Animal & Plant Health Agency

Import of Intermediate Products

Import Information Note (IIN) ABP/20

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1. Important Information

Import Information Notes are technical documents containing import requirements and are for use by importers and veterinary staff.

Please be aware that import conditions may be updated due to changes in policy or legislation. Please ensure that you check the current version of the Import Information Note online.

Importers should note that the information given relates only to animal health and public health conditions of import. It does not give guidance on other conditions that may need to be met.

EU legislation as it stood on 31 December 2020 that the UK already complies with has been incorporated into our domestic law as “retained EU law” under the European Union (Withdrawal) Act 2018. References in our guidance and certification to such EU instruments should be taken to be references to this “retained EU law”. Our current standards will remain in force, without amendment, in the immediate months after our EU exit as part of UK domestic law (apart from corrections to make the EU legislation fully operable).

You can find further information on legislation, including Relevant EU Exit Statutory Instruments in the legislation section of this import information note.

Please note that any links to legislation provided in this document are for information purposes only and may not be the most recent version.

Further information regarding changes to the import controls from an EU country from 1 January 2021 can be found on GOV.UK at the below link:

https://www.gov.uk/guidance/import-animal-by-products-and-high-risk-food-and-feed-not-of-animal-origin-from-the-eu-to-great-britain

2. Scope

Import conditions for intermediate products in 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.

An intermediate product is defined in Annex I point 35 of Retained EU Regulation 142/2011 as a derived product:

(a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal 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 as follows:

(i) as material in a manufacturing process or in the final production of a finished product;

(ii) in validation or verification during a manufacturing process; or

(iii) in quality control of a finished product;

(b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);

(c) which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, *in vitro* diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;'

If a product cannot meet the above criteria (i.e. the product to be imported is **not** intended for use as per (a), (b) and (c) above) or the product to be imported requires further processing to extract a product which will then be used as above then the importer should contact the Animal and Plant Health Agency (APHA) Imports Team (see section 15) to determine the requirements for import.

- Retained EU Regulation 142/2011
- Retained EU Regulation 2015/9

Intermediate products must be derived from the following materials:

a. In the case of intermediate products to be used in the manufacture products referred to in 1(a) above must be derived from:
   i. Category 3 materials referred to in Article 10 of Retained EU Regulation 1069/2009 **other than** 10(c), 10(n), 10(o) or 10(p).
   ii. Products generated by the animals referred to in Article 10(i), 10(j) and 10(m) of Retained EU Regulation 1069/2009.
   iii. Mixtures of the materials referred to in points a.i and a.ii above.

b. In the case of intermediate products destined for medical and veterinary devices, in vitro diagnostic medical and veterinary devices and laboratory reagents must only be derived from:
   i. Materials that fulfil the criteria referred to in paragraph a.i. above except that they may have originated from animals which have been submitted to illegal treatments as defined in Article 1(2)(d) of Directive 96/22;

ii. Category 2 materials referred to in Article 9(f) and 9(h) of Retained EU Regulation 1069/2009.
iii. Mixtures of the materials referred to in points b.i. and b.ii above; and
iv. The importer must also demonstrate to the competent authority that the materials do not carry any risk of transmission of a disease communicable to humans or animals or are transported under conditions which prevent the transmission of any diseases communicable to humans or animals.

c. If an importer wishes to import intermediate products destined for the manufacture of active implantable medical devices, medicinal products and veterinary medicinal products which are derived from materials mentioned in b) above they should contact the APHA Imports Team as imports will only be permitted where the competent authority considers the use of such material justified for the protection of public or animal health.

- Retained EU Regulation 1069/2009
- Directive 96/22

References to imports into Great Britain in this Import Information Note also includes imports into the Channel Islands and the Isle of Man.

References to trading partners includes non-EU, EU and EFTA countries. Import requirements from non-EU and EU countries will be differentiated, where required, in this Import Information Note.

Information regarding transits can be found on gov.uk:
https://www.gov.uk/guidance/transiting-animals-and-animal-products-through-great-britain

3. Production standards

Intermediate products must have been produced and stored in accordance with the requirements of Annex XII of Retained EU Regulation 142/2011.

4. Country of origin

Imports are permitted from trading partners that are listed as a Member of the World Organisation for Animal Health (OIE).

- World Organisation for Animal Health (OIE)

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. Health certification/documentation

Imports must be accompanied by a declaration, which conforms to the model laid down in Annex XV, Chapter 20 of Retained EU Regulation 142/2011, and which is signed by the importer.

7. Labelling requirements

The outer packaging must be labelled applicable for the products usage in line with the following wording: “FOR MEDICINAL PRODUCTS/ VETERINARY MEDICINAL PRODUCTS/ MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES/ ACTIVE IMPLANTABLE MEDICAL DEVICES/ IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES/ LABORATORY REAGENTS/ COSMETIC PRODUCTS ONLY – ABC CATEGORY X”.

8. Pre-notifications of imports

From 1 January 2022, imports from the EU to Great Britain (GB) must be pre-notified. Please use the Import of products, animals, food and feed system (IPAFFS).

You must submit your notification in IPAFFS at least one working day before your consignment is due to arrive. You can submit your notification up to 30 days in advance.

Further information regarding IPAFFS is available on GOV.UK.

For pre-notifications from other trading partners see section below.

9. Veterinary checks

Until the end of 2023, imports from the EU, and certain imports from Greenland and EFTA countries, do not need to enter Great Britain via a Border Control Points (BCP) and are not subject to veterinary checks at the border.

However BCP checks will be required on EU goods from the end of 2023.

You can find additional information on imports from EFTA countries and Greenland in section 10.

- Consignments from trading partners (other than the EU, and some imports from Greenland and EFTA countries) may only be imported through an approved Border Control Post (BCP).
- The person responsible for the consignment must give notice of the proposed entry of the consignment at least one working day before arrival (with a derogation to 4 hours before arrival if there are logistical constraints).
- The notification shall be made to the inspection staff at the BCP using the Import of products, animals, food and feed system (IPAFFS). Further information regarding IPAFFS can be found on GOV.UK.
- Any other electronic means agreed with the BCP to inform about the intended arrival of a consignment in advance are not to be considered as an official pre-notification.

Following satisfactory checks at the BCP (for which a charge is levied), consignments may then circulate freely within Great Britain. If the consignment does not meet the import requirements, the consignment may be rejected and either re-exported or destroyed.

- Further guidance on veterinary checks on animal products
- Border Control Posts

The Trade in Animals and Related Products Regulations 2011 (TARP 2011) (applicable in England) and EU Exit amendments to TARP 2011 can be found here.

10. EFTA countries and Greenland

The UK government recognises that Norway, Switzerland and Liechtenstein implement EU veterinary legislation in relation to the movement of animals and animal products. Therefore, animals and animal products from Norway, Switzerland and Liechtenstein must comply with the same requirements and controls applying to live animals and animal products from EU Member States. This also applies to Iceland for products of animal origin for human consumption, composite products and aquaculture.

Furthermore, in relation to imports from Faroe Islands this also applies to fishery products and aquaculture only. In relation to imports from Greenland this applies to fishery products and fish by-products only too.

11. Movement to premises of destination

Once checked at the BCP the intermediate products must be transported directly from the BCP either to:

(a) a registered establishment or plant for the production of laboratory reagents, medical devices and *in vitro* diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Retained EU Regulation 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product; or

(b) An establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24(1)(i) of Retained EU Regulation 1069/2009, from where they must be dispatched to an establishment or plant referred to (a) above for the uses referred to at (a) above.

12. Safeguard measures

Emergency safeguard action can be taken at very short notice to prohibit or restrict the importation of certain products from certain countries following an outbreak of disease or a public health issue. Information on the latest updates concerning disease outbreaks which may affect imports into the UK can be found on our Topical Issues page on the website.

Further information on the International and UK monitoring of animal diseases may be found on the animal disease monitoring website.

Importers can get the latest news about exotic notifiable disease outbreaks from the APHA subscription service.

- Topical issues
- Animal diseases: international and UK monitoring
- Exotic notifiable disease outbreak subscription service

13. Legislation.gov.uk

Consolidated legal texts, which integrate the basic instruments of retained EU legislation with their amendments and corrections in a single, non-official document, are available.

Each consolidated text contains a list of all legal documents taken into account for its construction.

You can search for consolidated texts by inputting the ‘document number’ and ‘year’ and then clicking the option ‘All UK Legislation (including originating from the EU)’ on legislation.gov.uk.

Once you press ‘search’, you can find the relevant legislation listed with the full title of the legislation. Once you have selected the legislation, you may see the following message at the top of the page:

‘’Changes to legislation: There are outstanding changes not yet made to XXX. Those changes will be listed when you open the content using the Table of Contents below. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.’’

Please note that the consolidated text may not contain the latest amendment to the legislation, as it takes several weeks for this to be updated. EU Exit amendments to legislation may take several months too. We advise to read the legislation alongside the EU Exit amendments made in the below UK laws:

- The Import of, and Trade in, Animals and Animal Products (Miscellaneous Amendments) (EU Exit) Regulations 2020
- The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020
- The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020
- The Aquatic Animal Health and Alien Species in Aquaculture, Animals, and Marketing of Seed, Plant and Propagating Material (Legislative Functions and Miscellaneous Provisions) (Amendment) (EU Exit) Regulations 2020
- The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020
- The Trade in Animals and Animal Products (Legislative Functions) and Veterinary Surgeons (Amendment) (EU Exit) Regulations 2019

Texts provided in this section are intended for information only. Please note that these texts have no legal value. For legal purposes please refer to the texts published in legislation.gov.uk.

Further information on changes in relation to EU legislation and UK law can be found on legislation.gov.uk. Please continue to use legislation.gov.uk to find EU retained law applicable to Great Britain. Please avoid using the EU Commission website for information on imports into Great Britain.

14. Northern Ireland

Movements from Northern Ireland

Trade movements from Northern Ireland into Great Britain are treated as national movements and as such, no animal health conditions are applicable in respect of those movements. You can find additional information on movements from NI to GB here.

Movements to Northern Ireland

Northern Ireland continues to apply EU law and EU requirements as laid down by the Northern Ireland Protocol. Please seek advice from DAERA on the import requirements for direct imports to Northern Ireland.

https://www.daera-ni.gov.uk/articles/introduction-importing-animals-and-animal-products

15. 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.