Importation of research and diagnostic samples from third countries

The importation of products of animal origin for research and diagnostic purposes from third countries is prohibited unless authorised in advance by a licence issued by the Department of Agriculture, Food and the Marine.

A revised annual VET15 licence to import samples of products of animal origin for research and diagnostic purposes from third countries is being introduced for an initial trial period. This licence is intended as a single annual licence per registered establishment and will cover the range of animal by-products and derived products an establishment is registered to use (see point 3 below). The applicant should be the “operator” referred to in the Certificate of Registration.

This information note sets out the licence application procedures and conditions for the importation into Ireland of samples of products of animal origin for research and diagnostic purposes from third countries.

1. Legislation


European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014)

2. Definitions

‘research and diagnostic samples’ means animal by-products and derived products intended for the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of research or educational activities

‘animal by-products’ means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen

‘derived products’ means products obtained from one or more treatments, transformations or steps of processing of animal by-products

Access to any of the EU legislation quoted may be enabled through the following link: http://eur-lex.europa.eu/homepage.html. When researching legislation by this means select the “Latest consolidated version” to determine the legislation as it currently applies.
‘operator’ means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users

‘user’ means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes

‘establishment’ or ‘plant’ means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel

3. Registration of establishments

An establishment using animal by products and/or derived products for research or diagnostic purposes must be registered by the Department of Agriculture, Food and the Marine and the registration must be in date (Article 23 of Regulation (EC) No 1069/2009).

Application for registration of an establishment should be made to:

Milk and Meat Hygiene/ABP/TSE Division
Grattan House, Grattan Business Centre, Dublin Road, Portlaoise, Co Laois
Lo call Number: 0761 064440
Email Address: AnimalByProducts@agriculture.gov.ie

Further information on registration of establishments, including application forms and conditions, are available at: http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/.

A copy of the Certificate of Registration must accompany an application for a VET15 licence.

4. Conditions applicable to the importation of samples of animal products for research and diagnostic purposes

a. Each consignment must be delivered directly to the establishment registered to use animal by products and/or derived products for research or diagnostic purposes indicated on the application.

b. The consignment must be imported through Shannon Airport or Dublin Airport.

c. Each consignment must be accompanied by:
   – A copy of an import licence (Vet15) issued by the Department of Agriculture, Food and the Marine, and
   – An original signed commercial document in accordance with the model in Annex I

d. A completed electronic copy of the commercial document in the format provided in Annex I must be transmitted by email to the relevant point of entry at least 24 hours prior to arrival at that point of entry.

e. The consignment must bear a label with the following words visibly and legibly displayed “for research and diagnostic purposes”.

f. The consignment, if requested, must be made available for examination by an officer of this Department at the authorised point of entry.

2 BIPS.DubAirport@agriculture.gov.ie or BIPS.ShanAirport@agriculture.gov.ie
g. The consignment must be transported in accordance with IATA and ADR Regulations as appropriate and travel directly from the authorised point of entry to the registered user referred to at point (a).

h. When importing from a third country via another Member State, the consignment must be presented at an approved Union border inspection post\(^3\) in the Member State of entry listed in Annex 1 to Commission Decision 2009/821/EC in accordance with Art 27(2) of Regulation (EC) No. 142/2011.

i. During transport and storage the material or its packaging, must not be allowed to come into contact with animals or products of a different animal or public health status.

j. The material is for examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology and in the context of educational or research activities at the registered establishment.

k. The materials are not for human consumption, re-sale or supply to any other establishment and must not be removed from the registered establishment except as referred to at point (p) below.

l. The materials may not be used in a manufacturing process or in the final production of a finished product; in validation or verification during a manufacturing process; or in quality control of a finished product. Use of research and diagnostic samples for purposes other than in the context of diagnostic, educational or research activity is prohibited.

m. The category and type of material imported must be in accordance with the Certificate of Registration issued to the establishment and conditions set out for establishments registered to use animal by-products and/or derived products for diagnostic, educational or research purposes.

n. Users at the registered establishment shall take all necessary measures to avoid the spreading of disease communicable to humans or animals during the handling of the materials under their control, in particular by way of good laboratory practice.

o. If at any time the conditions of the licence cannot be met or a pathogen\(^4\) is discovered in the imported material, work must be suspended and the particulars reported to animalproductimports@agriculture.gov.ie immediately.

p. Unless kept for reference purposes or re-dispatched to the third country of origin, research and diagnostic samples and any products derived from the use of those samples must be destroyed in accordance with Section 1 of Chapter III of Annex XIV of Regulation (EC) No. 142/2011.

q. The user at the registered establishment must keep a register of consignments of research and diagnostic samples received which shall include the information referred to in Section 1 of Chapter I of Annex VI of Regulation (EC) No. 142/2011. A template Annex II Register of Consignments of Research and Diagnostic Samples is available at http://www.agriculture.gov.ie/agri-foodindustry/tradeimportsexports/importofanimalsandanimalproducts/

r. The register for the preceding licence period must be submitted to animalproductimports@agriculture.gov.ie prior to any licence renewal.

---
\(^3\) Consignments introduced with a licence which fulfill the conditions for importation will not require veterinary checks at a Border Inspection Post.

\(^4\) The import of pathogens and pathogenic agents is prohibited except under licence issued in accordance with the Importation of Pathogenic Agents Order, 1997 (S.I. No. 373 of 1997). Further information, including application forms may be obtained from animalproductimports@agriculture.gov.ie.
5. Licence application

Application forms for an annual Vet15 licence must be completed by the operator indicated in the Certificate of Registration submitted in support of the application. Application forms are available at the following link:


The original completed signed application form, together with a copy of the Certificate of Registration, should be submitted as early as possible, and in any case, not less than 7 working days before the intended date of import to

Animal Product Imports
Department of Agriculture, Food and the Marine
1 East Agriculture House
Kildare Street
Dublin 2
DO2 WK12
Phone: 01 6072000
Email: animalproductimports@agriculture.gov.ie

Please note the application should be completed by the “operator” referred to in the Certificate of Registration.

To expedite the processing of a Vet15 application form for licence to import products of animal origin for research and diagnostic purposes the applicant may email a scanned copy of the signed application form and a copy of the Certificate of Registration to animalproductimports@agriculture.gov.ie, however, the licence will not be issued until the original signed copy of the application form has been received.

6. Samples from EU Member States

There is no requirement for a Vet15 import licence in relation to the movement of research and diagnostic samples between EU Member States.

In addition, research and diagnostic samples from Andorra, Channel Islands, Isle of Man, Faeroe Islands, Iceland, Liechtenstein, Norway, San Marino and Switzerland may also be imported without a Vet15 import licence.

Further queries regarding the movement of research and diagnostic samples between EU Member States should be directed to AnimalByProducts@agriculture.gov.ie.

Important:

Products of animal origin that do not comply with import conditions and controls can be seized either for destruction or return to the country of origin at the importers expense.

The import licences referred to above are issued without prejudice to import controls that may be required other than for public or animal health reasons and does not exempt importers from any prohibition, regulation or restriction imposed by any other Agency or Department.