# Memorandum D19-9-1 The Administration of Health Canada Acts and Regulations Relating to Certain Controlled, Prohibited or Regulated Goods

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The Canada Border Services Agency (CBSA) assists Health Canada with the administration and enforcement of acts and regulations that relate to travellers, conveyances, cargo and certain controlled, prohibited, hazardous or regulated goods under CBSA's and Health Canada's legislation.

This memorandum includes border policies and procedures related to the importation of human and veterinary drugs (including active ingredients), veterinary health products, natural health products, medical devices, consumer products, cosmetics, radiation emitting devices, hazardous products and pest control products, and tobacco and vaping products, herein referred to as "goods" when used in general terms.

This document does not amend or supersede the relevant legislation. In case of any discrepancy between this document and the legislation, the legislation will prevail.

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# Updates made to this D-memo

- New information was added regarding the importation of veterinary health products, vaping and nicotine products
- New information was added regarding the transshipment of Health Canada regulated goods
- New information was added with regard to Health Canada's Interim Orders and Urgent Public Health Need importation programs

- Updated the information with regard to casual importations of fertilizers, pesticides and fertilizer-pesticide combination goods
- Updated the contact information for the CBSA and Health Canada

# Definitions

For the purpose of this memorandum, the following definitions are used:

**Goods:** Defined as drugs, veterinary health products, natural health products, medical devices, consumer products, cosmetics, radiation emitting devices, hazardous products and pest control products.

**Interim order:** Issued by the Minister of Health in exceptional situations where immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment, under certain subsections of legislation in order to apply temporary measures or directives.

**Minister:** The Minister of Public Safety Canada administers the, *Canada Border Services Agency Act*, and associated regulations. The Minister of Health and the Department of Health ("Health Canada") administer all Health Canada legislation as listed in the Reference section of this memorandum.

#### Drugs, natural health products, veterinary health products and medical devices:

Active ingredient: means a drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect.

**Device:** means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:

- (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
- (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
- (c) diagnosing pregnancy in human beings or animals,
- (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or,
- (e) preventing conception in human beings or animals.

It **does not include** such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal. **Drug:** includes any substance or mixture of substances manufactured, sold, or represented for use in a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, b) restoring, correcting or modifying organic functions in human beings or animals, or c) disinfection in premises in which food is manufactured, prepared or kept.

Drugs can be for human or veterinary use, include prescription, non-prescription (over-the-counter (OTC)) and controlled drugs.

**Note:** Drugs regulated under the <u>Controlled Drugs and Substances Act</u>, for the purpose of this document, are included in the definition of 'Drugs', however, import requirements are covered in <u>Memorandum D19-9-2</u>, <u>Importation and Exportation of Controlled Substances and Precursors</u>.

**Drug establishment licence (DEL):** a licence that allows a person to conduct a specified licensable activity (fabricate, package/label, distribute, import, wholesale or test a drug as required under Part C, Division 1A of the *Food and Drug Regulations* in a building in Canada. A DEL is not required for natural health products. Instead, these products require a site license as per the *Natural Health Products Regulations* to conduct the activities of fabrication, package/label and import for sale.

**Drug identification number (DIN):** is a computer-generated eight digit number assigned by Health Canada to a drug prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

**Drugs for an urgent public health need:** Drugs, which are permitted to be imported into Canada to address an urgent public health need. These drugs have been authorized for sale by a foreign regulatory authority (e.g. United States, Switzerland, or the European Union) but are not market authorized for sale in Canada (i.e. no Drug Identification Number (DIN)).

**Medical device:** means a device within the meaning of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals. Medical devices are classified as Class I, II, III, or IV, depending on their risk level.

**Medical device establishment licence (MDEL):** Licence issued to Class I manufacturers as well as importers or distributors of all device classes to permit them to import or distribute a medical device in Canada.

**Medical device licence (MDL):** A licence issued to manufacturers authorizing them to import or sell Class II, III, or IV medical devices in Canada.

**Natural health products:** means a substance set out in Schedule 1, or a combination of substances, in which all the medicinal ingredients are substances set out in Schedule 1 of the *Natural Health Products Regulations*, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or,
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Natural health products **do not include:** substances set out in Schedule 2 of the *Natural Health Products Regulations*, any combination of substances that includes a substance set out in Schedule 2, or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

**Natural product number (NPN or DIN-HM):** is an eight (8) digit numerical code assigned to each natural health product or homeopathic medicine approved to be marketed under the *Natural Health Products Regulations*.

**Non-prescription drugs (also known as over-the-counter drugs):** are health products that can be bought without a doctor's prescription. They are any drug that is not a prescription drug or controlled substance, but are distinguished from natural health products and veterinary health products, which need to meet specific criteria as per their definitions.

**Prescription drugs**: means a drug that is set out in the Prescription Drug List, as amended from time to time, or a drug that is part of a class of drugs that it is included in the Prescription Drug List.

**Sell:** includes (a) offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons, whether or not the distribution is made for consideration, and (b) lease, offer for lease, expose for lease or have in possession for lease.

**Veterinary health product (VHP):** means any of the following drugs that is in dosage form and that is not manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms:

- (a) a substance set out in Column I of Part 1 of List C of the Food and Drug Regulations that is consistent with the descriptive information set out in Columns II to V, or any combination of any substances in which all the medicinal ingredients are substances set out in Column I of Part 1 of that list if that combination is, in respect of each of those substances, consistent with the descriptive information set out in Columns II and III and the descriptive information set out in Columns IV and V that is, within each of those columns, common to those substances;
- (b) a homeopathic medicine set out in Column I of Part 2 of List C of the Food and Drug Regulations that is consistent with the descriptive information set out in Columns II to V, or any combination of homeopathic medicines set out in Column I of Part 2 of that list if that combination is, in respect of each of those homeopathic medicines, consistent with the descriptive information set out in Columns II and III and the descriptive information set out in Columns IV and V that is, within each

of those columns, common to those homeopathic medicines; and

(c) a traditional medicine set out in Column I of Part 3 of List C of the Food and Drug Regulations that is consistent with the descriptive information set out in Columns II to V, or any combination of traditional medicines set out in Column I of Part 3 of that list if that combination is, in respect of each of those traditional medicines, consistent with the descriptive information set out in Columns II and III and the descriptive information set out in Columns IV and V that is, within each of those columns, common to those traditional medicines.

These are veterinary drugs in dosage form, containing only substances from List C of the *Food and Drug Regulations*, which are substances such as: vitamins, minerals, or traditional and homeopathic medicines. They are used to maintain or promote health and welfare of companion animals and certain food-producing animals and are not for use to treat, prevent or cure disease.

**Site licence (SL):** a licence issued by Health Canada which provides the licensee authorization to conduct the activities of fabricating, packaging/labelling, and importing natural health products for sale.

Consumer products, cosmetics, radiation emitting devices and vaping products:

**Consumer product:** A product, including its components, parts or accessories that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.

**Danger to human health or safety:** Any unreasonable hazard, existing or potential, that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health, including an injury, whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health.

**Cosmetic:** Includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

**Radiation emitting device:** Any device that is capable of producing and emitting radiation, or any component of or accessory to a device that is capable of producing and emitting radiation.

**Vaping products:** Previously referred to as e-cigarettes and electronic nicotine delivery systems. Vaping products are defined as (a) a device that produces emissions in the form of an aerosol and is intended to be brought to the mouth for inhalation of the aerosol; (b) a device that is designated to be a vaping product by the *Vaping Products Labelling and Packaging Regulations*;; (c) a part that may be used with those devices; and (d) a substance or mixture of substances, whether or not it contains nicotine, that is intended for use with those devices to produce emissions. It **does not include** devices and substances or mixtures of substances that are excluded by the regulations, cannabis or cannabis accessories (as defined in subsection 2(1) of the *Cannabis Act*), ), tobacco products or their accessories.

Includes vaping devices, and their individual parts such as atomizers (heating element) and vaping liquids.

#### Pest control products:

**Pest control product**: is (a) A product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects; (b) an active ingredient that is used to manufacture anything described in paragraph (a); or, (c) any other thing that is prescribed to be a pest control product.

**Note:** Pest control products are classified as domestic, commercial, restricted or manufacturing. A pest control product can include a chemical, a device or a microbial agent.

**Device:** An article, an instrument, an apparatus, a contrivance or a gadget. Devices that are contained in Schedule 1 of the *Pest Control Products Regulations* are subject to registration under the *Pest Control Products Act*.

**Microbial agent:** A pest control product whose active ingredient is a micro-organism. It includes any metabolites and toxins produced by the micro-organism.

**Note:** A micro-organism is any organism too small to be visible to the naked eye, and includes viruses, bacteria, protozoa, algae, etc., that are represented for or used in controlling pests.

**Pest control product registration number (PCP Reg. No.):** Numerical code assigned to each pest control product approved under the *Pest Control Products Act* for import, distribution and use. The code consists of up to five digits or five digits with two additional characters at the end (e.g. 12345 or 12345.xx).

**Research authorization certificate number (RA No.):** Alphanumerical code assigned to each Research Authorization Certificate, authorizing specific pest control products for specific research purposes. The code consists of four digits, RA, and then the last two digits of the year issued (e.g. 1234-RA-12). Research Authorization Certificates are issued by Health Canada after review and approval of the appropriate information as outlined in the *Pest Control Products Regulations*, to conduct research on pest control products in support of registration or amendments to existing registrations.

**Research notification certificate number (RN No.):** Alphanumerical code assigned to each Research Notification Certificate, authorizing specific pest control products for specific research purposes. The code consists of four digits, RN, and then the last two digits of the year issued (e.g. 1234-RN-12). Research Notification Certificates are issued by Health Canada after review and approval of the appropriate information as outlined in the *Pest Control Products Regulations*, to conduct research on pest control products in support of registration or amendments to existing registrations. RN No.'s are issued for smaller scale research once the applicant notifies Health Canada, for research that does not require a full Research Authorization.

**Foreign product use (FPU) certificate number:** Numerical code assigned to each Foreign Product Use Certificate issued according to the Grower Requested Own Use Program, authorizing importation of specific unregistered pest control products for specific agricultural purposes. The code consists of six or seven digits, a dash, then three digits (e.g. 123456-123 or 1234567-123).

**Scheduled under the** *Pest Control Products Act*: This statement refers to pest control products that are not required to be registered (and as such would not have a PCP Reg. No.) in order to be imported and distributed for sale and use, as they are "are exempt from registration"). For a complete list, please refer to Schedule 2 of the *Pest Control Products Regulations*.

#### Hazardous products:

**Hazardous product:** Any product, mixture, material or substance that is classified in accordance with the *Hazardous Products Regulations* in a category or subcategory of a physical or a health hazard class listed in Schedule 2 of the *Hazardous Products Act.* 

**Note:** A hazardous product cannot be a(n):

- "consumer product" as defined under the Canada Consumer Product Safety Act,,
- "pest control product" as defined under the Pest Control Products Act
- "cosmetic", "device", "drug" or "food" as defined under the Food and Drugs Act,
- nuclear substance, within the meaning of the Nuclear Safety and Control Act, that is radioactive
- hazardous waste, being a hazardous product that is sold for recycling or recovery or is intended for disposal
- tobacco or a tobacco product as defined under the Tobacco and Vaping Products Act
- manufactured article
- explosive as defined under the Explosives Act
- wood or product made of wood

**Label:** A group of written, printed or graphic information elements that relate to a hazardous product. Labels are designed to be affixed to, printed on or attached to the hazardous product or the container in which the hazardous product is packaged.

**Safety data sheet:** A document that contains, under the headings that, by virtue of the *Hazardous Products Regulations,* are required to appear in the document, information about a hazardous product, including information related to the hazards associated with any use, handling or storage of the hazardous product in a work place.

**HMIRA registry number:** An identification number assigned to a hazardous product by Health Canada in the context of the *Hazardous Materials Information Review Act* to exempt a supplier subject to the *Hazardous Products Act* from having to disclose confidential business information, such as the chemical name of one or more trade-secret hazardous ingredients, on the safety data sheet or label of the hazardous product. As a replacement for confidential business information, the *Hazardous Materials Information Review Act* registry number is required to be shown on the safety data sheet of the hazardous product and, for certain claims, on the label of the hazardous product.

# **Guidelines**

#### Introduction

The CBSA assists Health Canada in administering Health Canada legislation as it relates to the importation of goods at the border.

#### Role of the Canada Border Services Agency

- 1. The CBSA is not required to verify, validate, stamp, and/or return any permits or licenses for goods on behalf of Health Canada.
- 2. The CBSA may detain goods under the authority of the <u>Customs Act</u> and refer them to Health Canada for an admissibility recommendation and disposition decision, either as a result of specific information or in the event that a border services officer finds/determines suspected contraventions of Health Canada's legislation.
- 3. The CBSA, in the case of suspect counterfeit products, works with the rights holder (i.e. an individual who owns a copyright or trademark) where they have filed a <u>Request for Assistance</u> to temporarily detain suspected counterfeit goods at the border to afford the rights holder the opportunity to potentially pursue legal action. For more information about the CBSA's Intellectual Property Rights Program, please refer to D19-4-3, Copyright, Trademarks and geographical indications.
- 4. The CBSA's enforcement role, on behalf of Health Canada, beyond the initial detention is limited to *Customs Act* contraventions. In such cases, the CBSA may seize the goods under the Customs Act.

#### **Role of Health Canada**

- 5. Health Canada is responsible for the administration and enforcement of all its legislation and regulations.
- 6. Health Canada will identify to the CBSA certain goods that may contravene Health Canada's legislation and regulations that pose a potential risk to human health, the safety of Canadians, or to the environment. Health Canada will request that the CBSA to detain these goods at the time of importation.
- 7. Health Canada's inspectors may examine, open, test, seize, take photographs and/or sample goods detained by the CBSA and may make copies of any record and/or document related to the detained goods in accordance with the relevant provisions of Health Canada's legislation and regulations.
- 8. Health Canada may follow-up with the importer, exporter or person responsible for the imported goods to gather information regarding admissibility and disposition of regulated products in the shipment.
- 9. Health Canada will provide a recommendation to the CBSA regarding the admissibility of detained goods that are suspected to be in contravention of Health Canada's legislation and regulations.
- 10. Health Canada's inspectors may provide opportunity or order disposition of goods detained by the CBSA in accordance with the relevant provisions of Health Canada's legislation and regulations that are reasonably believed to be in contravention. Health Canada will inform the CBSA of any processes

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being pursued, under their legislation and regulations, that may require the goods to be transferred to Health Canada or moved to another storage facility.

#### **Role of importers**

- 11. Importers are responsible for ensuring that all imported commodities are compliant with the requirements of applicable CBSA and Health Canada legislation.
- 12. Importers must also obtain and have available for examination all required licences, permits, registry numbers, labels, safety data sheets and/or documents as required by the Health Canada legislation. In some circumstances, these documents should accompany the shipment to facilitate the importation. Such documents may include: a copy of the establishment license; a copy of the site license; a No Objection Letter for clinical trial drugs; a Letter of Authorization under the Special Access Program; a Research Authorization or Research Notification Certificate; a Foreign Product Use certificate; or product label.
- 13. Importers, distributors, suppliers, transporters, manufacturers and/or retailers may obtain more information about Health Canada's requirements by visiting Health Canada's <u>website.</u>
- 14. Importers, and other entities that are recognized as being the "regulated party", may be responsible for all costs relating to the movement, destruction, disposal or exportation of goods that Health Canada has deemed inadmissible to Canada.

#### Interim orders (IO)

15. Interim Orders are issued by the Minister of Health under exigent circumstances. These orders are specific only to the goods specified in the Interim Order, outline measures and are valid for a limited duration. Upon expiration, they no longer apply and goods will continue to be processed as they were prior to the Interim Order coming into effect.

#### Single window initiative

- 16. CBSA's Single Window Initiative (SWI), Integrated Import Declaration (IID) release service option (SO) 911 allows importers and brokers to submit and obtain electronic release for commercial goods regulated by Participating Government Departments and Agencies.
- 17. The SWI IID <u>Electronic Commerce Client Requirements Document (ECCRD)</u> provides technical and system requirements information. Appendix B of the ECCRD includes a list of required data elements for all of Health Canada's import programs.
- Health Canada is a participant in the SWI and they have 12 different import programs, which includes: Consumer Products; Human Drugs; Natural Health Products; Controlled Substances and Precursors; Veterinary Drugs; Radiation Emitting Devices; Blood and Blood Components; Cells, Tissues and Organs; Active Pharmaceutical Ingredients; Donor Semen; Medical Devices; and, Pesticides.
- 19. When an importer or broker utilizes the SWI IID to obtain a release for goods that are regulated by Health Canada, they must submit all required Health Canada data elements or they may be issued an Administrative Monetary Penalty.
- 20. For more information on the SWI IID, please refer to CBSA's website.

For further information on release of commercial goods, please refer to <u>D17-1-4 Release of Commercial</u> <u>Goods.</u>

Note: Export or in-transit shipments of commercial goods are out of scope for the SWI IID.

#### Transhipments of Health Canada regulated goods

#### Food and Drugs Act

21. Section 38 of the *Food and Drugs Act*, pertains to the in-transit movement of packaged food, drugs, cosmetics and medical devices that enter Canada for the sole purpose of export and cannot be sold

for use or consumption in Canada.

- 22. Section 38 states that the conditions under which a transhipment is exempt from the *Food and Drugs Act*:
  - it is manufactured or prepared outside of Canada;
  - it is imported solely for the purpose of export and is not sold for consumption or use in Canada and;
  - it meets any other prescribed requirement.
- 23. A shipment may be split into multiple shipments for various destinations outside of Canada, but must remain in bond throughout its entire passage through Canada. However, for the exemption to apply, no manufacturing, packaging, labelling, testing or any other manipulation of the goods may be conducted in relation to the shipment while in Canada.
- 24. There is no exemption from the requirements of the *Food and Drugs Act* and regulations in instances where a health product is imported into Canada for further manufacturing, packaging (other than break bulk), labelling or testing and then the product is exported.

#### Pest Control Products Regulations

- 25. Section 3.1(1) of the <u>Pest Control Products Regulations</u> pertains to the in-transit movement of pest control products. If pest control products are moving in-transit through Canada, they are exempt from registration requirements. For pest control products that are not subject to the <u>Transportation of</u> <u>Dangerous Goods Act</u>, specific information must accompany the shipment (outlined in section 3.2 of the Pest Control Products Regulations)) pertaining to:
  - Safety Information
     Identification
     Hazard identification
     Active ingredient
     First aid measures
     Firefighting, handling, transport and storage
     Accidental release, decontamination and safe disposal
     Toxicological and ecological risk reduction
     Packaging
     Storage and transport
- Importation of drugs (prescription and non-prescription), natural health products, veterinary

# health products and medical devices for commercial activities under the Food and Drugs Act

# <u>Commercial importation of drugs (prescription and non-prescription), natural health products, veterinary health products</u>

26. Health Canada generally considers the following to be examples of commercial importations:

- An import shipment destined for a retailer, distributor, or other commercial establishment. This includes shipments being sent to independent sales contractors/distributors; to a health care practitioner for use in their practice; or to a qualified investigator of a drug that is to be given to or used to treat a patient or subject in a clinical trial.
- An import shipment from a single foreign supplier that consists of individually addressed parcels where the importer of record is an individual or company and there is no separate invoice for each of the individually addressed parcels.
- An import shipment that contains more than a 90-day supply of drugs, natural health products, veterinary health products, or medical devices (e.g. contact lenses) based on their directions for use or reasonable consumption, subject to inspector discretion and enforcement priorities established with the CBSA.
- An import shipment that is part of a pattern of repeat personal importations of the same drug, natural health product, veterinary health product, medical device to the same importer within a 90day period, where the total quantity imported in all shipments totals more than a 90-day supply based on its directions for use or reasonable intake, subject to inspector discretion.
- An import shipment that is accompanied by or associated with materials to be used for advertising
  or promotion.
- An import shipment destined for export sale, different requirements apply for transshipments (refer to paragraphs 21-24 of this memo).
- 27. The <u>Food and Drug Regulations</u> requires that all human and veterinary drugs in finished dosage form, imported for sale, be labelled with a Drug Identification Number (DIN). Similarly, all natural health products imported for sale must be labelled with a Natural Product Number (NPN) or Homeopathic Medicines Number (DIN-HM) in accordance with the <u>Natural Health Products Regulations</u>.
- 28. Importers of veterinary health products (VHPs) for sale are required to notify Health Canada prior to import. A Health Canada Notification Number (NN) should be referenced on the product. Shipments may be required to be referred to Health Canada for verification of notification. VHPs do not require a Site Licence (SL), nor does the importer have to hold a Drug Establishment Licence (DEL).
- 29. Shipments of human drugs and natural health products not available in Canada may be authorized for importation through the Special Access Program or the clinical trial provisions of the *Food and Drug Regulations* or the *Natural Health Products Regulations*. Veterinary drugs not available in Canada may

be authorized for importation through either the Emergency Drug Release Program (EDR) or an Experimental Study Certificate (ESC). These shipments of human/vet drugs and NHPs may not be labelled with a DIN/NPN/DIN-HM, but will be accompanied by a Health Canada authorization letter (No Objection Letter, Notice of Authorization, or Letter of Authorization, as appropriate).

- 30. For human drugs, human drug active ingredients, veterinary drugs, veterinary active pharmaceutical ingredients, and natural health products, importers of commercial shipments must hold aa Drug Establishment Licence (DEL) or Site Licence (SL) for the activity of importation for the category of drug being imported. The foreign manufacturing site must be listed on the Importer's DELL.
- 31. For veterinary active pharmaceutical ingredients on List A, importers of commercial shipments must hold a Drug Establishment Licence (DEL) for the activity of importation for the category of APIs set out in List A that are for veterinary use. The foreign manufacturing site must be listed on the Importer's DEL. These requirements also apply to importation by a pharmacist, a veterinary practitioner or a person who compounds a drug under the supervision of a veterinary practitioner, of an active pharmaceutical ingredient for veterinary use that is for the purpose of compounding, pursuant to a prescription, a drug in dosage form that is not commercially available in Canada, if that ingredient is set out in List A.

- 32. Importers of ingredients for use in manufacturing veterinary health products or natural health products are not required to have a Drug Establishment Licence (DEL) or Site Licence (SL) for the activity of importation.
- 33. Bulk veterinary active ingredients are considered to be drugs in final dosage form when they are intended for direct administration to animals (e.g. topically, in water, in feed) without further compounding by a pharmacist or veterinarian or manufacturing). **DIN and DEL requirements apply in these circumstances.**
- 34. The *FDR* permit importation of certain foreign unauthorized drugs to address an <u>Urgent Public Health</u> <u>Need</u> in Canada, these drugs can be found on the <u>List of Drugs for an Urgent Public Health Need</u>. They **do not** require a DIN, but they are required to be imported by a DEL holder with the activity of import. The drug must be exported directly from the foreign regulatory authority/foreign country (Only United States, Switzerland or European Union countries) as specified for the drug on the List.
- 35. Under Section C.01.045 of the *Food and Drug Regulations*, importation of prescription drugs is restricted to practitioners, drug manufacturers, wholesale druggists or registered pharmacists, or a resident of a foreign country while a visitor in Canada.
- 36. The CBSA may detain and refer drugs, natural health products, and veterinary health products to Health Canada for an admissibility recommendation when the requirements noted in this section are not suspected to be met.

#### Commercial importation of medical devices

- 37. The <u>Medical Device Regulations</u> require that Class II, III and IV medical devices have a medical device licence (MDL) for each device in order to be imported for sale in Canada.
- 38. Importers of commercial shipments of medical devices must hold aa Medical Device Establishment Licence (MDEL). However, the following are exempt from the requirement of having an MDEL to import medical devices:

39. Retailers, including:

- Companies that sell medical devices to the end-user (ultimate consumer) for their own personal use; and
- Canadian manufacturers of Class I medical devices who sell their devices solely to ultimate consumers or end users;
- Healthcare facilities;
- Manufacturers of Class II, III or IV medical devices;
- Manufacturers of Class I devices that import or distribute solely through a person that holds an MDEL;
- Importations of a medical device by a person for their own personal use, unless there is evidence that the operation of the device would require assistance of another individual, including a professional, the person's doctor, or a health practitioner;
- Establishments that import or sell devices only for use on animals (label of the device must state that it is for use on animals);
- Dispensers; and,
- Establishments that only import or sell custom-made devices, medical devices for special access, or, medical devices for investigational testing involving human subjects, such as for clinical trials.

# Importation of drugs (prescription and non-prescription), natural health products and veterinary health products for personal use under the *Food and Drugs Act*

#### Personal use importation of prescription drugs

40. Health Canada considers a personal importation as an importation by an individual for their own use or for use on a person or animal under their care or guardianship and which does not meet the definition of a commercial importation as set out in paragraph 26 of this memo.

41. Under Section C.01.045 of the *Food and Drug Regulations,* importation of prescription drugs is restricted to practitioners, drug manufacturers, wholesale druggists or registered pharmacists, or a resident of a foreign country while a visitor in Canada.

**Note:** drugs imported by practitioners for treating patients or animals are not considered to be personal importations but rather commercial importation for sale.

Canadian residents

42. Health Canada may exercise enforcement discretion to permit a Canadian returning from abroad to bring with them, on their person, a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug. This discretion is reserved for Canadian residents returning to Canada with prescription drugs, which were dispensed for a treatment prior to leaving Canada, or drugs obtained through a renewed prescription while abroad or filled prescription to treat an illness, injury, or as part of medical care while abroad.

43. Prescription drugs imported, as per paragraph 27 above, must be for the individual's personal use or the use of a person or animal for whom they are responsible and with whom they are travelling.
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Additionally, all personal importations of prescription drugs must be packaged in the hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains.

- 44. The CBSA may detain and refer prescription drugs to Health Canada when these conditions are not met.
- 45. Canadian residents may not import prescription drugs by mail or courier.

#### Non-residents of Canada

- 46. Visitors to Canada and non-residents arriving from abroad are permitted to import a single course of treatment or a 90-day supply of a prescription drug hand-carried for their personal use or the use of a person or animal under their care and with whom they are travelling.
- 47. Visitors and non-residents are allowed to import a single course of treatment or a 90 day supply of a prescription drug by mail or courier.
- 48. All personal importations of prescription drugs must be packaged in the hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains.
- 49. The CBSA may detain and refer prescription drugs to Health Canada when import requirements are not met.

#### Personal use importation of non-prescription drugs, natural health products, and veterinary health products

- 50. Residents, non-residents and visitors to Canada can import for their own use or for a person or a companion animal under that individual's care, a single course of treatment or up to a 90-day supply of veterinary health products, natural health products and non-prescription drugs every 90 days. The medication must be packaged in hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains and no indication of sale in Canada, subject to inspector discretion for personal quantity.
- 51. The CBSA may detain and refer veterinary health products, natural health products and nonprescription drugs to Health Canada when these requirements are not met.

#### Personal use importation of veterinary drugs for food producing animals

- 52. Personal importation of market authorized veterinary drugs or notified veterinary health products (VHPs) for food producing animals or animals intended as food (including all horses) is restricted to a single course of treatment or a 90-day supply per animal.
- 53. For veterinary drugs or veterinary health products (VHPs) not authorized or notified in Canada, import is restricted to a single course of treatment or a 90-day supply per animal, and only to drugs on List B - List of Certain Veterinary Drugs Which May Be Imported but Not Sold. Importers may provide information on the species and the number of animals being treated in order to indicate how they meet the requirements prescribed on List B.

#### Personal use importation of medical devices

54. Personal use generally does not include medical devices that require the intervention of another person (i.e. use on an individual). The Medical Device Regulations do not apply to importation of medical devices for personal use. As an example, breast implants, an x-ray machine or a defibrillator are not considered to be a personal use import.

Importation of consumer products, cosmetics, radiation emitting devices and vaping products for commercial activities under the Canada Consumer Product Safety Act and the Tobacco and Vaping Products Act

Note: The information in this section applies to both commercial and personal use importations except where otherwise indicated.

#### Commercial and personal use importation of consumer products

- 55. Under the Canada Consumer Product Safety Act, the importation into Canada, manufacture, sale and advertisement of consumer products are regulated by Health Canada.
- 56. This legislation applies to commercial and non-commercial (e.g. personal use) importations of new or used consumer products (including their components, parts or accessories and packaging), and allows inspectors designated under the Act to examine, test, seize, detain and/or take samples of consumer products imported into Canada.

Note: For the purposes of this memorandum, consumer products may be grouped into two categories: prohibited and regulated products.

Prohibited consumer products

57. Schedule 2 of the Canada Consumer Product Safety Act (refer to Appendix A of this memorandum) lists certain products which are prohibited from importation, sale, manufacture or advertisement in

Canada. Importers may contact one of the regional Health Canada Consumer Product Safety Offices to verify whether specific products are prohibited (refer to <u>Appendix B</u> of this memorandum).

58. The CBSA will detain prohibited products listed under Schedule 2 of the *Canada Consumer Product Safety Act*, and refer them to Health Canada.

#### Regulated consumer products

- 59. The Canada Consumer Product Safety Act stipulates that no person shall import, sell, or advertise a consumer product that does not meet the requirements set out in the regulations or that is a danger to human health or safety. These products must meet the prescribed requirements and conditions set out in the Canada Consumer Product Safety Act and regulations made thereunder to be legally imported into Canada.
- 60. The CBSA will detain regulated consumer products and refer them to Health Canada to verify import requirements when it is suspected that a regulated product may pose a danger to human health and/or safety.

#### Commercial and personal use importation of cosmetics

61. The CBSA will detain cosmetic importations (personal and commercial shipments) and refer them to Health Canada to determine import requirements when it is suspected that a product may contravene the *Food and Drugs Act* or the <u>Cosmetic Regulations</u>.

#### Commercial and personal use importation of radiation emitting devices

62. The CBSA will detain radiation emitting devices importations (personal and commercial shipments) and refer them to Health Canada to determine import requirements when it is suspected that a radiation emitting device may pose a danger to human health or safety, or may contravene the *Radiation Emitting Devices Act* or its regulations.

### Commercial importation of vaping products

- 63. As per the *Tobacco and Vaping Products Act* and *Canada Consumer Product Safety Act*, nicotine is permitted in vaping products sold in Canada without a prescription. "Vaping products" (previously referred to as e-cigarettes and electronic nicotine delivery systems) include vaping devices, and their individual parts such as atomizers (heating element) and vaping liquids, which all fall under Health Canada's Consumer Product Safety portfolio.
- 64. The following commercial shipments of vaping products may be referred to Health Canada for an admissibility recommendation:
  - A shipment that discloses a nicotine concentration of more than 66 mg/mL or is suspected to contain more than 66mg/mL (Product Safety referral);
  - Any vaping products that make health claims, regardless of ingredients contained including nicotine (Health product referral);
  - Unlicensed vaping products labelled or tested to contain health product ingredients other than nicotine as the sole ingredient (e.g. NHP, non-prescription, prescription ingredients, or a mixture of health product ingredients) (Health product referral);
  - Unlicensed health products (other than vaping products) containing nicotine (Health product referral).

### Personal use importation of vaping products

- 65. Personal shipments of vaping products containing 66 mg/mL or less of nicotine (only identifiable where the vaping product specifies the concentration), non-prescription (i.e. not on the <u>Prescription</u> <u>Drug List</u> and not containing a controlled substance in a schedule to the <u>Controlled Drugs and</u> <u>Substances Act</u>) or <u>Natural Health Products ingredients</u>, including re-usable delivery systems, with or without health claims may be imported for personal use (reasonable amounts for 90 day supply within a 90 day period).
- 66. Note, vaping devices that contain substances or mixtures of substances that are excluded by the regulations, including cannabis, as defined in subsection 2(1) of the Cannabis Act, must adhere to those regulated product import requirements, be it the Food and Drugs Act or the Cannabis Act or the (refer to Memorandum D-19-9-2, Importation and Exportation of Cannabis, Controlled Substances and Precursors.). In such cases, the device is not considered a vaping product regulated under the Tobacco and Vaping Products Act.
- 67. Vaping products that indicate they contain nicotine, but do not disclose a concentration may be referred as followed: with health claims (health product referral to Health Canada); without health claims (product safety referral to Health Canada). Vaping products without any indication of nicotine or other active ingredient: with health claims (health product referral to Health Canada); without health claims (may be released).

#### Commercial and personal use importation of tobacco

68. Any product made in whole or in part of tobacco, including tobacco leaves:

• These products fall under the *Tobacco and Vaping Products Act* (Tobacco and Vaping referral).

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• A tobacco product also includes papers, tubes and filters intended for use with that product; a device, other than a water pipe, that is necessary for the use of that product and the parts that may be used with the device.

#### Commercial and personal use importation of nicotine

69. Loose, Tobacco-free leaves containing Nicotine:

- Considered a prescription drug Any nicotine containing product with loose leaves, or ground-up leaf material, (i.e. leaves which are not in a pouch/sachet/etc.) for consumption are considered Prescription Drugs.
- Personal importations Only permitted if the importer is a visitor to Canada, practitioner or registered pharmacist for their own personal use (90-day supply).
- 70. Tobacco-free leaves in pouches for oral absorption containing greater than 4mg of nicotine per dosage unit (i.e. per pouch):
  - Considered a prescription drug the amount of nicotine specified refers to the amount per dosage unit, which would be a single pouch. It does not refer to a concentration, or an amount in a tin or box, etc.
  - Personal Importations Permitted only if the importer is a visitor to Canada, practitioner or registered pharmacist for their own personal use (90-day supply).
- 71. Tobacco-free leaves in pouches for oral absorption containing 4 mg or less of nicotine per dosage unit (i.e. per pouch):
  - Considered as Natural Health Product the amount of nicotine is calculated per pouch / dosage unit.
  - Personal importation Permitted for anyone to import for their own personal use (90 day supply).

#### Importation of Pest Control Products for commercial activities under the <u>Pest Control Products</u> <u>Act</u>

#### Commercial importation of pest control products

- 72. Pest control products imported into Canada must meet the requirements in the *Pest Control Products Act* and its regulations. They must be either:
  - registered (with a PCP Reg. No.) and bear the Canadian label;
  - authorized for specific research purposes (with a RA No. or RN No.);
  - authorized under the Grower Requested Own Use Program for specific agricultural use (with a Foreign Product Use certificate number);
  - scheduled or otherwise authorized and meet the Canadian labelling requirements; or
  - manufactured only for export and contain an active ingredient that is registered in Canada.
- 73. The CBSA will detain pest control products and refer them to Health Canada to verify import requirements when it is suspected that the product endangers human health or safety or the environment, or may otherwise contravene the *Pest Control Products Act* or its regulations.

#### Importation of Pest Control Products for personal use under the Pest Control Products Act

#### Personal use importation of pest control products

- 74. There is an exemption from the <u>Pest Control Products Regulations</u>, for any pest control product imported into Canada, for small amounts for personal use, when the following conditions are met:
  - (a) Not an organism or a device of a type described in Schedule 1 of the *Pest Control Products Regulations*;
  - (b) The product is being imported by a user for their personal use (i.e. not intended for distribution,
    - including sale);
  - (c) The product is in their personal possession at the time of the importation;
  - (d) The quantity is not more than 500 g or 500 mL;
  - (e) By virtue of its active ingredient and concentration, the product would have the product class designation of "DOMESTIC" if it were registered in Canada ((registered Domestic Class products can be found here: <u>https://pr-rp.hc-sc.gc.ca/ls-re/index-eng.php;);</u>
  - (f) The product is registered or otherwise authorized in the country of origin as a product equivalent to a pest control product;
  - (g) The product is in its original package with the original label intact; and
  - (h) The information on the package and label is in either English or French, is clear and legible, allows for the determination of the active ingredient, concentration and quantity of the product and includes the registration or authorization number assigned by the regulatory body in the country of origin.

Importation of hazardous products for commercial activities under the Hazardous Products Act

#### Commercial importation of hazardous products (not permitted for personal use importation)

- 75. The importation into Canada, and sale of hazardous products intended for use, handling or storage in a workplace in Canada are regulated under the <u>Hazardous Products Act</u>, and the <u>Hazardous</u> <u>Products Regulations</u>. This legislation applies to commercial importations of hazardous products (including their packaging), and allows inspectors designated by Health Canada to examine, test, seize, detain or take samples of hazardous products imported into Canada.
- 76. The following products are <u>not</u> subject to the *Hazardous Products Act* and the *Hazardous Products Regulations*:
  - Any nuclear substance, within the meaning of the <u>Nuclear Safety and Control Act</u>, that is radioactive;
  - Any hazardous waste, being a hazardous product that is sold for recycling or recovery or is intended for disposal;
  - Any tobacco or a tobacco product as defined in section 2 of the *Tobacco and Vaping Products Act*,
  - Any manufactured article, as defined under section 2 of the Hazardous Product Act;
  - Any pest control product as defined in subsection 2(1) of the Pest Control Products Act;
  - Any explosive as defined in section 2 of the *Explosives Act*;
  - Any cosmetic, device, drug or food, as defined in section 2 of the Food and Drugs Act;
  - Any consumer product as defined in section 2 of the Canada Consumer Product Safety Act; and
  - Any wood or product made of wood.
- 77. In accordance with the *Hazardous Products Act*, an importer must obtain or prepare, on or prior to the importation of the hazardous product, a safety data sheet that meets the requirements set out in the *Hazardous Products Regulations*. However, the safety data sheet may travel separately from the imported product or the safety data sheet may have already been obtained by the importer. If the hazardous product being imported into Canada is not accompanied by a safety data sheet, the BSO may request the information from the importer of the product as the importer would be the responsible party to provide this information. If they are unable to obtain the information, it would be up to CBSA's discretion if they choose to allow the product to enter into Canada or refuse it's entry. The importer must also affix, print or attach to the hazardous product or the container in which the hazardous product is packaged, a label that meets the requirements set out in the aforementioned regulations. However, a non-compliant label is permitted for importation, if the hazardous product is used or sold.
- 78. No supplier shall sell or import a hazardous product that is intended for use, handling or storage in a workplace in Canada if the hazardous product or the container in which the hazardous product is packaged has affixed to, printed on or attached to it, information about the hazardous product that is false, misleading or likely to create an erroneous impression with respect to the information that is required to be included on a label or safety data sheet for that hazardous product, in order for the supplier to comply with the *Hazardous Products Act*.
- 79. The CBSA will detain hazardous products and refer them to the Workplace Hazardous Materials Bureau of Health Canada to verify import requirements when it is suspected that a hazardous product may contravene the *Hazardous Products Act* or its regulations.

#### **Penalty information**

80. Penalties (including administrative monetary penalties, fines and imprisonment) may apply for failure to comply with the *Food and Drugs Act, Canada Consumer Product Safety Act, Radiation Emitting Devices Act, Pest Control Products Act, Hazardous Products Act, <u>Hazardous Materials Information Review Act</u>, and/or the <i>Customs Act*. The penalties are outlined in the respective legislation.

#### Health Canada contact information

81. Any questions concerning Health Canada's administration of its legislation should be directed to Health Canada. Please refer to <u>Appendix B</u> for a list of Health Canada contacts.

82. For more information regarding the CBSA's administration of Health Canada legislation as it relates to goods being imported into Canada, call the Border Information Service at **1-800-461-9999**. From outside Canada, call **204-983-3500** or **506-636-5064**. Long distance charges will apply. Agents are available Monday to Friday (08:00 – 16:00 local time / except holidays). TTY is also available within Canada: **1-866-335-3237**.

# Appendix

#### Appendix A – Prohibited consumer products

Under the *Canada Consumer Product Safety Act*, section 5, it is prohibited to manufacture, import, advertise or sell a Consumer Product listed in Schedule 2. Those consumer products are:

- 1. Jequirity beans (*abrus precatorius*) or any substance or article that is made from or that includes jequirity beans in whole or in part.
- 2. Spectacle frames that, in whole or in part, are made of or contain cellulose nitrate.
- 3. Baby walkers that are mounted on wheels or on any other device permitting movement of the walker and that have an enclosed area supporting the baby in a sitting or standing position so that their feet touch the floor, thereby enabling the horizontal movement of the walker.
- 4. Products for babies, including teethers, pacifiers and baby bottle nipples that are put in the mouth when used and that contain a filling that has in it a viable micro-organism.
- 5. Structural devices that position feeding bottles to allow babies to feed themselves from the bottle while unattended.
- 6. Disposable metal containers that contain a pressurizing fluid composed in whole or in part of vinyl chloride and that are designed to release pressurized contents by the use of a manually operated valve that forms an integral part of the container.
- 7. Liquids that contain polychlorinated biphenyls for use in microscopy, including immersion oils but not including refractive index oils.
- 8. Kites any part of which is made of uninsulated metal that is separated from adjacent conductive areas by a non-conductive area of less than 50 mm and that either
  - (a) has a maximum linear dimension in excess of 150 mm, or
  - (b) is plated or otherwise coated with a conductive film whose maximum linear dimension exceeds 150 mm.
- 9. Kite strings made of a material that conducts electricity.
- 10. Products made in whole or in part of textile fibres, intended for use as wearing apparel, that are treated with or contain tris (2,3 dibromopropyl) phosphate as a single substance or as part of a chemical compound.
- 11. Any substance that is used to induce sneezing, whether or not called "sneezing powder", and that contains
  - (a) 3,3'-dimethoxybenzidine (4,4'-diamino-3,3'-dimethoxybiphenyl) or any of its salts;
  - (b) a plant product derived from the genera Helleborus (hellebore), Veratrum album (white hellebore) or Quillaia (Panama Wood);
  - (c) protoveratrine or veratrine; or
  - (d) any isomer of nitrobenzaldehyde.
- 12. Cutting oils and cutting fluids, that are for use in lubricating and cooling the cutting area in machining operations, and that contain more than 50 μg/g of any nitrite, when monoetha-nolamine, diethanolamine or triethanolamine is also present.
- 13. Urea formaldehyde-based thermal insulation, foamed in place, used to insulate buildings.
- 14. Lawn darts with elongated tips.
- 15. Polycarbonate baby bottles that contain 4, 4'-isopropylidenediphenol (bisphenol A).
- 16. Products that are made, in whole or in part, of polyurethane foam that contains tris (2-chloroethyl) phosphate and that are intended for a child under three years of age.

#### Appendix B - Health Canada product specific contact information

General questions regarding the	Email: healthproduct-import-produitsante@hc-	
importation of drugs, veterinary health	sc.gc.ca	
products, natural health products and	Phone: 833-622-0414	
medical devices		
Questions regarding the importation	Email: hpbcp-pcpsf@hc-sc.gc.ca	
requirements of health products, please	Phone: 1-800-267-9675	
contact the Health Product Border		
Compliance Program		
Regional questions related to health	Atlantic Region: insp.aoc-coa@hc-sc.gc.ca	
product referrals	Tel: 1-902-426-4775	
	Quebec Region : <u>QC.UIF-BIU@hc-sc.gc.ca</u> Tel: 1-800-561-3350	
	Ontario Region: <u>ON.BIU-UIF@hc-sc.gc.ca</u>	
	Tel: 1-416-973-1600	
	Provinces of Manitoba and Saskatchewan:	
	insp_msoc_coms@hc-sc.gc.ca	
	Tel: 1-204-594-8061	
	Provinces of Alberta, Northwest Territories,	
	Nunavut, and Yukon: insp_aboc-coa@hc-	
	sc.gc.ca	
	Tel: 1-780-495-0490	
	British Columbia Region: insp_woc-coo@hc-	
	sc.gc.ca	
	Tel: 1-604-666-3350	
Consumer Products and Cosmetics	General Enquiries: Tel: 1-866-662-0666	
	Atlantic Region: <u>Atlantic.ProdSafe@hc-sc.gc.ca</u>	
	Quebec Region: Quebec.Prod@hc-sc.gc.ca	
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	Ontario Region: <u>Tor.ProdSafe@hc-sc.gc.ca</u>
	Provinces of Manitoba and Saskatchewan: MBSK.ProdSafe@hc-sc.gc.ca
	Provinces of Alberta, Northwest Territories, Nunavut and Yukon: <u>Alberta.ProdSafe@hc-</u> <u>sc.gc.ca</u>
	British Columbia Region: <u>Bby.ProdSafe@hc-</u> <u>sc.gc.ca</u>
	Enquiries from the United States of America Tel: 1-866-662-0666
	Enquiries from international locations other than the United States
	Africa: Alberta.ProdSafe@hc-sc.gc.ca
	Asia: <u>Bby.ProdSafe@hc-sc.gc.ca</u>
	Australia: <u>Alberta.ProdSafe@hc-sc.gc.ca</u>
	Central and South America: MBSK.ProdSafe@hc- sc.gc.ca
	Europe: <u>Atlantic.ProdSafe@hc-sc.gc.ca</u>
Radiation Emitting Devices	Consumer and Clinical Radiation Protection Bureau:
	<u>ccrpb-pcrpcc@hc-sc.gc.ca</u> Tel: 613-954-6699
Pest Control Products	
	Pesticide Compliance Program
	<b>General enquiries regarding importation</b> <b>requirements of pest control products:</b> pcp-pcp@hc-sc.gc.ca Tel: 613-736-3673
	Questions related to pest control product importation referrals:
	British Columbia, Yukon, Northwest Territories and Nunavut bcpesticides@hc-sc.gc.ca Tel: 604-653-5473
	Alberta, Saskatchewan and Manitoba info.pesticides.prairies@hc-sc.gc.ca Tel: 403-473-4555
	<b>Ontario</b> info.pesticides.ontario@hc-sc.gc.ca Tel: 519-826-2895
	<b>Quebec</b> info.pesticides.quebec@hc-sc.gc.ca Tel: 514-283-7306
	New Brunswick, Nova Scotia, Prince Edward

	Island, and Newfoundland and Labrador info.pesticides.atlantic@hc-sc.gc.ca Tel: 902-365-8669
Hazardous Products	General Enquiries: Tel: 1-855-407-2665
	Regarding the Hazardous Products Act or its Regulations: whmis-simdut@hc-sc.gc.ca
	Regarding the Hazardous Materials Information Review Act or its Regulations: <u>whmis.claim-</u> <u>demande.simdut@hc-sc.gc.cawhmis.claim-</u> <u>demande.simdut@hc-sc.gc.ca</u>

# References

Consult these resources for further information.

# Applicable legislation /Regulatory Customs Act

Canada Border Services Agency Act Food and Drugs Act <u>Hazardous Materials Information Review Act</u> Food and Drug Regulations Natural Health Products Regulations Medical Device Regulations Cosmetic Regulations Pest Control Products Regulations Hazardous Products Regulations

### Acts

Customs Act – Sections 101 and 102 and subsection 107(5)

<u>Canada Border Services Agency Act</u> – Subsections 5(1) and 5(2)

Cannabis Act

Food and Drugs Act - Sections 2, 16, 23, 25, 27, 37, 38

<u>Canada Consumer Product Safety Act</u> – Section 2, 5-9, subsections 13(1) and 13(5), 21(1) and 21(2), section 31, subsections 32(1) and 32(2) and Schedule 2

Controlled Drugs and Substances Act

Radiation Emitting Devices Act - Sections 2, 3, 4, 5, subsections 8(1) and 8(5) and section 10

<u>Pest Control Products Act</u> – Section 2, subsections 6(1)-(3), sections 48 and 52, subsections 53(1) and 53(2), section 55, subsections 57 (1)-(3) and 59(1)-(3)

Hazardous Products Act - Sections 2, 12, 14, 14.1, 14.2, 20-26, 28, and Schedule 1

Hazardous Materials Information Review Act - Sections 10 and 11

Nuclear Safety and Control Act

<u>Tobacco and Vaping Products Act</u> – Section 2 <u>Transportation of Dangerous Goods Act</u>

### Regulations

Cosmetic Regulations – Sections 5-8, subsections 9(1) and 9(2), and section 30

- A.01.026, A.01.040, A.01.041, A.01.043, A.01.044 (1) and (2), C.01.001(1), C.01A.002(3), C.01A.004 (1) to (3), C.01.014 (1) and (2), C.01.045, C.01.613(1) and (2), C.01.615 (1), C.10.001 (2)

<u>Hazardous Products Regulations</u> – Parts 1, 3, 4, and Schedules 1-5

<u>Medical Devices Regulations</u> – Sections 1, 2, 26, and subsections 44(1), (2), (3) and (4)

<u>Natural Health Products Regulations</u> – Subsections 1(1), 4(1)-(3), 27(1) and (2), and section 100

<u>Pest Control Products Regulations</u> – Section 1, paragraphs 3(1)(a) and 3(1)(f), sections 3.1, 3.2, 3.3, 4, 36, 42, 47 and 51

Vaping Products Labelling and Packaging Regulations - Part 2, section 49

## Superseded memoranda D

D19-9-1, January 24, 2017

### **Issuing office**

Other Government Department (OGD) Programs Unit

Program and Policy Management Division Commercial and Trade Directorate Commercial Branch

# **Contact us**

Contact border information services

# **Related links**

D19-9-2 Importation and Exportation of Cannabis, Controlled Substances and Precursors