



**EUROPEAN COMMUNITIES ACT 1972**

The Trade in Animals and Related Products Regulations 2011 (as amended)  
Animal By-products (Enforcement) (England) Regulations 2013,  
Animal By-products (Enforcement) (Scotland) Regulations 2013,  
Animal By-products (Enforcement) (Wales) Regulations 2014.

**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 the terms of Paragraph 4 of Schedule 3 of The Trade in Animal and Related Products Regulations 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 & plasma 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.**

Signed:  

Dated: 14 October 2021

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. 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. 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.
5. 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.
6. 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 of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009<sup>1</sup>;
  - 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;
7. 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 European Regulations<sup>2</sup> 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.
  - iii. the animals from which samples were collected did not show any sign of infectious disease at the time of collection
8. **In accordance with Article 27.2 of Regulation (EU) 142/2011, research and diagnostic samples from Third countries which are intended to be imported via a Member State other than the MS of destination must come in at an approved Border Control Post (BCP). They will not be subject to veterinary checks but the BCP must inform the MS of**

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<sup>1</sup> OJ No L 300, 14.11.2009, p.1.

<sup>2</sup> Council Directive 82/894/EEC of 21 December 1982 (as amended) on the notification of animal diseases within the Community

**destination of the introduction of the sample by means of the TRACES system**  
(<https://webgate.ec.europa.eu/sanco/traces/>)

9. The consignment must be sent directly from the point of entry into the Union to the authorised user at the destination address on page 1.
  10. 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.
  11. The products must remain in their original wrapping at all times until their arrival at the destination address on page 1.
  12. 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.
  13. The samples and material derived from the samples shall be for in vitro use only.
  14. Samples must be handled and stored under a minimum of containment level 2 (ACDP CL2 ) conditions.
  15. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.
  16. The material must be produced, processed, transported, handled, labelled, stored, used and disposed of, in accordance with the Animal By-products Regulations.
  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 6 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 samples and any products derived from their use, shall be disposed of:
    - i. As waste by incineration or co-incineration;
    - ii. By pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
  20. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.
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## NOTES

- A. When expired or exhausted this authorisation is to be returned to the address below.
- 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. EU legislation as it stood on 31 December 2020 that the UK already complies with has been incorporated into our domestic law as “retained EU law” under the European Union (Withdrawal) Act 2018. References in our guidance and certification to such EU instruments should be taken to be references to this “retained EU law”. Our current standards will remain in force, without amendment, in the immediate months after our EU exit as part of UK domestic law (apart from corrections to make the EU legislation fully operable). Relevant EU Exit Statutory Instruments are below:
- [The Import of, and Trade in, Animals and Animal Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2020](#)  
[The Official Controls \(Animals, Feed and Food, Plant Health etc.\) \(Amendment\) \(EU Exit\) Regulations 2020](#)  
[The Official Controls \(Animals, Feed and Food, Plant Health etc.\) \(Amendment\) \(EU Exit\) \(No. 2\) Regulations 2020](#)  
[The Aquatic Animal Health and Alien Species in Aquaculture, Animals, and Marketing of Seed, Plant and Propagating Material \(Legislative Functions and Miscellaneous Provisions\) \(Amendment\) \(EU Exit\) Regulations 2020](#)  
[The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020](#)  
[The Trade in Animals and Animal Products \(Legislative Functions\) and Veterinary Surgeons \(Amendment\) \(EU Exit\) Regulations 2019](#)

Further information regarding changes to the import controls from an EU country from 1 January 2021 can be found on GOV.UK at:  
<https://www.gov.uk/guidance/importing-animals-animal-products-and-high-risk-food-and-feed-not-of-animal-origin-from-1-january-2021#import-from-an-eu-country-from-1-january-2021>

## 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 (as amended) or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013 and 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, Imports Team  
 Centre for International Trade – Carlisle  
 Eden Bridge House,  
 Lowther Street,  
 Carlisle, CA3 8DX Tel: 03000 200 301 Email: [imports@apha.gov.uk](mailto:imports@apha.gov.uk)