

**Agriculture and Rural Economy Directorate**  
 Animal Health and Welfare Division

**Commission Regulation (EU) No 142/2011**<sup>1</sup> 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**”)

**Commission Delegated Regulation (EU) No 2019/2122** supplementing **Regulation (EU) 2017/625** of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers’ personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending **Commission Regulation (EU) No 142/2011** (“**Commission Delegated Regulation 2019/2122**”)

**The Trade in Animals and Related Products (Scotland) Regulations 2012**<sup>2</sup>  
**The Animal By-Products (Enforcement) (Scotland) Regulations 2013**<sup>3</sup>

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

The Scottish Ministers, under Article 27 of Regulation (EU) 142/2011, Article 4 of Commission Delegated Regulation 2019/2122, and paragraph 3 of schedule 3 of the Trade in Animals and Related Products (Scotland) Regulations 2012 authorise

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

*Name and full address of importer responsible for consignment*

*Full address of destination premises (if different from importer) – This address must be in Scotland*

to import, in accordance with the conditions set out below,

Whole blood, serum or plasma from companion animals (pet dogs and cats) Samples are from healthy animals that are not known to be (or suspected to be) infected with a pathogen which causes a notifiable disease according to EU regulations intended for particular studies or analyses only. (Not for resale).

*Product*

from

All Countries

*Countries of origin*

at

<sup>1</sup> [Commission Regulation \(EU\) No 142/2011 \(legislation.gov.uk\)](https://legislation.gov.uk/eur-lex/regulation/2011/142)

<sup>2</sup> [The Trade in Animals and Related Products \(Scotland\) Regulations 2012 \(legislation.gov.uk\)](https://legislation.gov.uk/ukdsi/2012/50001/1)

<sup>3</sup> [The Animal By-Products \(Enforcement\) \(Scotland\) Regulations 2013 \(legislation.gov.uk\)](https://legislation.gov.uk/ukdsi/2013/50001/1)

All ports and airports in Scotland
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*Ports of entry*

**This authorisation expires on 31 March 2030**



Signed:

Dated: 31 March 2025

Name: Jacqueline Quigley

A member of staff of the Scottish Minister

### **CONDITIONS ATTACHED TO THIS AUTHORISATION**

1. The authorisation is valid for multiple consignments and the net weight per consignment must not exceed **5kg**
2. Any breach of these conditions must be reported to the Scottish Government (at the contact address below).

#### 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. The packaging must be clearly labelled to indicate the nature of the product, that it is intended for *in vitro* use in research or diagnostics and that it is **not** for human or animal consumption.
6. 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.
7. The products must always remain in their original packaging and wrapping until their arrival at the destination.

#### Storage, use and handling

8. The samples and material derived from the samples shall be for *in vitro* use only.
9. None of the material this authorisation relates to shall be used for human or animal consumption under any circumstances.
10. 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.
11. 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. In doubt, contact the Health and Safety Executive.

12. 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.
13. Unless they are kept for reference purposes or re-dispatched to the third country of origin, the research and diagnostic samples, products derived from their use and waste shall be disposed of appropriately. This must be done in accordance with Section 1 of Chapter III of Annex XIV to Regulation 142/2011.
14. Any transfer of the imported research and diagnostic samples and any products derived from the samples from the authorised user to any other user must be pre-authorised by the Scottish Government.

#### Transportation

15. The consignment must be sent directly from the point of entry into Scotland to the authorised user at the destination address listed on the commercial document.
16. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.
17. Before starting operations, the transporter and destination address must be registered or approved (see note D) in accordance with the Animal By-Products (Enforcement) (Scotland) Regulations 2013.

#### Import Documentation

18. Each consignment must be accompanied by a:
  - copy of this authorisation
  - commercial documentation (see point 18)
19. 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:

- is derived from animals which did not show any signs of disease communicable to humans or animals.
- does not originate from animals located in, and has not been dispatched from holdings, establishments or zones which are subject to restrictions due to the presence of a serious transmissible disease, to which species the products are obtained from are susceptible:
  - listed in Annex I to Directive 92/119/EEC; or
  - listed by the WOAAH in Chapter 1.3 of the Terrestrial Animal Health Code, [2024] edition, and in Chapter 1.3 of the Aquatic Animal Health Code, [2024] edition

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**NOTES**

- A. 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 the Scottish Government, at the address below.
- B. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.
- C. 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 2 years for presentation to the competent authority.
- D. 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>
- E. 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 Scottish Government.

Any breach of any conditions attached to this Authorisation may constitute an offence against regulation 33 of the Trade in Animals and Related Products (Scotland) Regulations 2012 or regulation 18 of the Animal By-Products (Enforcement) (Scotland) Regulations 2013.

**CONTACT FOR FURTHER INFORMATION**

Scottish Government  
Agriculture and Rural Economy Directorate  
Animal Health and Welfare Division  
P Spur  
Saughton House  
Broomhouse Drive  
EDINBURGH  
EH11 3XD  
United Kingdom

**Email:** [animal.health@gov.scot](mailto:animal.health@gov.scot)