

Health Canada Santé Canada

INDUSTRIAL HEMP GUIDE

SCHEDULE 4

PROCESSING

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Aussi disponible en francais

SCHEDULE 4

INDUSTRIAL HEMP GUIDE - PROCESSING

SCHEDULE SPECIFIC REGULATORY REFERENCES	
Industrial Hemp Regulations	Specific Sections 3, 8 (1)(d)(f)(h)(j) and (I)] and 9 (2) (d), 31, 32, 33, 35, 37, 38
Seeds Regulations	Part IV of the Seeds Regulations— Approved Conditioner.

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 on the Regulations 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.
 - (a) **Processors**
 - Definition: "Process", in respect of seed, viable grain or non-viable cannabis seed, includes conditioning it, pressing it, or, in the case of seed or viable grain, rendering it non-viable.
 - Licences are required for processing activities, such as pressing seeds or grain into oil. The maintenance of a clear audit trail is also required.
 - Special requirements apply if the processing is for cleaning and/or conditioning. See Schedule 4 for more details.

B. WHO MUST HAVE A LICENCE:

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

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C. FORMS TO BE COMPLETED:

- 1. Industrial Hemp Licence Application
- 2. Schedule 6 if the applicant is a Corporation, Cooperative or Partnership
- **3.** Schedule 4

D. COMPLETING THE <u>SCHEDULE 4</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) The name given on the Industrial Hemp Licence Application is to be used here.
- (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 here. Records cannot be stored in a Post Office Box.
 - 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

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should not be listed here since that site must be licensed for that activity.

- (f) List all forms in which the industrial hemp will be stored.
- (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** issued for the establishment 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.
- (j) Indicate the activity for which a licence is requested.

2. About the Processing:

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

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

(b) List all forms in which the industrial hemp will be stored.

3. Licence to Process 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.

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, a completed Schedule 6 must also be submitted.
- **3.** Include a completed Schedule 4 form.
- 4. Attach other documents which are required by the Industrial Hemp Licence Application.

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

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

G. POINTS TO BE CONSIDERED BY PROCESSORS:

- **1.** Licensee must ensure compliance.
- 2. Sampling must be done by authorized sampler.
- **3.** THC testing may be required by regulation, or as a condition of licensing. (Identify these requirements early to avoid problems. Requirements may be posted on the web and supplied as attachments to your Industrial Hemp Licence)
- 4. You must clean processing and handling equipment thoroughly.
- 5. You must provide adequate security.
- 6. You must report thefts to police and the Bureau of Drug Surveillance.
- 7. You must ensure that both transportation and storage are secure.
- 8. You must purchase seed or viable grain from licensed seed supplier.
- 9. You must only provide Industrial Hemp to licensed parties.
- **10.** You must carry out these 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 explained below:

There are three types of establishment registrations 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;"

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 you can 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.

LICENCE TO PROCESS INDUSTRIAL HEMP

This schedule is to be completed by those intending to process Industrial Hemp.

Applicant Information

The surname and given names of the applicant must be on this Schedule.

- The complete legal description of the site being licensed must be provided.
- The address at which the records, books, electronic data or other documents required by the Regulations will be kept must be provided.

About the Processing

- All forms of industrial hemp which will be processed must be indicated. If applicant intends to process non-viable Cannabis seed to produce oil or seed cake, an authorization is required. Thus, this activity should be indicated, if applicable.
- The activities for which a licence is being requested are to be indicated. If two activities are contemplated, then check both.
- If the conditioning of seed or viable grain is to be licensed, the applicant must attach a copy of the Certificate of Registration issued under Part IV of the *Seeds Regulations* for establishments must be attached.
- If requesting licensing as a conditioner then a copy of the operator's licence issued under Section 96 of Part IV of the *Seeds Regulations* must be attached.
- If requesting licensing as a conditioner then the complete name of the Licensed Operator must be provided.
- The complete address at which Industrial hemp will be stored only is to be listed. As it is illegal to store at an unlicensed location all such locations must be listed. However, if processing is to take place at a location then it is not to be listed here. In this latter case a separate Schedule 4 must be completed

Certification

- The name of the person responsible for ensuring compliance with the Regulations, the title of this person within the organization and his/her telephone number must be provided.
- The person responsible for ensuring compliance with the Regulations must sign the application.