Department for Environment, Food and Rural Affairs

Scottish Government

Welsh Government

Commission Regulation (EU) 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive ("Regulation 142/2011")

The Trade in Animals and Related Products Regulations 2011

The Trade in Animals and Related Products (Scotland) Regulations 2012

The Trade in Animals and Related Products (Wales) Regulations 2011

The Animal By-products (Enforcement) (England) Regulations 2013

The Animal By-Products (Enforcement) (Scotland) Regulations 2013

The Animal By-Products (Enforcement) (Wales) Regulations 2014

General authorisation to import research and diagnostic samples (IMP/GEN/2024/13)

Date issued: 16 December 2024

Valid until further notice or unless revoked by the Secretary of State, Scottish ministers, Welsh ministers or both

Details

You must comply with the conditions of this general authorisation if you import any of the following products into Great Britain:

- research and diagnostic samples

Where all the following apply:

- they consist of animal by-products and derived products intended for only 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.
- they are not intended for re-sale

Originating from:

- European Union member states
- European Free Trade Association member states
- Greenland and the Faroe Islands where they align with EU sanitary and phytosanitary rules

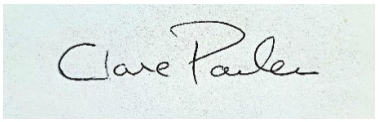
Arriving at (point of entry):

- any point of entry in Great Britain

Authorisation issued on 16 December 2024 under Article 27 of Regulation (EU) 142/2011 on behalf of the:

Secretary of State for Environment, Food and Rural Affairs by:

Clare Parnham, officer of the Department for Environment, Food and Rural Affairs

Signature:  **Official stamp:** 

Scottish ministers by:

Jesus Gallego, a member of staff of the Scottish ministers

Signature: 

Welsh ministers by:

Dr Richard Irvine MRCVS, Chief Veterinary Officer for Wales, a member of staff of the Welsh ministers

Signature: 

Conditions attached to this authorisation

1. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.

Packaging

2. The material must be packed in leak-proof sealed containers.
3. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.
4. The packaging must be clearly labelled to indicate the nature of the product, that it is intended for use in research and that it is not for human or animal consumption.
5. Irrespective of the mode of transport, all specimens must be packaged so that they fully

comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.

6. The products must always remain in their original packaging and wrapping until their arrival at the destination.

Storage, use and handling

7. The samples, and material derived from the samples, shall be for in vitro use only.
8. None of the material this authorisation relates to shall be used for human or animal consumption under any circumstances.
9. Any subsequent use of these products for purposes other than those referred to in point 38 of annex 1 of Regulation (EU) No 142/2011, is prohibited.
10. Samples must be handled and stored under a containment level which is appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002.
11. Users shall take all necessary measures to avoid spreading diseases communicable to humans or animals during the handling of the materials under their control, particularly by applying good laboratory practice.
12. Unless they are kept for reference purposes or re-dispatched to the third country of origin, research and diagnostic material, products derived from their use and waste shall be disposed of appropriately. This must be done in accordance with The Waste (England and Wales) Regulations 2011 or The Waste (Scotland) Regulations 2012 or Section 1 of Chapter III of Annex XIV Regulation (EU) 142/2011.
13. Any transfer of material from the authorised user to any other user must be pre-authorised by APHA.

Transportation

14. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address listed on the commercial document.
15. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.
16. Before starting operations, the transporter and destination address must be registered or approved (see general note 6) in accordance with the relevant Animal By-Products (Enforcement) Regulations.

Import documentation

17. Each consignment must be accompanied by a:
    - copy of this authorisation

- commercial documentation (see point 18)

18. Each consignment must be accompanied by a commercial document signed by a person with knowledge of, and responsibility for, the relevant parts of the production process. It must be on company letter-headed paper and dated within 2 months of the importation date of each consignment. The document must include the:

    - description of the product and animal species of origin
    - category of the product (1, 2 or 3) as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009
    - quantity of the product
    - place and country of origin
    - place of dispatch of the product
    - name and address of consignor
    - name and address of the consignee or user, or both

    The document should also confirm that the product (see general note 7):

    - is not derived from animals known or suspected to be infected with a pathogen which causes a disease that is notifiable in England, Scotland, Wales or the European Union, and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales) Order 2008
    - does not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible

General notes

1. References to European Union (EU) legislation within this document are references to direct EU legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023. This can be viewed on the UK legislation website (legislation.gov.uk).
2. This authorisation is granted under animal and public health import legislation. It gives no exemption from any prohibition, regulation or restriction imposed by any other government department or agency.
3. Import conditions in general authorisations can be subject to change and importers are advised to check they are using the current version.
4. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 24 months for presentation to the competent authority.
5. Any products, or records relating to the product, imported under this authorisation must be provided for inspection if requested by an officer of the Animal and Plant Health Agency or an enforcement authority, at any place nominated by them. The importer or their agent must provide any assistance required by the officer to carry out the inspection. The importer will be

responsible for meeting any costs related to carrying out the inspection.

6. For information on registration or approval, visit https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered
7. In Great Britain, notifiable diseases are animal diseases that you're legally obliged to report to the Animal and Plant Health Agency, even if you only suspect that an animal may be affected. Notifiable diseases are named in Section 88 of the Animal Health Act 1981, an Order made under that Act or are diseases that are required to be notified in accordance with assimilated EU legislation. For further information on notifiable diseases in Scotland, England and Wales, visit:
    - England: https://www.gov.uk/government/collections/notifiable-diseases-in-animals
    - Scotland: https://www.gov.scot/collections/animal-diseases-notifiable-and-non-notifiable-diseases/
    - Wales: https://www.gov.wales/notifiable-diseases

    In the EU, a notifiable disease is any disease that is required by law to be reported to government authorities. The diseases are categorised in accordance with Regulation (EU) 2016/429 (known as Animal Health Law) and Commission Implementing Regulation (EU) 2018/1882.

Caution

1. It is the responsibility of the importer to ensure that any import covered by this authorisation complies with the terms and conditions as set out.
2. 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, The Trade in Animals and Related Products (Wales) Regulations 2011, regulation 33 of The Trade in Animals and Related Products (Scotland) Regulations 2012, or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013, The Animal By-Products (Enforcement) (Wales) Regulations 2014 or regulation 18 of The Animal By-Products (Enforcement) (Scotland) Regulations 2013.

Contact for further information

Animal and Plant Health Agency (APHA)
Imports Team
Centre for International Trade - Carlisle
Eden Bridge House, Lowther Street
Carlisle
CA3 8DX
Telephone: 03000 200 301
Email: imports@apha.gov.uk

Find other general licences and authorisations to import live animals or animal products at www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations