



Psilocybin and Psilocin Exemption (Food and Drug Act) Regulations

Exemption

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1 Psilocybin material, as defined in subsection 1(1) of the *Access to Psilocybin for Medical Purposes Regulations* and in relation to which an activity is conducted in accordance with the *Access to Psilocybin for Medical Purposes Regulations*, is exempt from the application of the *Food and Drugs Act*, unless the psilocybin material

(a) is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, or in restoring or correcting organic functions, in human beings or animals;

(b) is represented for use in modifying organic functions in human beings or animals;

(c) is manufactured, sold or represented for use in disinfection in premises in which food is manufactured, prepared or kept;

(d) is an active pharmaceutical ingredient as defined in subsection C.01A.001(1) of the *Food and Drug Regulations*;

(e) is sold to be used for the purpose of a clinical trial, as defined in section C.05.001 of the *Food and Drug Regulations*, or an experimental study, as defined in section C.08.013 of the *Food and Drug Regulations*.

Psilocybin for medical purposes

2 Despite paragraph 1(a), psilocybin material that is manufactured or sold in accordance with the *Access to Psilocybin for Medical Purposes Regulations* is exempt from the application of the *Food and Drugs Act* from the time it is manufactured or sold by any of the following persons, unless it is represented for a use referred to in that paragraph:

(a) a person to which a licence was issued under Part 1 of the *Access to Psilocybin for Medical Purposes Regulations*; and

(b) a designated person as defined in Part 8 of the *Access to Psilocybin for Medical Purposes Regulations*.