacturer or supplier of each active ingredient (all active ingredients must be registered); and
- A cheque made out to the Receiver General of Canada for the appropriate registration fee.

An Initial product must meet current data requirements for registration under the *Pest Control Product (PCP) Act*. The Plant Industry Directorate may require supporting data upon review of any application to register a control product.

Initial Product status can only be granted to fully registered products that are not manufacturing concentrates or technical active ingredients. A product may have both Initial Product and Master Product status (consult DIR93-20).

Note: The Certificate of Registration for the Initial Product must be issued **before** an application to register a Private Label will be accepted for review.

2.0 Registration of a Private Label Product

Each Private Label application package **must** contain the following:

- *Application for Registration of Private Label Product* (AGR 2577) completed according to the instruction sheet;
- Five (5) copies of the final printed label; and
- A \$154.00 cheque made out to the Receiver General of Canada.

Note: If the Initial Product registrant signs box 16 of the *Application for Registration of Private Label Product* (AGR 2577) for the Private Label Applicant, a letter of signature authorization from the Private Label Applicant is required.

It is the responsibility of the Initial Product registrant to assign consecutive registration numbers to Private Label products using the Initial Product PCP number and a decimal point followed by two digits.

Example: PCP Number for Initial Product: xxxxx
 PCP Number for Private Label Product A: xxxxx.01
 PCP Number for Private Label Product B: xxxxx.02
 PCP Number for Private Label Product C: xxxxx.03

If the Private Label application package is properly documented, the Certificate of Registration will be issued to both the Private Label applicant and the Initial Product registrant within 10 working days. The newly registered Private Label product may then be sold.

If the Private Label application package is incomplete, the package will be returned to the Initial Product registrant without being reviewed.

3.0 Limitations Placed on the Private Label Product by the Initial Product Registration

Private Label products must be identical in formulation and must be formulated on the same production line as the Initial Product.

The container size(s) and type(s) must be selected from the size(s) and type(s) approved on the specification form of the Initial Product.

The label of the Private Label Product must have exactly the same layout as the label of the Initial Product.

The label of the Private Label Product must use the same language(s) as the label of the Initial Product.

4.0 Permitted Differences Between an Initial Product and a Private Label Product

The label of the Private Label Product may differ from the label of the Initial Product in the following ways:

- trade dress
- company name and address
- product name
- PCP registration number (see item 2 above)

5.0 Amendments to the Registered Initial Product

Amendments to the Initial Product can be made only if the changes do not affect the Private Label or if there are no Private Label Products registered.

To amend a registered Initial Product, the following package must be forwarded to the Plant Industry Directorate:

- *Application for New or Amended Registration* (AGR 1170); and
- A cheque made out to the Receiver General of Canada for the appropriate registration fee.

The following may also be required:

- *Product Specification* form (AGR 1168);
- Five draft labels; and
- Letter of Confirmation of source of supply of active ingredient.

6.0 Amendments to the Registered Private Label Product

Amendments to the registration of a Private Label Product will be restricted to changes in trade name, trade dress, company name or address. The application package for such an amendment must contain the same components as an application for registration of a new Private Label Product (see item 2 above). The same registration number may be used.

Note: If the Initial Product/Private Label fast track system does not provide enough versatility for your needs, the Master Copy Registration Process may be more suitable. Details of the Master Copy Registration Process are found in Regulatory Directive DIR93-20.

Please direct any inquiries regarding this Regulatory Directive to:

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