



Regulatory Directive

Importation for Manufacturing and Export Program (IMEP)

Discussion Document D94-05, dated December 21, 1994, proposed a program for the importation of pest control products solely for manufacturing and export. This Regulatory Directive, implementing the IMEP, is based on that proposal with only minor modifications arising from the public consultation.

(publié aussi en français)

December 8, 1995

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Canada

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1.0 Introduction

This document sets out regulatory procedures and information requirements for registering pest control products (technical or formulated) imported solely for the purpose of manufacturing and export. These products are registered under the authority of the *Pest Control Products (PCP) Act and Regulations* administered by the Pest Management Regulatory Agency (PMRA) of Health Canada.

Every control product (including technical active ingredients, manufacturing concentrates, and end-use products) used in the manufacture (e.g., formulating, repackaging, etc.) of control products as well as those that are imported into, or used in Canada, must be registered under the *PCP Act*.

The broader aspects of manufacture, transportation and storage for all potentially toxic products, including pesticides, are covered by other federal and provincial laws. It is the responsibility of the applicant/registrant to obtain all necessary approvals and to comply with all legislated requirements pertaining to the import, transportation, manufacture and storage of the products under consideration. Applicable federal legislation includes the *Transportation of Dangerous Goods Act*, the *Hazardous Products Act*, and the *Fisheries Act*. Products regulated under the authority of the *PCP Act* are exempt from the provisions of the *Canadian Environmental Protection Act*. Appendix 5 provides a representative list of the relevant provincial legislation and departmental contacts.

The information requirements for registering this type of product under the *PCP Act* have been adapted to focus on specific matters which are not adequately regulated under other applicable laws or international agreements. The information specified in this document must accompany all submissions for registration. In lieu of specified data, surrogate data or a request for waiver with a scientific rationale will be considered.

Pest control products for which registration has been previously suspended, cancelled or voluntarily withdrawn in Canada because of health and safety or environmental impact concerns and pest control products which have been previously assessed for registration and found to be unacceptable are not eligible for IMEP. For chemical pesticides, it is also necessary that the product imported into Canada be approved for sale or registered in the United States or in a European Union (EU) or OECD country.

2.0 Applicable Legislation and Guidelines of the Importing Countries

Products exported from Canada must be acceptable to the receiving country. Most developed countries have regulations controlling the import and use of pest control products. For example, the United States Environmental Protection Agency has requirements for registering foreign manufacturing plants and products as a prerequisite for importation of pest control products. The Canadian exporter is responsible for obtaining the necessary approvals to allow the export of a finished product to the destination country.

3.0 Procedures and Information Requirements

Applicants wanting to register a pest control product for importation into Canada solely for manufacturing and export should submit an application to the PMRA, Health Canada, consisting of the following:

- ! a covering letter briefly outlining the intent of the submission;
- ! a completed and signed *Application for New and Amended Registration Form* ;
- ! a completed and signed *Product Specification Form* for the product to be imported;
- ! the appropriate fee (for an active ingredient not previously assessed or evaluated, or an active ingredient from a source not previously assessed or evaluated, the fee is CAN \$3,000.00. Otherwise, the fee is CAN \$300.00);
- ! three (3) copies of a draft, manufacturing-use label (refer to Appendix 2 for a model label);
- ! if the applicant is not the manufacturer of a technical active ingredient under consideration, a letter confirming the source of supply from the manufacturer of the technical active ingredient; and
- ! three (3) copies of the information outlined in Appendix 1.

Note: Appendix 4 contains a checklist of submission requirements to assist in interpretation and submission preparation.

Once the application and supporting documentation are received by the PMRA, a submission file will be opened and the applicant will be informed of the submission control number. The application must include all required information without cross-referencing other submissions.

The PMRA will endeavour to review the application and notify the applicant of a registration decision within 60 days of receipt. If the application is acceptable, the registration number, approved draft label, and registration certificate will be issued. If the application is not approved, a letter explaining the decision will be sent to the applicant, who can either provide supplementary information or withdraw the submission.

Documentation is required for the importation of all pest control products including products registered under IMEP. A *Declaration by Importer of Control Products* form, must accompany **all** shipments of control products to be imported into Canada. These forms can be obtained at any customs office and all regional offices of the Food Production and Inspection Branch of Agriculture and Agri-Food Canada.

4.0 Amendments

The registrant of any control product is responsible for informing the PMRA of any changes to the product register (ie., the information in Appendix 1) or of changes to the regulatory status of the exported product in the country of destination (especially if the exported product label is affected) or of any significant findings relating to the health and environmental safety of the product in any country. Should it be necessary to reevaluate the status of a product registered under IMEP, the registrant may be required to submit a formal amendment application with the supplementary information.

The registration period for IMEP products is five (5) years and is renewable. In order to amend or renew the registration, registrants must submit an Application for New and Amended Registration accompanied by any information that amends what already exists on the control product register.

5.0 Export Notices (Prior Notification)

Companies exporting finished products under IMEP are required to notify importing countries in advance that the finished products in question have been assessed in Canada only for manufacturing and export purposes and not for local or domestic use. This export notice must make clear that Canada has not assessed environmental or health safety relating to the product's proposed use in the importing country.

Export notices must contain all the information set out in Appendix 3 and be sent by telex, facsimile or registered mail after an offer for export of the product has been accepted by the country of destination but prior to the first shipment. All importing countries have designated a national authority responsible for receiving export notices. Names and addresses of these authorities are published under the authority of the *Canadian Environmental Protection Act* in the *Canada Gazette* (Part 1, December 14, 1991. Department of the Environment. *List of Toxic Substances Authorities*).

A copy of the export notice shall be sent simultaneously to the Director, Information Division, PMRA, Health Canada, Ottawa, Ontario, K1A 0Y9, the designated Canadian National Authority for pesticides.

Information Requirements for a Chemical Pest Control Product Registered Under the Importation for Manufacturing and Export Program (IMEP)

1. A complete Material Safety Data Sheet (MSDS), as defined in the *Hazardous Products Act*, for the material to be imported.
2. Recommended precautions and emergency measures, including personal protective equipment, leak and spill clean-up procedures, handling procedures, storage requirements and first aid measures (MSDS may be cited).
3. The identification of other government agencies, either foreign or within Canada, that have been or will be notified of the importation and manufacture of the control product, and the purpose of such notification.
4. An estimate of the quantity of product to be imported on a per annum basis.
5. The following specifications for each technical active ingredient in the imported product (the numbering system follows that of Appendix 1 of Regulatory Directive Dir93-02):
 - 2.1 Name and Office Address of the Basic Manufacturer of each Technical Active Ingredient
 - 2.2 Date of Specifications
 - 2.3 Trade Name
 - 2.4 Common Name: ISO or CSA common names in CSA standard CAN/CSA-Z143
 - 2.5 Chemical Name: Chemical Abstracts and IUPAC, if available
 - 2.6 Chemical Abstracts Services Registry Number
 - 2.7 Structural Formula: also includes Wiswesser line notation, if available, for the active (a linear representation of the structural configuration)
 - 2.8 Empirical Formula
 - 2.9 Molecular Weight
 - 2.10 Canadian Patent Status: number, date issued and expiry date

-
- 2.11 Name and Address of Manufacturing Plant of each Technical Active Ingredient
- 2.15 Analytical Data and Methodology:
- Specific analytical methodology (such as GC or HPLC with MS detection or other appropriate techniques) used to precisely identify and determine the level of the active ingredient in the product should be submitted. Methods should be validated using standards. Validation data should be included with the submission. This should include chromatograms of a sample formulation and of a blank (placebo) formulation to demonstrate absence of interference.
- 2.16.1 Chemical and Physical Properties of each Pure Active:
- ! Melting Point or Range (for solids)
 - ! Boiling Point (for liquids)
 - ! Solvent Solubility (representative polar and non-polar solvents) (g/100 g)
- 2.16.2 Chemical and Physical Properties of the Imported Material:
- ! Colour
 - ! Odour
 - ! Physical State
 - ! Density or Specific Gravity
 - ! Viscosity
 - ! Vapour Pressure at 20EC
 - ! Stability (Oxidation and Thermal)
6. Samples: A 2.5 g analytical reference standard of each active ingredient in the imported product. Please send samples directly to:
- Evaluation Unit
Pesticide Laboratory
Agriculture and Agri-Food Canada
Plant Products Building
No. 22, Central Experimental Farm
Ottawa, Ontario
K1A 0C6
7. The following environmental chemistry and toxicity data (the numbering system follows that in Regulatory Directive Dir93-01):
- 6.2.1.1 Vapour Pressure
- 6.2.1.2 Hydrolysis
-

- 6.2.1.4 Solubility in Water
 - 6.2.1.5 Octanol-Water Partition Coefficient
 - 6.2.2.1 Adsorption/Desorption Measurements
 - 6.2.4 Analytical Methodology (Soil, Water)
 - 6.2.3.1 Biotransformation in Soil
 - 7.2.2 Toxicity to Fish (Rainbow Trout) (summary only)
 - 7.3.7 Toxicity to *Daphnia magna* (summary only)
8. The following mammalian toxicity data (complete studies) (the numbering system follows that in Regulatory Directive Dir93-01):
- 3.2.2 Acute Oral
 - 3.2.3 Acute Dermal
 - 3.2.4 Acute Inhalation
 - 3.2.5 Primary Eye Irritation
 - 3.2.6 Primary Dermal Irritation
 - 3.2.7 Dermal Sensitization
9. Information indicating that the imported product is approved for sale or registered in the United States or in an EU country.
10. The following information regarding the Canadian manufacturer/formulator and the product to be exported:
- ! name and address of the Canadian manufacturing/formulator plant;
 - ! letter of support from the Canadian manufacturer/formulator;
 - ! draft labels of the products to be exported (when available);
 - ! MSDS for exported products (when available); and
 - ! product specification form for exported product (when available).

**Draft Label for a Pest Control Product
Registered Under the Importation
for Manufacturing and Export Program (IMEP)**

PRODUCT NAME

FOR MANUFACTURING USE ONLY

Precautionary Symbols and Warnings

READ THE LABEL BEFORE USING

GUARANTEE: Common Name(s) or Chemical Name(s) X%

REGISTRATION NUMBER xxxxxxxx PEST CONTROL PRODUCTS ACT

Net Contents _____ kg

Registrant's
Name and Address
Telephone No.: _____

Manufacturer's
Name and Address
(if different from registrant)
Telephone No.: _____

DIRECTIONS FOR USE:

To be used only in the manufacture (formulating, repackaging, repouring) of a pest control product solely for export from Canada. Read Technical Bulletin for formulating details.

PRECAUTIONS:

ENVIRONMENTAL HAZARDS:

FIRST AID: If on skin; if in eyes; if ingested; etc.

TOXICOLOGICAL INFORMATION:

STORAGE:

DISPOSAL:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the provincial regulatory agency.

NOTICE TO USER:

This product is to be used only in accordance with the directions on this label. It is an offense, under the *Pest Control Products Act* to use a control product under unsafe conditions.

**Prior Notification of Export:
Information required in an export notice
for pest control products under the Importation
for Manufacturing and Export Program (IMEP)**

1. Exporting country.
2. Name and address of exporter.
3. Names of the pest control product and active ingredient.
4. Chemical Abstracts Services (CAS) registry number for the active ingredient, where applicable.
5. Importing country and name and address of importer.
6. Name and address of the Designated National Authority in the importing country that will receive the export notice (as specified in the List of Toxic Substances Authorities compiled pursuant to subsection 42(2) of the *Canadian Environmental Protection Act*).
7. Review status in Canada. The export notice should state: "The products in question have been assessed in Canada for manufacturing and export purposes only, and not for local or domestic use. Canada has not assessed environmental or health safety of the product based on the proposed use in the importing country."
8. Name and address of the Designated National Authority for pesticides in Canada: Director, Information Division, PMRA, Health Canada, Ottawa, Ontario K1A 0Y9.
9. Intended uses of the pest control product as specified by the importer.
10. Quantity of the pest control product in the shipment being exported to the importing country.
11. Name, title and address of the person providing the information contained in the export notice.
12. Date on which the export notice is prepared.

Submission Requirements for Registration of Pest Control Products Under the Importation for Manufacturing and Export Program (IMEP)

Information Check List for Chemical Products

| Information | Submitted | Received | Comments |
|---|-----------|----------|----------|
| 1. General | | | |
| - Cover Letter | | | |
| - Application Form | | | |
| - Product Spec. Form | | | |
| - Fee | | | |
| - Draft Label | | | |
| - Letter of Confirmation | | | |
| - Material Safety Data Sheet for Imported Product | | | |
| - Precautions and Emergency Measures | | | |
| - Government Agencies Contacted | | | |
| - Quantity of Product Imported | | | |
| - Approval/registration in U.S. or EU | | | |
| 2. Specifications | | | |
| - Basic Manufacturer | | | |
| - Specification Date | | | |
| - Trade Name | | | |
| - Common Name | | | |
| - Chemical Name | | | |
| - Chemical Abstracts Registry Number | | | |
| - Structural Formula | | | |
| - Empirical Formula | | | |
| - Molecular Weight | | | |
| - Canadian Patent Status | | | |

| Information | Submitted | Received | Comments |
|--|-----------|----------|----------|
| - Name and Address of Manufacturing Plant | | | |
| - Analytical Methodology | | | |
| 3. Chemical and Physical Properties | | | |
| - Melting Point | | | |
| - Boiling Point | | | |
| - Solvent Solubility | | | |
| - Colour | | | |
| - Odour | | | |
| - Physical State | | | |
| - Density or Specific Gravity | | | |
| - Viscosity | | | |
| - Vapour Pressure | | | |
| - Stability | | | |
| - Sample(s) of active ingredient(s) | | | |
| 4. Environmental Chemistry & Toxicity | | | |
| - Vapour pressure | | | |
| - Hydrolysis | | | |
| - Solubility in Water | | | |
| - Octanol-Water Partition Coefficient | | | |
| - Adsorption/ Desorption Measurements | | | |
| - Analytical Methodology (Soil, Water) | | | |
| - Biotransformation in Soil | | | |
| - Toxicity to Fish (Rainbow trout) | | | |
| - Toxicity to <i>Daphnia magna</i> | | | |

| Information | Submitted | Received | Comments |
|---|-----------|----------|----------|
| 4. Mammalian Toxicity Data | | | |
| - Acute Oral | | | |
| - Acute Dermal | | | |
| - Acute Inhalation | | | |
| - Primary Eye Irritation | | | |
| - Primary Dermal Irritation | | | |
| - Dermal Sensitization | | | |
| 5. Canadian Manufacturer | | | |
| - Name, Address of Canadian Manufacturing Plant | | | |
| - Letter of Support From Manufacturer | | | |
| - Draft Label for the Product to be Exported | | | |
| - Specification Form | | | |
| - MSDS for Exported Product | | | |

A Representative List of Relevant Provincial Legislation and Responsible Departments*

***Note:** This is a representative list only. It is the responsibility of the applicant/registrant to obtain all necessary approvals prior to importing the pest control product for manufacturing use.

ALBERTA

| | | |
|--|-------------------|----------------|
| Alberta Labour | General Inquiries | (403) 427-6971 |
| Occupational Health & Safety Division | FAX | (403) 427-5698 |
| Room 902 | WHMIS | (403) 427-2687 |
| 10808-99 Avenue | | |
| Edmonton, Alberta | | |
| T5K 0G5 | | |

BRITISH COLUMBIA

The Workers' Compensation Board is mainly responsible for occupational health and safety in British Columbia.

Workers' Compensation Board of British Columbia
6951 Westminister Highway
Richmond, British Columbia
V7C 1C6

Mailing Address:

| | | |
|-----------------------------|-------------------|----------------|
| Workers' Compensation Board | General Inquiries | (604) 273-2266 |
| Box 5350 | FAX | (604) 279-7409 |
| Vancouver, British Columbia | WHMIS | (604) 273-2266 |
| V6B 5L5 | | |

MANITOBA

| | | |
|-----------------------------|-------------------|----------------|
| Workplace Safety and Health | General Inquiries | (204) 945-3446 |
| Manitoba Labour | Toll-free | 1-800-282-8069 |
| 1000 - 330 St. Mary Avenue | WHMIS | (204) 945-3603 |
| Winnipeg, Manitoba | | |

R3C 3Z5

NEW BRUNSWICK

| | | |
|--|-------------------|----------------|
| Occupational Health and Safety Commission | General Inquiries | (506) 453-2467 |
| P.O. Box 6000 | Toll-free | 1-800-442-9776 |
| Fredericton, New Brunswick E3B 5H1 | WHMIS | (506) 453-2467 |

NEWFOUNDLAND

| | | |
|--|-------------------|----------------|
| Occupational Health and Safety Division | General Inquiries | (709) 729-2721 |
| Department of Employment and Labour Relations | FAX | (709) 729-6639 |
| Confederation Building | Toll-free | 1-800-563-5471 |
| P.O. Box 8700 | WHMIS | (709) 729-5548 |
| St. John's, Newfoundland A1B 4J6 | | |

NOVA SCOTIA

| | | |
|--|-------------------|----------------|
| Occupational Health and Safety Department of Labour | General Inquiries | (902) 424-8400 |
| 5151 Terminal Road, 6th Floor | FAX | (902) 424-3239 |
| P.O. Box 697 | Toll-free | 1-800-424-8603 |
| Halifax, Nova Scotia B3J 2T8 | WHMIS | (902) 424-5402 |

ONTARIO

| | | |
|--|-------------------|----------------|
| Occupational Health and Safety Division | General Inquiries | (416) 326-7744 |
| Ministry of Labour | FAX | (416) 326-7745 |
| 400 University Avenue, 9th Floor | WHMIS (London) | (519) 439-3231 |
| Toronto, Ontario M7A 1T7 | | |

PRINCE EDWARD ISLAND

| | | |
|--|-------------------|----------------|
| Occupational Health and Safety Division | General Inquiries | (902) 368-5470 |
| Department of Provincial Affairs and Attorney General | FAX | (902) 368-5526 |
| | WHMIS | (902) 368-5470 |

31 Gordon Drive
P.O. Box 2000
Sherwood, Prince Edward Island
C1A 7N8

QUÉBEC
Santé et sécurité des travailleurs

| | | |
|---|--|----------------|
| Commission de la santé et de la sécurité | Informations générales | (514) 873-7545 |
| au travail du Québec | Télécopieur | (514) 864-2912 |
| 1199, rue de Bleury | Service du répertoire toxicologique (<i>SIMDUT</i>) | (514) 873-6374 |

C.P. 6056, succursale A
Montréal (Québec)
H3C 4E1

Transport des matières dangereuses

| | | |
|---|-------------|----------------|
| Ministère des Transports | Téléphone | (418) 643-2235 |
| Division du transport des matières dangereuses | Télécopieur | (418) 644-9072 |

700, boul. René-Lévesque est
Place Hauteville, 23^e étage
Québec (Québec)
G1R 5H1

Environnement (procédé industriel, entreposage, gestion des déchets)

| | | |
|------------------------------|---------------------------|----------------|
| Ministère de l'Environnement | Informations générales | (418) 643-6071 |
| 3900, rue de Marly | Application réglementaire | (514) 873-3636 |
| Sainte-Foy (Québec) | Télécopieur | (514) 873-5662 |

G1X 4E4

SASKATCHEWAN***Occupational Health and Safety Act***

| | | |
|--|--------------------|----------------------------------|
| Occupational Health and Safety Branch | General Inquiries | (306) 787-4496 |
| Department of Human Resources, Labour and Employment | Toll-free WHMIS | 1-800-567-7233 (306) 787-4496 |
| 1870 Albert Street Regina, Saskatchewan S4P 3V7 | | |

Environmental Management and Protection Act

| | | |
|---|-------------------|----------------|
| Air and Land Protection Branch | General Inquiries | (306) 787-6185 |
| Environment and Resource Management | FAX | (306) 787-0197 |
| 3085 Albert Street Regina, Saskatchewan S4S 0B1 | | |

Dangerous Goods Transportation Act

| | | |
|---|-------------------|----------------|
| Regulation and Safety Branch | General Inquiries | (306) 787-5527 |
| Highways and Transportation | FAX | (306) 787-8610 |
| 1855 Victoria Avenue Regina, Saskatchewan S4P 3V5 | | |

Pest Control Products (Saskatchewan) Act

| | | |
|---|-------------------|----------------|
| Sustainable Production Branch | General Inquiries | (306) 787-4662 |
| Agriculture and Food | FAX | (306) 787-0428 |
| 3085 Albert Street Regina, Saskatchewan S4S 0B1 | | |

NORTHWEST TERRITORIES

| | | |
|---|-------------------|----------------|
| Department of Safety and Public Services | General Inquiries | (403) 873-7468 |
| P.O. Box 1320 | FAX | (403) 873-0117 |
| Yellowknife, Northwest Territories X1A 2L9 | WHMIS | (403) 873-7468 |

YUKON

| | | |
|-----------------------|-------------------|----------------|
| Department of Justice | General Inquiries | (403) 667-5450 |
| P.O. Box 2703 | FAX | (403) 667-3609 |
| Whitehorse, Yukon | Toll-free | 1-800-661-0408 |
| Y1A 2C6 | WHMIS | (403) 667-5450 |