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Committee on Import Licensing

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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES¹

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES (2015)

CANADA

The following communication, dated 30 September 2016, is being circulated at the request of the delegation of Canada.

Introduction

Import licences are required for goods subject to restrictions related to measures taken to safeguard domestic producers against injurious imports pursuant to either GATT Article XIX or international commitments (e.g. narcotics and endangered species of fauna and flora). Import controls are also imposed on some products on grounds of public interest, or for monitoring purposes. This is accomplished either through import licensing measures or through certain other formalities at the port of entry. Effective 1 January 1995 (1 August 1995 for wheat, wheat products, barley, barley products, butter, dry whey and cream), Canada converted its agricultural import controls to a system of tariff rate quotas (TRQs); import licences are required as a condition of importation of quantities eligible for the in-quota rate of duty.

Import controls are administered by a limited number of government departments. It is not practical, however, to provide a general description of the procedures involved as they vary, in certain particulars, from department to department. Consequently, replies to the Questionnaire have been organized according to the different legislative instruments under which import controls are maintained.

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¹ See G/LIC/3, Annex, for the Questionnaire.

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1 CONTROLLED DRUGS AND SUBSTANCES ACT

Outline of system

1. The importation of controlled substances, industrial hemp and precursor chemicals is governed by regulations made under the *Controlled Drugs and Substances Act* (CDSA), which was enacted in 1996 and came into force in 1997. The CDSA is the means by which Canada fulfils its obligations under the UN Single Convention on Narcotic Drugs, 1961, the UN Convention on Psychotropic Substances, 1971, and the UN Convention Against Illicit Traffic in Narcotics Drugs and Psychotropic Substances, 1988.

The CDSA establishes a legislative framework that essentially prohibits all activities, e.g., importation, exportation, production, distribution, etc., with controlled substances, industrial hemp and precursor chemicals, unless authorized by regulation. The regulations made under the CDSA therefore set out the circumstances under which activities with controlled substances, precursor chemicals, cannabis and industrial hemp are permitted.

The substances regulated under the CDSA are grouped into six Schedules (Schedules I to VI) to the Act. Schedules I to V list controlled substances (including analgesics, stimulants, sedatives, hallucinogens and anabolic steroids) while Schedule VI lists precursor chemicals.

The following regulations outline provisions pertaining to the legal import of controlled substances, precursor chemicals and industrial hemp:

"Controlled Substances"

- Benzodiazepines and Other Targeted Substances Regulations: Sets out the circumstances and requirements in which producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct regulated activities including possession, sale, distribution, importing and exporting, and production of substances listed in the Schedules to the Regulations. These Regulations also apply to benzodiazepines and other psychoactive substances defined as targeted substances under the regulations.
- Narcotic Control Regulations: Sets out the circumstances and requirements in which producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct regulated activities including possession, sale, distribution, importing and exporting, and production of substances listed in the Schedule to these Regulations referred to as "narcotics". Examples of narcotics included in this group are cocaine, opium, codeine, morphine and cannabis (marihuana).
- Access to Cannabis for Medical Purposes Regulations: The regulations provide reasonable access to cannabis for medical purposes by allowing medically authorized individuals the option of purchasing from one of the producers licensed by Health Canada, or, registering with Health Canada to produce a limited amount for their own medical purposes, or designating someone to produce it for them. As of August 24, 2016, the Access to Cannabis for Medical Purposes Regulations replaced the former Marihuana for Medical Purposes Regulations
- Part G of the Food and Drug Regulations ["controlled drugs"]: Governs the activities of producers, distributors, importers, exporters, pharmacists, practitioners, and hospitals including possession, sale, distribution, importing, exporting, and production of substances listed in the Schedule to these Regulations and referred to as "controlled drugs" such as stimulants, sedatives, and anabolic steroids.
- Part J of the Food and Drug Regulations ["restricted drugs"]: Governs the activities of producers, distributors, importers, exporters, and research institutions including possession, sale, distribution, importing, exporting, and production of substances listed in the Schedule to these Regulations and referred to as "restricted drugs" such as MDMA, LSD, and psilocybin.

"Industrial Hemp"

- Industrial Hemp Regulations: Sets out the circumstances and requirements for the importation, exportation and possession, as well as the production, sale, provision, transport, sending or delivering of industrial hemp for commercial purposes. Hemp is defined in these Regulations as the *Genera Cannabis* plant, its leaves and flowering heads containing less than 0.3% of tetrahydrocannabinol (THC), and includes the derivatives of the plant and plant parts, and the derivatives of non-viable cannabis seed.

"Precursor Chemicals"

- Precursor Control Regulations: Sets out the circumstances and requirements in which producers, distributors, importers, exporters, pharmacists, practitioners, and hospitals may conduct regulated activities, including production, sale/provision, packaging, importation and exportation of two broad classes of chemicals listed in Parts 1 and 2 of Schedule VI to the CDSA:
 - Class A precursors: ephedrine, pseudoephedrine, piperidine, red/white phosphorus, etc.
 - Class B precursors: acetone, hydrochloric acid, toluene, etc.

While these regulations govern the import of controlled substances, precursors and industrial hemp may be referred to as three different "licensing/permit systems" – as procedures vary somewhat between the classes of substances – overall, the "systems" are very similar. In this regard, unless otherwise specified in the text below, procedures are the same for each type of substance.

Purpose and coverage of licensing

- 2. Prospective importers of controlled substances, precursors or industrial hemp must be authorized under respective regulations to conduct activities, including importation, with specific substances. With the exception of Class B precursor chemicals, the authorized importer must apply for an import permit for each individual shipment. The application must specify the supplier's name, address and country, the quantity and type of substances being imported as well as the method of transport and the Customs port of entry. Import permits are valid for one shipment only.
- 3. The system applies to controlled substances, industrial hemp and precursor chemicals from all countries. While there is no actual restriction on which countries these substances can be imported from, substances are rarely imported from countries that are not party to the UN Drug Control Conventions. However, not all substances that are controlled in Canada are controlled in other jurisdictions (e.g., impurities, analogs or derivatives of certain controlled substances, anabolic steroids, etc.).
- 4. The import permit system is intended to ensure the legitimate trade in controlled substances and precursor chemicals and minimize the risk of those substances being diverted to illicit markets by monitoring internationally the movement of shipments of these substances, taking into consideration, among other things, annual national estimates for controlled substances submitted by Canada to the International Narcotics Control Board (INCB). The Canadian regulatory system is required to have an import control component to it under the UN Drug Control Conventions.
- 5. See paragraph 1.

Procedures

6. I. Allocations of quotas for narcotic drugs and psychotropic substances (considered "controlled substances" in Canada) are published by the United Nations, and this information is provided to dealers upon request and is available on the INCB website. Any nation exporting controlled substances may obtain information on Canadian quotas through the INCB. Canada does not allocate a specific quantity to any foreign country or domestic importer.

- II. The quotas for narcotic drugs and psychotropic substances ("controlled substances") are allocated annually in accordance with the requirements of the INCB.
- III. Permits to import controlled substances, industrial hemp and Class A precursor chemicals are only issued to dealers who are licensed to import and conduct other activities with the relevant substances. Licensed dealers are also required to inform the Office of Controlled Substances (Health Canada) when an import has taken place, including the quantity imported. Unused portions of permits for these substances and unused portions of cancelled permits are credited back to the quota for the current year. The names of licensed importers are not published for confidentiality and security reasons. The Office of Controlled Substances sends three copies of the permit to the applicant, and it is the applicant's responsibility to send copies of import permits to the exporting country and the customs broker. Permits to import cannabis under the Access to Cannabis for Medical Purposes Regulations are only issued to licensed producers. Consistent with the Single Convention on Narcotic Drugs, imports of cannabis may be for medical or research purposes only. Licensed producers must apply for and receive an import permit before the import takes place.
- IV. All quotas are established on an annual basis, and an application amendment to this quota may be made at any time during the year. Import permit applications are accepted year round. Quotas submitted to the INCB are annual estimates of controlled substances for legitimate needs in Canada. When necessary, Canada may amend the estimates by submitting supplementary estimates to the INCB.
- V. Import permits are usually issued within twenty business days of receipt of the application for industrial hemp, and within 30 (thirty) business days for controlled substances and precursors. Processing time for applications for cannabis import under the *Access to Cannabis for Medical Purposes Regulations* vary based on the context of the import (e.g. for clear medical or scientific purposes).
- VI. Import permits for controlled substances, precursor chemicals and industrial hemp are issued for immediate importation except when a dealer has indicated a wish to import during the following calendar year. In this case, the permit becomes valid January first of that year. Permits for controlled substances are valid for maximum four months from the date of issue with none extending beyond December 31st of any given year, or until the expiry date of the licence, whichever is earlier. Permits for precursor chemicals are valid for a maximum of six months or until the expiry date of the licence, whichever is earlier. Permits for industrial hemp are valid for maximum three months from the date of issuance or until the expiry date of the licence whichever is earlier. For cannabis, under the Access to Cannabis for Medical Purposes Regulations, intended for medical purposes, import permits are valid for six months or until the expiry date of the producer's licence if this is prior to the six months period, and may not cross two calendar years.
- VII. All applications to import controlled substances, industrial hemp and precursor chemicals are reviewed by the Office of Controlled Substances. Applications to import cannabis under the *Access to Cannabis for Medical Purposes Regulations* are reviewed by the Office of Medical Cannabis. Import permits are issued by the Office on the behalf of the Minister of Health.
- VIII. Import permits are issued on a first-come, first-serve basis, provided that the applicant is a licensed dealer or a licensed producer and submits a complete application. There is no maximum amount allocated per applicant. Applications are examined for accuracy on receipt.
- IX. In accordance with the UN drug control conventions, a shipment of narcotic drug, psychotropic substances or precursor must be authorized by both the importing and exporting countries.
- X. Not applicable.
- XI. Yes, there are products for which licences are issued with conditions that the goods should be exported and not sold in the domestic market.

- 7.(a) Import permits are usually issued within twenty business days for industrial hemp or thirty business days for controlled substances and precursors upon receipt of a complete permit application. The time to issue import permits for cannabis under the *Access to Cannabis for Medical Purposes Regulations* may take longer than this, depending on the complexity of the application. Import permits cannot be obtained at the time goods arrive at the port.
- (b) Import permits are usually issued within twenty business days for industrial hemp or thirty business days for controlled substances and precursors upon receipt of a complete permit application. The time to issue import permits for cannabis under the *Access to Cannabis for Medical Purposes Regulations* may take longer than this, depending on the complexity of the application.
- (c) No. Permits are valid for at least three months from the date of issue and none extend beyond 31 December of the year in which they were issued for controlled substances. For precursor chemicals, permits are valid for six months or until the expiry date of the licence, and may cover two calendar years. For cannabis intended for medical purposes, permits issued under the *Access to Cannabis for Medical Purposes Regulations* are valid for six months or until the expiry date of the producer's license, and may not cover two calendar years.
- (d) All applications to import controlled substances, industrial hemp and precursor chemicals are reviewed by the Office of Controlled Substances. Applications to import marijuana for medical purposes under the Access to Cannabis for Medical Purposes Regulations are reviewed by the Office of Medical Cannabis. Import permits are issued by the Office on the behalf of the Minister of Health.
- 8. Generally, an application for an import permit will be refused if the applicant does not hold a dealer's or producer's licence for the substance that is to be imported or holds a dealer's licence that will expire before the date of importation, if the applicant has provided false or misleading information in the application, or if there are reasonable grounds to believe the importation would contravene the laws of the country of export or any country of transit/transhipment. This information is clearly provided to the applicant. Yes, the applicant is given a right to appeal, as is listed in the above Regulations.

Eligibility of importers to apply for a permit

9. For controlled substances, industrial hemp, cannabis and Class A precursor chemicals, eligibility to apply for import permits is limited to individuals or companies licensed to conduct regulated activities with these substances in Canada. While businesses that import Class B precursors must be registered with Health Canada, import permits are not required for individual shipments of those substances. A list of licensed companies authorized to import is maintained and can be provided on request to licensed dealers. There is no fee attached to import permits. However, a fee and other requirements apply to obtain the licence to conduct regulated activities with controlled substances domestically. There is no fee for a Class A precursor licence, a Class B precursor registration or an industrial hemp licence.

Documentational and other requirements for a permit application

- 10. For controlled substances, industrial hemp and Class A precursors, applicants must provide in the import permit application the name and quantity of substances, the address of the importer and exporter, mode of transport, port of entry and the name of transit/transhipment country. In addition, applicants for Class A precursor import permits must also provide the date of entry. For cannabis intended for medical use, the importer must specify the form and quantity of marijuana involved, the source and destination addresses, method of conveyance, any countries of transhipment and customs port of import.
- 11. Canadian import permits and in most cases export permits from the exporting (supplying) country.
- 12. No.
- 13. No.

Conditions of licensing

- 14. Import permits for controlled substances are valid for maximum four months from the date of issuance with none extending beyond December 31st of any given year, or until the expiry date of the licence whichever is earlier. Permits for industrial hemp are valid for maximum three months from the date of issuance or until the expiry date of the licence if this is prior to the three month period. For precursor chemicals, import permits are valid for six months, or until the expiry date of the licence if the period is less than the six-month period and may also cross two calendar years. For cannabis intended for medical use, permits under the *Access to Cannabis for Medical Purposes Regulations* are valid for six months or until the expiry date of the producer's licence, and may not cover two calendar years.
- 15. No.
- 16. No.
- 17.(a) Special conditions may be added on a case by case basis
- (b) Special conditions may be added on a case by case basis

Other Procedural Requirements

- 18. No.
- 19. No.

2 FOOD AND DRUGS ACT

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Food and Drugs Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

For convenience, the entire questionnaire for the Food and Drugs Act is provided below.

<u>Note</u>: The following relates to import licensing and administrative procedures for health products under the **Food and Drugs Act** and its associated regulations. Different health products, covered under the Act, are subject to different regulations as listed below:

- Food and Drug Regulations;
 - Blood Regulations;
- Medical Devices Regulations;
- Natural Health Products Regulations;
- Processing and Distribution of Semen for Assisted Conception Regulations;
- Safety of Cells, Tissues and Organs for Transplantation Regulations.

Outline of system

1. The importation into Canada of drugs, blood, natural health products and medical devices is subject to establishment or site licensing to ensure that imported substances meet Canadian standards of safety, efficacy and quality. The import of these products is covered by the Food and Drug Regulations, the Blood Regulations, the Natural Health Products Regulations, and Medical Devices Regulations respectively. In addition to establishment or site licences permitting persons to, among other things, import a health product, product licences or authorizations are required for the sale of each specific health product in Canada.

The importation of semen for assisted conception and cells, tissues and organs (CTO) for transplantation are not subject to licensing, but imported products are expected to meet Canadian standards for safety and quality as expressed in the respective regulations. Canadian CTO establishments are required to be registered with Health Canada.

Purpose and coverage of licensing

2. Establishment licences are required for "import for sale" of drugs (including pharmaceuticals, active pharmaceutical ingredients, biologics, vaccines, blood products, and radiopharmeuticals), blood, and medical devices.

Site licences are required for "import for sale" of natural health products (including vitamins and minerals; herbal remedies; homeopathic medicines; traditional medicines; probiotics; and other products like amino acids and essential fatty acids).

Registration is required for all CTO (organs and minimally manipulated cells and tissues) establishments, except for retrieval and transplant establishments that are not considered source establishments.

- 3. The above systems apply to the specified health products from all countries.
- 4. The licensing is not intended to restrict the quantity or value of imports; it is intended to ensure that imported health products meet Canadian standards of safety, quality, and efficacy. Licensing is the most cost effective way to monitor imports.
- 5. Licensing is a regulatory requirement under the Food and Drugs Act and its Regulations as listed above.

Product designation is not subject to administrative discretion.

Legislative approval would be required to abolish the licensing/registration systems described above.

Procedures

- 6. Import of health products by licence holders is not restricted as to the quantity or value of the imports.
- 7.(a) A licence or registration for the importer must have been obtained prior to importation. No, licences cannot be obtained in a shorter time frame for products arriving at the port where the importer has not already obtained one.
 - Time to obtain a licence depends on a variety of factors and will depend on the individual case.
- (b) No, a licence cannot be granted immediately on request. Establishment licences, site licences, and product licences are issued if a review of the application indicates that all requirements of the applicable regulations have been met. CTO registration is issued if a review of the application indicates that all the requirements of registration are met, including a statement that they are in compliance with the regulations.
- (c) No, licence applications and importation are not limited according to time of year.
- (d) Health Canada is the only authority with respect to the above licences or registration.
- 8. Failure to meet the criteria specified in the regulations will result in an application being refused. Reasons for refusal are given to the applicant. There are regulatory requirements for Health Canada to provide the applicant with an opportunity to be heard. Review of the decision is internal to Health Canada. Applicants have a final right of appeal through the federal court system.

Eligibility of importers to apply for licence

9. Any person, firm or institution is eligible to apply for a licence or registration.

Applicants that do not have a Canadian address must provide the address of a representative in Canada with the exception of medical devices where the applicant is not required to have a

Canadian representative. There are fees associated with drugs and medical devices for both product and establishment licences. There are no other fees. There is a published list of drug and medical devices. For CTO establishments, this information is made available upon request.

Documentational and other requirements for application for a permit to import

- 10. Applications for product licences vary according to product but all the requirements are detailed in the applicable regulations. Applications for establishment and site licences and CTO registration must contain information on the applicant's name and address and contact information; the activities proposed; the product type; the address of each building where an activity will take place; and evidence that they meet the applicable requirements of the regulations.
- 11. No specific documents are required upon importation, just evidence that the applicable licences are in place. The Health Products and Food Branch of Health Canada can confirm that these have been issued.
- 12. There are no fees for semen, blood, CTO, or NHP, as these are not cost recovered. There are fees for drugs and medical devices. These are published in the Fees in Respect of Drugs and Medical Devices Regulations and depend on the type of licence involved.
- 13. Where fees apply a deposit or advance payment is required for the issuance of a licence. Again this amount varies as per the licence and is published in the regulations.

Conditions of permit

14. Establishment licences are subject to annual renewal prior to 1st April each year; CTO registration is subject to renewal in the year following the year in which the registration is issued; and drug and medical device product licences require annual notification. NHP site licences must be renewed annually for the first 3 years, every other year for the next 6 years, and every third year after that; product licences are for an indefinite period.

The validity period cannot be extended.

- 15. No penalty is imposed for non-utilization of a licence or registration.
- 16. Licences are issued to a specific person. To change the name of the licence holder a notification or amendment to the licence is required.
- 17. An establishment licence may be subject to terms and conditions as specified by the Minister on the licence when the licence is issued. These conditions vary according to the licence.

Other procedural requirements

- 18. No.
- 19. Not applicable.

3 EXPLOSIVES ACT

Outline of system

1. The importation of explosives is governed by the Explosives Act and Regulations, which is administered by the Department of Natural Resources. The legal definition of explosives includes blasting explosives, detonators, propellants, sporting and industrial cartridges, and all types of fireworks and pyrotechnic devices. Before an explosive may be imported into Canada or manufactured in Canada it must be declared an authorized explosive by the Chief Inspector of Explosives appointed under the Explosives Act. The process of authorizing an explosive consists of the manufacturer submitting data on the nature and composition of the explosive and on its packaging and markings. Such an application is subject to a minimum user fee of CAN\$125. Samples are usually required for laboratory examination. Testing fees depend on the type of tests to be carried out and the number of samples to be examined. This can vary, for example, from

CAN\$2108 for one fireworks sample and up to CAN\$16881 for ten fireworks samples. The criteria for authorization are based on the safety characteristics of the explosive substances or articles during handling, storage, transport and use. The objective of the authorization process is to confirm that characteristics meet declared values and relevant standards. Authorization also confirms that the product classification is in conformity with the recommendations of the Committee of Experts on the Transport of Dangerous Goods as adopted by the Economic and Social Council (ECOSOC) of the United Nations.

Purpose and coverage of licensing

- 2. Once an explosive is authorized, any person may import it into Canada provided he has the proper storage facilities for the type and quantity of explosives in question. Two kinds of importation permits are issued; a single use permit issued for a specific quantity in one shipment, and an annual permit issued for unlimited shipments of authorized explosives during a twelve-month period.
- 3. The system applies to explosives from all countries.
- 4. The system is intended only to ensure that the same degree of safety exists with imported explosives as with those of domestic manufacture. There is no intent whatsoever to restrict the quantity or value of the explosives imported.
- 5. The Explosives Act, R.S., c.E-17 as amended, and the Explosives Regulations, 2013 (SOR/2013-211). The system is a statutory requirement which does not convey any administrative discretion and would require legislative approval to be abolished.

Procedures

- 6. Not applicable.
- 7. (a) The import permit is issued within thirty days after receipt of the application if the explosive has been previously authorized and facilities exist in Canada for the safe and secure storage of the quantity being imported. Permits may be obtained in a shorter time but nevertheless should be on hand when a shipment arrives at Customs to prevent dangerous accumulations. Naturally, delays will occur if the explosive has not been authorized previously.
- (b) Permits may be granted immediately on request provided all is in order.
- (c) There are no limitations as to the period of the year during which an application for an importation permit may be made.
- (d) The importer need only approach the Explosives Regulatory Division of the Department of Natural Resources. No other administrative bodies are involved.
- 8. An application for an explosives importation permit may only be refused for failure to meet safety or security criteria. Reasons for such refusal would be given to the applicant who would have the right of appeal to the Minister of Natural Resources under Section 17 of the Explosives Act.

Eligibility of importers to apply for licence

9. Any importer who has satisfied the requirements of the Explosives Regulations relative to the storage, sale, purchase and possession, and of the Transportation of Dangerous Goods Regulations relative to transport, of the explosive to be imported may apply for an importation permit.

Documentational and other requirements for application for licence

10. The latest application form and guidelines are located on Natural Resources Canada's webpage: http://www.nrcan.gc.ca/explosives/importation/9913.

- 11. The latest import process is described in Canada Border Services Agency's D19-6-1 memorandum that can be found at: $\frac{\text{http://www.cbsa-asfc.gc.ca/publications/dm-md/d19/d19-6-1-eng.html}}{1-eng.html}$.
- 12. The present fee is CAN\$160.00 for a single use Importation Permit and a minimum of CAN\$160.00 for an Annual Importation Permit with a maximum fee of CAN\$1 300.
- 13. Other than the fee, there is no deposit or advance payment associated with the issuance of an importation permit.

Conditions of licensing

- 14. Explosives Importation Permits can be issued for a period of 12 months. Single use importation Permits are valid for one shipment while Annual Importation Permits are valid for any number of shipments.
- 15. There is no penalty for the non-utilization of an explosives importation permit.
- 16. Permits are not transferable between importers and only the products made by the manufacturer(s) specified in the permit may be imported.
- 17. There are no conditions attached to the issuance of an explosives importation permit relative to quantitative restrictions other than safe and secure storage location in Canada. Depending on the quantity to be stored, a magazine (i.e. storage) licence issued by the Explosives Regulations Division may be required. Importation permit applicants will be advised if this is the case.

Other procedural requirements

18-19. Persons not resident in Canada or not having a chief place of business in Canada are required to post a bond before being permitted to import explosives (Explosives Act Section 9 (2.1)).

4 NUCLEAR SAFETY AND CONTROL ACT

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Nuclear Safety and Control Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

5 NATIONAL ENERGY BOARD ACT

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the National Energy Board Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14, remains valid for the year 2015.

6 EXPORT AND IMPORT PERMITS ACT

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Export and Import Permits Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

7 ANIMALS, PLANTS, FISH, AND AGRICULTURAL PRODUCTS

The Centre of Administration of the Canadian Food Inspection Agency delivers and coordinates the full range of operational administrative services required for import related permissions under this section (http://inspection.gc.ca/about-the-cfia/permits-licences-and-approvals/eng/1395348112901/1395348237219). All permit applications are sent to the Centre of Administration, Regulatory Permissions and Registration Division, National Service Centres Directorate of the Canadian Food Inspection Agency.

7.1 Plant Protection Act

Note: Canada wishes to inform the Committee on Import Licensing that the notification submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015 with respect to the Plant Protection Act.

For convenience, the entire questionnaire for Plant Protection Act is provided below.

Outline of system

1. A permit to import outlines phytosanitary conditions import requirements which must be met prior to export from the country of origin, during export and upon arrival in Canada. These conditions are required to prevent the introduction or spread within Canada of a plant pests.

Purpose and coverage of licensing

- 2. In accordance with Section 31 of the *Plant Protection Regulations* and pursuant to the *Plant Protection Act*, a prospective importer must apply in writing for an import permit. According to section 32 and section 43 of the *Plant Protection Regulations*, the Minister of Agriculture and Agri-Food, on the basis of a pest risk assessment, may issue a permit for the importation of a thing that is either a plant pest, constitutes or could constitute a biological obstacle to the control of a plant pest or is/could be infested with either a plant pest or a biological obstacle to the control of a plant pest if, the Minister determines that every precaution necessary can and will be taken to prevent the introduction into Canada or the establishment and spread within Canada of a plant pest or biological obstacle to the control of a plant pest.
- 3. The system applies to plant pest (e.g., disease cultures, insects), plants and plant products and any other article whose importation into Canada is regulated under the *Plant Protection Act* and Regulations from all countries.
- 4. The permit system is not intended to restrict the quantity or value of imports. The purpose of the import permit system is to ensure that plant pest, plants and plant products and other articles regulated under the *Plant Protection Act* and Regulations imported in Canada conform to Canada's plant protection phytosanitary import requirements. The permit system protects against the introduction into and spread of pests injurious to plants in Canada.
- 5. The permit system is legislated and regulated under the *Plant Protection Act* and the *Plant Protection Regulations*. The permit system is statutorily required. The determination that a product needs a permit is based on the assessment of the phytosanitary pest risk it poses. Lastly, it is not possible for the government to abolish the system without a regulatory amendment.

Procedures

- 6. There are no quantitative or value limits on the importation of products from other countries.
- 7.(a) An importer must obtain a valid import permit prior to importation. Written permit applications may be mailed/e-mailed or faxed to the Licensing, Permitting and Registration Division, National Inspection and Investigation Services Directorate of the Canadian Food Inspection Agency (CFIA). Once all required information has been received and a review of the permit application form has been completed, the CFIA will endeavour to issue a Permit to Import between five to ten business days (subject to change).
 - The Canadian Food Inspection Agency will not issue an import permit for regulated commodities that have already arrived in Canada. This is because an import permit is not retroactive.
- (b) No. An application cannot be granted immediately upon request as it must be subject to a pest risk review.
- (c) No, there are no limitations as to the period of the year in which an application for a permit to import can be submitted.

- (d) Yes. All applications for a permit to import are sent to and approved by one administrative body. All applications are sent to the Licensing, Permitting and Registration Division, National Inspection and Investigation Services Directorate of the Canadian Food Inspection Agency. However, some commodities may be regulated by other governments departments and may be subjected to other requirements.
- 8. The plant protection import permit may be refused on the grounds that the plants, plant products or other matter intended for importation will result or is likely to result in the introduction into Canada of a plant pest. A permit can also be refused or revoked if a person has contravened the Act and/or Regulations. The importer is advised of the refusal or revocation. The *Plant Protection Act* or *Plant Protection Regulations* do not prescribe an appeal procedure in cases where a permit is refused or revoked.

Eligibility of importers to apply for licence

9. An applicant for a Permit to Import must be one of the following: 1) a Canadian citizen or permanent resident; 2) a person authorized under the laws of Canada to reside in Canada for a period of six months or more and who will have possession, care or control of the thing to be imported; or 3) in the case of a corporation with a place of business in Canada, the applicant must be an agent or officer of the corporation who resides in Canada.

Note: The CFIA will not accept applications for Permits to Import submitted by Brokerage Firms on behalf of their clients. The actual Canadian importer (person/company) must submit the application.

Documentational and other requirements for application for a permit to import

- 10. An application for a permit shall be in writing, signed and dated by the person applying for the permit and contain the following information:
- (a) The name, complete address and telephone number of the person;
- (b) The name, complete address and telephone number of the owner of the thing to be imported, if different from paragraph (a);
- (c) The name and complete address of the exporter;
- (d) A description and the common and scientific names of the thing;
- (e) The quantity of the thing;
- (f) The purpose for which the thing is to be admitted into Canada;
- (g) The place of entry and the location of the place of destination of the thing in Canada;
- (h) The country and place where the thing was propagated or produced, and the country and place from which it was shipped to Canada;
- (i) The number of packages, if sent by mail or courier service; and
- (j) Any other information respecting any activity undertaken in respect of the thing, or the precautions that will be taken to prevent the spreading of any pest or biological obstacle to the control of a pest while the thing is transported, as the Minister may require.
- 11. The documents (e.g., phytosanitary certificate, certificate of inspection, certificate of treatment, certificate of origin, affidavit, etc.) specified on the permit are required at the time of importation.
- 12. Fees for each permit application can range between CAN\$15 and CAN\$250, depending on the reason for importation and the need for a pest risk assessment.

13. There is no deposit or advance payment that is required or associated with the issuance of a permit. However, full payment is required before a permit can be issued.

Conditions of permit

- 14. Permits to import are valid for the period of time specified on the permit. The permit to import is valid for multiple shipments and unlimited quantities unless otherwise specified. Permits to import issued to persons travelling or collecting will be valid for no more than one year. When a permit has expired, it is the responsibility of the importer to apply for a new permit.
- 15. There is no penalty for the non-utilization of a permit or a portion of a permit.
- 16. Import permits are not transferable between importers.
- 17. The issuance of an import permit is only subject to the provisions of the *Plant Protection Act* and Regulations.

Other procedural requirements

- 18. Generally, there are no other administrative procedures apart from the import permit application procedures.
- 19. Not applicable.

7.2 Health of Animals Act

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Health of Animals Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

7.3 Fish Inspection Act

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Fish Inspection Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

For convenience, the entire questionnaire for the Fish Inspection Act is provided below.

Outline of system

1. Other than for personal consumption or personal use as trade samples, the importation of all fish and fish products into Canada as food for human consumption is subject to licensing under the Fish Inspection Act and its Regulations, which is administered by the Canadian Food Inspection Agency (CFIA). The Fish Inspection Act and its Regulations contain requirements for wholesomeness, labelling, packaging, grading and human health and safety.

Purposes and coverage of licensing

- 2. See No.1 above.
- 3. The system applies to fish and fish products from all countries. See the *Fish Inspection Regulations* for exceptions or additional requirements for products from certain countries. The list of specific countries that are approved to export live or raw molluscan shellfish is available at: http://www.inspection.gc.ca/food/fish-and-seafood/imports/molluscan-shellfish/eng/1377987441620/1377987693551. Other non-quantitative restrictions exist for the import of certain species. For example, the importation of live freshwater mitten crab (genus Eriocheir) or puffer fish (family Tetraodontidae) is not permitted under the Fish Inspection Regulations.
- 4. The purpose of licensing is to ensure that importers understand their responsibility for ensuring that the fish they import will meet all the applicable Canadian regulatory requirements. Imports must also meet all the applicable import licence and fish inspection regulatory requirements.

5. The authorization of imports is maintained under the Fish Inspection Act and its Regulations. The licensing is statutorily required (see Fish Inspection Regulations). The Fish Inspection Act allows the Governor-in-Council to regulate imports of fish. There is no administrative discretion with respect to the products subject to licensing. Legislative approval would be required in order to abolish elements of the import system described in the Fish Inspection Regulations. Any person or organization who wishes to import fish or fish products into Canada, for sale or distribution for human consumption, must first obtain an import licence from a CFIA office. Fish for personal consumption and personal use as trade samples are exempt from these requirements.

Procedures

- 6. There are no quantitative or value restrictions.
- 7. Where there is no quantitative limit on importation of a product or on imports from a particular country:
- (a) Licences are granted by CFIA in a timely manner. Waiting time depends on the complexity of the request. The process for CFIA to grant an import licence requires the importer to submit to CFIA a complete application package for a fish import licence which must include:
 - completed application form for a fish import licence;
 - for new importers, Application for Credit CFIA/ACIA 0015;
 - for a Quality Management Program for Importers (QMPIU) licence, the applicant must submit a written QMPI plan;
 - \$500 fee for a fish import licence or \$5000 for a QMPI Fish Import Licence as fixed by the Canadian Food Inspection Agency Fees Notice;
 - Canada Revenue Agency Business Number documentation.

In addition to the application package for a fish import licence, importers are required to advise CFIA how they will meet the following regulatory requirements:

- import products that are not tainted, decomposed or unwholesome and meet all Canadian regulatory requirements;
- store products in a way that prevents contamination and deterioration;
- track distribution of product they import including name and address of person to whom they sold the fish and the date it was sold;
- track complaints and investigate information that they receive which questions the safety of their product;
- obtain process control documents for canned and ready-to-eat products you import (see Section 4.7.4 Process Control Documents).

The applicant of a QMPI licence must develop a written QMPI plan that meets the QMPI Reference Standard http://www.inspection.gc.ca/food/fish-and-seafood/imports/documents/qmpi-reference-standard/eng/1360870958448/1360871089672.

A fish import licence expires one year after the date of issue and is not transferable.

- (b) See response to part (a).
- (c) There are no limitations regarding the time of year during which an application can be made.
- (d) The application for a Fish Import Licence is submitted solely to the importer's local CFIA office for review; it is a "single-window" process. The office receiving the application coordinates the submission with other CFIA offices.
- 8. The Fish Inspections Regulations allow for the CFIA to refuse to grant (or renew) a Fish Import Licence under certain conditions in addition to failure to meet the ordinary criteria. The FIR state that the CFIA shall issue a licence, upon receipt of a complete application and the applicable fee, unless there are reasonable grounds to believe that the applicant will not comply with the Fish Inspection Act or Regulations (e.g. providing false information, non-notification of imports, a poor history of compliance). The applicant should be provided with the reason(s) for refusal. CFIA policy allows for an appeal of refusal to issue a licence. The Regulations allow for appeals to the

Regional Director in cases of a suspension or revocation of a licence and describe the procedures to do so.

Eligibility of importers to apply for licence

9. Any person or company meeting the criteria is eligible to apply for a Fish Import Licence.

Documentational and other requirements for application for licence

10. To hold a fish import licence, importers must maintain specific records, for no less than 3 years, at an address in Canada. The fish import licence application form and application for credit which must accompany the import licence application can be found online:

Fish import licence application form (see form # 5587): http://www.inspection.gc.ca/food/fish-and-seafood/imports/eng/1299825431569/1299825501933.

Application for credit which must accompany import licence application (see form # 0015): http://www.inspection.gc.ca/food/fish-and-seafood/imports/eng/1299825431569/1299825501933.

Importers must notify the closest CFIA fish inspection office in writing using the **Fish Import Notification (FIN)** prior to the importation of a product, or within 48 hours following importation. Notification must include all items identified in the "Instructions to Complete the Fish Import Notification"(http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/c5588 re 1383911986940 eng.pdf), including but not limited to: importer name and license number, foreign producer, storage conditions, product description, product source and country of harvest, end use, etc.

- 11. Each written notification of importation must include the production codes for all canned and ready-to-eat fish (first-time imports of these products require documentation describing the process and processing controls applied to the lot for each processor for each type of product which indicate that the product was adequately processed and will remain safe for its entire shelf-life). Failure to provide proper written notification for each imported shipment may result in enforcement action by CFIA.
- 12. The fee for a Fish Import Licence is CAN\$500. Importers may apply for a voluntary program where they have additional responsibility for sampling and testing. The fee for this Quality Management Program for Importers (QMPI) licence is CAN\$5000. CFIA Inspection service fees reflect the resources needed to inspect different product types and are applied based on the declared weight and type of product (as described on the Fish Import Notification).
- 13. Importers are responsible to pay service fees as a condition of holding a fish import licence. The importer applies for credit account with the CFIA at the time of application for an import licence. The service fees apply to each lot imported and are applied to the importer's account with CFIA. The importer is sent invoices on a regular basis (monthly) for the service fees applied to the fish imported during the billing period. There is no deposit or advance payment associated with the issuance of import licences.

Conditions of licensing

- 14. Licences are valid for 12 months. Importers must apply to renew their licence if they wish to continue to import fish after the expiry of their licence.
- 15. No.
- 16. Licences are not transferable between persons or businesses.
- 17. Other conditions attached to the issue of a licence:
- (a) Not applicable.

(b) No.

Other procedural requirements

- 18. No.
- 19. Not applicable.

7.4 Canada Agricultural Products Act

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Canada Agricultural Products Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.

7.5 Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Endangered Species to Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 regarding endangered species remains valid for the year 2015.

For convenience, the entire questionnaire for the Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act is provided below.

Outline of system

1. By virtue of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), of which Canada is a member, specimens of such species and their parts and derivatives are listed on Schedule I of the Wild Animal and Plant Trade Regulations established under the Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act (WAPPRIITA) and subject to licensing. Species which may be harmful to Canadian ecosystems if ever released to the wild, are listed in Schedule II of WAPPRIITA and are also subject to licensing.

Purposes and coverage of licensing

- 2. The purpose of this coverage is:
- (a) to place a strict limitation on trade in specimens and parts and derivatives of species classified as endangered or harmful to Canadian ecosystems;
- (b) to establish a system of monitoring on specimens and susceptible to becoming endangered through the mechanism of back-to-back licensing; and
- (c) to allow individual countries to exercise surveillance on importation in other countries specimens and parts and derivatives of species which are considered endangered by the exporting country only.
- 3. The system applies to endangered species originating in and exported from all countries.
- 4. The purpose of the licensing system is to allow importation in endangered species and their parts and derivatives in internationally agreed circumstances and, in the case of species in Schedule II, where there are sufficient safeguards and security to prevent escapes to the wild.
- 5. Licensing is effected by the Wild Animal and Plant Trade Regulations made under the WAPPRIITA. Individual products are not designated in the Act. Species were placed in Schedules I of the Wild Animal and Plant Trade Regulations, established by the Governor-in-Council to implement an intergovernmental arrangement or commitment (see No. 1 above).

Procedures

6.I. Information as to the formalities for complying with the requirements of this control is published in the Canada Gazette, on the website of the Department of the Environment, in press releases and in Notices to Importers distributed to associations and traders and, in addition, available upon request from the Department of the Environment.

Other questions under I, and II, III, IV, V, VI, VII, VIII, IX, X and XI are not applicable.

- 7.(a) Individual import permits can be applied for at least 40 days prior to the expected date of arrival and are not granted retrospectively.
- (b) An individual import permit is normally granted within 40 days from receipt provided the criteria for issuing a permit are met. Import permits can be obtained within a shorter time limit in special circumstances such as live animals.
- (c) Not applicable.
- (d) Permit applications are processed by the CITES Authorities of the Department of Environment Canada.
- 8. If the criteria have not been met, the applicant will be informed. In such event, the applicant may request reconsideration by providing new information.
- 9. Citizenship and residency are not criteria.

Documentational and other requirements for application for licence

10. The importer is required to provide all the information requested by the Act and regulations depending on the type of animal or plant specimen intended for import. There are many application forms specific to the type of animal or plant specimen and trade activity.

CITES documents issued by the appropriate CITES authorities in the country of origin or in any subsequent re-exporting country, must accompany all applications.

- 11. Same documents as in the response to Question 10. Products arriving in Canada without a duly authentic CITES export permit will not be cleared by Canada Customs and are subject to seizure. Specimens of species listed on Appendix I of CITES as indicated in Schedule I of the Wild Animal and Plant Trade Regulations must be accompanied by a Canadian CITES import permit. Customs entry forms are also required.
- 12. No fees.
- 13. Not applicable.

Conditions of licensing

- 14. CITES import permits are valid for one year from the date of issue. In cases of permit expiration before use, the applicant can apply for a replacement permit upon return of the expired permit.
- 15. No.
- 16. No.
- 17. No.

Other procedural requirements

18. Applicants for import permits have to meet any provincial/territorial/federal administrative procedures with regards to the specimen such as provisions for possession or transport within Canada.

19. Not applicable.

8 EXPORT AND IMPORT OF ROUGH DIAMONDS ACT

Note: Canada wishes to inform the Committee on Import Licensing that the notification regarding the Export and Import of Rough Diamonds Act submitted under Article 7.3 of the Agreement contained in the document G/LIC/N/3/CAN/14 remains valid for the year 2015.