Part I : Details of consignment

I.1. Consignor
Name
Address
Country ISO Code

I.2. IMSOC Reference
I.2.a. Local Reference

I.5. Consignee
Name
Address
Country ISO Code

I.3. Central competent authority
I.4. Local competent authority

I.7. Country of origin ISO Code

I.9. Country of destination ISO Code

I.8. Region of origin Code

~~I.10. Region of destination~~

I.11. Place of Dispatch
Name
Address
Approval Number
Country ISO Code

I.12. Place of destination
Name
Address
Approval Number
Country ISO Code

I.13. Place of Loading
Name
Address
Approval Number
Country ISO Code

I.14. Date and time of departure

I.15. Means of Transport

Mode	International transport document	Identification

I.16 Entry Point

I.18. Transport conditions
Ambient ☐ Frozen ☐ Controlled temperature ☐ Chilled ☐

I.17. Accompanying documents
Commercial document reference
Date of issue
Country
Place of issue

I.19. Container No / Seal No

I.20. Certified as
Pharmaceutical use ☐ Technical use ☐ Other ☐

I.21. For transit through a third country ☐
Country ISO Code
EU Exit Authority BCP code
EU Entry Authority BCP code

I.22. For transit through Member State(s) ☐
Country ISO Code

I.23. Total number of packages	I.25. Total net weight	I.25. Total gross weight

I.28. Description of consignment

1. 05 PRODUCTS OF ANIMAL ORIGIN, NOT ELSEWHERE SPECIFIED OR INCLUDED

0510 Ambergris, castoreum, civet and musk; cantharides; bile, whether or not dried; glands and other animal products used in the preparation of pharmaceutical products, fresh, chilled, frozen or otherwise provisionally preserved

051000 Ambergris, castoreum, civet and musk; cantharides; bile, whether or not dried; glands and other animal products used in the preparation of pharmaceutical products, fresh, chilled, frozen or otherwise provisionally preserved

05100000 Ambergris, castoreum, civet and musk; cantharides; bile, whether or not dried; glands and other animal products used in the preparation of pharmaceutical products, fresh, chilled, frozen or otherwise provisionally preserved

Commodity	Species	Slaughterhouse	Manufacturing plant	Package count

Net weight	Batch number

Part II: Certification

II. Health information

I, the undersigned, official veterinarian(8) of the (insert name of competent veterinary authority of the Member State of the EU), after due inquiry and to the best of my knowledge, do hereby certify that the animal by-products described above:

II.1. Consists exclusively of products taken from animals slaughtered within the EU member state(s) of: (insert name of country (ies) here)

II.2. Are all derived from animals ○ born and raised in (insert country name here) or ○ legally imported from (insert country name here), which is/are recognized by (2) Canada as free of the following diseases of concern (listed in notes by susceptible species) OR ○ that the animals from which the products are derived were present in the country of slaughter (insert country name here) without restrictions (outside of quarantine) for the (3)time required by species of origin;

II.3. The product and container(s) bears a label which bears the words “For medicinal purposes” or “À des fins médicinales”, or the words “For pharmaceutical purposes” or “À des fins pharmaceutiques”, as the case may be;

II.4. The product was manufactured in an establishment that was operating under a Hazard Analysis Critical Control Point (HACCP) principles based system determined by the Canadian Food Inspection Agency (CFIA) to be equivalent to the Food Safety Enhancement Program (FSEP) established by the Agency and from a country and an establishment approved to export both edible and inedible meat products to Canada by CFIA;

II.5. Has been prepared exclusively with the following animal by-products (name species of origin and tissue type):

II.6. None of the animals from which the products/by-products are derived were suspected or confirmed of the following disease(s), nor any other reportable disease as defined by Canada (either through confirmatory negative testing, or “suspect” testing): anthrax, foot-and-mouth disease, rinderpest or Bovine Spongiform Encephalopathy and none of the animals from which the products/by-products are derived were under any official restrictions by the competent veterinary authority for any serious epizootic (4)disease to which the species from which the by-product was derived is susceptible and that can be transmitted by the by-product (see Notes II.1 and II. below);

☐ [(5)II.7. Additional certification for either swine or lagomorph origin products:

☐ [(5)II.7.1. For products derived from swine (or containing a mixture of products that include swine origin material), the animals from which the products were derived:

II.7.1.1. Showed no clinical sign of Aujeszky Disease (AD) on the day of slaughter;

II.7.1.2. Have not been in contact with animals from establishments not considered free from AD during their transport to and at the abattoir;

II.7.1.3. Have not been vaccinated against AD; and

II.7.1.4. Had no contact with any swine or swine products that were in an area not designated free from AD in accordance with Commission Decision 2008/185/EC Annex I as amended, or the premises of origin and all farms within a radius of three kilometres were free from any clinical or epidemiological evidence of AD for a period of 12 months prior to collection of the products/by-products.]

☐ [(5)II.7.2. For products derived from lagomorphs, the animals:

II.7.2.1. Showed no clinical sign of myxomatosis on the day of shipment to the approved abattoir; and

II.7.2.2. Were kept since birth, or for the six months prior to slaughter, in an establishment where no case of myxomatosis was officially reported during that period; and

(1)either ○ [7.2.2.1. Come from an establishment considered free from rabbit haemorrhagic disease (RHD), shown, by serological testing, that the disease has not been present for at least one year, and that no vaccination has been carried out in the previous 12 months and such establishments are regularly inspected by the competent veterinary authority;]

Part II: Certification

II. Health information

(1)or ○ [II.7.2.2.2. Were kept in an establishment where no case of RHD was reported during the 60 days prior to transport to the approved abattoir (as per II.4.); and showed no lesions of RHD at post-mortem inspections; and the shipment does not include any pelts from any lagomorph;]]]

II.8. All the animals by-products which are covered by the present certificate:

II.8.1. Were subject to and passed ante-mortem inspection and were subject to post mortem inspection, both carried out by an inspector under the supervision of an official veterinarian(8) or an official veterinarian(8) of the competent veterinary authority within an abattoir approved for export to Canada by CFIA;

II.8.2. were all:

(1)either ○ [II.8.2.1 stunned (humanely rendered unconscious) before slaughter;]

(1)or ○ [II.8.2. 2 (In the case of animals slaughtered in conformance with ritual slaughter procedures) The products within this shipment and covered by this certificate are derived from animals that received (Kosher, Halal) slaughter, as based upon documentation provided by religious authorities or by (Kosher, Halal) label declaration and the poultry products within this shipment and covered by this certificate are derived from birds slaughtered by rapid decapitation without prior electrical (6)stunning;]

II.9. The container in which the products/by-products are being shipped is completely enclosed and leak-proof; and

(1)either ○ [II.10. The products contain no ruminant origin products/by-products;]

(1)or ○ [II.11. The product contains products/by-products of ruminant origin, and the ruminant animals were slaughtered as per BSE slaughter process. They were not subjected, before being slaughtered, to a stunning process in which a device is used to inject compressed air or gas into the animal's cranial cavity; nor to a pithing process involving laceration, after stunning of the animal, of the animal's central nervous tissue by means of an elongated rod-shaped instrument that is introduced into the animal's cranial cavity.]

AND

(1)either ○ [II.11.1. sourced only from ruminant animals born and raised for the first year of their life in (insert country(ies) name(s)) which is (are) a negligible risk for BSE country as recognized by (7)Canada;]

(1)or ○ [II.11.2. sourced from a mixture of ruminant animals both born and raised in (insert 3rd country(ies) name(s)) and legally imported into (insert country name) and does not contain any of the following tissues of any bovine animals:

(1)either ○ [II.11.2.1. the skull, brain, trigeminal ganglia, eyes, palatine tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older; and the distal ileum of cattle of all ages (if product contains any tissues from ruminant animals from controlled risk for BSE countries as recognized by Canada but no tissues from animals from undetermined risk for BSE (7)countries);]

(1)or ○ [II.11.2.2. The palatine tonsils, the skull, the brain, trigeminal ganglia and eyes, the spinal cord and the vertebral column, (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), from bovine animals aged 12 months or older and the distal ileum of all ages of bovine animals (if product contains any tissues from ruminant animals from undetermined risk for BSE countries as recognized by (7)Canada).]]

Notes

Part I

· Box reference I.6.: Indicate CFIA permit number if applicable (if for end use Technical or other)

· Box reference I.11.: indicate the shipping establishment and the Member State competent veterinary authority approval number

· Box reference I.12.

o Health Canada Establishment license number is mandatory when the end use is pharmaceutical or cosmetic. If no Health Canada Establishment license number is provided then the certificate must not be issued.

Part II: Certification

II. Health information		

o The EL must be verified on the Health Canada web site Drug Establishment Licences Listing. Searches may be done either by a) Licence number (Site optional), b) Company name, c) Activity and/or Province. http://webprod5.hc-sc.gc.ca/el-le/prepare-search-recherche-del-leppp.do?lang=eng

· Box reference I.22.: Commodities certified for must identify the end use. Note that "Pharmaceutical use" includes also cosmetic manufacture, “Technical use” applies to commodities not intended for human or animal consumption, and ” Other“ is intended for purposes not listed elsewhere in this classification. Where ”Technical use . or ”Other” is chosen, a CFIA Import Permit is required. The Import Permit number must be clearly indicated in Box Reference I. 6

· Box reference I.25 Identification of the commodities. This is where the Approval number of establishments eligible (approved by CFIA Meat Programs) for export to Canada of edible meat products should be listed. Based on Annex A certification requirements as negotiated between CFIA and EU SANTE. For more details visit: http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-10/annex-a/eng/1336318487908/1336319720090 and http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-10/annex-a/european-union/eng/1336803459318/1336803636873

Custom code and title: Use the appropriate Harmonised System (HS) code.

Part II

· (1) Delete as appropriate.

· (2) Under the EU Canada Veterinary agreement, for those diseases for which Canada has done evaluations for country or zone freedom, CFIA recognizes EU disease eradication and control zones when they are published in EU directives. When a disease incursion occurs in a previously free area, and Canada has recognized the control zones, full freedom is only regained when the control zone meets the requirements for freedom under the OIE guidelines.

Diseases of concern for Canada for animal products & by-products covered by this certificate are:

o For poultry: Notifiable Avian Influenza and Newcastle disease

o For ruminants: Contagious bovine pleuropneumonia; Foot-and-mouth disease (FMD); Lumpy skin disease; Peste des petits ruminants; Rift valley fever and Sheep pox and goat pox; Vesicular Stomatitis

o For swine: African swine fever; Classical swine fever (Hog cholera); Foot and Mouth Disease; Swine vesicular disease; Vesicular Stomatitis

o For Horses &other equids: African horse sickness and Vesicular Stomatitis

o For lagomorphs (commercially reared): rabbit viral haemorrhagic disease and myxamotisi

o Vesicular Stomatitis - EU zoning is recognized by Canada; Animals must be from a free zone as declared by the CCVA and that zone recognized by Canada (once the EC zoning decision is published) and the animals are not from an area or zone with an active outbreak of the disease, nor have been in direct contact with animals from either a declared outbreak, control or monitoring zone for vesicular stomatitis.

o Rabbit viral haemorrhagic disease and myxamotosis. No CFIA country freedom list has been established, so establishment (farm) freedom is acceptable provided that it meets the requirements listed for lagomorphs in II.7.2.

List of Countries which Canada has recognized as being free from the certain diseases:

Terrestrial Animal Health Status By Disease: (note after disease incursion for formerly free zones, full freedom recognition will be indicated by removal of the zoning notice here.)

http://www.inspection.gc.ca/animals/terrestrial-animals/diseases/status-by-disease/eng/1306649804251/1306649991822

Terrestrial Animal Health Status by Country: (note after disease incursion for formerly free zones, full freedom recognition will be indicated by removal of the zoning notice here.)

http://www.inspection.gc.ca/animals/terrestrial-animals/diseases/status-by-country/eng/1306648587424/1306649135327

· (3) Time requirements for an animal to be considered part of a national herd or flock (imported and housed with animals of the importing country without restriction)

For avian (poultry & ratite, or other): 21 days;

For ruminants: 90 days;

For swine: 90 days;

For horses & other equids: 60 days;

For lagomorphs (commercially reared): 60 days.

Part II: Certification

II. Health information

· (4) Note this section refers only to those diseases to which the species of animals from which the products/by-products are derived, is susceptible (as identified above).

· (5) Keep if appropriate.

· (6) The option for rapid decapitation without prior stunning is to be applied ONLY to poultry and not ratites (strike out inapplicable.

· (7) Canada publishes a list of BSE Categorization of countries on the Bovine Spongiform Encephalopathy Import Policy for Bovine Animals and Their Products and By-Products TAHD-DSAT-IE-2005-9-5 http://www.inspection.gc.ca/animals/terrestrial-animals/imports/policies/general/2005-9/eng/1321066760292/1426255335689 The CFIA BSE import policy for bovine animals and animal products, animal by-products, germplasm, animal food, meat, meat by-products and veterinary biologics, of bovine origin, adheres closely to the recommendations of the World Organisation for Animal Health (OIE) and the list of negligible risk and controlled risk for BSE countries is updated regularly. The updates are initiated following the updating of lists of negligible and controlled risk for BSE countries by the OIE at the annual general council.

· (8) The official veterinarian who signs this certificate must meet the Canadian definition of “official veterinarian”; which is defined under the Health of Animals Regulations as a veterinarian employed by the government of that country (vétérinaire officiel).

Further clarifications for Part I

· CFIA Import Permit:

The Import Permit number in box I.6 is required if end use anything other than pharmaceutical or cosmetic as indicated in I.22.

· Establishment Approval Number:

Approval number in box I.11 is the EU Member State Central Competent Authority approval number of the establishment from which the product is being exported and must be verified on the applicable CFIA database.

· Health Canada Establishment Licence Number:

Approval Number -2 means the Health Canada Establishment Licence Number (EL) and must be indicated in box I.12 The EL must be verified on the Health Canada web site Drug Establishment Licences Listing. Searches may be done either by a) Licence number (Site optional), b) Company name, c) Activity and/or Province. http://webprod5.hc-sc.gc.ca/el-le/prepare-search-recherche-del-leppp.do?lang=eng

· Description of container in box I.21 is required in detail only where a standard shipping container (large metal box of a standard design and size used for the transport of goods by road, rail, sea, or air) is not used and there is no seal number and no container number. Example – Products shipped in sealed impermeable carton with plastic liners with (insert company name “A”, brand name or commodity name on label “Porcine Pancreas Insul-Z” and description of the tamper evident mechanism (such as tamper evident tape or labelling).

· Note that within the signature block below the term official inspector must be struck out & initialled by the signing official veterinarian and the name of competent authority of named of Member State must appear as well as the stamp.

Certifying Officer

Name (in capital letters)	Qualification and title
Date of signature	Signature
Stamp	