THERAPEUTIC PRODUCTS PROGRAMME (TPP) INDUSTRIAL HEMP GUIDE

OVERVIEW

Please read carefully. Incomplete or illegible applications cannot be processed and will be returned.

This guide does not have any official legal status. It is a reference document and appropriate official documents should be consulted.

Ce document est également disponible en français.

1. PURPOSE

This guideline refers to the ***Industrial Hemp Regulations (IHR)***, annexed to the ***Controlled Drugs and Substances Act (CDSA)*** and is intended to provide an explanation of the Regulations. The Regulations and the ***Regulatory Impact Analysis Statement (RIAS)*** were published in Canada Gazette, Part II, on March 13, 1998. While other groups may be able to provide information on the Regulations, please note that for detailed interpretation of the Regulations, you should contact the Bureau of Drug Surveillance, Health Canada.

These documents are available from the **Therapeutic Products Programme (TPP)** website **(http://www.hc-sc.gc.ca/hpb-dgps/therapeut)** or **Canada Communications Group, Ottawa, Ontario, KlA 0S9 Telephone - (613) 956-4802 or 1-888-566-6660**

Copies of the *Controlled Drugs and Substances Act* are available from:
Internet: **canada.justice.gc.ca/FTP/EN/Laws/** or the Canada Communications Group, Ottawa, Ontario, K1A 0S9, Phone - (613) 956-4802.

2. BACKGROUND

The *Industrial Hemp Regulations* introduced a licensing framework which provides a complete audit trail. All persons importing, cultivating, processing, transporting, testing viable seed, or exporting industrial hemp from Canada must obtain authorization, meet security requirements and maintain records.

Import and export permits are also required to ensure that each shipment is in compliance with the Regulations. This requirement supports the audit trail and provides Revenue Canada (Customs) with the information required to ensure that shipments entering or exiting Canada are not in contravention of the requirements of the *United Nations Single Convention on Narcotic Drugs.*

The Therapeutic Products Programme *Industrial Hemp Guide* was developed by the Therapeutic Products Programme (TPP), Health Canada, after consultation with those stakeholders most affected by the Regulations, some Provincial Governments, and other Federal Departments. The *Industrial Hemp Regulations* will be referred to in this document as “the Regulations”.

3. SCOPE

The scope of the publication includes activities relating to importation, exportation, possession, production, sale, provision, transport, sending, delivering and offering for sale, of industrial hemp.

Industrial hemp does not include any derivative of seed, viable grain or non-viable cannabis seed, or product made from that derivative, if the derivative or product contains no more than 10 mcg/g THC. The *Industrial Hemp Regulations* do not apply to the importation, exportation, sale or provision of whole industrial hemp plants, including sprouts, or the leaves, flowers, or

bracts of those plants, or any derivative or product made from them. These activities remain prohibited under the *Controlled Drugs and Substances Act*.

These guidelines state generally applicable principles and practices that are acceptable to the TPP and that should facilitate compliance with the *Industrial Hemp Regulations*. **The content of this publication should not be regarded as an official interpretation of the Regulations.**

During the evaluation of applications for licences, authorizations, or permits, and during inspections and other on-site activities carried out under the authority of the *Controlled Drugs and Substances Act*, the TPP will use this publication as a guide in judging compliance with the Regulations. Alternative means of complying with the Regulations will also be considered at such times.

These guidelines are not intended to cover every conceivable case. Further, as new technologies emerge, different approaches may be included.

Research Licences:

The Industrial Hemp Regulations do not apply to the Research Licence activities for industrial hemp, but some of the same principles may apply. **Health Canada will continue to issue licences for approved research studies related to the cultivation of hemp for industrial purposes under the *Narcotic Control Regulations*.**

The objectives of the research projects and the proposed methodology to reach the objectives must be described in sufficient detail to facilitate the evaluation of the scientific aspects of the research project.

Evaluation procedures are not the same for both types of applications. There are two process streams. In the case of research applications, a joint evaluation is conducted involving scientists from both Health Canada and Agriculture and Agri-Food Canada. Commercial applications are evaluated by a team of specialists in Health Canada.

Harmonization between both licensing schemes has been adopted where feasible.

4. GLOSSARY OF TERMS

The definitions contained in the Regulations appear in Appendix I.

Clarification is being provided in this section for some of the terms used in this document. They may have different meanings in other contexts. Definitions in the Regulations supersede any given in these Guidelines. They are “explained” here for reasons of clarification only.

(a) Where a **Section** number is referred to in the Guide, it refers to the section in the *Industrial Hemp Regulations* and not to sections in the Guide.

(b) **Person**, as defined in the Regulations, includes an individual, corporation, a cooperative and a partnership. The word “person” is used repeatedly in this sense throughout the document.

(c) **Production** is the method or process used in obtaining a controlled substance by any means. For example, it includes cultivation as well as processing grain to produce oil.

(d) **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 ½ of Lot 9, Concession II, Township of Goulburn, County of Carleton

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

(e) **Licensed location** refers to the site where the activity requiring licensing is going to take place. In the case of cultivation, the Global Positioning System (GPS) coordinates must also be provided.

(f) **Conditioner** is a person, or company applying a process to a seed lot that will modify the consistency of the lot in some manner.

(g) **Form of industrial hemp** appears several times in the Regulations and will be clarified below by examples.

FORM OF INDUSTRIAL HEMP	EXAMPLES
Seed	C "seed" is defined as any part of an industrial hemp plant that is represented, sold or used to grow a plant C this would include viable (capable of growing) achenes C this may be seed that is acquired, sold or provided for sowing C this may be seed resulting from cultivation under the appropriate conditions for sowing
Viable Grain	C "viable grain" means a viable achene of an industrial hemp plant, **not** represented, sold or used to grow a plant C viable achenes resulting from cultivation, but not grown for sowing C intact viable achenes that are used for processing

FORM OF INDUSTRIAL HEMP	EXAMPLES
Non-viable Cannabis Seed	C are intact seeds or viable grain which have been steam sterilized for at least 15 min. to render them non-viable and have subsequently been shown to be incapable of germination (see *Industrial Hemp Technical Manual - TPP-BDS-005 and -006*) C are excluded from Schedule II of the CDSA and therefore excluded from the Regulations
Seed Derivatives	C derivatives of seed, viable grain and non-viable cannabis seed, include hemp seed oil, hemp seed cake, hemp seed extract C derivatives are included unless there is evidence that they contain no more than 10 micrograms per gram THC [1] C does not include intact seed or viable grain
Products made from Seed Derivatives	C products made from hemp seed derivatives include items such as shampoo which contains hemp seed oil C products are included unless the starting derivative or product contains 10 mcg/g THC or less and the product is not modified to increase the THC level.

For a licencee growing for viable grain:

C the form in which it will be cultivated is viable grain, but the form in which it will be possessed and stored could include seed (before planting) and viable grain (after harvesting).

For a processor who is going to produce oil from viable grain:

C the form in which it will be produced is oil, but the form in which the industrial hemp is possessed and stored would be viable grain, oil, seed-cake, etc.

For a licencee growing for fibre:

[1] delta-9-tetrahydrocannabinol

- the form in which it will be produced is fibre, but the form in which the industrial hemp is possessed and stored would be seed (before planting) since the fibre is excluded.

When seed or viable grain is harvested, the plants are cut down. This means that the mature stalks which result, if **free from leaves, flowers, seeds or branches**, fall out of the scope of the Regulations.

If a distributor possesses a seed derivative such as oil that contains no more than 10 mcg/g THC, it is below the limit defined as "industrial hemp" and would no longer be referred to as the "form". The oil would have to be tested, by a competent laboratory, to prove that it contains no more than 10 mcg/g THC. (See Appendix I Definitions).

5. LICENCES

(a) Requirement to Hold a Licence

The Application section of the Regulations, Sections 2 and 3 describe which activities do and do not apply within the licensing framework.

(b) Who must have a licence

An industrial hemp licence or authorization is required for all persons in Canada engaged in any of the following activities related to the production of industrial hemp. The activities are importation, exportation, possession, production, sale, provision, transport, sending, delivering, and offering for sale of industrial hemp (Regulations - Section 5).

A person who performs THC testing will require a valid licence as a dealer of narcotics under the *Narcotic Control Regulations* (NCR). Also, an establishment where these tests are performed may require an Establishment Licence under separate regulations.

Persons wishing to receive a licence as the Qualified Person in Charge of the testing laboratory, should send a written request to the Bureau of Drug Surveillance.

(c) General Licensing Information

All parties, licensed or authorized, must identify a person resident in Canada who will be responsible for the licensed activities

To obtain a licence for the importation, exportation, production, or sale of industrial hemp, applicants will be required to produce the **original** of a current police security check.

The Regulations require that applicants provide data on convictions for any "designated drug offence" during the last 10 years. See Appendix 1 for definition. This may be forwarded directly by the police service.

Authorizations will be required for transportation, when products are transported outside the direction or control of a licence holder, or for possession for the purpose of testing for viability or sampling of industrial hemp.

(d) Licence/ Authorization Amendments

Section 10 of the Regulations defines requirements for a licence amendment, including the following changes:

- Change in licensed activities
- Change in licensed location
- Change in number of hectares and GPS coordinates
- Change in storage address
- Change in the form of industrial hemp for licensed activity
- Change in conditions affecting security, public health or safety hazards related to licensed activities

There may be other changes that take place that are not significant enough to trigger the need for an amended licence but about which it may be prudent to advise the TPP to avoid accidental breaches of the license conditions.

(e) Licence/ Authorization Notification

Section 11 of the Regulations defines changes which require that the licence holder notify the TPP **within 15 days** after making the change:

- Change in officers, directors, etc.
- Change in address where records kept.
- Change in the licensed operator in a Registered Seed Establishment.
- Change in the mailing address.
- Change in ownership of the cultivation site.
- Change in the approved cultivar being sown, or variety being sown in the case of a plant breeder.
- Person ceases to be member of Canadian Seed Growers Association (CSGA).
- Person ceases to be a holder of required certificates, or licences.

Health Canada must be notified as soon as possible if a licence or authorization is lost or stolen.

(f) Refusal to Issue License/ Authorization/ Amendment

Sections 9(2) and 10(2) specify the situations in which an application for a licence, authorization, or amendment *must* be refused and sections 9(3) and 10(3) specify the situations in which it *may* be refused.

Applicants will be notified in writing of the rationale for refusing to issue or amend a licence or authorization. The applicant will be provided with an opportunity to present an appeal, if the applicant believes that the refusal is not warranted.

(g) Licence/Authorization Revocations

Section 13(2) specifies the circumstances in which a licence or authorization *will* be revoked and section l3(3) specifies the circumstances under which it *may* be revoked.

Applicants will be notified in writing of the rationale for revocation of the licence or authorization. The applicant will be provided with an opportunity to present an appeal, if the applicant believes that the refusal is not warranted.

(h) Appeal Procedures

Appeals of refusal to issue or amend a licence or authorization, or a revocation of a licence or authorization, must be received within **30 calendar days** following issuance of written notice of the TPP decision. All appeals must be received in writing, by mail or fax and addressed to the Director General (DG) of the Therapeutic Products Programme. The DG will review the decision in question in consultation with the Bureau of Drug Surveillance and send the appellant a reply, which will include the decision on the appeal and the rationale for the decision.

6. APPLICATION

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.

Application Form

The application form is one provided by Health Canada. A hard copy of the form, **with original signatures**, must be submitted to the Bureau of Drugs Surveillance. See Appendix II for details.

- The form must be completed by persons making application for a licence, permit or authorization with details on each activity to be regulated.

- Persons are encouraged to consolidate all of their information on sites, activities and personnel in one application package using multiple Schedules as necessary, although the sites may be in different locations. This should lead to administrative efficiencies for both the applicant and the Therapeutic Products Programme.

One licence number will be issued for each location although multiple activities may be approved for that site. **Licences are issued to persons to perform specified activities at one site.**

- Application should be made well in advance of commencing the activity, unless excluded by Regulations, to provide the authorities with enough time to evaluate, issue, or refuse to issue approval documents for the activity. The applications will be processed in the order received. Exceptions will be made in those cases where the activity, such as importing, will be essential to other applicants.

- Table I, Appendix III, is provided as a quick reference of the application forms to be completed and submitted to Health Canada. To ensure an expedited review of your

application, use the specific Guide and complete all the sections on the Application Forms that apply.

Completing the Form

- All applicants must complete the Industrial Hemp Licence Application Form.
- Schedules l to 8 are to be used as necessary depending on the activity for which licensing is required.
- Applications will not be processed without the appropriate **original** signatures.

7. IMPORTERS AND EXPORTERS

- Importers and exporters of industrial hemp, in the form of seed or viable grain, must be licensed. In addition to holding a licence, they are required to obtain a permit for each shipment.

- A person or company wishing to ***import*** seed under sub-section 8(1)(i) of the *Industrial Hemp Regulations* must be registered as an ***Authorized Importer.*** Registration as an *Approved Conditioner* or *Bulk Storage Facility* does not fulfill this requirement. See Schedule 2, Application Form and Guide.

  - "authorized importer" means an establishment that prepares imported seed and in respect of which a registration as an authorized importer is in force.

- A list of countries approved as sources 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. Viable grain may only be imported from listed countries. The list, *Industrial Hemp Regulations - Designated Countries*, will be amended from time to time. See Appendix IV.

- Importers and exporters of derivatives will be required to provide proof with each shipment that the shipment contains no more than 10 mcg/g of THC for each lot. Similarly, products made from the derivatives of seed or grain must be accompanied by evidence that each shipment contains no more than 10 mcg/g of THC.

- *No person will be permitted to import, or export a derivative or a product produced from a derivative that contains more than 10 mcg/g of THC. IHR - Paragraph 2(2)(c).*

- *No person will be permitted to import, sell, provide, or produce any derivative, or any product made from a derivative of whole plants, including sprouts, leaves, flowers or bracts of industrial hemp. IHR paragraph 2(2)(b).*

8. DISTRIBUTORS

The term "distributor" does not appear in the Regulations. It relates to persons or companies who are licensed to possess, sell and/or provide regulated forms of industrial hemp. In order to define the scope of the distributor who must obtain a licence for activities such as

possession and sale, the licensing framework excludes establishments which are only engaged in the retail sale of derivatives (providing that the derivatives are covered by certificates of analysis showing that the derivatives or products made from the derivative have a THC level of 10 micrograms per gram or less).

- *As a condition of licensing, Distributors will only be permitted to distribute approved cultivars in the case of seed, and only to licensed growers.*

- In the case of viable grain, distribution will be restricted to licensed processors.

- See Table II - Permitted Movement of Industrial Hemp - Appendix V.

9. CULTIVATION

"Approved cultivar" means any variety of industrial hemp designated by the Minister in accordance with section 39 and set out in the *List of Approved Cultivars* published by the Department of Health, as amended from time to time. See Appendix VI.

(a) General

- Only approved varieties (cultivars) of industrial hemp seeds, as listed on Health Canada's *List of Approved Cultivars* may be planted.

- Commencing January 1, 2000, only pedigreed seeds of approved varieties may be planted.

- Growers are required to identify their fields, including GPS coordinates, and maintain records of production and distribution.

- Administrative guidelines will provide information concerning compliance action where the crop produced from approved varieties exceeds the 0.3% THC limit stated in the Regulations.

- Enforcement options range from immediate harvesting to destruction depending on the THC level and the circumstances.

- Growers are responsible for ensuring that their seed supplier is licensed by Health Canada.

- To allow the use of non-certified seed of approved cultivars during a transition period, the Regulations have been modified to provide an exemption until January 1, 2000.

- A 4 hectare minimum applies to growing for fibre or grain.

- Seed growers are restricted to a 0.4 hectare minimum plot size.

- Plant breeders are not restricted to minimum plot sizes.

- Seed growers are required to demonstrate current membership in the Canadian Seed Growers Association as part of their licence application.

- The pedigreed seed restriction which applies to growers in the year 2000 does not apply to plant breeders nor does the limitation to the *List of Approved Cultivars.*

- The cultivation of industrial hemp within one kilometre of any school grounds or any other public place usually frequented by persons under the age of 18 years is prohibited.

(b) Plant Breeders

Plant breeders are persons who, using known varieties, will be introducing new Canadian varieties, or producing breeder seed in Canada.

Breeders must be:

- Recognized by the Canadian Seed Growers Association as a full plant breeder and obtain a certificate or other documentation to prove that recognition. (Submit a copy of this documentation at the time of application for a licence). The intent is that Plant Breeders will be able to enter new varieties into the system.

(c) Sampling

- Sampling for THC content must be done at the time of harvest (if for fibre), or, at the latest, when 50% of the seeds resist compression, that is, before seeds are mature.

- This monitoring will allow for better control over the varieties which are sown in Canada.

- Sampling must be carried out by persons trained and experienced in seed sampling. The sampler shall be independent of any commercial interest which might influence the sampling duties being carried out. The national or provincial department of agriculture may be able to advise on who can provide this service.

- Field sampling of hemp stands must be conducted by provincially designated professional or technical agrologists (or equivalent for those provinces having no such designation process), with experience in crop production and sampling, or by pedigreed-seed crop inspectors recognized by the Canadian Seed Growers Association for that purpose.

- Samplers must be authorized by Health Canada to perform the activity.

- In addition to the sampling performed on behalf of growers, designated government inspectors sample selected crop sites and testing is performed in government labs on those government samples as part of the monitoring process.

(d) Harvesting

- Details on the time of harvesting can be found in the *Industrial Hemp Technical Manual*.

- Harvesting for fibre is done at the same time as sampling for THC content, when 50% of the seeds resist compression (or before).

- Harvesting for seed or viable grain is done when the seeds are mature, although sampling for THC content must be done when 50% of the seeds resist compression.

(e) Farm Equipment Cleaning:

Section **17.** of the *Industrial Hemp Regulations* requires that a person who holds a licence to cultivate industrial hemp shall ensure that all equipment that is used to sow or harvest the hemp is thoroughly cleaned after each such use in order to avoid the accidental sowing of industrial hemp.

Failure to properly clean farm equipment could lead to "volunteer" plants in areas that are not licensed (outside the area identified with GPS coordinates) or appearing in rotational crops.

It is important to confine your cultivation of industrial hemp within licensed areas. If plants are observed, outside the licensed areas, this could potentially lead to police action, the laying of charges and/or the denial of a licence.

(f) Global Positioning System Coordinates (GPS)

GPS is a satellite based radio-navigation system which allows users to determine their three-dimensional position, velocity and time anywhere in the world. Based on current information, as a surveying tool, the available and affordable systems are able to provide a satisfactory level of accuracy that is acceptable to Health Canada.

The *Industrial Hemp Regulations* clearly stipulate that GPS coordinates must be submitted as part of the application in the case of the cultivation of industrial hemp. Subparagraph **8(1)(g)** of the Regulations (see Appendix VII) states that a person who applies for a licence or authorization shall submit certain information to the Minister, including the GPS coordinates to situate each site to be cultivated and a map showing the location of the site in terms of its legal description.

For an application to be complete, GPS coordinates sufficient to delimit the proposed site of cultivation **must** be included. You may request amendments to the licence at a later date to describe slight variations that may occur, if necessary.

See Schedule 2 or Schedule 7 Guides for more details.

10. 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 seed for sowing, or viable grain. See Schedule 4 for more details.

Derivatives

- Derivatives of seed or grain, such as oil and seed cake, are exempted from the Regulations if there is evidence that the derivatives contain no more than 10 mcg/g of THC and they carry appropriate labelling statements. Testing of these derivatives by the method outlined in the *Technical Manual* must support the labelling claims.

- Products made from derivatives of seed or grain are exempted if there is evidence that each lot or batch contains no more than 10 mcg/g of THC. Testing of these derivatives by the method outlined in the *Technical Manual* must support the labelling claims.

- Regulatory controls respecting the sale of foods cosmetics or animal feed *may* apply under separate regulations. Contacts are listed in Appendix VIII.

11. TESTING

“Competent laboratory” means a laboratory that is owned or operated by a person who is a licensed dealer under section 9 of the *Narcotic Control Regulations*, or a laboratory outside Canada that is recognized as a qualified laboratory, for the application of the United Nations’ *Single Convention on Narcotic Drugs, 1961*, as amended from time to time by the competent authorities of the country in which it is located.

- Testing for the level of THC in leaves or in derivatives must be done by a competent laboratory according to standards defined by Health Canada.

- Each country that is a signatory to the United Nation’s *Single Convention on Narcotic Drugs* is expected to have a competent authority in place. The designation of qualified foreign laboratories rests with the competent national authorities. The competent authority for each nation is listed in *Competent National Authorities under the International Drug Control Treaties, 1996* published by the United Nations, ISSN 0251-6799.

- In Canada, the competent national authority that issues licenses to laboratories which test for THC levels is Health Canada’s Therapeutic Products Programme. For more information, please submit a written request to the Bureau of Drug Surveillance.

- The *Industrial Hemp Regulations* do not require additional licensing of these laboratories as only facilities licensed as licensed dealers under the *Narcotic Control Regulations* are authorized to possess THC for the purpose of testing.

- The laboratories must maintain records of testing and meet other general licensing provisions contained within the Regulations.

- Laboratories must use test methods described in the *Industrial Hemp Technical Manual*.

- Written proposals for addition to the methods in the Technical Manual may be submitted for review. Any tests submitted must be able to meet the conditions set out in the *Acceptable Methods Guidelines* published by Health Canada. (Catalogue No. H42-2/63 - 1994).

12. COMPLIANCE

- The Regulations include compliance provisions such as: licensing or authorization of persons responsible for the activity, testing requirements, record keeping and controls on the location of fields for cultivation.

- *A Compliance Policy and Enforcement Guideline* will be developed and posted on the Therapeutic Products Programme website so that this information is readily available to all parties.

- This Guideline, which will be developed in cooperation with other Departments, will delineate the responsibilities of the respective departments and agencies.

- Persons failing to comply with the regulatory requirements within the Regulations could have their licence, authorization or permit revoked or refused.

- Persons in illegal possession of *Cannabis*, including unauthorized industrial hemp, will be liable for prosecution under the *Criminal Code* and penalties defined within the *Controlled Drugs and Substances Act*.

- Failure to properly clean farm equipment could lead to “volunteer” plants in areas that are not licensed (outside the area identified with GPS coordinates).

- No person shall advertise to imply that a derivative or product is psychoactive.

Crops Testing In Excess of 0.3% THC W/W

Where the THC content of a crop is found to exceed the expected maximum levels of 0.3% as stated in the Regulations, the issue will be handled administratively according to Health Canada guidelines which could include immediate harvesting all the way through to destruction depending on the individual circumstances.

13. END USE AND POSSESSION

Whereas the *Industrial Hemp Regulations* do not mandate the end use of the industrial hemp, producers may be wise to note that other government regulations may not permit the use of industrial hemp or its derivatives in products intended for oral or topical use. Examples are oil in foods for human consumption, or cosmetics and seedcake for animal feed.

While there is no requirement in the Regulations for the licensee to indicate an end user, it should be noted that possession, beyond the licensed period, of forms of industrial hemp that require licensing and/or authorization is prohibited under the *CDSA* and could result in charges being laid.

Since the possession and distribution of mature stalks and fibre derived from the stalks are not restricted under the Act, persons wishing to use these materials can engage freely in trade in this area providing that the stalks are free from seeds, branches, leaves, bracts and flowers.

14. ADMINISTRATIVE

The information that is required with the licence application will be entered into the *Industrial Hemp Licence System* (IHLS) database in order to generate the official licence, permits and related documents. It is important to ensure that all the relevant information and attachments are submitted. **Incomplete or illegible applications will not be processed, but will be returned to the applicant.**

15. OTHER REGULATORY CONTROLS

- Regulatory controls respecting the sale of foods, cosmetics or animal feed *may* apply under separate regulations. For example, the *Food and Drugs Act Cosmetics Regulations;* The *Feeds Act*.

- For contact names for food cosmetics and animal feed, see *Other Contacts* in *Appendix VIV*.

16. POINTS TO CONSIDER

- Bulk seed or grain must be stored and transported in a sealed “package” which could be a sack, bag, barrel, case or any other container in which seed or viable grain, or their derivatives, are placed or packed. It is intended that silos and boxcars would qualify as packages under the definition as it is used in these Regulations.

- The package must be sealed in a way that makes it impossible for it to be opened without leaving evidence that it was opened.

- If you intend to plant seed, you should retain the seed tags or proof that it is of an approved cultivar. An inspector may request that you produce this evidence.

APPENDIX I INDUSTRIAL HEMP REGULATIONS - Definitions

The definitions in this section apply in these Regulations.

C "**Act**" means the *Controlled Drugs and Substances Act*. (*Loi*)

C "**approved cultivar**" means any variety of industrial hemp designated by the Minister in accordance with section 39 and set out on the *List of Approved Cultivars* published by the Department of Health, as amended from time to time. (*cultivar approuvé*)

C "**competent laboratory**" means a laboratory that is owned or operated by a person who is a licensed dealer under section 9 of the *Narcotic Control Regulations*, or a laboratory outside Canada that is recognized as a qualified laboratory, for the application of the United Nations' *Single Convention on Narcotic Drugs*, 1961, as amended from time to time, by the competent authorities of the country in which it is located (laboratoire compétent)

C "**designated drug offence**" means

- an offence against section 39, 44.2, 44.3, 48, 50.2 or 50.3 of the *Food and Drugs Act*, as those provisions read immediately before May 14, 1997;
- an offence against section 4, 5, 6, 19.1 or 19.2 of the *Narcotic Control Act*, as those provisions read immediately before May 14, 1997;
- an offence under Part I of the Act, except subsection 4(1); and
- a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in paragraphs (*a*) to (*c*). (*infraction désignée en matière de drogue*)

C "**industrial hemp**" means

- the plants and plant parts of the genera *Cannabis*, the leaves and flowering heads of which do not contain more than 0.3% THC w/w, and includes the derivatives of such plants and plant parts. It also includes the derivatives of non-viable cannabis seed. It does not include plant parts of the genera *Cannabis* that consist of non-viable cannabis seed, other than its derivatives, or of mature cannabis stalks that do not include leaves, flowers, bracts, seeds or branches, or of fibre derived from those stalks. (*chanvre industriel*)

C "**person**" includes a corporation, a cooperative and a partnership. (*personne*)

C "**package**" includes a sack, bag, barrel, silo case or any other container in which seed, viable grain or its derivatives are placed or packed. (*emballage*)

C "**plant breeder**" means a person who is recognized as a plant breeder pursuant to the circular entitled *Regulations and Procedures for Pedigreed Seed Crop Production*, as amended from time to time, published by the Canadian Seed Growers' Association. (*sélectionneur de plantes*)

C "**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, render it non-viable. (*transformer*)

C "**seed**" means any part of an industrial hemp plant that is represented, sold or used to grow a plant. (*semence*)

C "**THC**" means delta- 9-tetrahydrocannabinol ((6aR, 10aR)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol). (*THC*)

C "**variety**" has the same meaning as in subsection 2(2) of the *Seeds Regulations*. (*variété*)

C "**viable grain**" means a viable achene (a small fruit with a dry, shell-like covering similar to barley, wheat, corn and rice) of an industrial hemp plant, not represented, sold or used to grow a plant, that is used for processing. (*grain viable*)

APPENDIX II Sources of Industrial Hemp Licence Application Forms

Licence application forms are available from:

Industrial Hemp Program, Bureau of Drugs Surveillance
Therapeutic Products Directorate, Health Protection Branch
Address Locator #AL 0201D3, Finance Building
Tunney's Pasture
Ottawa, Ontario, KlA lB9
Phone: (613) 954-6524, Fax: (613) 941-5360

Licence application forms can be obtained in hard-copy:

- by mail
- by pre-arranged pick-up at the Finance Building, Tunney's Pasture, Ottawa, Ontario, first floor
- from Health Protection Branch Regional Offices - Contact List, Appendix VIII
- by pre-paid or COD courier service

Licence application forms can be obtained in electronic format:

- from the Therapeutic Products Website **(www.hc-sc.gc.ca/hpb-dgps/therapeut/)**
- by e-mail to: **Hemp_Tpd@hc-sc.gc.ca**

Electronic filing is not available because of the need for signatures.

Applications will be received and processed by, the Industrial Hemp Unit. Completed applications should be sent to the above address.

Questions regarding the processing of licence applications should be directed to the Industrial Hemp Program, at (613) 954-6524.

Instructions for completing the Application Form can be found in Appendix VII.

APPENDIX III

TABLE I: FORMS TO BE SUBMITTED TO HEALTH CANADA

PERSONS WISHING TO	If an individual	If a corporation, cooperative and/or partnership
Cultivate Industrial Hemp	C Industrial Hemp Application C Schedule 1	C Industrial Hemp Application C Schedule 1 C Schedule 6
Import Industrial Hemp	C Industrial Hemp Application C Schedule 2 C Import permit application if licensed to import	C Industrial Hemp Application C Schedule 2 C Schedule 6 C Import permit application for each importation, if licensed to import
Export Industrial Hemp	C Industrial Hemp Application C Schedule 3 C Export permit application if licensed to export	C Industrial Hemp Application C Schedule 3 C Schedule 6 C Export permit application if licensed to export
Process Industrial Hemp	C Industrial Hemp Application C Schedule 4	C Industrial Hemp Application C Schedule 4 C Schedule 6
Sell or Provide	C Industrial Hemp Application C Schedule 5	C Industrial Hemp Application C Schedule 5 C Schedule 6
Conduct Plant Breeding of Industrial Hemp	C Industrial Hemp Application C Schedule 7	C Not applicable
Conduct Industrial Hemp Viability Testing	C Not applicable	C Industrial Hemp Application C Schedule 6 C Schedule 8
Authorization to possess, transport, send deliver, if not licensed	C Industrial Hemp Application C Schedule 9	C Industrial Hemp Application C Schedule 6 C Schedule 9
Authorization to Sample	C Application for Authorization to Sample	C Not Applicable

APPENDIX IV

IMPORTATION OF VIABLE GRAIN

Designated Countries

Section 19(l) 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 are equivalent to those set out in these Regulations. The Therapeutic Products Programme will prepare and make available a list of those designated countries as countries are recognized that meet this requirement.

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.

APPENDIX V

TABLE II - PERMITTED MOVEMENT OF INDUSTRIAL HEMP

LICENSEE	FORM THAT MAY BE DISTRIBUTED	FORM WHICH MAY ONLY BE DISTRIBUTED PROVIDED OR SOLD TO
Importer	C imported seed C test samples	C plant breeder C seed grower C grain grower C fibre grower C distributor C conditioner C processor C viability test laboratory C exporter
	C imported viable grain C test samples	C distributor C conditioner C processor C viability test laboratory C exporter
Distributor	C imported seed C Canadian produced seed C test samples	C plant breeder C seed grower C grain grower C fibre grower C distributor C conditioner C processor C exporter C viability test laboratory
	C imported viable grain C Canadian produced grain C test samples	C processor C exporter C viability test laboratory
Seed Grower	C Canadian produced seed C test samples	C seed grower (multiply pedigreed) C grain grower C fibre grower C distributor C conditioner C processor C exporter C viability test laboratory

LICENSEE	FORM THAT MAY BE DISTRIBUTED	FORM WHICH MAY ONLY BE DISTRIBUTED PROVIDED OR SOLD TO
Conditioner	C imported seed C Canadian produced seed C test samples	C seed grower C grain grower C fibre grower C distributor C processor C exporter C viability test laboratory
Grain Grower	C Canadian produced viable grain C test samples	C processor C exporter C viability test laboratory
Fibre Grower	C test samples	C viability test laboratory C competent laboratory
Processor	C imported viable grain C Canadian produced grain C test samples	C processor C exporter C viability test laboratory C competent laboratory
Exporter	C seed C viable grain C test samples	C foreign buyer only C viability test laboratory

APPENDIX VI

APPROVED CULTIVARS FOR THE 1999 GROWING SEASON

THERAPEUTIC PRODUCTS PROGRAMME
INDUSTRIAL HEMP REGULATIONS

PROVISIONAL LIST OF APPROVED CULTIVARS FOR THE 1999 GROWING SEASON
Cannabis sativa

The following Industrial Hemp varieties are approved for commercial cultivation in 1999:

VARIETY	COUNTRY WHERE MAINTAINED
Anka	Canada
C S	Italy
Carmagnola	Italy
Fasamo	Germany
Fedora 19	France
Fedrina 74	France
Felina 34	France
Ferimon	France
Fibranova	Italy
Fibriko	Hungary
Fibrimon 24	France
Fibrimon 56	France
Futura	France
Kompolti	Hungary
Kompolti Hibrid TC	Hungary
Kompolti Sargaszaru	Hungary
Lovrin 110	Romania
Uniko B	Hungary

The *List of Approved Cultivars* applies to all of Canada and no varieties are exempted from routine testing as outlined in the *Industrial Hemp Technical Manual.*

A person who applies for a licence or authorization shall submit the following information and documents to the Minister, on a form provided by the Department of Health:

(1) in the case of the cultivation of industrial hemp,

(2) the approved cultivar that will be sown, or the variety of industrial hemp if the applicant is a plant breeder,

(3) the number of hectares to be cultivated for seed or viable grain and the number of hectares to be cultivated for fibre,

(4) the number of hectares cultivated for industrial hemp, at each site, in each of the previous two years,

(5) the Global Positioning System coordinates to situate each site to be cultivated and a map showing the location of the site in terms of its legal description,

(6) if any part of the site is to be cultivated for seed or viable grain, the Global Positioning System coordinates to situate that part of the site, and an indication on the map of its location within the site,

APPENDIX VII

INDUSTRIAL HEMP LICENCE CONTACT LIST

Mr. Niels Hansen-Trip

Phone: (613) 954-6524
Fax: (613) 941-5360

Manager, Industrial Hemp Regulation
Bureau of Drugs Surveillance
Therapeutic Products Programme
Health Protection Branch
Finance Building
A. L. #0201D3
Tunney's Pasture
Ottawa, Ontario, KlA lB9
Internet: Hemp_BdsTpd@hc-sc.gc.ca

Mr. Bruce Rowsell, Director

Phone: (613) 954-6522
Fax: (613) 952-7738

Director
Bureau of Drugs Surveillance
Therapeutic Products Directorate
Health Protection Branch
Finance Building
A. L. #0201D3
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Mr. Dann Michols, Director General

Tel: (613) 952-3603
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Director General
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Phone: (604) 666-2793
FAX: (604) 666-3149

Rod Neske (Inspector - British Columbia/Yukon)
3155 Willingdon Green
Burnaby, BC, V5G 4P2

Phone: (403) 495-3380
FAX: (403) 495-2624

Elaine Radulski (Inspector - North. Alberta/NWT)
840-9700 Jasper Ave
Edmonton Alberta, T5J 4C3

Phone: (403) 292-5081
FAX: (403) 292-4644

Miles Brosseau (Inspector - Southern Alberta)
282 - 220 4th Avenue S.E.
Calgary, Alberta
T2G 4X3

Atlantic Region Phone: (902) 426-7648. FAX: (902) 426-6676 **Sandra Decoste (Inspector)** 1992 Baffin Street Dartmouth, Nova Scotia, B3B lY9 Mailing address: P.O. Box 1060 Dartmouth, Nova Scotia, B2Y 3Z7	**Central Region** Phone: (306) 975-4126 FAX: (306) 975-6040 **Lori Postnikoff (Inspector)** 412 - 101 22nd St. E. Saskatoon, Saskatchewan S7K 0El Phone: (204) 983-3747 FAX: (204) 983-5547 **Rick Brown (Inspector)** 510 Lagimodiere Blvd. Winnipeg, Manitoba R2J 3Yl
Ontario Region Phone: (416) 973-1481 FAX: (416) 954-4583 **Faye Pearce (Inspector)** 2301 Midland Avenue Scarborough, Ontario, M1P 4R7	Quebec Region Phone: (514) 646-1353 FAX: (514) 928-4102 **Andrée Bernard (Inspector)** 1001 ouest, rue St-Laurent Longueuil, Québec, J4K 1C7

APPENDIX VIII

OTHER CONTACTS

FOODS:	Dr. Harry Conacher 3rd Floor East Frederick Banting Building A.L. #0223G2 Ottawa, Ont. K1A 0L2 Phone: (613) 957-0973 Fax: (613) 954-4674 E-mail: harry-conacher@hc-sc-gc.ca	**COSMETICS:** Dr. Hugh Davis Head, Chemistry, Cosmetics and Flammability Section Products Safety Bureau A.L. #0301B2 Ottawa, Ont. K1A 0L2 Phone: (613) 957-7926 Fax: (613) 952-1994 E-mail: hdavis@hc.sc.gc.ca
CFIA	Luc Mougeot Plant Production and Protection Division Canadian Food Inspection Agency 59 Camelot Drive Nepean, Ontario K1A 0Y9 Phone: (613) 225-2342 Fax: (613) 228-6614 Catherine Italiano Animal Health & Production Division Animal Products Directorate Canadian Food Inspection Agency 59 Camelot Drive Nepean, Ontario K1A 0Y9	**CSGA:** Mr. Randy Preater P.O. Box 8455 240 Catherine St. Suite 202 K1G 3T1 Phone: (613) 236-0497 Fax: (613) 563-7855