Animal & Plant Health Agency

Import Information Note (IIN) ABP/42 will not be in use after 31 July 2025. It will be replaced by IIN ABP/47 and IIN ABP/48

Import of Milk/milk-based Products and Blood Products (not exceeding 10% concentration) for use as a stabiliser or carrier for certain materials (Research & Diagnostic Samples)

Import Information Note (IIN) ABP/48

July 2024

Contents

1. General Information

This Import Information Note (IIN) must be read in conjunction with the IIN for general information for imports of animal by-products (ABP), which provides information on pre-notifications, veterinary checks, risk categories, etc.

General information for imports of animal by-products (ABP) (defra.gov.uk)

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).

2. Scope

This IIN only applies to the products listed below which also meet the definition of research and diagnostic samples.

Research and Diagnostic Samples are defined in Regulation (EU) 142/2011 as 'animal by-products and derived products intended for the following purposes:

- examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities.'

Any subsequent use of research and diagnostic samples for purposes other than those referred to above shall be prohibited. They cannot for example be used for commercial use.

This IIN covers the importation of **treated milk/milk-based products** and **treated blood products** (at a concentration either not exceeding 3% or not exceeding 10%) for use as a stabiliser or carrier 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

a. **At a concentration not exceeding 3%**

The animal by-product used as the stabiliser or carrier is at a concentration of 3% or less of the entire product, with no limit on the individual unit size.

b. **At a concentration not exceeding 10%**

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. Production Standards

Treated milk and milk-based products

The milk, milk-based products and milk derived products must comply with Section 4, Chapter I of Annex XIV to Regulation (EU) 142/2011.

Treated blood products (excluding from Equidae)

The blood products must have been produced and stored in accordance with the requirements of Section 2, Chapter II of Annex XIV to Regulation (EU) 142/2011.

Treated blood products from Equidae

The blood and blood products from Equidae must have been collected, produced and stored in accordance with the requirements of Section 3, Chapter II of Annex XIV and Point 1(a) and Point 2 of Chapter IV of Annex XIII to Regulation (EU) 142/2011.

The blood products must have been submitted to the appropriate treatment method as set out in Point 2(b)(ii) of Chapter IV of Annex XIII to Regulation (EU) 142/2011.

Please see the relevant Import Information Note (IIN) on the website for more information on the import requirements for treated milk/milk-based products and treated blood products.

- Import Information Notes

Operators and users of research and diagnostic samples must meet the requirements of Section 1, Chapter I of Annex VI to Regulation (EU) 142/2011.

The consignment must be sent directly from the point of entry to the authorised user.

4. Country of origin

Imports are permitted from trading partners listed in a document published by the Secretary of State, with the consent of the Scottish and Welsh Ministers for:

- Non-EU countries
- EU and EFTA countries

Treated milk and milk-based products

Must come from countries listed in the documents for milk and milk products.

The country of origin must have been free from foot and mouth disease and rinderpest for 12 months immediately prior to export and have not practised vaccination against rinderpest during that period.

Treated blood products (excluding from Equidae)

Must come from countries listed in either the documents for fresh meat of ungulates, poultry and poultry products, meat of wild Leporidae, of certain wild land mammals and of farmed rabbits, or Japan.

Treated blood products from Equidae

Must come from countries listed in the document for fresh meat of ungulates, from which imports of fresh meat of domestic Equidae is authorised.

5. Approved establishments

Products must be produced in an establishment approved to export to Great Britain. Importers should check prior to importation that the premises are listed on the appropriate list.

Consolidated lists of approved establishments/plants are available here:

Establishments approved to export animals and animal products to Great Britain - data.gov.uk

If the establishment or plant is not listed, importers are urged to contact the company concerned, who should contact their competent authority immediately. If the plant is not included on the appropriate list when veterinary checks are carried out the consignment is likely to be held and could be rejected and re-exported or destroyed.

6. Import documentation

The following general import authorisations are available which lay down the import conditions for the products listed in Section 2 above. **Each consignment must be accompanied by the relevant import authorisation and other documentation as required by the conditions of the general import authorisation.**

a. **IMP/GEN/2024/09** for treated milk and milk-based products and treated blood products, for use as a stabiliser or carrier (not exceeding 3% concentration)

   or

b. **IMP/GEN/2024/03** for treated milk and milk-based products and treated blood products, for use as a stabiliser or carrier (not exceeding 10% concentration)

7. Packaging and labelling requirements

The material must be packed in leak-proof sealed containers, with inner and outer packaging being swabbed with suitable disinfectant before leaving the exporting address.

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.

8. Approval or Registration of destination premises

Any operator, establishment or plant that generates, transports, handles, processes, stores, places on the market, distributes, uses or disposes of animal by-products including research and diagnostic samples, trade samples or display items must be registered or approved by APHA under Animal By-Products Enforcement Regulations before commencing operations. This requirement is provided for in Article 23 or Article 24 of Regulation (EC) 1069/2009. Further information is available on the GOV.UK website.

- Animal by-product categories, site approval, hygiene and disposal

9. Transporters/couriers

Any independent hauliers (including couriers) of animal by-products including research and diagnostic samples, trade samples or display items should also be registered as described above. The registration process only needs to be done once for each haulier.

10. Veterinary checks

Research and diagnostic samples are not subject to veterinary checks.

11. Disposal or re-export of research and diagnostic samples

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 either:

- Animal By-Product Regulations (Regulation (EC) 1069/2009 and Regulation (EU) 142/2011).

    a. as waste by incineration;

    b. by pressure sterilisation and (see Processing Method 1 in Chapter III of Annex IV to Regulation (EU) 142/2011) subsequent disposal or use in accordance with Articles 12 to 14 of Regulation (EC) 1069/2009; or

    c. in accordance with point 4(b) of Section 1, Chapter I of Annex VI to Regulation (EU) 142/2011 in cases of:

        i. quantities not exceeding 2000 ml; and

        ii. provided the samples or derived products have been produced and dispatched from third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) 206/2010.

    or

- The Waste (England and Wales) Regulations 2011/The Waste (Scotland) Regulations 2012.

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

12. Contact for further information

For further information regarding import requirements, contact the Animal and Plant Health Agency (APHA) Imports team:

Centre for International Trade - Carlisle
Eden Bridge House
Lowther Street
Carlisle
CA3 8DX

Email: Imports@apha.gov.uk

Telephone: 03000 200 301

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to us at:

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www.gov.uk/apha

The Animal and Plant Health Agency (APHA) is an executive agency of the Department for Environment, Food & Rural Affairs, and also works on behalf of the Scottish Government and Welsh Government.