



Agriculture and
Agri-Food Canada

Agriculture et
Agro-alimentaire Canada

Canada

Food Production
and Inspection Branch

Direction générale,
Production et inspection des aliments

Plant Industry Directorate

Direction de l'industrie des produits végétaux

DIR93-20
version 2

Regulatory Directive

Master Product/Master Copy Registration Process

The Master Copy 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 Master Product status, it may be used as a precedent for the registration of subsequent Master Copies. Master Product status may be requested in the initial submission for registration or, through amending a currently registered product. Master copy products will be processed on a priority basis.

This Regulatory Directive replaces Memorandum to Registrants T-1-256, dated December 31, 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 The Master Copy Registration Process

The Master Copy Registration Process allows for submissions to be given two 21-day periods for processing. The first period is for evaluation of the submission. If all is found in order, a registration number will be assigned and the registrant will be requested to provide final printed labels. The second period is for review of final printed labels. If they are accepted, the Certificate of Registration will be issued.

If the Master Copy application package is incomplete, it will be returned to the applicant without being reviewed.

The Master Product must be registered before an application to register a copy will be accepted for review.

2.0 Master Product Registration

A product with Master Product registration status is used as a precedent for registration of subsequent copies.

The Master Product application package must contain the following:

- an *Application for New or Amended Registration* (AGR1170);
- a *Product Specification* form (AGR1168);
- five (5) copies of the draft Master 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.

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

Master Product status can only be granted to fully registered products that are not manufacturing concentrates or technical active ingredients. A product may have both Master Product and Initial Product status (consult DIR93-21).

3.0 Registration of Master Copy Products

Each application package to register a Master Copy must contain the following:

- *An Application for New or Amended Registration* (AGR1170);
- *A Product Specification* form (AGR1168);
- Five (5) copies of the draft label of the copy;
- A Letter of Authorization from the Master Product registrant giving access to data and confirming that the Master Product is being copied;
- 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 \$154.00 cheque made payable to the Receiver General of Canada.

Once the copy is registered the Registration Certificate and the approved label will be returned to the applicant.

4.0 Allowable Differences Between a Master Product and its Master Copy Products

- The copy may be made in a different plant from the Master Product.
- The copy may contain alternative sources of non-active ingredients.
- The label of the copy may contain all, or a subset of, the use claims and label text presently found on the Master Product label.

Please direct any inquiries regarding this Regulatory Directive to:

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