Department for Environment, Food and Rural Affairs

For export of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products intended for dispatch to or for transit through the European Union or Northern Ireland

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NOTES FOR GUIDANCE (NFG) FOR THE EXPORTER

1. APPLICABLE LEGISLATION:

Council Regulation (EC) No 1069/2009 and Commission (EU) Regulation 142/2011 (as amended)

Any other EU legislation referenced in the declaration must be complied with and can be accessed on the following link:

https://eur-lex.europa.eu/homepage.html

IMPORTANT

These notes provide guidance to Exporters. The NFG should have been issued to you together with the relevant export declaration applicable for exports of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products intended for dispatch to or transit through the EU or Northern Ireland. The NFG should not be read as a standalone document but in conjunction with the declaration.

We strongly suggest that exporters obtain full details of the importing country's requirements from the veterinary authorities in the country concerned, or their representatives in GB, in advance of each consignment.

2. SCOPE OF THE DECLARATION

This Model 8341 declaration may be used for the export of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products intended for dispatch to or transit through the EU or Northern Ireland, in accordance with the relevant requirements described in Regulation (EU) No 142/2011.

- An intermediate product is defined in Annex I of Regulation (EU) No 142/2011 as meaning 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 diagnostics medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products.

- Intermediate products must:

a) be derived from the following materials :

i. Category 3 material, other than materials referred to in Article 10(c), (n), (o) and (p) of Regulation (EC) No 1069/2009;

ii. Products generated by the animals referred to in Article 10(i), (l) and (m) of regulation (EC) No 1069/2009; or

iii. Mixtures of the materials referred to in points (i) and (ii) above;

b) In the case of intermediate products destined for the production of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:

i. Materials which fulfil the criteria referred to in point (a) above, except that they may have originated from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;

ii. Category 2 material referred to in Article 9(f) and (h) of Regulation (EC) No 1069/2009; or

iii. Mixtures of the materials referred to in points (i) and (ii) above;

c) In the case of intermediate products destined for the production of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in point (b) above, where the competent authority considers the use of such materials justified for the protection of public or animal health.

3. COMPLETION BY THE EXPORTER

The declaration is to be completed and signed by the exporter of a consignment (referred to as “importer” in the document) in ink of any colour other than black.

The Exporter should keep a copy of the signed declaration for his/her own records.

Declaration in foreign language/s of the EU Member States (MSs).

Declarations in the foreign language/s of the EU MS where the Border Control Post – BCP (a list of EU BCPs can be found here: https://ec.europa.eu/food/animals/vet-border-control/bip-contacts_en) of entry is situated and the EU MS of destination is/are required and this/these must accompany the consignment.

The declaration(s) in the foreign language (as received from the APHA CSC at Carlisle and bearing the same unique reference number as the declaration in English) should be considered official and accurate translations of the accompanying declaration in English.

Every word in the foreign language declarations is an accurate translation of the English version. The (sub-) paragraphs / options and how they are numbered and formatted is identical too. Therefore, when the same phrases/sentences in the foreign language versions/s as in the English version is/are struck through, the former can and must be signed (as opposed to being initialled) by the exporter as a genuine and proper authorised translation of the declaration in English.

This also applies to any instructions in the guidance notes to strike out certain paragraphs or to certify statements that the country is free of certain notifiable diseases etc.

The foreign language version/s of the declarations must be attached to the English version so as to create one indivisible single document, by stapling and fan-signing all the different language versions.

The declaration accompanying the consignment will then comprise the original English declaration and any required additional declarations in the foreign language/s. These should be arranged in order with the English version on the top, followed by the foreign language/s version/s, and finally the page(s) of the schedule (if any) at the bottom, all stapled together, then collectively ‘fan signed’ so that each leaf carries a part of a single signature so that removing a page or replacing it would be detectable.

Part I: DETAILS OF THE CONSIGNMENT

Please complete all the boxes in Part I of the certificate.
The Harmonised System (HS) Code is a commodity classification system used as a basis for customs tariffs and for international trade statistics.

It is the exporter's responsibility to ensure that the HS code is entered correctly and accurately reflects the product(s) being consigned.

Further information on HS Codes can be found online at:

https://www.gov.uk/trade-tariff/sections and http://madb.europa.eu/madb/euTariffs.htm

PART II: HEALTH INFORMATION DECLARATION

The Exporter signing the export declaration must ensure that the intermediate products described in Part I.18 on page 1 of the declaration satisfies the definition provided for in point 35 of Annex I of Commission Regulation (EU) No 142/2011 as detailed in the Scope Section 2 above and meets the requirements listed in Part II of the declaration. The starting material used must be relevant to the intermediate product being exported.

II.(1) Intended use

The exporter should select the applicable option(s) in relation to the intended final product. The non-applicable options should be struck through.

II.(2) Required stage of transformation.

As defined in Scope Section 2 above- to meet the conditions to enter the EU supported by an exporter's declaration the intermediate product must have already been sufficiently transformed to require such processes as mixing with other components, coating, assembling or packaging in order to make it suitable for placing on the market.

II (3) Source materials
The exporter must select from the listed options to accurately reflect the animal by-product source materials from which the intermediate products have been derived. All non-applicable options should be struck through.

II (4) Labelling in relation to intended use.
The outer packaging of the consignment must be labelled as detailed in the declaration statement specifically in relation to the intended use.

II (5) Transport and establishment of destination.

The intermediate products must be inspected at an EU border control post on entry to the EU if the CN code is listed in Regulation (EU) No 2019/2007 and from there transported directly to the place of destination entered in Part I which must be:

Either- an establishment or plant **registered** for the production of the intended final product in accordance with Article 23 of Regulation (EC) 1069/2009. This must be established with the operator plant of intended destination. A List of registered premises within the EU can be accessed at https://ec.europa.eu/food/safety/animal-by-products/approved-establishments_en

Or- an establishment or plant **approved** in accordance with Article 24(1) (i) for the storage of animal by-products from where they may only be dispatched to a registered plant as above. This must be established with the plant operator of intended destination. The list of approved premises within the EU can be accessed at https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en [

4. CONSIGNMENTS OR PARTS OF THE CONSIGNMENT ORIGINATING FROM, NI, EU MEMBER STATES OR FROM THIRD COUNTRIES (TRIANGULAR TRADE)

NI origin:

Animal By Products are handled in accordance with EU Control Regulation 1069/2009, which is implemented by the EU Implementing Regulation 142/2011, and ABP statements for materials originating in NI, can be certified on that basis.

When the certificate requires specific information to be included, such as the date of slaughter or the date of introduction into NI, the exporter must also request this information from the exporter in NI. The NI exporter may forward the request to the relevant NI exporter to provide the necessary information requested by the GB exporter. This supporting information must be in writing and kept by the GB exporter. The exporter is not required to attach it as a supporting document to the declaration, unless requested by the EU Border Control Post or told otherwise.

EU origin:

It is possible that some consignments may contain animal products that are of EU origin and were exported to GB on a Commercial Document or Intra-Trade Animal Health Certificate (ITAHC). The Commercial Document may not contain enough information to allow the exporter to sign a declaration.

In such cases, the exporter will need further information from the EU member state regarding particular attestations on the declaration that cannot be signed by the exporter without further information. Thus, the GB exporter must request from the EU exporter a written declaration or a replica ‘Third Country to EU’ certificate completed to the extent possible that will provide the required information to the exporter to certify the relevant attestations on the declaration.

Third country origin:

It is also possible that some consignments may contain animal products that are of non-EU (Third Country) origin, which GB exporters intent to export to EU (known as Triangular Trade). In these cases the exporter may obtain the necessary supporting information from a copy of the original declaration used for import of these products into GB.

The exporter in GB is not required to attach a copy of the Third Country declaration as a supporting document to the GB-EU declaration, unless requested by the EU Border Control Post or told otherwise.

It is the GB exporter’s responsibility to ensure timely request of information from the EU member state exporter/Third Country exporter, to allow the declaration to be signed in good time before export to the EU.

5. GB APPROVED ESTABLISHMENTS TO EXPORT TO THE EU

The exporting establishment must be authorised and listed by the GB as a 'GB approved establishment' for animal by- products not for human consumption (ABP). A list of approved establishments can be found on the European Commission's list of approved establishments' link below:

https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en

Please note that the list is updated regularly and ONLY establishments on the list are approved to export to the EU and does not include establishments with pending applications for approval/registration.

If the final product contains animal products from other establishments, or products were previously processed in different establishments in the production chain, then these establishments should also be listed on the EU website as GB approved establishments.

6. CERTIFIED COPIES OF EXPORT HEALTH CERTIFICATES

When completing export certification Certifying Officers (CO) (Official Veterinarians (OV) and Environmental Health Officers (EHO)) must make photocopies of, or scan and save all documents they certify. This includes all documents that:

- are certified with the COs signature and stamp
- form part of any export documentation
- will accompany the consignment, or
- any support documentation (documentation provided by the CO at the premises of origin to enable the CO at the premises of loading to certify the final export certificate).

Examples of export documents required to be saved are:

- Export Health Certificates (EHC)
- Supplementary certificates
- Schedules to EHCs.

Where it is impossible to copy documents at the premises immediately after certification then a photocopy of the certificate could be made before travelling to the place of certification, and the certification details transposed onto the copy at the same time as completing the certificate. When a paper copy is made, mark the photocopy as 'Certified Copy' and initial.

COs must retain copies of all export documentation for a period of two years.

Return of export documents to the Centre for International Trade - Carlisle (CITC) are only required for the following live animal export commodities:

- cattle
- pigs
- sheep
- goats
- Camelids

This should be done by scanning and emailing the documents on the same day as certification.

These certified copies are required to enable APHA to provide information to other Competent Authorities on Brucellosis, Tuberculosis or Bovine Spongiform Encephalopathy cases found in herds subsequent to export, to enable the country of destination to take the appropriate notifiable disease action.

For the purposes of completing routine Quality Assurance checks on export certification, CITC may request certified copies of certification from COs.

Please visit APHA Vet Gateway for further information in certification procedures:

http://apha.defra.gov.uk//External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

7. LEGAL STATEMENT

The existing EU legislation that the UK already complies with will be 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”. Under the Withdrawal Act we will ensure that current EU standards 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).

8. DISCLAIMER

This certificate is provided on the basis of information available at the time and may not necessarily comply fully with the requirements of the importing country. It is the exporter’s responsibility to check the certificate against any relevant import permit or any advice provided by the competent authority in the importing country. If these do not match, the exporter should contact the Animal and Plant Health Agency (APHA) in Carlisle, via the link below: https://www.gov.uk/government/organisations/animal-and-plant-health-agency

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

enquiries regarding this publication should be sent to us at

product.exports@apha.gov.uk

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