

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

EUROPEAN COMMUNITIES ACT 1972

THE TRADE IN ANIMALS AND RELATED PRODUCTS REGULATIONS 2011
THE ANIMAL BY-PRODUCTS (ENFORCEMENT) (ENGLAND) REGULATIONS 2013

GENERAL IMPORT AUTHORISATION

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under the terms of Paragraph 4 (4) of Schedule 3 of the Trade in Animals and Related Products Regulations 2011 authorises subject to and in accordance with the conditions set out below, the landing in England of:

*Research and diagnostic samples (whole carcasses, parts of carcasses, faeces, urine or other body fluids or tissues/materials, derived from them) from animals of the Order *Primates* that are:

- Born and bred in laboratories; and
- Not known or suspected to be infected with pathogens controlled under the Specified Animal Pathogens Order 2008 (SAPO)

Please note this authorisation excludes viable semen, ova and embryos intended for artificial breeding purposes and *samples intended for resale.

*see point 17

Product

from

Any third country

Countries of origin

at

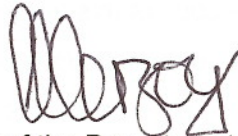
All ports and airports in England

Ports of entry

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

Dated: 31st March 2014




Officer of the Department for
Environment, Food and Rural Affairs

Conditions attached to this authorisation

General conditions

1. This authorisation is valid for multiple consignments and the net weight of the imported material must not exceed 15 kg per consignment.
2. The importer/user must inform the [Centre of International Trade - Carlisle](#) of any intention to rely on/use this authorisation.
3. If at any time the importer/user is unable to meet the conditions of the authorisation, or discovers any animal pathogen controlled under the Specified Animal Pathogens Order 2008 (SAPO) or other relevant legislation in the imported material, work must be suspended immediately and the facts reported at once to your [local AHVLA office](#).
4. The consignment must be sent directly from the point of entry into the European Union to the authorised user at premises registered or approved in accordance with Article 23 or Article 24 of Regulation (EC) 1069/2009 for research or diagnostic purposes(see note M).
5. The samples must be worked on and stored in facilities working to at least ACDP containment level 2 (see note N).
6. The importer/user must ensure that the person(s) sending the material to the UK is aware of the conditions of this authorisation.
7. None of the material to which this authorisation relates shall be used for human or animal consumption under any circumstances.
8. 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 and compliance with the requirements of UK Health and Safety Legislation
9. The consignment or its packaging must not be allowed to come into contact with any ruminating animals, swine, poultry, primates or horses.

Documentation

10. Each consignment must be accompanied by:
 - A copy of this authorisation
 - A commercial/shipping document which must specify the:
 - i) Name and address of consignor;
 - ii) Name and address of the consignee;
 - iii) Name and address of establishment of origin;
 - iv) Country of origin;

- v) Description of the product;
- vi) Category of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009¹; and
- vii) Quantity of the material (net weight).

11. Each consignment must be accompanied by a declaration (see note C) signed by a veterinarian or director of the laboratory/establishment of origin in the exporting country confirming that the products:

- Are derived from animals born and bred in a laboratory and kept isolated from other animals not born and bred in a laboratory;
- Are **not** derived from animals:
 - known or suspected to be infected with a pathogen controlled by the Specified Animal Pathogens Order 2008 (SAPO) (as amended)
 - known or suspected to be infected with a disease as listed in European* or the animal health legislation of the exporting country;
 - Do not originate from animals in a premises or region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals are susceptible according to European* or other national animal health legislation in the exporting country.
 - known or suspected to be infected with a disease transmissible to humans (zoonotic disease).

*Council Directive 82/894/EEC² of 21 December 1982 (as amended) on the notification of animal diseases within the EU.

Packaging and labelling

- 12. 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 and diagnostic purposes only'.
- 13. The products must remain in their original wrapping at all times until their arrival at the premises of destination.

Action on completion of testing

- 14. On completion of the testing, and unless they are kept for reference purposes or re-dispatched to the third country of origin (see note E), any residues of the material and any products derived

¹ OJ No L 300, 14.11.2009, p. 1.

² OJ No L 378, 31.12.1982, p. 58.

from the use of those samples shall be disposed of in accordance with the requirements of Annex XIV, Chapter III, Section 1 of Regulation (EU) No 142/2011³ (see note A).

15. If the product is to be supplied to another establishment for further research, the importer/user must make the recipient aware of the requirement to destroy or re-export the residues of the product (see notes A and E).

Audit and inspection

16. Products imported under this authorisation are for research or diagnostic use only (see note I). A complete record/audit trail which includes the information referred to in condition 10 above as well as the date and method of disposal must be kept by all parties that handle the material.
17. Products must NOT under any circumstances be supplied to a third party as a commercial transaction or used for the creation/ manufacture of a product for commercial resale.
18. 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 AHVLA at any place nominated by the Officer for such inspection. The importer/user or his agent shall afford all assistance necessary to enable the Officer to carry out the inspection in such a manner as the Officer shall determine and the importer/user shall be responsible for meeting any costs of carrying out such an inspection.

NOTES

Animal By-products must be disposed of in accordance with Environmental and Animal By-products legislation.

- A. Guidance on the importation of [Specified Animal Pathogens](#) and pathogens covered by the Importation of Animals Pathogen Order 1980 (as amended) is available at on the [Defra website](#).
A copy of the Specified Animal Pathogens Order 2008 and the amendment can be obtained from the following website:
http://www.legislation.gov.uk/ukxi/2008/944/pdfs/ukxi_20080944_en.pdf;
http://www.legislation.gov.uk/ukxi/2009/3083/pdfs/ukxi_20093083_en.pdf
- B. Please refer to the [Importer Information Notes](#) (IINs) on the Defra website for further information on importing Research and Diagnostic samples.
- C. It is the responsibility of the importer/user to ensure that the exporter provides the necessary declaration as at point 11 above.
- D. If the material is being imported via a Member State (MS) that is different to the MS of destination, the consignment must enter the EU at an approved Border Inspection Post (BIP) so that the competent authority of the BIP can notify the competent authority of the MS of destination of the introduction into the consignment by means of the TRACES system. Please contact the Centre for International Trade - Carlisle for further information.

³ OJ No L 54, 26.2.2011, pg. 1.

- E. If the material is to be re-exported, the importer/user should ensure that the importing country will permit entry and that the paperwork accompanying the consignment meets the requirements of the importing country.
- F. This authorisation is granted under animal health legislation and gives no exemption from any prohibition, regulation or restriction imposed by any other Government Department or Agency.
- G. 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 2009, the provisions of the Food Safety Act 1990 and Regulations made under it, the Animal By Products (Enforcement) England Regulations 2013, the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, the Control of Substances Hazardous to Health, the Air Navigation (Dangerous Goods) Regulations 2002, the Control of Trade in Endangered Species (Enforcement) Regulations 1997 or by any regulation superseding or amending the same.
- H. Please note that this licence is current at the time of its issue. Importers should check the [website](#) to ensure conditions for import have not changed.
- I. Research and diagnostic samples are defined in Annex I of 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'.
- J. Any subsequent use of research and diagnostic samples for purposes other than those referred to in note I above shall be prohibited.
- K. Display Items and Trade Samples are defined separately in Regulation (EU) No 142/2011. Should you wish to import them, please contact the Centre for International Trade – Carlisle.
- L. This authorisation only relates to animal products. If you wish to import live animals or any other products, please contact the Centre for International Trade – Carlisle for further advice.
- M. Importers/users of animal by-products should ensure that they are generated, handled, stored, labelled, transported, processed, distributed, placed on the market, used and disposed of in accordance with the requirements of Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. Premises must be registered for the use of animal by-products. Further information is available on the [AHVLA website](#).

Specific Notes

- N. Containment level 2 must be used for work with biological agents in hazard group 2. Laboratory personnel must receive suitable and sufficient information, instruction and training in working safely with agents in hazard group 2. A high standard of supervision of the work should be maintained. Further information is available:

<http://www.hse.gov.uk/pubns/priced/microbiologyiac.pdf>
- O. In addition, please note that there are statutory requirements on the importer under the following legislation:

- The Control of Substances Hazardous to Health (2002) (COSHH)
- Management of Health and Safety at Work Regulations (1999)
- Health and safety at Work Act (1974)

P. It is the importers responsibility to:

- Provide the required information on the goods for import and if potentially hazardous to health, where appropriate provide, by means of a Material/Chemical Safety Data Sheet, sufficient information to allow adequate risk assessment by the end user
- Provide any other relevant information for the end user, including disposal requirements following use of the product
- Measures to be taken if the end user is exposed to hazardous substances contained in the product.

CAUTION

It is the importer/user'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 Regulation 39 of the Trade in Animals and Related Products Regulations 2011 or Regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2011.

CONTACT FOR FURTHER INFORMATION

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