

POLICY FOR THE INCLUSION OF CANNABIS VARIETIES ON THE LIST OF APPROVED CULTIVARS

Drug Strategy and Controlled Substances Programme

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1. Effective Date

The *Policy for the Inclusion of Cannabis Varieties on the List of Approved Cultivars* came into effect August 4, 2006.

2. Context

All holders of an industrial hemp licence for cultivation are required under the *Industrial Hemp Regulations (IHR)* to sow seed of a pedigreed status that is an approved cultivar for that region. They are also required to have their field(s) sampled by an authorized sampler and tested by a competent laboratory for the presence of delta-9-tetrahydrocannabinol (THC) in the leaves and flowering heads unless the cultivar has been exempted from testing. THC test results obtained contribute to the overall profile of the variety and provide a basis for accepting or rejecting a variety for inclusion on the *List of Approved Cultivars (LOAC)*.

Cannabis sativa L. is wind-pollinated and inter-crosses freely. After several generations of reproduction, plant populations cultivated without geographical or mechanical isolation will change, and may increase their level of THC. For this reason, producers are obliged to plant pedigreed seed. Other factors may also cause an increase in THC, such as stress induced by drought, flooding, disease, infection by particular moulds and other fungi, and exposure to cold at certain stages of development. During the development of the Industrial Hemp Regulatory Framework, it was recognized that one of the critical aspects of the control program was to ensure that the level of THC found in the leaves and flowering heads of the cultivated plants remained stable.

To assure, insofar as is possible, the use of varieties that can be expected to consistently produce plants containing an acceptable THC content, it is necessary to ensure that only seed varieties that have been subjected to testing during their development are planted. It is also necessary to

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monitor the performance of industrial hemp varieties under Canadian growing conditions on an annual basis, until it can be demonstrated that THC testing is no longer required for a cultivar.

An Interdepartmental Working Group-Cultivars, comprised of expert representatives from different government departments and agencies that have responsibilities related to the production of industrial hemp from the marketing or regulatory perspectives, has been created. The mandate of the Working Group is to make recommendations to the Director of the Office of Controlled Substances (OCS), regarding those varieties that should be considered for inclusion on the LOAC, those that should be removed from the list or placed under observation due to a potential to exhibit elevated THC levels, and those varieties that can be exempted from annual THC testing.

3. Definitions

For the purposes of this policy, the following terms will be understood to have the same meaning as given in the *Industrial Hemp Regulations (IHR)* and are set out below for convenient reference:

"Industrial hemp" means the plants and plant parts of the genus *Cannabis*, the leaves and flowering heads of which do not contain more than 0.3% w/w of delta-9-tetrahydrocannabinol (THC), 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, seeds or branches, or of fibre derived from those stalks.

"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.

"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.

4. Policy

It is the objective of this policy to establish the criteria under which the Minister will designate or remove varieties of industrial hemp from the LOAC pursuant to section 39 of the *IHR*.

This policy applies to proposals submitted along with supporting performance data to the OCS, for the inclusion of new varieties on the LOAC, as well as suggestions for the removal of varieties from the list.

5. Process

a) Eligibility Requirements

Adding a New Variety to the LOAC

The Working Group will evaluate proposals for varieties to be included on the LOAC and make recommendations to the Director, OCS, for the addition of those varieties to the list, if the following criteria are fulfilled:

1. The variety must be recognized as a true variety by the responsible authorities of a member country of the Organization for Economic Cooperation and Development Seed Scheme, a member of the Association of Official Seed Certifying Agencies, the Canadian Food Inspection Agency Variety Registration Program, or the Canadian Seed Growers' Association.
2. Sufficient evidence must be provided by the plant breeder, or the applicant for inclusion of the variety, to demonstrate that the variety will consistently produce industrial hemp containing 0.3% THC (w/w) or less when sampled at licensed locations according to the method set out in the *Industrial Hemp Technical Manual*. For initial inclusion on the LOAC, sample data must establish that analytical results for testing of the variety consistently show a THC content of 0.3% (w/w), or less.
3. All sample data submitted in support of a request to include a variety on the LOAC must originate from tests conducted by a competent laboratory, in accordance with procedures described in the *Industrial Hemp Technical Manual*.
4. The applicant must submit a copy of the variety's "Certification Eligibility Application for a Variety Exempt from Registration" form submitted to Canadian Seed Growers' Association, or all of the information contained therein.

Maintaining a variety on the LOAC

1. Analytical test results for each variety must demonstrate that no test result exceeded 0.35% THC (w/w) unless the level(s) are the result of cultivation under stress conditions such as:
 - drought
 - flooding
 - insect infestation
 - infection by fungi or moulds
 - extreme temperature

The Working Group will consider all such information provided by the OCS, breeder or grower(s).

2. Test results must be less than or equal to 0.3% THC (w/w) on average for every variety, every year.

3. If the average for a variety in a growing season is between 0.3% THC (w/w) and 0.35% THC (w/w), the variety will be put under observation. This season will be considered supporting evidence for the removal of a variety from the LOAC as outlined below, regardless of information provided on mitigating stress factors. A minimum of ten results for a variety for a single growing season are required before the average is included as supporting evidence for removal. If fewer than ten results are available, results from multiple years will be used.
4. Varieties that are exempt from testing will remain on the LOAC.

b) Timing

Proposals for the addition of new cultivars on the LOAC will be evaluated by the Working Group at the same time as varieties are evaluated for exemption from THC testing for a growing season. This occurs in December of each year. A recommendation for the addition of varieties to the LOAC will be submitted for the Director's consideration at the same time as the recommendation of varieties to be excluded from THC testing for a growing season.

c) General

Commercial licences will not be issued for sale or production in Canada of varieties not listed on the LOAC, however licences may be issued for plant breeding or research. Varieties that are to be excluded from the list will appear on the LOAC for a one year grace period to permit existing seed stocks to be demoted and cleared from the system. Grain and fibre produced during the grace period and in previous years from varieties that are removed from the list will be permitted to be sold for processing and consumption after removal of the variety from the LOAC, provided THC levels are below the permitted levels.

6. Enquiries

Enquiries related to this policy should be directed to Health Canada, Drug Strategy and Controlled Substances Programme at :

Head, Industrial Hemp Section
Licences and Permits Division
Office of Controlled Substances
Drug Strategy and Controlled Substances Programme
Healthy Environments and Consumer Safety Branch
123 Slater Street
A.L. 3502A
Ottawa ON K1A 1B9

Tel.: (613) 954-6524
Fax: (613) 941-5360
E-mail: hemp@hc-sc.gc.ca

7. References

a) Pertinent Legislation

- *Controlled Drugs and Substances Act*
- *Industrial Hemp Regulations*
- *Industrial Hemp Technical Manual*
- *List of Approved Cultivars*

b) Other Information Sources

Information is available on the Health Canada Web site at:

www.healthcanada.gc.ca/hemp