



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

AUTHORISATION FOR THE IMPORTATION FROM THIRD COUNTRIES OF RESEARCH AND DIAGNOSTIC SAMPLES

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under Article 27 of Regulation (EU) 142/2011, authorises:

Mr Stuart Marshall
Biobest Laboratories Ltd
6 Charles Darwin House
The Edinburgh Technopole
Milton Bridge, Nr Penicuik,
EH26 0PY

Name and full address of importer responsible for consignment

Dr Paul Burr
Biobest Laboratories Ltd
6 Charles Darwin House
The Edinburgh Technopole
Milton Bridge, Nr Penicuik, EH26 0PY

Full address of destination premises (if different from importer)

to land in England, in accordance with the conditions set out below,

Whole blood, serum and plasma samples from pet cats and dogs, intended for particular studies or analyses only. (Not for resale).

Product

from

All countries outside the EU

Countries of origin

at

All ports and airports in England

Ports of entry

This licence expires on 2 years less one day from the date of signature. After this date the licence should have either been renewed if required and deleted or cancelled and archived.

Signed:

Dated: 09 May 2024

Name: Andrew Lee
Officer of the Animal and Plant Health Agency
authorised by the Secretary of State.

CONDITIONS ATTACHED TO THIS AUTHORISATION

1. This authorisation is valid for multiple consignments and the net weight per consignment must not exceed 1 Kg.
2. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.

Packaging

3. The material must be packed in leak-proof sealed containers.
4. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.
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 packaging must be clearly labelled to indicate the nature of the product, that this is intended for *in vitro* use for research and that it is **not** for human or animal consumption.

Import Documentation

7. Each consignment must be accompanied by a copy of this import authorisation and a commercial document which must confirm:
 - i. The description of the material and the animal species of origin;
 - ii. The category, 1, 2 or 3, of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009¹;
 - iii. The quantity of the material;
 - iv. The place of origin and the place of despatch of the material;
 - v. The name and the address of the consignor;
 - vi. The name and address of the consignee and/or user;
8. Each consignment must be accompanied by a signed and dated declaration completed by a veterinarian, on official paper, confirming that:
 - i. the products are **not** derived from animals known or suspected to be infected with a pathogen which causes a notifiable disease to which the animals from which the products are derived are susceptible according to retained European Regulations² or the Animal Health Regulations of the exporting country; and
 - ii. the products **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 Regulations.

¹ <https://www.legislation.gov.uk/eur/2009/1069/title/I/chapter/I/section/4>

² <https://www.legislation.gov.uk/eudr/1982/894>

- iii. the animals from which samples were collected did not show any sign of infectious disease at the time of collection

Transportation

9. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address on page 1.
10. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.
11. The transporter and destination address must be registered or approved (see note E) in accordance with the relevant Animal By-Products (Enforcement) Regulations, (ABPE) before commencing operations.
12. The products must remain in their original wrapping at all times until their arrival at the destination address on page 1.

Storage, Use and Handling

13. Users 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.
14. The samples and material derived from the samples shall be for in vitro use only.
15. Samples must be handled and stored under containment level conditions which are 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.
16. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.
17. 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.
18. Importers shall keep a register of consignments of samples imported under this authorisation, which should contain the information referred to in condition 7 above as well as the date and method of disposal.
19. Unless they are kept for reference purposes, transferred 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, in accordance with The Waste (England and Wales) Regulations 2011/The Waste (Scotland) Regulations 2012 or Animal By-Product Regulations (Regulation (EC) 1069/2009 and Regulation (EU) 142/2011).

Transfer of Material

20. Any transfer of material from the authorised user to any other user must be pre-authorised by APHA.

NOTES

- A. When expired or exhausted this authorisation is to be deleted or cancelled and archived.
- B. Please note that while this authorisation was current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with Animal and Plant Health Agency, Imports Team, Carlisle, at the address below.
- C. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.
- D. 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.
- E. For information on registration/approval, please see the website: <https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered>
- F. 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), and can be viewed on the UK legislation website (legislation.gov.uk)

Further information regarding changes to the import controls from an EU country from 31 January 2024 can be found on GOV.UK at:

<https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain>

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. If you cannot comply with any of the conditions above, please contact the APHA Imports Team.

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 2013.

CONTACT FOR FURTHER INFORMATION

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