



Animal &
Plant Health
Agency

Import of Laboratory Reagents and derived products for pharmaceutical use, including the manufacture of pharmaceuticals and laboratory reagents

Import Information Note (IIN) ABP/46

January 2024

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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 \(ABP\) \(defra.gov.uk\)](https://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

Import conditions for:

- **Laboratory reagents** consisting of or made from animal by-products or derived products
 - A laboratory reagent is defined in Annex I point 36 of Regulation (EU)142/2011 as:
“...a packaged product, ready for use, containing animal by-products or derived products and intended as such or in combination with substances of non-animal origin for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances”.
- Derived products for **pharmaceutical use**, including the **manufacture of pharmaceuticals** and **laboratory reagents***.

*The Import Information Note does **not** apply to the import of any of the following products:

- [Animal by-products to be used for purposes outside the feed chain](#) (IIN ABP/8A)
 - This includes **unprocessed** animal by-products for the manufacture of derived products, including pharmaceuticals and laboratory reagents.
- [Intermediate products](#) (IIN ABP/20)
 - For the manufacture of medicinal products, veterinary medical products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products
- Animal by-products and derived products destined for establishments or plants **for the manufacture of the following products**:
 - **Cosmetic products** as defined in Article 2(1)(a) of Regulation 1223/2009/EC which is carried out in accordance with Regulation 1223/2009/EC
 - **Active implantable medical devices** as defined in Article 1(2)(c) of Directive 90/385/EEC which is carried out in accordance with the Medical Devices Regulations 2002

- **Medical devices** as defined in Article 1(2)(a) of Directive 93/42/EEC which is carried out in accordance with the Medical Devices Regulations 2002
- **In vitro diagnostic medical devices** as defined in Article 1(2)(b) of Directive 98/79/EC which is carried out in accordance with the Medical Devices Regulations 2002
- **Veterinary medicinal products** as defined in Article 1(2) of Directive 2001/82/EC which is carried out in accordance with the Veterinary Medicines Regulations 2013
- **Medicinal products** as defined in Article 1(2) of Directive 2001/83/EC which is carried out in accordance with the Human Medicines Regulations 2012

If an importer is unsure whether this Import Information Note applies to a product, then the importer should contact the Animal and Plant Health Agency (APHA) Imports Team (see section 9) to determine the requirements for import.

3. Production standards

Imports must take place under the requirements as laid down in [Regulation \(EU\) 142/2011](#) in relation to the **ABP/derived products they consist of or have been made from**.

For example, if a laboratory reagent consists of or has been made from a blood product then conditions for importing blood products will apply. If it consists of or has been made from a milk product then the requirements for milk products will apply.

Please see the relevant Import Information Note (IIN) for more information about the import requirements for the ABP/derived product it consists of or has been made from.

- [Import Information Notes](#) (IIN)

If you cannot comply with the conditions as set out in the relevant IIN, or if an appropriate IIN does not exist, you may require a **specific import authorisation**, issued by the Animal and Plant Health Agency (APHA). Importers wishing to apply for an authorisation should apply using an application form IV58 for a specific authorisation to the contact address below.

Alternatively, there may be a **general import authorisation** which is appropriate to the product, which can be found here:

- [General licences and authorisations to import live animals or animal products - GOV.UK \(www.gov.uk\)](#)

4. Country of origin

Imports are permitted from third countries as listed in the relevant IIN for the ABP/derived product it consists of or has been made from, or on the appropriate general import authorisation.

If you need to apply for a specific import authorisation, the permitted country of origin will be assessed on a case-by-case basis.

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 correct list.

Consolidated lists of approved establishments/plants are available on:

- data.gov.uk for **non-EU countries**
- and [here](#) for **EU Countries**

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. Border Target Operating Model (BTOM) Risk Categorisation*

- Products which consist of or are made from ABP/derived products that **can** meet the import conditions set out in the appropriate health certificate/import information note for those products, and are considered to be '**highly processed**', are categorized as **low risk** under the [Border Target Operating Model](#) (BTOM)
- Products which consist of or are made from ABP/derived products that **can** meet the import conditions set out in the appropriate health certificate/import information note for those products, but are not considered to be '**highly processed**', are categorized as **medium risk** under the [Border Target Operating Model](#) (BTOM)
- Products which contain ABP/derived products that cannot meet the conditions of the relevant health certificate, or for which no appropriate health certificate exists (i.e. they contain non harmonised ABP/derived products), are categorised as **medium risk** under the [Border Target Operating Model](#) (BTOM).

Further information regarding risk categories can be found at the links below.

[Import risk categories for animals and animal products imported from the EU to Great Britain, from 31 January 2024 - GOV.UK \(www.gov.uk\)](#)

[BTOM risk categories for animal and animal product imports from non-EU countries to Great Britain: summary tables - GOV.UK \(www.gov.uk\)](#)

(*) Please note that BTOM risk categorisation will apply to animal products from EU and EFTA countries from 31st January 2024 and from non-EU countries from 30th April 2024.

‘Highly Processed’ Laboratory Reagents and derived products for pharmaceutical use, including the manufacture of pharmaceuticals and laboratory reagents

To be considered ‘**highly processed**’ the intermediate product must have **undergone processing** which ensures it:

- **Does not carry any risk of transmission of a disease communicable to humans or animals**

AND

- **Cannot be returned to its original structure or composition.**

An importer should, if requested by the competent authority, be able to provide evidence to demonstrate that the product meets these criteria.

Whilst it may not be possible to confirm that a product is free from human and animal pathogens, the importer should have sufficient knowledge of the product to be able to demonstrate that it has been sourced and processed in such a way to mitigate the risk of the product being capable of transmitting a disease communicable to humans and animals.

To do this, the following are examples of the types of assurances that may be provided as evidence.

Safe sourcing of products

Laboratory reagents and derived products for pharmaceutical use, including the manufacture of laboratory reagents and pharmaceuticals should already meet safe sourcing requirements in line with the import conditions for the animal by-products and derived products which they consist of or have been made from.

By providing additional assurances of safe sourcing, this can help demonstrate the appropriateness of the subsequent processing method applied to the product, in order to mitigate any risks of disease transmission e.g. sourcing ABP from specific pathogen free animals.

Processing

Assurances should be provided about:

- **the suitability of the processing method** e.g. by demonstrating the application of appropriately validated scientific methodology or by using recognised production standards, such as International Organisation for Standardisation (ISO) or Good Manufacturing Practice (GMP)

and/or

- **the effectiveness of the processing method** e.g. by using suitable laboratory analysis to quantitatively or qualitatively demonstrate that, within analytical limits of detection, negligible levels of an indicator pathogen* is present after processing.

* An indicator pathogen is an organism representative of one which is consistently present in the product before processing. It should not be less resistant to the lethal aspects of the processing method than other endogenous pathogens in the product and should be relatively easy to quantify, identify and confirm.

7. Health certification/documentation

Imports to Great Britain must be accompanied by a health certificate (*), which conforms to the model found on GOV.UK.

[Model health certificates for exports of live animals and animal products to Great Britain - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/model-health-certificates-for-exports-of-live-animals-and-animal-products-to-great-britain)

OR

Where there is no appropriate health certificate or general import authorisation (**), prior to importation, authorisation must be obtained from the Animal and Plant Health Agency (APHA). To apply for an authorisation please complete the application form and return it to [APHA Centre for International Trade](https://apha.gov.uk/centre-for-international-trade).

- [Application form](#)

Consignments which have not been authorised prior to import will not be permitted into the UK and will have to be destroyed or re-exported.

(*) Please note that this requirement will be introduced for animal products from EU and EFTA countries only in the medium risk category from 31st January 2024.

() Please note that this requirement will not be introduced for imports from EU and EFTA countries until 1 February 2025. Until then, if there is no appropriate health certificate available for imports of ABP from the EU and EFTA countries, there is NO requirement for either a specific or general authorisation. However, the consignment must be accompanied by a commercial document.**

8. Labelling requirements

The outer packaging must be labelled in accordance with the requirements laid out in [Annex XIV, Regulation \(EU\) 142/2011](#), for the ABP/derived product the product consists of or has been made from, or in accordance with the conditions of any general or specific authorisation.

For imports from EU/EFTA countries, where a product cannot meet the requirements of Annex XIV, Regulation (EU) 142/2011, the product must be clearly labelled in accordance with [Chapter II, Annex VIII, Regulation \(EU\) 142/2011](#).

9. 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



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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.