Import permit for samples from EU/EØS and 3. countries, accepted by the EU in animal health terms for use in research and diagnostics.

The Danish Food and Veterinary Authority, Veterinary Control Office East, hereby grants permission to import samples of Category 1, 2, and 3 materials, for use in research and diagnostics, as provided by the Animal Byproduct Regulation\(^1\), Article 17 and Article 41, (2,d) and the Implementing Regulation\(^2\), Article 11, Article 20, Annex I, Annex VI, Chapter I, Section 1 and Annex VIII, Chapter II, (2, xv).

This permit is valid for five years from the date of this document.

Conditions for import of Category 1, Category 2 and Category 3 materials:

- The material must be imported in leak proof, secure packaging.
- The samples shall be imported by courier company.
- The material shall be delivered directly to the Danish Technical University, Veterinary Institute laboratories approved for processing of the material in question, at either Lindholm or Frederiksberg. The material may not be used at other locations.
- The shipment shall be accompanied by a commercial document that includes the following information:
  - description of the material and information on the species of origin
  - the material’s Category
  - the amount of material
  - the material’s place of origin and place of dispatch of the material
  - the name and the address of the consignor


the name and the address of the consignee and/or user

The shipment shall be labelled clearly and legibly with the following text XXXXX on the packaging:

“For research/diagnostics”


Analyses of serious, communicable diseases (List 1 in Danish Regulation no. 54 of January 26, 2011) may only be carried out with the acceptance of the veterinary authorities in the country of origin. Contact with the veterinary authorities in the country of origin shall be established via the Danish Food and Veterinary Authority.

Danmark’s Technical University, Veterinary Institute may however, always perform analyses of diseases of fish and molluscs from member countries of the European Union, in that the institute is the European Union’s reference laboratory. The laboratory may also receive samples from the entire world suspected of VHS virus, in that the institute’s section for aquatic diseases is OIE’s reference laboratory for VHS virus.

The Veterinary Institute may also perform analyses of samples received from laboratories in other countries for whom the institute serves as a reference laboratory or with whom the institute has other special agreements.

In the case of laboratory results that lead to suspicion of a serious, communicable disease, the laboratory shall inform the Danish Food and Veterinary Authority, who in turn will notify the veterinary authorities in the country of origin.

Users that handle research and diagnostic samples shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.

Users that handle research and diagnostic samples shall keep a register of consignments of such samples. The register shall include the information required in the commercial document and the date and method of disposal of the samples and of any derived products.

Any subsequent use of samples for research and diagnostics, for purposes other than research and diagnostics, is prohibited.

Unless they are stored for reference purposes, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:

1. as waste, by incineration or co-incineration
2. in case of the animal by-products or derived products referred to in Article 8 (a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No 1069/2009 which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves and subsequent disposal as waste or wastewater in accordance with relevant Union legislation,

3. by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.

- In addition, the requirements in the Danish Regulation nr. 734 of 27 June, 2011, on Veterinary Control of import of breeding material and animal non-food products, shall apply.

It should be noted that import requirements can undergo change and it is the responsibility of the importer to ensure that the product fulfills the applicable requirements at the time of importation.

It should be emphasized that the above applies to veterinary import requirements alone.

Complaints

This decision can be appealed to the Danish Ministry of Food, Agriculture and Fisheries’ Complaint Center within four weeks of the receipt of this letter.
The complaint must be received by the Danish Food and Veterinary Authority before the deadline. Complaints received after the deadline will usually not be considered.

Sincerely,

Amir Selimovic, Glostrup