Animal & Plant Health Agency

Authorisation No:	ITIMP19.1186

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

European Communities Act 1972

Trade in Animals and Related Products Regulations 2011

Animal By-products (Enforcement) (England) Regulations 2013, Animal By-products (Enforcement) (Scotland) Regulations 2013, Animal By-products (Enforcement) (Wales) Regulations 2014

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 postal 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	Name and full postal address of destination premises (if different from importer)

Subject to and in accordance with the conditions set out below, the landing in England of:

Whole blood, serum & plasma from pet cats and dogs, intended for particular studies or analyses only. (Not for resale).	Product
All countries outside the EU	Countries of origin
All ports and airports in England	Ports of entry
10/10/2021	Expiry Date

Dated: 10/10/2019

Officer of the Department for Environment, Food and Rural Affairs

DEPARTMENT FOR ENVIRONMENT, FOOD & RURAL AFFAIRS APHA

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[1];

    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 declaration (see note D) completed by the veterinarian responsible for the care of the animal on headed 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[2] 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 samples were taken from healthy animals which had no sign of disease.

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 Inspection Post (BIP). They will not be subject to veterinary checks but the BIP must inform the MS of destination of the introduction of the sample by means of the TRACES system (https://webgate.ec.europa.eu/sanco/traces/)**

[1] OJ No L 300, 14.11.2009, p.1.
[2] Council Directive 82/894/EEC of 21 December 1982 (as amended) on the notification of animal diseases within the Community

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 F) under the Animal By-Products (Enforcement) (England) Regulations 2013 (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 to be handled and stored under containment level 2 conditions

15. None of the material to which this authorisation relates shall be used for human consumption under any circumstances.

16. 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, shall be prohibited.

17. 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.

18. Unless they are kept for reference purposes, 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.

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

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. The material must be produced, processed, transported, handled, labelled, stored, used and disposed of in accordance with the Animal By-products Regulations.

D. All declarations must be written on headed paper, dated and signed.

E. 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.

F. 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

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.

Any samples imported under this authorisation are only for use at the destination premises on page 1. If you wish to move these samples to another premises for any purpose other than destruction, please contact the APHA Imports Team.

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