

Health Canada

INDUSTRIAL HEMP GUIDE

SCHEDULE 2

IMPORTATION

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Aussi disponible en francais

SCHEDULE 2

INDUSTRIAL HEMP GUIDE - IMPORTATION

SCHEDULE SPECIFIC REGULATORY REFERENCES	
Industrial Hemp Regulations	Specific Sections 2, 3, 8 (1)(d)(e)(f)(i)(j) (1), 9 (2) (d), 18, 20, 21, 22, 23, 24, 25, and 32.
Seeds Regulations	Part IV of the Seeds Regulations - Authorized Importer

A. BACKGROUND:

These guidelines state generally applicable principles and practices that are acceptable to the Therapeutic Products Programme (TPP) and that should facilitate compliance with the *Industrial Hemp Regulations*

- **1.** All persons wishing to apply for licences, authorizations or permits should read the *Therapeutic Products Programme (TPP) Industrial Hemp Guide Overview.* It provides the necessary background to make it easier for applicants to comply with the Regulations.
- 2. The definitions contained in the Regulations in Appendix I and the explanations in the Glossary of Terms in Section 4 of the Overview must be well understood by the applicant.
- **3.** To be eligible to hold a licence, permit, or authorization, a person must be a resident of Canada. At least one of the partners in the case of a partnership, or, if the person is a corporation or cooperative, must have its head office in Canada or operate a branch office in Canada.
- 4. Importers of industrial hemp, in the form of seed or viable grain, must be licensed. *In addition to holding a licence they are also required to obtain a permit for each shipment.*
- 5. The importer must ensure that shipments of viable grain are accompanied by foreign certification as required by paragraph 19(1) to establish that the grain originates from that country. A list of countries approved for the importation of viable grain will be published by Health Canada indicating which countries are designated as having equivalent controls on the production of grain. Grain may only be imported from listed countries. See Attachment 1
- 6. Importers of derivatives must provide proof with each shipment that the shipment contains no more than 10 micrograms/gram (mcg/g) of THC for each lot. Similarly, products made from the derivatives of seed or grain must be accompanied with evidence that each shipment contains no more than 10 mcg/g of THC.
- 7. Person <u>are not</u> permitted to import a derivative or a product produced from a derivative if that product contains more than 10 mcg/g of THC.
- 8. Persons <u>are not</u> permitted to import, sell, or produce any derivative, or any product made from a derivative of whole plants, including sprouts, leaves, flowers or bracts of industrial hemp.

B. WHO MUST HAVE A LICENCE:

All persons wishing to import industrial hemp must apply for a licence.

C. FORMS TO BE COMPLETED:

- **1.** Industrial Hemp Licence Application
- 2. Schedule 6 if the applicant is a Corporation, Cooperative or Partnership
- **3.** Schedule 2

D. COMPLETING THE <u>SCHEDULE 2</u> FORM:

An applicant who does not own or operate an establishment registered under Part IV of the *Seeds Regulations* that will condition or prepare, as the case may be, the seed or viable grain, **cannot be licensed** for this activity.

1. Applicant Information:

- (a) Provide the surname and given names if the applicant is an individual.
- (b) Provide the Registered name if the applicant is a Corporation, Cooperative or Partnership.
- (c) Use the same name here that you gave on the Industrial Hemp Licence Applicatione.
- (d) Provide the complete legal description of the site to be licensed. A Post Office Box is not acceptable as a post office box cannot be licensed.

Legal Description: There are several ways used to provide a legal description of the location to be licensed. Systems will vary from Province to Province and even within a Province. For example, the legal description for a cultivation site in Ontario may be:

North 1/2 of Lot 9, Concession II, Township of Goulburn, County of Carleton

Only in New Brunswick it is the 911 number, which is the accepted "legal description" in that province.

- (e) Provide the address at which the records, books, electronic data or other documents required by the Regulations will be kept. If the records are kept at a place other than the licensed site, the licence holder must make them available for inspection as necessary.
 - A Post Office Box is not acceptable. You cannot store records in a post office box.

- (f) Provide the number issued under the *Seeds Regulations* to this **Authorized Importer** establishment.
- (g) Enclose a **copy** of the **operator's licence** issued under Section 96 of Part IV of the *Seeds Regulations*.
- (h) Enclose a **copy** of the **Certificate of Registration** for establishments under Part IV of the Seeds Regulations.
- (i) Provide the surname and given names, date of birth, sex, and the position within the organization, of the licensed operator.

2. About the Importation

(a) Indicate all forms in which the industrial hemp is to be imported.

Example:	If the applicant anticipates importing both seed and oil, then both
	should be checked on the application.

- (b) List the complete address at which industrial hemp will be stored only and no other activity requiring a licence will take place.
 - **Note:** As it is illegal to store industrial hemp at an unlicensed location all such locations must be listed. If, however, sale or distribution is to take place at a location it should not be listed here as it must be licensed for that activity.
- (c) List all forms in which the industrial hemp will be stored.

3. Licence to Import Industrial Hemp Certification

- (a) Provide the name, title and telephone number of the Person Responsible for ensuring compliance with the Regulations.
- (b) In the case of a corporation, cooperative or partnership, the name provided must be of a person who has the authority to bind the company. This is usually a Director or officer.
- (c) This is to be signed by the person signing the Industrial Hemp Licence Application, who may or may not be the person certifying, above.
- (d) Consent for Publication of Company Name:
 - This is to be signed by the person signing the Industrial Hemp Licence Application, who may or may not be the person responsible for ensuring compliance as named above.

If consent is given, the laboratory Name, Address, Phone Number, Fax Number, e-mail address and the activity for which the laboratory is licensed, will be published by Health Canada. Publication will include, but is not limited to, posting on the Therapeutic Products Programme's website (www.hc-sc.gc.ca/hpb-dgps/therapeut).

E. SUBMISSION TO HEALTH CANADA:

- 1. The Schedule 1 form submitted to Health Canada must bear an **original** signature. A **faxed or photocopied form will be considered incomplete and will be returned to the applicant.**
- 2. In the case of a corporation, cooperative or partnership, Schedule 6 must also be submitted.
- **3.** The completed Schedule 2 form
- **4.** Other documents which are required to satisfy the requirements of the Industrial Hemp Licence Application.

F. RECORDS TO BE KEPT A MINIMUM 2 YEARS INCLUDE:

- **1.** The form and quantity in which industrial hemp is purchased or sold.
- 2. The Variety of industrial hemp (cultivar) purchased and sold.
- **3.** The quantity and source of seed or viable grain of each approved cultivar imported.
- 4. The name of the person to whom seed or grain is delivered.
- **5.** Other information as outlined in the Regulations, paragraph 38(1)

G. POINTS TO BE CONSIDERED BY IMPORTER:

- **1.** You must ensure compliance with the Regulations.
- 2. You must provide adequate security.
- **3.** You must report thefts to police and the Bureau of Drug Surveillance.
- **4.** You must ensure transportation and storage are secure.
- **5.** You must only provide Industrial Hemp to licensed parties.

6. You must carry out the activities at licensed location only.

The requirement for a person or company to be a registered establishment under *Part IV* of the *Seeds Regulations* for purposes of conditioning seed or importing seed under the *Industrial Hemp Regulations*, is explaned below:

There are three types of establishment registration under the *Seeds Regulations* as referred to in Section 96 and defined in Section 78 of those regulations:

- **1.** Authorized Importer (AI)
 - "authorized importer" means an establishment that prepares imported seed and in respect of which a registration as an authorized importer is in force;
- **2.** Approved Conditioner (AC)
 - "approved conditioner" means an establishment that prepares seed of pedigreed status and in respect of which a registration as an approved conditioner is in force;
- **3.** Bulk Storage Facility (BSF)
 - "bulk storage facility" means an establishment that stores in bulk seed graded with a Canada pedigreed grade name and in respect of which a registration as a bulk storage facility is in force;

There is a requirement under the *Industrial Hemp Regulations* that a copy of the Certificate of Registration, issued under *Part IV* of the *Seeds Regulations* for the establishment at which the conditioning or seed preparation will take place, is submitted with applications to import or condition seed or viable grain. This requirement refers to the appropriate registration for the applicable activity.

Section 8(h)(ii)

"if the application is for conditioning seed or viable grain, a copy of the Certificate of Registration issued under Part IV of the *Seeds Regulations* for the establishment at which the conditioning will take place;" and

Section 8(i))

• "in the case of an importer of seed or viable grain, a copy of the Certificate of Registration issued under Part IV of the *Seeds Regulations* for the establishment at which the imported seed or viable grain will be prepared, and the address of that establishment;"

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Therefore, a person or company wishing to *condition* seed under sub-section 8(h)(ii) must be registered as an *Approved Conditioner*. Registration as an *Authorized Importer* or *Bulk Storage Facility* does not fulfill this requirement. A person or company wishing to *import* seed under sub-section 8(i) must be registered as an *Authorized Importer*. Registration as an *Approved Conditioner* or *Bulk Storage Facility* does not fulfill this requirement.

In both cases, the operator must also have the applicable licence from the Canadian Food Inspection Agency (CFIA) covering operation of the registered establishment for the specified purpose.

If you wish to import seed and do not fulfill the prerequisite condition for registration as an *Authorized Importer*, or *Approved Conditioner* you may wish to:

- Contact your local inspection office for the Canadian Food Inspection Agency, or the Registrar, Registered Seed Establishments at (613) 225-2342 for guidance as to how you may become a Registered Establishment of the applicable kind, or
- Make arrangements with a company that is an *Approved Conditioner* or *Authorized Importer* to have them apply for an Industrial Hemp Licence for the appropriate activity and handle this activity on your behalf.

ATTACHMENT 1

THERAPEUTIC PRODUCTS PROGRAMME INDUSTRIAL HEMP REGULATIONS

DESIGNATED COUNTRIES

Section 19(1) of the Regulations makes reference to countries or associations of countries which have been designated by the Minister as having controls on the production of viable grain that meet the requirements that are equivalent to those set out in these Regulations. The Therapeutics Products Programme will prepare and make available a list of those designated countries.

Present Status

At this time there are no designated countries or associations of countries.

Future Considerations

- Health Canada will add a country or association of countries when the requirements are met.
- Health Canada will collect data on the controls being applied in other countries.