



Tunney's Pasture/Pré Tunney  
OTTAWA, Ontario  
K1A 0L2

March 12, 1998

le 12 mars 1998

**Notification of passage of Schedule**

**Avis d'adoption d'une annexe**

Please be advised that the following  
Schedule of Amendments was passed by  
Order-in-Council and appears in the *Canada  
Gazette*, Part II of:

Veillez prendre note que l'annexe qui suit a  
été adoptée par décret et apparaît dans la  
*Gazette du Canada*, Partie II du:

**DATE:** April 1, 1998

**DATE :** 1 avril 1998

(Schedule No. 1089)  
*Industrial Hemp Regulations*

(Annexe N° 1089)  
*Règlement sur le chanvre industriel*

**REGISTRATION :** SOR/98-156

**ENREGISTREMENT:** DORS/98-156

**P.C.:** 1998-352

**P.C.:** 1998-352

amendment to Schedule II of the *Controlled  
Drugs and Substances Act*

modification à l'Annexe II de la *Loi  
réglementant certaines drogues et autres  
substanceset*

**REGISTRATION:** SOR/98-157

**ENREGISTREMENT:** DORS/98-157

**P.C.:** 1998-353

**P.C.:** 1998-353

amendment to the Schedule to the *Narcotic  
Control Regulations*

modification à l'Annexe de la *Règlement sur  
les stupéfiants*

**REGISTRATION:** SOR/98-158

**ENREGISTREMENT:** DORS/98-158

**P.C.:** 1998-354

**P.C.:** 1998-354

**PASSAGE :** March 12, 1998

**PASSAGE:** 12 mars 1998

o/s

Lauraine Bégin  
Policy Division / Division de la politique

Attachments

Pièces jointes

## REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the regulation)

### **Description**

The *Industrial Hemp Regulations* (Regulations) will permit the legal production and processing of hemp for commercial purposes while providing compliance and enforcement mechanisms to prevent diversion of *Cannabis* to the illicit drug market. Cultivation of hemp is currently permitted for scientific studies only under licenses issued by Health Canada under the *Controlled Drugs and Substances Act* (CDSA).

Hemp refers to varieties of the *Cannabis* plant that have a low content of delta-9-tetrahydrocannabinol (THC) which are generally cultivated for fibre. Varieties with a high content of THC are referred to as marihuana. The psychoactive ingredient in marihuana is THC.

Health Canada considers 0.3% content of THC in the plants as the upper limit for determining which varieties of *Cannabis* are classified as industrial hemp and are permitted for commercial cultivation.

The Regulations define industrial hemp as the plants and plant parts of the *Cannabis* plant, the leaves and flowering heads of which do not contain more than 0.3 per cent THC. It includes the derivatives of the plant and plant parts such as the oil derived from hemp seeds.

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

Industrial hemp does not include non-viable *Cannabis* seed, other than its derivatives, or mature *Cannabis* stalks. Leaves, flowers, seeds or branches, or fibre derived from those stalks are included.

### **Historical Perspective**

Hemp production was prohibited in Canada in 1938 under the *Opium and Narcotic Drug Act*, but the prohibition was relaxed briefly during World War II when traditional sources of fibres were unavailable. The prohibition was renewed after the war. Since 1961 Health Canada has allowed limited production in Canada for scientific purposes.

### **International Perspective**

These Regulations were developed after evaluation of regulatory models in other jurisdictions.

## Europe

There is no one European model. Several countries permit commercial cultivation of low-THC hemp. There are significant differences in the way regulation is handled from one country to the next. The European Commission has adopted 0.3 per cent as the acceptable content of THC in industrial hemp. Some other European countries allow higher concentrations of THC.

The large land mass available for growing industrial hemp in Canada makes monitoring a larger problem than it is for European countries. In addition, subsidies for growing hemp have an impact on the methods of regulating in the European Union (EU). While it is an objective to harmonize regulations, where feasible, the European solutions may not be appropriate for Canada.

Recently, concerns have been expressed by the EU that controls over industrial hemp farming and the monitoring activities of national authorities are insufficient. The EU is now looking at means to enhance controls and monitoring operations.

## Australia (State of Victoria)

*The Drugs, Poisons, and Controlled Substances (Amendment) Bill* was passed on October 14, 1997. It allows a person to apply to the Department of Natural Resources and Environment for an authority to cultivate and process low-THC *Cannabis*. Applicants are required to prove they intend to undertake bona fide research or commercial activity related to the non-therapeutic use of *Cannabis*. Commercial production is limited to those who can demonstrate they have a market for the crop produced.

## United States

The United States does not permit the commercial cultivation of hemp. Cultivation of hemp for research purposes is extremely limited. The derivatives of hemp seeds are not controlled. All hemp seeds must be rendered non-viable by a licensed company in the United States before distribution.

The *Controlled Substances Act* (CSA) and Drug Enforcement Administration (DEA) regulations define Schedule I hallucinogenic controlled substances to include any material, compound, mixture or preparation which contains any quantity of tetrahydrocannabinols. The oil made from the plant *Cannabis sativa* is not controlled in the United States if it is free of controlled portions of the *Cannabis sativa* plant such as the resin, flowering tops, or foliage. If the oil made from the seeds of *Cannabis sativa* is contaminated with any quantity of tetrahydrocannabinols (THC), such oil is a Schedule I controlled substance. The importer of any Schedule I controlled substance into the United States must be registered with the DEA and must obtain an import permit.

Internationally, *Cannabis* falls under the United Nations' *Single Convention on Narcotic Drugs, 1961* which Canada has signed and ratified. The *Convention* requires measures to prevent the misuse of, and illicit traffic in, the leaves of the *Cannabis* plant. However it does not prohibit the cultivation of industrial hemp for commercial purposes.

Health Canada is responsible for implementation of the requirements of the *Single Convention on Narcotic Drugs, 1961*, the *Convention on Psychotropic Substances*, and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*. The Minister of Health fulfills these international obligations with respect to *Cannabis* through the provisions of the *Controlled Drugs and Substances Act* and the *Narcotic Control Regulations*.

### **Canadian Situation**

The *Controlled Drugs and Substances Act* (CDSA), which came into force on May 14, 1997, replaced the *Narcotic Control Act* and Parts III and IV of the *Food and Drugs Act*. However, the existing *Narcotic Control Regulations*, as well as Parts G and J of the *Food and Drug Regulations* dealing with the controlled and restricted drugs requirements remain in force, under the authority of the CDSA. While *Narcotic Control Regulations* do not permit the issuance of licences to cultivate industrial hemp for commercial purposes, the CDSA allows the Governor in Council to create regulations to permit the commercial cultivation of industrial hemp.

*Cannabis* and its derivatives are listed in Schedule II of the CDSA, therefore the possession, trafficking, import, export and production of all varieties of *Cannabis* regardless of the THC content are prohibited. Non-viable *Cannabis* seeds and mature stalks that do not include leaves, flowers, seeds or branches as well as fibre derived from such stalks, are excluded from Schedule II of the CDSA. Thus the fibre and products made from such stalks may be imported, processed or sold in Canada without restriction.

Hemp seed oil, and seed cake, regardless of the viability of the seed source, are considered derivatives of *Cannabis* and are therefore controlled under the CDSA. To make this clear, these Regulations modify Schedule II to the CDSA and the Schedule to the *Narcotic Control Regulations* to clarify the status of derivatives.

Additional Acts and Regulations which may apply to the importation and sale of hemp are:

- Plant Protection Act and Regulations*
- Plant Protection Fees Regulations*
- Seeds Act and Regulations*
- Seeds Fee Notice*
- Weed Seeds Order*
- Canada Agricultural Products Act*

The importation and sale of seed, and the cultivation of crops for seed purposes, are regulated in Canada under the *Seeds Act* and the *Canada Agricultural Products (CAP) Act*, administered by the Department of Agriculture and Agri-Food through the Canadian Food Inspection Agency. The *Industrial Hemp Regulations* do not conflict with the requirements in either of these Acts.

Recently, there has been renewed interest in the cultivation of industrial hemp. It has been suggested that this may provide an alternative crop for some regions of Canada. The introduction of industrial hemp may thus translate into new jobs in agriculture, industry, research and retail.

In response to this renewed interest, the following Regulations were developed. Schedule II of the CDSA and the Schedule to the *Narcotic Control Regulations* are also amended to provide clarity and consistency.

The Regulations consist of the following components:

- Importers and exporters of industrial hemp, in the form of seed or viable grain, will be licensed. In addition to holding a licence they will also be required to obtain a permit for each shipment.
- The importer must ensure that shipments of viable grain are accompanied by foreign certification. A list 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. This will ensure that grain imported will not produce a plant containing more than 0.3% THC.
- Seed growers will be restricted to a 0.4 hectare minimum plot size and will be required to demonstrate current membership with the Canadian Seed Growers Association as part of their licence application. Seed growers will be required to provide the number of hectares grown in the previous two years as part of their licence application.
- Plant breeders will not be restricted by minimum plot sizes. Persons applying for a licence as a plant breeder must be registered with the Canadian Seed Growers Association and may only cultivate industrial hemp under this regulatory framework. 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"
- Growers for fibre or grain will require a licence before they can purchase seeds from a distributor or cultivate industrial hemp. Growers will be required to provide the number of hectares grown in the previous two years as part of their licence application.
- Only approved varieties 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 will be required to identify their fields, and maintain records of production and distribution.
- Licences and audit trail requirements will also be required for processing activities such as pressing seeds into oil. All parties licensed or

authorized will be required to 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 a police security check.
- Derivatives of seed or grain, such as oil and seed cake, will be exempted from the Regulations if there is evidence that the derivatives contain no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram and carry appropriate labelling statements. Products made from derivatives of seed or grain will be exempted if there is evidence that each lot or batch contains no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram.
- Importers and exporters of derivatives will be required to provide proof with each shipment that the shipment contains no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram for each lot to ensure that the product is within the limit. Similarly products made from the derivatives of seed or grain must be accompanied with evidence that each shipment contains no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram.
- No person will be permitted to import or export a derivative or a product produced from a derivative that contains more than 10 micrograms of delta-9-tetrahydrocannabinol per gram.
- No person will be permitted to import or sell whole plants, including sprouts or the leaves, flowers or bracts of industrial hemp; or import, sell, or produce any derivative or any product made from a derivative of the above.
- 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.
- No person shall advertise to imply that a derivative or product is psychoactive.
- 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.

To maintain an audit trail, and the credibility of the industry (importers, seed dealers, growers, processors and exporters), licences are considered essential as a compliance tool. The regulatory framework provides criteria to assist in the measurement of the suitability of an individual to conduct a licensed activity. The resulting framework will also provide Health Canada with the necessary information to identify licensed industrial hemp producers and hence ease the burden on enforcement agencies. The

record keeping and auditing provisions will assist in the identification of illegal activities. To ensure accurate record keeping of quantities of industrial hemp moving in and out of the country, as well as identifying legitimate shipments for Canada Customs, a permit or proof that the product is acceptable or that the product is exempt from the regulations is required for each shipment.

It is government policy to charge external users appropriate rates for goods, services, property, and limited rights and privileges provided by government, to promote more business-like, consistent and equitable management. Health Canada will develop a cost recovery initiative in the future to recover the costs associated with this new framework. The cost recovery initiative will be developed in line with Treasury Board policy and provide Canadians with a full opportunity to comment through an early consultation process, and the prepublication of the proposal in *Canada Gazette*, Part I. There will also be an assessment of the impact of a cost recovery scheme on industry.

### **Alternatives**

The options outlined below provide an overview of the possibilities over the full range of potential models, from an unregulated environment to strict government control of industrial hemp and hemp products.

- 1) Maintain existing prohibition of the commercial cultivation of industrial hemp and maintain the Minister's authority to issue licences for the production of industrial hemp for scientific purposes.

Pros: This option makes use of well established procedures to evaluate industrial hemp researchers and their activities.

Cons: This option does not address the emergence of an industrial hemp industry, is inflexible and acts as a barrier to the development of a potential market. It limits trade unnecessarily and is inconsistent with the direction taken by other jurisdictions such as the European Union and Australia.

- 2) Allow the commercial cultivation of industrial hemp with appropriate controls. The controls may range from registration to licensing. This model would require an exemption or authorization by regulation for industrial hemp and the development of a regulatory and administrative framework for compliance and enforcement purposes. The Minister's authority to issue licences for the production of industrial hemp for scientific purposes would be maintained with this option.

Pros: The CDSA allows for the drafting of such regulations. This model is consistent with the UN Convention and the direction taken in other jurisdictions such as the European Union and Australia. It will minimize the risk of the production of products with high THC levels and should not unnecessarily restrict consumer access to low THC level products. Products produced from mature stalks, that do not contain leaves,

flowers, seeds or branches, could maintain their current exempt status. Limited authorization will permit the development of the commercial hemp industry and provide a consistent level of control of persons and activities. This model is supported by many stakeholders in the industrial hemp industry.

Cons: The cultivation of industrial hemp will necessitate an improved public understanding of the difference between industrial hemp and marijuana and how each is controlled. Although there is general international acceptance respecting the maximum content of 0.3% THC in industrial hemp, there is no international standard. Compliance and related activities such as licensing, inspections and testing will increase with a concomitant increase in cost.

- 3) Allow the commercial cultivation of industrial hemp without any intervention. This free market model would require an exemption under section 55 of the CDSA or the removal of industrial hemp from Schedule II of the CDSA.

Pros: This model would facilitate the development of the industrial hemp market.

Cons: This model does not address the concerns of the enforcement agencies to control the illicit drug market. Furthermore, it would represent a departure from the Health Canada mandate to protect the public from deceptive and misleading products. There is increased potential for the cultivation of products with higher levels of THC than industrial hemp, which in turn could result in increased trafficking. A major education program would be required since this free market model would be "buyer beware". This model is inconsistent with that of other jurisdictions and the UN Convention. There may be a negative impact on trade if standards of evidence for claims were not equivalent to those in other regulatory jurisdictions.

Each option was assessed using the following criteria:

*Mandatory criteria*

- The option must be in conformity with the authorities contained in the CDSA and comply with Canada's international obligations.
- The option must not facilitate the production of illicit drugs.
- The option must provide an appropriate means of control (compliance).

*Screen criteria*

- The option must not hinder trade.
- The option must not be an undue burden on government and industry.
- The option must be responsive to future needs.
- The option must not undermine public confidence.

Based on the process described above, option 2 was chosen resulting in a framework composed of the following:



- The commercial cultivation of industrial hemp be permitted by a limited authorization under the *Controlled Drugs and Substances Act* through the creation of separate *Industrial Hemp Regulations*.
- A licensing and permit scheme be used for controlling activities under the *Industrial Hemp Regulations* in order to provide Health Canada with the required compliance and enforcement mechanisms.

### ***Benefits and Costs***

A Business Impact Test was not conducted on this proposal. This is a permissive regulation as it removes some prohibitions in the current legislation. As there are no stakeholders in Canada currently involved in the commercial cultivation of industrial hemp, a valid test could not be conducted at this time.

This amendment is expected to impact on the following sectors:

- **Public**

Benefits:

The development of this industry may result in job creation. Industrial hemp may be used in textiles, oil based products, and by the pulp and paper industry. Due to the diversity of the products, secondary industries may develop. The resultant job creation could impact positively on the wealth of Canadians and indirectly on their health, a stable job market being one of the determinates of population health.

The Regulations will permit Canadian growers to compete globally in an emerging industrial hemp market. This could result in an increase in the export of hemp products.

Industrial hemp is claimed by some to be an environmentally friendly plant. It reportedly suppresses some weeds and requires less pesticide compared to some other plants. Industrial hemp can be used to produce fibre suitable for some types of paper as an alternate source to wood fibre. The pulp and paper industry may use this renewable resource thus reducing the rate of depletion of Canadian forests.

The production of low cost industrial hemp fibre could result in the availability of cheaper products to Canadians.

The development of a commercial industrial hemp industry will create a need for specialized equipment for harvesting and processing. This could generate economic development and further spin off growth, as well as potentially increasing Canadian exports.

Hemp seed is claimed to be a good source of essential fatty acids. If a large industrial hemp industry is established in Canada it is expected that the cost of the hemp seed oil will decrease.

- **Industrial hemp processors**

Benefits:

The availability of a new product could promote new business opportunities.

The record keeping requirements are similar to those which must be maintained by businesses for the purposes of Revenue Canada.

Costs:

Costs will be associated with the police check, security requirements, testing and record keeping as mandated by the licensing scheme.

- **Grower**

Benefits:

The proposal may provide growers with an alternate crop.

Industrial hemp reportedly has a positive impact on the land thereby making it a good rotational crop.

Plant breeders will have an opportunity to develop Canadian varieties of industrial hemp. These may gain international certification and the result would be a potential decrease in the cost of pedigreed seeds. The Regulations have been modified to allow seed growers and plant breeders to plant smaller parcels of land than those cultivating for production of grain or fibre. Both seed growers and plant breeders need to meet additional requirements mandated by the Canadian Seed Growers Association to qualify for these designations.

The changes made to the framework after prepublication in *Canada Gazette* Part I provide opportunities for plant breeders to import industrial hemp and create new Canadian varieties. This will ensure that Canadian growers will have access to varieties better suited to Canadian climatic conditions.

Costs:

Costs will be associated with the security clearance, testing and record keeping requirements mandated by the licensing scheme. Growers will be required to identify the coordinates of their field by using global positioning system (GPS) and provide a legal description of the location of the land to be cultivated.

Costs will be incurred from the increased security requirements for seeds, grain stored or transported.

There will be a cost to new seed growers for membership in the Canadian Seed Growers Association and the related costs of licensing by the Department of Agriculture and Agri-Food through the Canadian Food Inspection Agency.

- **Importers/Exporters**

Benefits:

New business opportunities will be generated for importers/exporters.

Costs:

Costs will be incurred for the security clearance testing and record keeping requirements, and increased security requirements for imported products as mandated by the licensing scheme.

There will be costs associated with licence and permit applications.

There are fees for registration as a Registered Seed Establishment under the *Seeds Regulations* and for the licensed operator.

Importers will be restricted to the type of products allowed for importation.

- **Revenue Canada (Customs)**

Benefits:

Although this system does not directly benefit Customs, it includes a requirement for import and export permits or a document proving exemption from the Regulations which will assist Customs officials and facilitate importation.

Costs:

Processing of imports and ensuring compliance with all regulatory requirements will result in an increase in overall operating costs to Customs. The licensing scheme has been designed in an effort to minimize this cost through the provision of documents clarifying the status of imports and exports.

- **Authorized Laboratories for Viability Testing**

Benefits:

Creation of new clientele for laboratories accredited by the *Canadian Agricultural Products Act* for the purpose of testing the viability of seed.

New revenues will be generated for these laboratories.

Costs:

The laboratories will have to maintain records of testing and meet other general licensing provisions contained within the *Industrial Hemp Regulations*.

- **Competent Laboratories for THC Testing**

Benefits:

The 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.

New revenues will be generated for these laboratories which are expected to operate on a profit basis.

Costs:

The laboratories will have to 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*.

- **Law Enforcement agencies**

Benefits:

To reduce possible demands on law enforcement agencies, the inspection responsibilities will remain at this time with *Controlled Drugs And Substances Act* inspectors.

The cost of security clearances required by this framework will be borne by the applicant rather than directly by law enforcement agencies.

The proposal is beneficial as it helps the police distinguish between illicit and licit activities.

Costs:

Enforcement agencies have expressed concern that the development of industrial hemp may increase law enforcement costs. Agencies are also concerned that they will be expected to provide increased monitoring and surveillance as a result of this initiative.

- Department of Agriculture and Agri-Food, and Canadian Food Inspection Agency, and Canadian Seed Growers Association

Benefits:

The framework has been developed in concert with specialists from the Department of Agriculture and Agri-Food and the Canadian Food Inspection Agency therefore maximizing the harmonization of the systems administered by the two Departments.

Costs:

There will be increased costs due to the increased number of requests for establishment licences and for certification as licensed operators under the *Seeds Act* and *Regulations*.

The Canadian Seed Growers Association may receive additional applications for membership.

There will be increased pressure on the Department of Agriculture and Agri-Food and the Canadian Food Inspection Agency to create a variety registration

program for industrial hemp.

- **Health Canada**

Benefits:

These Regulations will permit Health Canada to meet its international commitments. Health Canada will be able to maintain its mandate to protect the health and safety of Canadians.

Costs:

There will be costs associated with determining the risks and benefits related to new industrial hemp products which are as yet unknown. This information will only be available after wide spread use of these products and consumer acceptance is known.

There will be increased costs to Health Canada associated with the provision and maintenance of the List of Approved Cultivars, the List of Countries Approved for the Importation of Viable Grain, and the development and maintenance of the Industrial Hemp Technical Manual and accompanying guidelines.

There will also be costs associated with inspection, auditing and confirmatory testing for THC content related to enforcement and compliance activities. There will also be additional costs related to the issuance of licences, authorizations and permits.

Health Canada will introduce a cost recovery initiative to cover the increased costs from commercial enterprises which will benefit from this framework. Furthermore, Health Canada has made a commitment to evaluate the impact of this regulatory proposal after the completion of two growing seasons. The regulatory framework will be amended as appropriate.

### **Consultation**

The complex nature of regulating this new industry makes it essential to consult with industrial hemp stakeholders, other federal departments and agencies, law enforcement agencies, and the general public.

In 1996, a committee made up of representatives from Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, the Royal Canadian Mounted Police, Solicitor General, and Health Canada was established to evaluate and advise on research licence applications. In 1997, the Department of Justice replaced the Solicitor General on the research licence application review committee.

An Interdepartmental Working Committee was created in September 1996 to identify issues, to assist in policy development, to advise the Therapeutic Products Programme in Health Canada on issues and to inform stakeholders. The Committee included representatives from the Departments of Agriculture and Agri-Food, the Canadian Food Inspection Agency, Industry, Environment, Justice, the RCMP, Solicitor General and the Therapeutic Products Programme. Recently,

Revenue Canada (Customs) was added to this Committee.

In October 1996 Health Canada consulted with the Drugs Branch of the Home Office of the United Kingdom and the Departments of Health and Agriculture of Germany to discuss hemp regulations in their jurisdictions.

Starting in 1994 and continuing to the present, Health Canada communicated with various licensed industrial hemp researchers. Through these communications, the Department developed a broader understanding of the issues surrounding industrial hemp production. A number of these parties submitted proposals and recommendations for a regulatory framework for industrial hemp. In addition, as a condition of their research licence, scientists were required to submit the results of their research.

A Multi-Stakeholder Consultation Workshop was held on March 17 - 18, 1997 to explore options for a regulatory framework to permit the development of a commercial industrial hemp industry in Canada. Participants were invited on the basis of their expertise. The collaboration and contribution of the participants provided Health Canada with background information from which the regulatory proposal was developed. A Notice of Intent outlining this regulatory framework was published on December 6, 1997.

The proposed Regulation, developed as a result of early consultation, was published with a 45 day comment period in *Canada Gazette Part I* on December 27, 1997 and also posted on the Health Canada, Therapeutic Products Programme Website (<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/>).

The Therapeutic Products Programme of Health Canada conducted a second consultation workshop on January 25-27, 1998 where the details and implications of the proposed Regulations were discussed. The comments collected at this workshop were evaluated, along with the responses received as a result of the pre-publication of the proposed regulation.

Changes made to the proposed Regulations are in response to concerns and suggestions expressed by stakeholders at the workshop and through written responses. A total of one hundred and seventy-six responses were received within the 45 day comment period provided in *Canada Gazette, Part I*. Forty-eight of those responses supported the proposal to have cultivation allowed for the 1998 growing season but expressed concern over some aspects of the proposal. Four comments fully supported the regulatory framework as originally proposed. Only two respondents objected to the proposal to permit the cultivation of industrial hemp in Canada. Most of the comments received (83) were either requests for additional information or for licence applications. Fourteen media contacts were received along with five requests for the decriminalization of marijuana. Six requests were for copies of the technical manual while fourteen responses had no comment on the Regulations but provided information relating to the hemp industry.

**Issue # 1 - Restriction related to THC level in leaves  
(0.3%)**

Stakeholders expressed concern that the 0.3% THC limit required by the Regulations was too restrictive. It

was pointed out that some testing conducted on plants grown in Canada under research licences have provided test results which exceeded the proposed 0.3% dry w/w limit.

#### **Response**

After evaluation of the data it was decided to maintain the current proposed limit in the Regulations as this is an internationally acceptable limit. It is recognized that environmental conditions in Canada could lead to unpredictable THC results in some varieties. To respond to stakeholder concerns, a recommendation was made to develop a Ministerial list of approved varieties. 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. The guidelines will provide flexibility for crops which exceed the 0.3% THC limit. Enforcement options range from immediate harvesting to destruction depending on the THC level.

#### **Issue #2 - Restriction to Organization for Economic Co-operation and Development (OECD) List of Seeds**

Another major problem identified was the proposed restriction to limit access to seeds for industrial hemp cultivation to those seeds listed on the OECD list. Stakeholders stated that not all seeds listed on the OECD list had consistently produced plants with less than 0.3% THC when cultivated in Canada. Additionally, stakeholders expressed concern that there was only a very limited supply of these seeds and that there were other varieties which had demonstrated acceptable limits under conditions similar to those in Canada which should be accepted. As well, some growers stated that they did not want to be forced to purchase "super-elite" seeds and provide proof with an OECD seed tag.

#### **Response**

In response to this concern, the Regulations have been modified to provide criteria by which the Minister may designate certain varieties which are suitable for Canadian use. This list will include some OECD varieties but will also include other varieties which meet the criteria set out in the Regulations. The change to the Regulations to permit the use of seeds contained on the Ministerial list should help to reduce the cost to growers; however, only approved cultivars will be permitted on the list to ensure a low THC starting point for the crop.

Additionally, a sunset clause has been written into the Regulation to permit growers to cultivate uncertified approved cultivars until December 31, 1999. The Regulations have also been modified to require official seed certification rather than an OECD seed tag. In addition, the varietal status of the imported seed must be validated by a designated authority in the country of origin. To allow the use of seeds of non-certified varieties during the sunset period, the Regulations

have been modified to provide an exemption until January 1, 2000.

Efforts are also underway to support the modification of Schedule III to the *Seeds Regulations* to include *Cannabis* and establish a variety registration system for Canada.

**Issue #3 - THC Limit in Derivatives and Products**

Some respondents objected to the prohibition of the sale of derivatives or products made from the derivatives of industrial hemp containing more than 10 µg/g of THC. It was requested by some that the limit be increased to 50 µg/g and that the limit apply to both imported and domestically produced derivatives.

**Response**

A 50 µg/g THC limit which was proposed by some respondents is accepted in Switzerland. However, published research indicates that oral ingestion of THC requires a single dose of 20 mg to produce psychotropic activity in a healthy adult (70 Kg), and 5 mg to produce physiological effects. Extrapolating these figures to a 20 Kg child, the corresponding values are 5.7 and 1.4 mg, respectively.

Oil at 50 µg/g represents 0.6 mg per tablespoon. Thus, three spoonfuls per day would provide 1.8 mg of THC to one's system. This amount is in excess of what would be expected to produce physiological effects in a 20 Kg child. Additionally, due to the extremely slow elimination rate of THC from the body, a constant daily dose would result in a gradual increase in the THC level in the body. Therefore this limit is considered unacceptable.

Extrapolating the figures cited above down to 10 µg/g gives a certain margin of safety for a 20 Kg child. This level represents 0.12 mg per tablespoon. A child would need to consume 12 spoonfuls per day to reach the level of physiological effect (1.4 mg/day). The Food Directorate of Health Canada has been informed of these findings and an evaluation will be forthcoming with potential regulatory action. It is possible that further regulatory controls respecting the sale of foods or cosmetics will be introduced.

The Regulations have been amended to require that documentation accompany each imported shipment to certify that the shipment contains no more than 10 µg/g of THC. This certification can then be presented to Customs prior to release in Canada and will ensure that all derivatives, whether produced domestically or imported, all meet the same requirements.

The 10 µg/g limit may change as further data becomes available. From a health and safety point of view, Health Canada may consider setting the limit as close to zero as is practicable, since technically and analytically there should not be a problem measuring a lower level.

**Issue #4 - Size of Plot Cultivated**



Many respondents complained that the requirement to plant a minimum of 4 hectares in industrial hemp was too restrictive and would limit the development of cottage industries as well as hamper seed production. On the other hand, law enforcement agencies indicated that it was necessary to maintain this 4 hectare restriction to enable them to make monitoring and enforcement of the Regulations feasible.

#### **Response**

After further analysis of the impact on the stakeholders, the Regulations were modified to introduce a 0.4 hectare minimum for seed growers. However, the 4 hectares minimum will be maintained for producers of fibre or grain. This resulted in numerous changes within the Regulations to provide a specialized framework for plant breeders and seed growers while ensuring more efficient enforcement.

Growers also wanted assurance that the fields would not be required to be contiguous since fields may often be divided by drainage ditches or farm pathways. A Guideline on Industrial Hemp will provide guidance in this regard and will allow for small divisions within a single site, hence balancing the need to maintain control of locations with the need to adapt to the environmental conditions present.

#### **Issue # 5 - Multiple Licensing Levels**

Some stakeholders expressed concern that licensing at multiple levels created an unnecessary burden on both applicants and the government and suggested the licensing system be simplified.

#### **Response**

The licencing scheme will remain as initially designed because it is necessary to maintain an audit trail. Many of the respondents were not aware that there will be only one application form which will apply to all persons wishing to conduct activities that require a licence. It will not be necessary to complete multiple forms. This explanation appeared to satisfy the concerns of many at the January 1998 workshop. A review is planned after two years of operation.

#### **Issue # 6 - Export**

It was suggested that the export requirements be eliminated from the regulatory framework.

#### **Response**

No change has been made to the Regulations as they are in line with our international commitments, and provide the export permits required by Customs.

#### **Issue # 7 - Need for Regulation and Follow-up Review**

A key message from stakeholders was the importance of having the Regulations in place for the 1998 growing season. They also indicated the need for follow-up evaluation of the regulatory framework, which might

result in changes to the framework.

**Response**

Health Canada is committed to reviewing the regulatory framework after two full growing seasons have passed and experience is gained. The Department will continue to co-operate with other Departments and stakeholders in an effort to provide appropriate regulatory controls as this industry evolves.

**Issue # 8 - Police Check**

There was a request to eliminate the screening requirement for previous drug convictions.

**Response**

The Regulations will include a requirement to provide data on previous drug convictions. This is deemed necessary both to lend credibility to those involved in the industry and to help ensure that commercial production of hemp is not used as a front to conceal illicit activity.

**Issue # 9 - Compliance**

Some stakeholders asked that a training program be established for inspectors. The question was raised concerning who would do the inspecting and ensure consistent application of the guidelines throughout Canada.

**Response**

A Compliance Policy and Enforcement Guideline will be developed and posted on the Therapeutic Products Programme website so that this information is readily available by all parties. This Guideline which will be developed in cooperation with other Departments will delineate the responsibilities of the respective agencies.

**Issue # 10 - Proximity to School Grounds or Other Public Places**

The prohibition of 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 year, was a concern to stakeholders.

**Response**

This restriction will remain for the present time to address the public perception that there may be a risk in locating growing areas close to schools and other public places and until there is more experience in regulating this industry. This restriction will be reviewed in two years.

**Issue # 11 - Packaging Requirements**

Some stakeholders indicated that the security requirements for the transport of bulk grain were unworkable. At the workshop it became apparent that

there was a misunderstanding of the definition of "package".

#### **Response**

In an effort to provide a better clarity the Regulations have been amended to include a definition for package which is consistent with the definition in the *Seeds Act*. The definition of package "includes a sack, bag, barrel, case, or any other container in which seed, viable grain or its derivatives are placed or packed". The Regulations were also modified to clarify the requirement to fasten the package in a manner which harmonizes the requirements with the *Seeds Regulations* -- fastened with respect to "package" means sealed in such a manner that it is impossible to open the package easily without leaving evidence of it having been opened.

#### **Issue # 12 - Availability of Viable Seed**

Some comments were received from individuals who were not in favour of restricting the sale of viable seeds to the general public.

#### **Response**

The limitation on the distribution of viable seed will remain. It is believed that, as the seeds are a biological entity, the control of the viable seed is critical to the regulator's ability to ensure that the seeds do not revert to produce a high THC variety plant. Additionally this control will help prevent diversion of unapproved seeds into cultivation.

#### **Issue # 13 - Harvesting Time**

Respondents indicated that harvesting time should not be restricted by regulation. It was argued that harvesting time is a farm management issue based on economic factors. Growers indicated that they should be able to switch from grain to fibre production at will, depending on the market demand.

#### **Response**

It is understood that industrial hemp when grown for grain production is planted at a different density than when planted for fibre. The decision is made at the time of planting rather than part way through the growing season. The Regulations require that the licence applicant state whether the crop is for grain or fibre.

The Regulations will therefore retain this restriction and the technical manual will provide further specifications concerning harvesting time. Concerns respecting the enforceability of this provision will be addressed in the compliance policy.

#### **Issue #14 - Global Positioning System (GPS) Coordinates**

Some participants at the workshop and some of those responding in writing requested that the proposed Regulations be modified to permit growers to submit

Global Positioning System (GPS) coordinates no later than 30 days after planting or alternatively, before July 10th of each year.

**Response**

This proposal was not supported by law enforcement agencies. Knowledge of the exact location of licensed fields is necessary to ensure they are not mistaken for illicit crops and inadvertently destroyed. Changes in field location will therefore require a licence amendment. Requests for change to the licenced site will be processed on an expedited basis to ensure there is no delay. In addition, the Regulations have been amended to include a requirement for a legal description of the land to facilitate inspection.

**Issue #15 - Technical Manual**

Comments were received on the draft Technical Manual suggesting that the test method should not be mandated, but that performance standards for testing should be set out permitting flexibility in the type of test performed.

**Response**

The Technical Manual has been modified to provide two basic testing procedures. New and improved testing procedures can be added to the Technical Manual, once the Therapeutic Products Programme is satisfied with their performance. This will not require a regulatory change.

**Issue #16 - Permission of Land Owner**

Some objected to the requirement that leaseholders obtain signed permission from the owner of the land to grow hemp on leased land. Growers stated that this was too burdensome and unnecessary. It was suggested that the link should be made instead with the person leasing the land.

**Response**

After further review it was decided that the position proposed in Canada Gazette Part I should be maintained for the present time. From a policy point of view, it was considered necessary that the owner know what is being grown on his or her land. Additionally, the consent may be useful from an evidence point of view, if enforcement agencies and prosecutors believe that both the owner and the lessee were working together in the case of a seizure of a controlled substance.

**Issue #17 - Methods for Rendering Seed Non-Viable**

Some stakeholders asked that the Technical Manual include more than one method to render seed non-viable.

**Response**

The Technical Manual will include a procedure acceptable to the Regulator for rendering seed non-viable.

**Issue #18 - Performance Standards**

Workshop participants requested that performance standards be established to ensure that growers, in particular, and those with research licences, not experience delay in the receipt of their licenses. Participants asked that applications be processed in two weeks if possible.

**Response**

Performance standards will not be instituted in the first year as the volume of applications could not be determined at this time. Furthermore, performance standards are a function of the resources available. Licence applications will be handled on a first come, first serve basis. The time taken to process applications will vary depending on the quality of the application and information submitted. However, every effort will be made to provide timely and efficient service to those requesting licences. The need for performance standards will be reviewed at a later date.

**Issue #19 - Licence Period**

Requests were received for multi-year rather than annual licences. It was stated that this would reduce the paper burden on industry and government.

**Response**

No change has been made to the Regulations in this regard. Current data, both on field location and drug conviction status, are required for enforcement agencies. Similar schemes, such as membership in the Canadian Seed Growers Association and licensed operator status with the Canadian Food Inspection Agency, are subject to annual renewal. As these are linked to the Regulations enacted for industrial hemp it is deemed appropriate to leave this as originally proposed.

**Issue #20 - Advertising**

It was suggested that to help maintain industry credibility and to discourage fraudulent claims an advertising provision should be included to prohibit the promotion of industrial hemp products to produce a psychotropic effect.

**Response**

The Regulations were amended to include such a provision. This will also be in line with Health Canada's international commitments.

**Issue #21 - Comments Outside the Scope of These Regulations**

Some of the comments received in response to the publication in *Canada Gazette*, Part I were unrelated to this proposal, e.g., supporting the medical use of marijuana and stating that hemp is not a drug.

## **Response**

These issues are outside the scope of these Regulations, and will not be addressed by this initiative.

If further information is required on this initiative please refer to the Therapeutic Products Programme Website (<http://www.hc-sc.gc.ca/hpb-dgps/therapeut>). The following information is provided on this site for the reference of interested parties.

- commercial cultivation of industrial hemp policy paper;
- multi-stakeholder consultation documents from the workshops;
- Industrial Hemp Technical Manual;
- Guidelines;
- List of Approved Cultivars;
- List of Countries Approved for the Importation of Viable Grain;
- licence application form

## ***Compliance and Enforcement***

This amendment does not alter existing compliance mechanisms under the provisions of the *Controlled Drugs and Substances Act* enforced by the Therapeutic Products Programme of Health Canada. Additional resources will be required and a new compliance policy has been developed to ensure that inspection mechanisms will be maintained and uniformly applied.

Persons failing to comply with the regulatory requirements within the Regulations could have their licence, authorization or permit revoked. If the person is in illegal possession of *Cannabis* other than industrial hemp, they will be subject to prosecution under the Criminal Code and penalties defined within the *Controlled Drugs and Substances Act*.

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. All of these requirements help facilitate enforcement activities.

In addition Health Canada is cooperating with other government departments to develop an inspection and compliance program which will be in place as this new industry gets up and running.

## ***Contact***

Lauraine Bégin  
Policy Division

Bureau of Policy and Coordination  
Therapeutic Products Directorate  
Health Protection Building  
Address Locator 0702B1  
Tunney's Pasture  
Ottawa, Ontario  
K1A 0L2

Telephone Number: (613) 957-0372  
Fax Number: (613) 941-6458  
Internet: [lauraine\\_begin@hc-sc.gc.ca](mailto:lauraine_begin@hc-sc.gc.ca)