



Department
for Environment
Food & Rural Affairs

The Trade in Animals and Related Products Regulations 2011

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

GENERAL IMPORT AUTHORISATION

The Secretary of State for the Environment, Food and Rural Affairs, by this authorisation issued under Regulation 15 (5) of The Trade in Animal and Related Products Regulations 2011 hereby authorises the landing in England, subject to and in accordance with the conditions set out below:

Treated milk and milk-based products and treated blood products, for use as a stabiliser or carrier (**not exceeding 10% concentration**) for any of the following materials:

- Monoclonal and polyclonal antibodies, proteins, enzymes, peptides and polypeptides separated from plasma or serum and purified to the extent that they do not contain any viable pathogenic microorganisms
- Cells which do not contain a pathogen
- Cell cultures more than one generation removed from tissue harvested from an animal
- Stem cells derived from animals born and reared exclusively in a laboratory environment
- Material other than animal by-products or derived products

FOR LABORATORY AND PHARMACEUTICAL USE ONLY WHICH INCLUDES COMMERCIAL USE

From

Must come from a country listed for the relevant category of product in the column headed "Third countries' lists" in—

- (a) for treated milk and milk-based products, Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; and
- (b) for treated blood products, Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011.

At

Any point of entry in **England** which has a Border Control Post designated for the import of the product described above.

[Until further notice or unless revoked by the Secretary of State]

Signed on behalf of the Secretary of State for the Environment, Food and Rural Affairs:

Name:

C. Parson

Date:

25 APR 2024



Conditions attached to this authorisation

General Conditions

1. Each Consignment must be accompanied by a commercial document signed by a senior manager of the facility, on company letter headed paper dated no less than 3 weeks from the date of import of each consignment, which must confirm:
 - i. Name of the establishment of production;
 - ii. Name and address of the consignor and consignee;
 - iii. Quantity shipped and identification marks;
 - iv. The country of origin;
 - v. A description of the material, the animal species of origin and intended use.
 - vi. The category, 1, 2 or 3, of the material as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009¹;
 - vii. The quantity of the material, in volume, weight or number of packages
 - viii. The name and address of the establishment or plant of origin of the material and its approval or registration number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004, (EC) No 853/2004 or (EC) No 183/2005 of the European Parliament and of the Council.
 - ix. the name and address of the establishment or plant of destination and the registration or approval number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004 or (EC) No 183/2005;
 - x. That the product complies with the conditions set out in this general import authorisation with reference number **IMP/GEN/2024/04**

2. Each consignment must be subjected to veterinary checks at a Border Control Post (BCP). Importers must pre-notify (via IPAFFS) the Border Control Post of the arrival of the consignment, present the consignment for checking and in some cases provide any further information deemed necessary at the BCP.

[Importing live animals, animal products and high-risk food and feed not of animal origin from non-EU countries to Great Britain - GOV.UK \(www.gov.uk\)](#)

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

4. Any breach of these conditions must be reported to APHA Imports Team, Centre for International Trade, Carlisle.

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

Specific Conditions

1. The product meets the requirements specified—
 - a) for treated milk and milk-based products, in entry 4 of Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; or
 - b) for treated blood products—
 - i. in entry 2 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011; or,
 - ii. in entry 3 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011 and have been treated in accordance with the requirements in point 2(b)(ii) of Chapter 4 of Annex 13 to Regulation 142/2011.
2. The animal by-product used as the stabiliser or carrier is at a concentration of 10% or less of the entire product, with a maximum individual unit size of 100 ml.
3. The product must be securely packaged in new, clean, leakproof containers.
4. The outer packaging must be clearly labelled 'NOT FOR FEED OR FOOD USE – FOR TECHNICAL USE ONLY.'
5. Every precaution must be taken to prevent contamination of the product.
6. The product is for laboratory or pharmaceutical use only.
7. The animal by-product used as the carrier or stabiliser is not for any subsequent use other than as a carrier or stabiliser.
8. The product must not be diverted at any stage within Great Britain for any use in food, feed, organic fertilisers or soil improvers.
9. The consignment, or its packaging must not be allowed to come into contact with any ruminating animals, swine, poultry or horses.
10. The products must remain in the original wrappings at all times until their arrival at the premises of final destination.
11. Any product or products derived from the use of the product products must 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).

NOTES

- A. This authorisation does not need to accompany the consignment.
- B. 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).

- C. This authorisation is granted under animal health import legislation and gives no exemption from any prohibition, regulation or restriction imposed by any other Government Department or Agency.
- D. If the material is to be re-exported, you should ensure that the importing country will permit entry and that you have the correct paperwork to accompany the product prior to export.
- E. Specific rules for the import of the products listed on page 1 of this authorisation, have not been laid down in Regulation (EU) 142/2011 at this time, so this authorisation is issued without prejudice to any future import rules.
- F. Please note that this authorisation is current at the time of its issue. Importers should check the [website](#) to ensure conditions for import have not changed.
- G. Any products and records, relating to the product imported under this authorisation, shall be made available if so required for inspection by an Officer of the Animal and Plant Health Agency at any place nominated by them for such inspection. The importer or their agent shall afford all assistance necessary to such an officer to enable the inspection in such a manner as the Officer shall determine. The importer shall be responsible for meeting any costs of carrying out such an inspection.
- H. 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, Centre for International Trade, Carlisle.

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.

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