

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

EUROPEAN COMMUNITIES ACT 1972

**THE PRODUCTS OF ANIMAL ORIGIN (THIRD COUNTRY IMPORTS) (ENGLAND)
REGULATIONS 2006 (AS AMENDED)**

GENERAL IMPORT AUTHORISATION

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under the terms of Regulation 4 of the Products of Animal Origin (Third Country Imports) (England) Regulations 2006 (as amended) authorises subject to and in accordance with the conditions set out below, the landing in England of:

Animal tissue derived from mammals and birds fixed in formalin intended for research use (as defined in Regulation (EU) No 142/2011) (see note p)	Product
from	
Third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) No 206/2010 (as amended) (see note p)	Countries of origin
at	
All ports and airports in England (but see note o)	Ports of entry

until further notice or unless revoked by the Secretary of State.

General Licence IMP/GEN/2010/02 is hereby revoked.



Dated: 21 March 2011

A handwritten signature in black ink, appearing to be 'K. M. ...', located to the right of the official stamp.

Officer of the Department for
Environment, Food and Rural Affairs

Conditions attached to this authorisation

1. This authorisation is valid for multiple consignments and the net weight of the imported material per consignment must not exceed 15 kg.
2. Each consignment must be accompanied by:
 - a copy of this authorisation;
 - a commercial document providing the name and address of consignor and consignee and/or user, type of description of the product and quantities, the place of origin, place of dispatch and the category of the material as defined in Regulation (EC) No 1069/2009;
 - a declaration (see note a) signed by a veterinarian or director of the laboratory/establishment confirming that the tissue has been thoroughly fixed in formalin such that the formalin has penetrated throughout the entire sample/specimen (see note c).
3. The packaging must be clearly labelled to indicate the general authorisation number under which the product is imported. The label should also state that material is for importation into the UK for research use.
4. The products must be sent directly from the point of entry into the European Union (EU) to the authorised user and it must remain in its original wrapping at all times until their arrival at destination premises.
5. The consignment, or its packaging, must not be allowed to come into contact with any ruminating animals, swine, poultry or horses.
6. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.
7. Unless kept for reference purposes, on completion of the testing any residues of the material and the remainder of the packaging must be either incinerated at the premises that has been approved for the disposal of animal by-products (see note f) or re-exported to the third country of origin (see note h) or in accordance with the requirements of Annex XIV, Chapter III, Section 1 of Regulation (EU) No 142/2011.
8. If there is an outbreak of a notifiable/reportable disease in the exporting country/countries, the conditions of this authorisation may change. In this event, you should contact Animal Health (see below). For information on animal diseases please see:
<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/notifiable.htm>

9. Products imported under this authorisation are for research use only. Users that handle research samples shall keep a register of such consignments. The register shall include the information referred to in condition 2, 2nd bullet point and the date of method of disposal.
10. Products must not under any circumstances be supplied to a third party as a commercial transaction.
11. If at any time you are unable to meet the conditions on the authorisation; or any unlicensed animal pathogen is discovered in the imported material, work must be suspended immediately and the facts reported at once to the local Animal Health Office <http://www.defra.gov.uk/animalhealth/about/contact-us/index.htm>
12. The importer is responsible for ensuring that the person(s) sending the material to the UK are aware of the conditions of this authorisation.
13. You must inform the local Animal Health Office if you intend to use this authorisation (see note i).
14. Any products and records relating to the product imported under this authorisation shall be made available if so required for inspection by an Officer of Animal Health at any place nominated by him/her for such inspection. The importer or his agent shall afford all assistance necessary to such an officer to enable him/her to carry out the inspection in such a manner as he/she shall determine and the importer shall be responsible for meeting any costs of carrying out such an inspection.

NOTES

- a) Please see the [guidance](#) for the declaration template.
- b) It is the responsibility of the importer to ensure that the exporter provides the necessary declaration referred to above.
- c) **Formalin:** Aqueous solutions of formaldehyde are referred to as formalin. 100% formalin consists of a saturated solution of formaldehyde (this is about 40% by volume or 37% by mass) in water. Importers should note that the time taken to fix the tissue varies with factors such as the thickness of the tissue. **When tissues are initially fixed in formalin it is normal to use about 10 volumes of fixative to one volume of tissue.** Formalin fixed specimens for research must be cut so that one dimension is no greater than one centimetre and must be placed in not less than 9 times its own volume of 10% formalin for at least 48 hours before being imported. Larger specimens for example for museum and educational purposes must be placed in not less than 9 times its own volume of 10% formalin for at least **two weeks** before being imported. When the tissue is imported into the UK, providing the tissue has been thoroughly fixed throughout, the same volume of fixative is not required.
- d) **Safety:** Importers are responsible for ensuring that the health and safety requirements relating to the specimens, any infectious agents and the fixative are

appropriately assessed and dealt with by ensuring suitable packaging and labelling. See condition 3.

- e) This authorisation cannot be used for animal material fixed in formalin that is intended for diagnostic work. If you wish to import material for diagnosis, you will need to apply for a specific authorisation. If the diagnostic work involves animal pathogens, you will need to [apply for a Pathogens Licence](#),
- f) A list of approved incineration premises is available on our website: <http://www.defra.gov.uk/foodfarm/byproducts/incinerators/index.htm>
- g) Further information on the importation of Specified Animal Pathogens is available from the Defra website at: <http://www.defra.gov.uk/foodfarm/farmanimal/diseases/pathogens/index.htm#list>
A copy of the Specified Animal Pathogens Order 2008 can be obtained from the following website: http://www.opsi.gov.uk/si/si2008/uksi_20080944_en_1
- h) If the material is to be re-exported, you should ensure that the importing country will permit entry and that you have the correct paperwork to accompany the consignment.
- i) Importers should notify Animal Health if they wish to use this Authorisation at APIChelmsford@animalhealth.gsi.gov.uk
- j) This authorisation only relates to animal products. If you wish to import live animals of the species listed above, you should contact Animal Health (see below).
- k) **Research and diagnostic samples** – are defined in Regulation (EU) No 142/2011 as 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 educational or research activities.
- l) Any subsequent use of research and diagnostic samples for purposes other than those referred to in note k) above shall be prohibited.
- m) Should you wish to import Display items or Trade Samples as defined in Regulation (EU) No 142/2011, please contact the Specialist Service Centre for Imports, Animal Health Chelmsford (see below).
- n) Please refer to [Importer Information Notes \(IINs\)](#) on the Defra website for further information on importing animals and animal products.
- o) If the research and diagnostic samples enter the EU via a Member State which is not the Member State of destination, the consignment must enter through a Border Inspection Post (BIP). The competent authority at the BIP must notify the competent

authority of the Member State of destination using the TRACES system. A list of BIPs is on the Defra website.

- p) European legislation is available on the [Commission website](#).
- q) Nothing in this authorisation gives exemption from any prohibition or restriction imposed by any other legislation including the Official Feed and Food Controls (England) Regulations 2006 , the provisions of the Food Safety Act 1990 and Regulations made under it, the Animal By-Products (Identification) Regulations 1995, the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 the Control of Substances Hazardous to Health, International Air Transport Association, the Convention on International Trade in Endangered Species or by any regulation superseding or amending the same.
- r) This authorisation is granted under animal health import legislation and gives no exemption from any prohibition, regulation or restriction imposed by any other Government Department or Agency.
- s) Please note that while this authorisation is current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with the Specialist Service Centre for Imports, Animal Health Chelmsford (see below).

CAUTION

It is the importer's responsibility to ensure that any import covered by this authorisation complies with the terms and conditions as set out.

Any breach of any conditions attached to this authorisation will constitute an offence against the Animal Health Act 1981.

CONTACT FOR FURTHER INFORMATION

Specialist Service Centre for Imports

Animal Health

Beeches Road

Chelmsford

Essex

CM1 2RU

Tel: 01245 454860

Fax: 01245 351162

e-mail APIChelmsford@animalhealth.gsi.gov.uk