Guidance

concerning the health rules and importation from Third Countries into the EU of animal by-products and derived products not intended for human consumption according to Regulation 1069/2009/EC and the implementing Regulation 142/2011/EU and other derogations.

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2 Scope

This document is intended to provide a **step-by-step guidance regarding the European animal by- products regulatory framework for suppliers, manufacturers, importers** and other interested parties of medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, *in vitro* diagnostic medical devices, cosmetic products, and laboratory reagents.

The animal by-products (ABP) framework is defined by Regulation 1069/2009/EC and the implementing Regulation 142/2011/EU. Regulation 1774/2002/EC was superseded with the intention of simplifying requirements and reducing the administrative burden on Industry, and with a particular focus on achieving a more risk-based approach in handling of those animal by-products destined for the manufacture of technical products which are not intended to enter the food or feed chain.

The legal act covers the importation, certification, handling and transportation requirements for 'raw' animal by-products, derived products, blood derived products and Intermediate Products, and defines when devices or products have reached their end point and/or are otherwise outside the scope of Regulation 1069/2009/EC.

The procedures and requirements described in the chapters of this document have been simplified to provide as clear guidance as possible, given the complexity of the animal by-products framework. This document is intended to provide guidance only and cannot replace an understanding of the legal framework: in all cases, please consult the legal texts laid down in Regulations 1069/2009/EC and 142/2011/EU. Further details and interpretative notes can be found in the appendices. Please note that quotes directly taken from the legislation are in *italics*.

This guidance document:

- Provides technical guidance on which products fall within the scope of Regulation 1069/2009/EC and which do not.
- Identifies the key provisions which are applicable to those products which fall within the scope of Regulation 1069/2009/EC.
- Provides technical mechanisms for compliance with the applicable provisions of Regulation 1069/2009/EC, in line with the recommendations within the implementing measures laid down in Regulation 142/2011/EU and other derogations.

On 1 January 2021, the United Kingdom left the EU as a member state. Consequently, they are a non-EU member and must comply with the EU rules applicable to non-EU countries when importing from the UK to the EU or exporting from the EU to the UK. This guidance document does not cover the specific UK rules applicable for animal by-products: the rules and procedures are new and might change over time. For an overview of UK requirements, see APHA website https://www.gov.uk/government/organisations/animal-and-plant-health-agency.

How to use this guidance document

In order to follow the animal by-products framework, both the final intended use and the type of material to be imported must first be determined.

The focus of the regulation is on the **intended use** of the material and not the type of material. Depending on the specific intended use, the same material or consignment may be imported under several different documentary procedures. It is the relationship between the material and the intended use which determines which elements of the regulation apply and which documentation is required to support the import into the EU of the product.

If using this guidance document for the first time, we recommend following these steps:

1. Use the decision tree (Chapter 3 below) to help determine how to classify products according to their intended use.
2. Refer to the relevant product chapter (for example Intermediate Products or Research and Diagnostic Samples).
3. Refer to the general chapters (for example Commercial Documents, Labelling or Plant Approval) for further information on general requirements, which need to be followed.
4. When developing documentation, it is important to verify with the relevant **B**order **C**ontrol **P**ost (BCP) how to import the materials prior to importation. Only the importer can attest to the intended use of a product. Some BCPs may however interpret the product classification differently according to their own understanding of the product and intended uses.
5. Be aware that if importing the product as a distributor for further commercial sale, some member states may require that you apply for an import permit on the basis that you cannot guarantee intended use.

Note: Regulation 1069/2009/EC and Implementing Regulation 142/2011/EU apply only to countries that are Member States of the European Union and refer primarily to import into the Union and intra-community shipments, and not export. Countries that are members of the EEA (the European Economic Area), such as Norway, Iceland, Switzerland and Liechtenstein require that animal products entering their territory must also comply with the EU regulations.

Note: On 1 January 2021, the United Kingdom left the EU as a member state. Consequently, they are a non-EU member and must comply with the EU rules applicable to non-EU countries when importing from the UK to the EU or exporting from the EU to the UK

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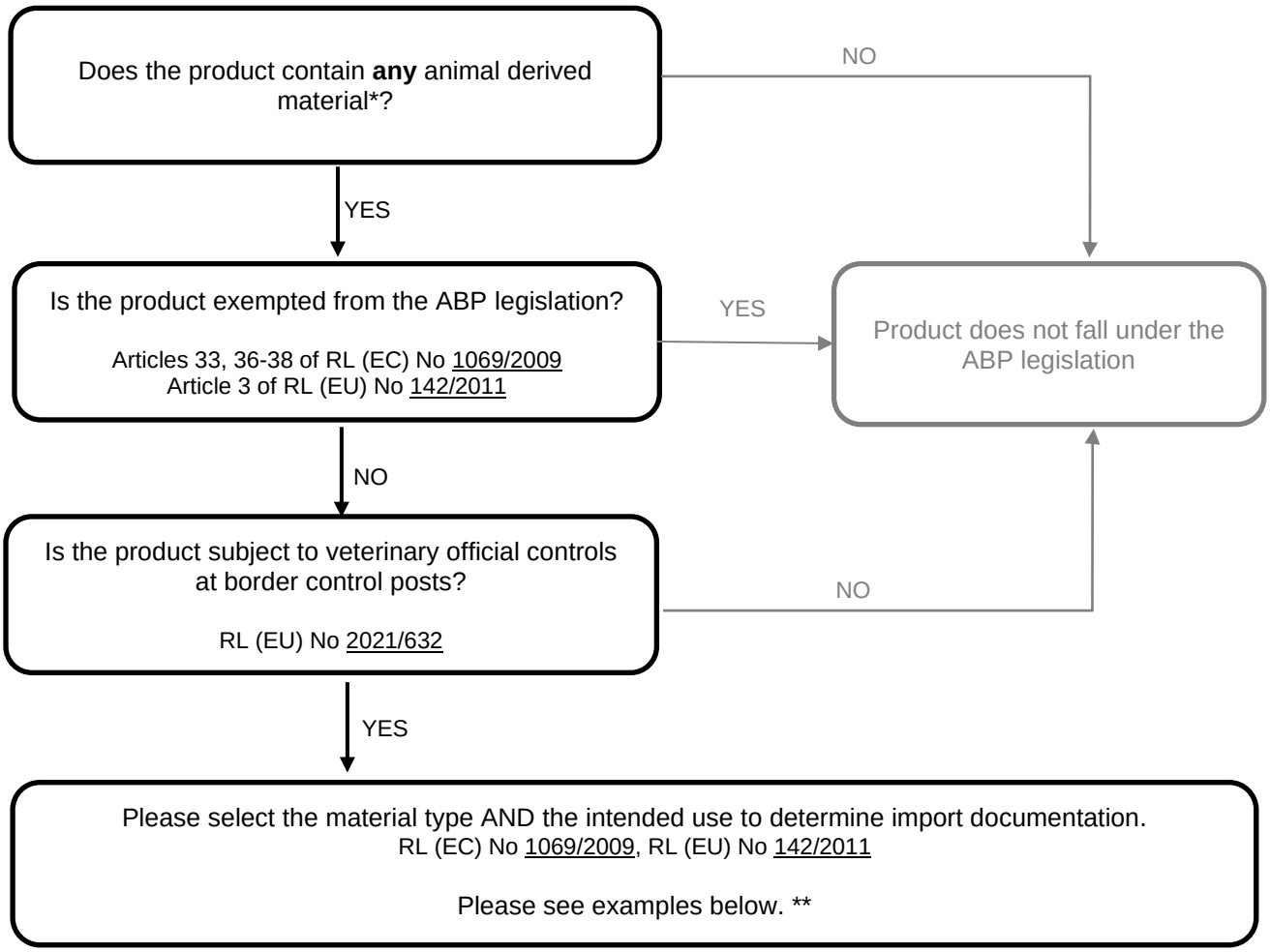
3 Decision Tree

This Decision Tree is intended to point the reader to where they may find more information on importation requirements in this Guidance.[1]



* Even material containing trace amounts of animal by-products falls under the ABP regulatory framework. This includes stabilizers and carriers.

** If requirements for the product are not clearly defined in the legislation, please check with the local authority and/or the designated border control post.

[1] The reader should note the following information when reading the term in the flowchart, “product does not fall und the ABP legislation”: products covered by Art.33 are exempted with a view to placing on the market, not necessarily with a view to importation. Also, products whose HS code is not in 2021/632 are not subject to official border controls. Legally, they may still be with the ABP framework.

	INTENDED USE				
MATERIAL TYPE		**Technical use, not otherwise specified** *(at time of importation)*	**Use in manufacturing finished products**[2]	**Research**	**QC or validation**
	Derived product	Blood products: Chapter 4 A, C or D Selected material: Chapter 2, 11, 12 or import permit from EU Competent Authority Other: Chapter 8	Chapter 20 *(intermediate product)*	Import permit from EU Competent Authority	Blood products: Chapter 4 A, C or D Selected material: Chapter 2, 11, 12 or import permit from EU Competent Authority Other: Chapter 8, Chapter 20
	Research and diagnostic sample	N/A	N/A	Import permit	Import permit
	Trade sample[3]	N/A	N/A	Import permit and Chapter 8	Import permit and Chapter 8
	Animal by- product	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority

[2] For use in manufacturing of the following finished products only: medicinal product, veterinary medicinal product, medical device, active implantable medical device, *in-vitro* diagnostic medical device or laboratory reagent.

[3] Trade samples are frequently not considered to be relevant for ISIA and MedTech Europe applications

3.1. Definitions

Note: An extensive list of relevant definitions can be found in Appendix 1 Glossary of Terms and Definitions

Animal by-products (ABP*):* *means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen*.[4]
Note: The regulation always distinguishes between animal by-products and derived products.

Finished products: are regulated under the scope of other EU legislation and do not fall under the ABP regulatory framework (even if they contain ABP material). The following product types are considered 'finished' and fall outside of the scope of the ABP regulatory framework: medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, in vitro diagnostic medical devices, cosmetic products.[5] For more information, see Chapter 4.6 Finished Products.

Derived products: *means products obtained from one or more treatments, transformations or steps of processing of animal by-products*.[6] A product is considered as 'derived' once the treatment, transformation or processing which the animal by-product has gone through is such that no subsequent treatment, transformation or processing could revert the product back to its original state.
Note: See 'treated', 'transformation' and 'processing methods' under Appendix 1 Glossary of Terms and Definitions.

- Blood products: may be imported with the appropriate health certificate[7]
  - Health Certificate Chapter 4A for equine blood and blood products
  - Health Certificate Chapter 4C for untreated blood products excluding those from equidae
  - Health Certificate Chapter 4D for treated blood products, excluding those from equidae
- If the material meets the 'intermediate product' definition, derived products may be imported under a Chapter 20 importer´s declaration, product details typically filled in by the supplier and completed as well and signed by the importer.
- For the following selected materials:
  - Material and products from aquatic, invertebrate and Rodentia and Lagomorpha, classified as Category 3 or other derived products not listed here may be imported using an import permit authorized by a member state competent authority[8], if the intended use is unclear or unspecified.
  - Milk-based products, milk derived products and bovine-derived colostrum products not intended for human consumption may be imported under a Health Certificate Chapter 2A or 2B health certificate as appropriate.[7]
  - Gelatin and collagen not intended for human consumption may be imported under a health certificate Chapter 11.
  - Hydrolised protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption may be imported under a Health Certificate Chapter 12.[7]
- Use in manufacturing:
  A Chapter 20 model declaration[7] may be used where the derived product is intended for the *manufacturing of 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 and cosmetic products.* Labelling and packaging are considered part of 'manufacturing'.
  For more information, see Chapter 4.4 Intermediate Products.
  - Note: Some member states may not allow a commercial entity operating as a distributor to import material for further storage and sale as an intermediate product, even though the final use is within the permitted uses of Intermediate Product.
  - Note: Once material is imported under a Chapter 20 declaration, it must be used in manufacturing and cannot be directly placed on the market.

[4] Regulation 1069/2009/EC, Article 3(1)
[5] Regulation 1069/2009/EC, Article 33
[6] Regulation 1069/2009/EC, Article 3(2)
[7] Regulation 142/2011/EU, Annex XV
[8] Regulation 142/2011/EU, Annex XIV, Chapter IV, Section 2

intermediate product *'means 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 product; [9]

Research and diagnostic samples: *mean 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*[10]

- The Import process of certain materials for use in quality control or other in-house uses is subject to interpretation of the above definition of research and diagnostic samples by the competent veterinary authorities. It is advised to contact the competent authorities for clarification.

Trade samples: *mean animal by-products or derived products intended for particular studies or analyses authorized by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment.*[11]

- Note: Trade samples are frequently not considered to be relevant for ISIA and MedTech Europe applications.
- Note: Trade samples must be imported using an import permit and a Health Certificate Chapter 8.[12] See Chapter 4.3 Samples.

[9] Regulation 142/2011/EU, Annex I (35)

[10] Regulation 142/2011/EU, Annex I (38)

[11] Regulation 142/2011/EU, Annex I (39)

[12] Regulation 142/2011/EU, Annex XV. Also see Annex XIV, Chapter III, Section 2.

4 Product Types

4.1. Animal By-Products & Derived Products

The range of animal by-products as defined in the previous section is extensive and may include almost every part of the animal. For the purposes of this industry, the animal by-products of interest are generally whole blood, fetuses and tissues and glands, usually from bovine, equine, porcine, ovine and caprine sources. These animal by-products are sourced directly from slaughterhouses or donor-blood establishments and have not been processed or refined in any way, and treatment is restricted to chilling or freezing only.

For the purposes of this guidance document, the scope of animal by-products is restricted to those materials intended for uses outside the food chain for humans and farmed animals.

A **'Derived product'** as defined in the previous section, is considered to be 'derived' once the treatment, transformation or processing is such that no subsequent treatment, transformation or processing could revert the product back to its original state.
Note: See 'treatment', 'transformation' and 'processing' under Appendix 1 Glossary of Terms and Definitions.

Derived products such as serum or plasma are regarded as unfinished since, although they are defined commercial products in their own right, their use is restricted to being an ingredient of or part of the manufacturing process of a finished product such as a vaccine or medical device. Whole blood may not be considered a derived product since it has not undergone any transformation.

For importation requirements of animal by-products and derived products see Chapter 3, the Decision Tree.

Categorisation

Article 7 of Regulation 1069/2009/EC states that:
Animal by-products shall be categorised into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.

and

Derived products shall be subject to the rules for the specific category of animal by-products from which they have been derived, unless otherwise specified.

Category 1 is the highest risk listing and Category 3, the lowest. Two essential components of this categorisation refer to Transmissible Spongiform Encephalopathies (TSEs), including BSE which has to do with the sourcing of the material, i.e., country of origin and which particular body part is involved, and secondly, the possibility of illegal substances having been introduced into the animal. Both of these issues are dealt with respectively in Appendix 4 Specified Risk Material and Appendix 5 Geographical TSE Risk by Country and Region.

For more information on categorisation, see Appendix 2 Categorisation of Animal By-Products & Derived Products.

Storage, Handling and Disposal

Animal by-products and derived products must be transported according to Chapter I of Annex VIII of Regulation 142/2011/EU. Animal by-products may only be handled, stored or processed by registered or approved facilities. For more information see Chapter 5.4 Plant Approval and Registration.

Disposal of Category 1, 2 and 3 materials must be as stated in Articles 12-14 of Regulation 1069/2009/EC and Annex III of Regulation 142/2011/EU.

4.2. Blood and Blood Products

What are blood and blood products?

Examples include blood, blood products, serum, plasma, serum albumin, polyclonal antibodies and antiserum: Definitions can be found in Appendix 1 Glossary of Terms and Definitions.
Antisera as well as polyclonal antibodies purified from antisera can be classified as Category 3 material [13], since they commonly do not pose serious health risks to humans or to other animals and therefore are not classified as Category 1 material under Article 8.a(iv) of 1069/2009/EC.[14,15]
Animal by-products derived from animals which have been submitted to illegal treatment[14] defined in EU legislation or containing residues of other substances and environmental contaminants, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation[15] are classified as Category 1 material.

Import procedures – blood and blood products

Blood and blood products of animal origin are subject to veterinary checks at the border. The checks are carried out at designated BCPs (**B**order **C**ontrol **P**osts) - at the point of first entry into the EU. Veterinary certificates must be issued in the official language of the exporting third country and in the official language of the Member State where the veterinary border checks are carried out AND in the official language of the Member State of destination if required. (BCPs may accept English versions.) The certificates must comply with the conditions set out in Annex XV of Regulation 142/2011/EU and the actual original document must be presented to the veterinarian at the border.

The BCP must be notified about the incoming shipment prior to its arrival (as a general rule 24 hours prior to arrival of the consignment). A documentary check is performed for 100 % of the shipments; additionally, a physical and a laboratory check may be performed based on random checking system. A CHED (**C**ommon **H**ealth **E**ntry **D**ocument) is issued as a proof of inspection and clearance.

After clearance by a veterinarian at a BCP, blood and blood products must be transported directly to an approved or registered establishment (the establishment defined in the CHED). The official veterinarian in charge of the establishment of final destination is informed about the incoming consignment by the means of TRACES (**TRA**de **C**ontrol and **E**xpert **S**ystem). The veterinarian then confirms the arrival of the goods at the place of final destination.

Documentation Required

Regulation 142/2011/EU as amended provides for the conditions and the corresponding model certificates for the import of most types of blood products. An import permit is required for blood or blood products not covered by the harmonised legislation.

The importation of blood (raw fresh blood) from equine sources is possible with health certificate Chapter 4A. The import of blood from other species is currently allowed with health certificate Chapter 8.

Note: the above requirements are valid for general importation of blood products. Blood products with a known specific end use may be imported as Intermediate Products. For more information, see Chapter 4.4 Intermediate Products. Blood products shipped under the conditions of an import permit are also described in this Chapter.

[13] Regulation 1069/2009/EC, Article 10
[14] Regulation 1069/2009/EC, Article 8(c)
[15] Regulation 1069/2009/EC, Article 8(d)

4.3. Samples

Introduction

There is a difference in what is meant by a 'sample' between the commonly understood definitions within the industry and the legal definitions given under the ABP regulatory framework.[16] The use of the word 'sample' may therefore be confusing. Within the industry a sample is commonly understood to consist of:

1. **a representative volume of a larger entity.** For example, a small sample of a homologous batch of media or serum which is provided to test for its suitability in an application; or
2. **a single use quantity of test material (specimen**) that may never be able to be replicated, for example, a volume of blood from an individual animal on test for a specific drug compound; or
3. **material** required for single use validation of Quality Assurance procedures.

When importing ABPs, the legal definitions (referenced under Chapter 3 Decision Tree) should be used. It is, however, recommended that the importation of a sample as described in point 1. above should be handled in exactly the same manner as the import of a larger batch of material. We strongly advise importers to check the specific requirements with their competent authority.

Samples and requirements for import

The importation rules for certain samples from animal by-products and derived products are not harmonised by the EU. The import conditions for these samples are subject to national rules in the individual Member States.

The application for an import permit (sometimes called import licence or import authorisation) must be submitted by the importer to the national veterinary health authority. Application forms and procedures may vary between the Member States.
As a general rule the applicant must specify the product, its origin, intended use and the volume of importation. Import permits may be valid for a single importation or for multiple shipments during a limited time period (up to 12 months).

Some Member States (e.g., France and Belgium) also have general import permits covering one or more products. Please contact your national veterinary health authority for further consultation on details.

I. Research and diagnostic samples

Note: An intermediate product cannot be a sample.

Research and diagnostic samples must comply with the special rules.[17] The legal requirements for their importation are at the discretion of the competent authorities of the Member State of destination. It is important therefore to check requirements with the local competent authority. The regulatory framework lays down the minimum requirements that must be applied by each Member State.

[16] Regulation 142/2011/EU

[17] Regulation 142/2011/EU, Annex VI, Chapter I, Section 1; and Articles 11 and 27

In summary, importation of research and diagnostic samples into the EU requires:

1. An import permit issued by the competent authority in the Member State.
2. After importation, a commercial document[18] must accompany the consignment.
3. No BCP Veterinary check is required.
4. The TRACES system should be used by the BCP to inform the Member State of destination.
   Note: TRACES is only a requirement for the importation of research and diagnostic samples into the EU from third countries. Research and diagnostic samples may move freely between member states without any further requirement for TRACES.
5. Direct transport is required from the point of entry into the Union to the designated (final) destination.
6. Operators must be able to demonstrate and document the safe use (as intended) and disposal to the competent authorities. They must therefore retain all documentation following disposal.
7. Some member states consider that material imported as samples cannot be intended for commercial use.

II. Trade samples

The definition of a trade sample can be found in Chapter 3 Decision Tree.

NOTE: Trade samples are normally not considered relevant for this Industry segment.

Due to the very rigorous importation procedures required, importers should select a different route for importation where possible. Importation of materials as research and diagnostic samples is often a possibility (although not for commercial purposes), and recent experiences with veterinary authorities confirm that this is an acceptable choice.

1. for importation into the EU a trade sample requires:
   a. An import permit issued by the competent authority in the member state of the designated destination
   b. Proof that the material comes from a third country or part of a third country as listed in Table 2 of Annex XIV, Chapter 2, Section 1, No 14 of Regulation 142/2011/EU
   c. Chapter 8 health certificate[19] to accompany the shipment
   d. Labelling stating 'trade sample not for human consumption' instead of the category of the animal by product or the derived product (Annex VIII to Regulation 142/2011/EU, Chapter II,2(xvi))
   e. In every case the authority at the place of destination is informed electronically (TRACES).
   f. When cleared for import, box II.13 "Acceptable for monitoring" in the CHED might be ticked. This means: under veterinary or customs supervision to the place of destination.

2. for transport within the EU, different, less stringent provisions are required:
   a. The competent authority may authorise transport, use and disposal of trade samples
   b. There is a requirement for trade samples moving between Member States to be controlled by TRACES. For more information see Chapter 5.5 TRACES.
   c. The shipment must be accompanied by a Commercial Document (there is no further requirement for a Health Certificate).

3. for handling and disposal, operators must be able to show and document the safe use (as intended) and disposal to the competent authorities. The material must be:
   a. disposed of, or used according to Article 12-14 of Regulation 1069/2009/EC or
   b. re-dispatched to the third country of origin.

[18] Regulation 142/2011/EU, Annex VI, Chapter 1, Section 1.1

[19] Regulation 142/2011/EU, Annex XV, Chapter 8

4.4. Intermediate Products

An intermediate product is a product derived from an animal source. A derived product is produced from an animal by-product (ABP) by at least one or more steps of transformation or purification. Products to be imported are defined by their intended use.
The definition for an intermediate product can be found in Chapter 3.1 Definitions.

Intermediate products can be sourced from registered facilities within third countries or from within the EU. Requirements for the import of intermediate products are specified within the legal framework of Regulation 142/2011/EU. Requirements for the transport and handling of intermediates are irrespective of the source of the materials. Note: For products containing Category 1 and/or 2 materials the importer must be able to 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 to humans or animals[20].

If the intended use is unclear at the time of import, then the material may not be imported as an intermediate product. The BCP may request proof of the nature of the derived products and their intended use. The importer is strongly advised to consult their BCP prior to importation.

It is the responsibility of the importer to complete the Chapter 20 model declaration, which identifies the intended use. Once the material has been imported as an intermediate product, it must be used for manufacturing and cannot be used as a finished product. For more information, see Appendix 8 How to Complete Chapter 20 Model Declaration.

Why import material as an intermediate product?

The importation procedures with a Chapter 20 Declaration are highly recommended whenever possible and applicable, since importation with a Chapter 20 Declaration provides the following advantages over importation with a health certificate:

- Shipping without the additional involvement of veterinary authorities from the third country. The intended use of an intermediate product can be specified only by the importer and not by the supplier. This is why a Chapter 20 is completed by the importer, unlike those health certificates, which are issued by the veterinary authorities of the exporting country.
- The third country must be a member of the OIE and is not limited to third countries on the fresh meat list.[21] [22]
- Information about the exporting facility of the intermediate product must be listed on the statement Details of animal derived materials that are components of the intermediate product are not required.
- Third country establishments supplying intermediate products generally require a lighter regime for registration than do establishments supplying other animal by-products or derived products. Intermediate products can be handled without further restriction under the ABP regulation, once they have reached their final destination.
- Many derived products can only be imported as intermediate products.
- Channeling may be used, if needed.

[20] Regulation 142/2011/EU, Annex XII, Point 1(g)

[21] Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 [lays] down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin

[22] Consignments pursuant Commission Regulation 206/2010/EU shall be permitted for entry into the Union until 20 October 2021 provided that the certificate was signed before 21 August 2021

Handling of intermediate products

An intermediate product may only be handled by a facility which is registered under Section VII: Plants or establishments manufacturing intermediate products. This applies to both Member States and third country establishments, which are listed on the Establishment lists for animal by-products on the Commission website.

If the establishment or plant is not listed in Section VII for the exporting country concerned, consignments cannot clear at the Border Control Post (BCP). Therefore, companies are strongly encouraged to register their establishments and plants. For further details on the requirements for eligible facilities for the manufacturing of intermediate products see Chapter 5.4 Plant Approval and Registration.

Documentation required

A shipment containing only **one** type of product as determined by tariff code, product description and other criteria must be imported under the appropriately completed model declaration Chapter 20. For each different type of product in a shipment (specified by its tariff code) a separate Chapter 20 document must be completed. For more information see Chapter 5.1 Tariff Codes/Commodity Codes.

Documents must be generated by the importer, since only the importer can attest to the intended use of the intermediate product. The importer may work with the supplier to complete this, e.g., supplier provide product and shipment related information. However, the final responsibility falls to the importer like signatures, handling of the inspection. The importer must be able to guarantee that the designated uses are one or more of the intended uses as described in the intermediate product definition above.

Note: Some member states do not allow a commercial entity operating as a distributor to import material for further storage and sale as an intermediate product. This is due to the fact that the importer may not be able to guarantee the final intended use.

Labelling requirements

The label attached to the outside of the package must bear the following statement in its entirety:

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

This wording cannot be altered or shortened. For more information see Chapter 5.3 Labelling.

Import procedures

Notification: It is a legal requirement to notify the BCP at least 24 hours prior to the arrival of a consignment into the EU.

Veterinary Inspection: The representative of the importer is required to provide information to the BCP for the completion of a **C**ommon **H**ealth **E**ntry **D**ocument (CHED), to be signed by the veterinarian at the BCP. The BCP will enter the consignment into TRACES in order to inform the authority in charge of the establishment of destination that the consignment has been verified. The CHED serves as proof of importation and it must accompany the consignment to the plant of destination and is later retained by the importer.

Transport restrictions

Intermediate products must be transported **directly** to their destination, which must be either:

- a registered establishment or plant which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009 for the production of laboratory reagents or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009; or
- an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009 for the storage of animal by-products.

"Directly" means that the consignment should be transported to the plant of destination, without undue delay and without detours.
Intermediate products taken to an approved storage plant can then only be dispatched from that place to a registered establishment or plant, as detailed above.

Final handling

On arrival at their point of destination intermediate products may be handled without further restrictions under the animal by-products legislation providing that the facility meets the requirements for handling and storage of intermediate products. See Article 23, point 2. of Regulation 142/2011/EU for further details.

Note: Some BCPs may request written confirmation (email might be acceptable) of receipt of shipment by the manufacturing site.

4.5. Laboratory Reagents

A 'laboratory reagent' means 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.[23]

For information on the importation of ABPs and derived products for further processing into laboratory reagents, either used as such or in combination with substances of non-animal origin, see Chapter 3 Decision Tree.

Most member states do not consider laboratory reagents to be finished products as they are not mentioned in Article 33 of Regulation 1069/2009/EC or in Article 3 of Regulation 142/2011/EU.

[23] See Annex I(36), Regulation 142/2011/EU

4.6. Finished Products

Finished products do not fall under the ABP regulatory framework (even if they contain ABP material). These are products which are ready to be placed or put into service on the EU market and are therefore regulated under other EU legislation. The following product types are considered 'finished' and fall outside of the scope of the ABP regulatory framework:

- cosmetic products as defined in Article 1(1) of Directive 76/768/EEC;[24]
- active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;[25]
- medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;[26]
- in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;[27]
- veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;
- medicinal products as defined in Article 1(2) of Directive 2001/83/EC;

Note: An otherwise 'finished' product, which still requires packaging or labelling to make it suitable for placing on the market according to EU legislation is NOT considered to be a finished product under the ABP regulatory framework and should be imported as a derived product or as an intermediate product. For example, if an *in vitro* diagnostic reagent or kit (IVD) is not CE-marked, it cannot be considered as a finished product, since it cannot be placed on the market as such within the EU.

Unlike all other IVDs, devices for performance evaluation (see Annex VIII of Directive 98/79/EC[27]) meet the definition of an IVD, but they are not CE-marked. As such, devices for performance evaluation are finished products falling out of the scope of the ABP regulatory framework.

Transport of finished products

Transportation of finished products within the EU member states carries no further requirement than normal commercial documentation such as invoices. Traceability records for the distribution of finished products should be retained in full for a minimum

Handling of finished products

Finished products containing animal derived materials should be handled in accordance with all local and government regulations regarding the handling and disposal of material containing biological materials.

[24] Repealed by Regulation (EC) 1223/2009; see Article 2, 1.(a)

[25] No longer in force, Date of end of validity: 25/05/2021

[26] The Medical Devices Regulation (EU) 2017/745 will repeal and replace the medical devices directives from the date of application of the MD Regulation: 25 May 2021. From that date, this section of the Animal By-Products legislation shall be understood as referring to the MD Regulation.

[27] The IVD Regulation (EU) 2017/746 will repeal and replace the IVD Directive (EC) 98/79 from the date of application of the IVD Regulation: 25 May 2022. From that date, this section of the Animal By-Products legislation shall be understood as referring to the IVD Regulation.

5 Importation Requirements

5.1. Tariff Codes/Commodity Codes

Introduction

All goods imported into or exported from the EU must be assigned a particular classification code for customs purposes. The EU uses a system known as the '**C**ombined **N**omenclature' (CN) which classifies goods to an eight-digit level, incorporating both the World Customs Organisation 'harmonised system' codes and further digits for legislative and market analysis purposes. It is important to note that customs codes are used not only to set tariffs but also to differentiate products in a legal sense – there are several key pieces of legislation which refer to products by their customs code. In particular, the CN code will alert a **B**order **C**ontrol **P**ost (BCP) whether or not a veterinary control of a product containing animal derived material is needed.

Note: Importers and exporters who regularly import/export the same material/product through the same BCP should experience little difficulty with tariff codes. However, new traders or those importing new materials or products should take especial care with this issue and confirm the tariff code with the relevant BCP prior to shipping.

Codes subject to official controls at border control posts

Commission Implementing Regulation (EU) 2021/632 lists the codes that are subject to veterinary inspection at the BCP, as stated in Annex I to this Regulation. Please note that this listing is updated periodically via Commission Implementing Decisions or Regulations. It is important to check for the most recent version to determine which CN codes are subject to controls at BCPs.
Commonly used codes within the industry sector include (but are not limited to):

- 3822: diagnostic or laboratory reagents
- 3002: blood and blood products, serum
- 3507: enzymes
- 3502: albumins
- 3504: peptones, other protein substances

Unlisted codes

Products with CN codes that are not listed in Commission Implementing Regulation (EU) 2021/632 are not subject to veterinary inspection at the BCP. The importer should however be aware that any animal derived material may be subject to border control regardless of its CN coding at the judgment of the official veterinarian of the BCP:
Products derived from animal by-products covered by Regulation 1069/2009/EC and Regulation 142/2011/EU are not specifically identified in Union law. Veterinary checks must be carried out on products that are partly processed but remain raw products to be further processed in an approved or registered establishment at destination. Official veterinarians at border control posts must assess and specify, when necessary, if a derived product is sufficiently processed to not require further the veterinary checks provided for in Union legislation.

Unclear coding

In cases where the coding is unclear it is advised that the importer consult the TARIC website. We also recommend contacting the customs authority prior to shipment to determine the status of the material to be imported. Importers should be aware that although the tariff system is intended to be harmonised worldwide, significant differences in its application may exist. Within the EU, in case of doubt, there exists a mechanism whereby the importer can request a Binding Tariff Information (BTI) decision, which will be applicable across the EU.

UN numbers

It should be noted that UN numbers do not apply to the products covered by this guidance.

5.2. Commercial Documents

Under the ABP regulatory framework, 'Commercial Document' refers to a specific template, which is described in Regulation 142/2011/EU, Annex XIII, Chapter 3.[28]

A Commercial Document is required for the movement of animal by-products and derived products among EU member states and EFTA (European Free Trade Association) member states (Iceland, Liechtenstein, Norway) plus Switzerland (mutual agreement). It is not required for importation. It is not to be confused with documents of a commercial nature produced by individual companies, such as an invoice or delivery note.

Competent authorities may accept a combined commercial document/commercial invoice for transportation of these materials, provided that all the following minimum information required[29,30] is given in this combined document:

- Date on which material was dispatched from the premises
- The origin and/or place of origin from which material is dispatched including its approval or registration number (if appropriate)
- The destination including name and address of receiver as well as the approval or registration number (if appropriate)
- The quantity of materials shipped
- A description of the animal by-products or derived products including the category, animal species and ear tag number (if applicable)

The commercial document accompanying a consignment must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.

5.3. Labelling

Identification of animal-derived materials

During importation, transit, transportation and storage, specific labelling of all materials containing animal by- products and derived products is legally required.[31]
'Packaged', in the view of the sector, means that the product is supplied in a stable and leak-proof container that is sealed and labelled appropriately.

Labelling requirements

Certain information must be available on the packaging, container or vehicle during importation, transport and storage of material containing animal by-products or derived products.

The current labelling requirements for external packaging are:

- material name
- temperature conditions for storage and handling
- relevant risk category and statement.

However, it is the industry recommendation that any labelling (including that on external packaging) should include at least the following information:

- material name
- weight or volume of the content
- batch number
- address of manufacturer
- temperature conditions for storage and handling
- relevant category statement

[28] The information in this chapter is summarized from Annex VIII, Chapter II (Identification) of Regulation 142/2011/EU.

[29] Minimum information required for commercial documents according to Article 21(3) of Regulation 1069/2009/EC

[30] Regulation 142/2011/EU, Annex VIII, Chapter III 4(f)

[31] The information in this chapter is summarized from Annex VIII, Chapter II (Identification) of Regulation 142/2011/EU.

Note: The veterinary certificate accompanying the shipment will carry further labelling requirements as indicated in the table below. It is advisable to combine colour-coding and label text on the same label, where possible.

Table 1: Label requirements summarized from Regulation 142/2011/EU

Consignment	**Text of label attached to outer packaging, container or vehicle**
Milk, milk derived products, colostrum, colostrum products, gelatin and others	**'not for human consumption'**
Blood products from equidae	**'blood and blood products from equidae. Not for human or animal consumption'**
Untreated and treated blood products, excluding of equidae	**'not for human or animal consumption'**
Intermediate Products**	**'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'**
Animal by products	**'animal by-products only for the manufacture of derived products for uses outside the feed chain' and the name and address of the EU establishment of destination**
Research or diagnostic sample*	**'for research and diagnostic purposes'**
Trade sample*	**'trade sample not for human consumption'**

***** relevant category statement

****** Note: Complex mixtures containing more than one animal-derived product will be classified according to the Category with the highest risk.

It is the responsibility of the importer to ensure that their consignments comply with requirements referred to in the EU legislation.

Colour-coding

All consignments being transported between Member States should be labelled with colour coding on the outer packaging, container or vehicle as follows:

- Category 1 colour black
- Category 2 colour yellow
- Category 3 colour green (with a high content of blue)

Imported consignments must display the appropriate colour code once they have passed the BCP of first entry into the EU. For transport within a member state, colour-coding is not required, however, some Member State authorities may require colour-coding for intra-member state transport.

5.4. Plant Approval and Registration

Introduction

European plants and establishments ("facilities") storing and/or handling animal by-products or derived products must be registered with **or** approved by the local competent authority. ISIA and MedTech Europe interpret the requirements for registration and approval in the following way: facilities handling intermediate products and other technical products (derived, non-feed material) must be registered but do not need to be approved.[32]

Approval is required for companies manufacturing pet food, organic fertilizers or fuel for combustion, but should not be required for companies supplying or manufacturing those products (including blood products), used in the sector. Approval is also required for storage facilities of animal by-products and certain derived products intended for disposal, fuel or combustion, feed or fertilizers (Art. 24.1(i, j) of Regulation 1069/2009/EC).

The requirements for the storage of intermediate products prior to dispatch to certain registered plants is still unclear as storage of intermediates in storage facilities approved for animal by-products (as required in Annex XII,3b) is unlikely to occur.

A few requirements, such as some general hygiene concerns, provisions for hazard analysis and critical control and disposal requirements are similar for both registration and approval. Approval however requires compliance with many additional requirements, such as an obligation to ensure complete segregation of materials by category in discrete facilities, provisions on personnel hygiene, specific sanitation procedures for movement between the unclean and clean sectors, checks of applicable parameters such as temperature/pressure/time/size of particles of ABPs being processed by pressure sterilisation, regular calibration of measuring equipment etc. These multiple requirements generally mean inspection of facilities by the competent authority prior to approval.

Registration requires notifying and providing information to the competent authorities on the nature of facility operations relating to ABPs and their category prior to commencing operations. For details of requirements for registration and approval, see below.

Note: This section relates to the ABP regulatory framework only. Other European and local legislation, i.e., relating to planning permission and environmental controls may also apply to the building and operation of facilities.

Facilities in the EU

EU countries' competent authorities approve and register establishments that handle animals, animal by- products and derived products. Approved or registered facilities can be found on the European Commission website (lists of approved facilities in EU Member States). Operators (including carriers, traders and users)[33] operating establishments handling animal by-products or derived products have a number of obligations with regards to registration and approval, which are listed in further detail below.

Operators additionally should be aware that EU Member States (including regions) may have vastly differing notification procedures and requirements for the registration of facilities. Operators are advised to confirm the application requirements with their local competent authority.

[32] The ABP regulatory framework supports this interpretation. See Regulation 142/2011/EU, Annex XII(3) and Annex XIV, Chapter II, Section 2, 3.1 b (ii), second indent [the text defining the conditions for importation of (untreated) blood products].
[33] See definition of 'operator' in APPENDIX 1

Facilities in Third Countries

Establishments of third countries that wish to export animal by-products or derived products to the EU need to be approved and/or registered by their competent authorities.
The sourcing of animal by-products and derived products is limited to facilities and plants of EU countries and certain third countries. These territories and third countries are generally defined by the so-called 'fresh meat list'[34] for animal by-products and by member countries of the World Organization for Animal Health (OIE)[35] for derived products.

Operators should check whether their third country-suppliers have current approval or registration. This can be checked on the European Commission website (lists of approved facilities in non-EU countries).

Approval or registration requirements of facilities in the EU

As there are many specific requirements relating to the approval or registration of plants and establishments, this guidance document will not attempt to list them all here. Instead, please consult the local competent authority for exact details of the regulatory requirements.

Registration and or approval of facilities may necessitate some or considerable investment on the part of the operator, depending on the existing infrastructure of the facility and the requirements of the local competent authority.

Currently registered or approved facilities

In the case of an approval the authorities must inspect the establishment and grant the approval before commencing operations. However, in the case of registration the operator can simply notify the authorities and having received the registration number commences operations. The authority will then audit the facility as time allows.

Once a facility is either registered or approved in the EU, there is no automatic requirement to re-apply: the registration and/or approval are granted on a once-only basis on the assumption that the facility maintains its current infrastructure and operations. Competent authorities may inspect the facility and withdraw the registration and/or approval status for a facility, which is not compliant with the requirements of the ABP regulatory framework. The competent authority is responsible to keep the lists of establishments up to date and to inform the Commission of any changes necessary.

A facility must be separately registered or approved for each category of material handled and for each separate section that describes its various activities published on the Commission website.

5.5. TRACES

On 4 March 2011 the EU Authorities launched a new section of their electronic database, the **TRA**de **C**ontrol and **E**xpert **S**ystem (TRACES Classic). In early 2020, the switch from TRACES Classic to the new database TRACES NT (TRACES **N**ew **T**echnology) was implemented. TRACES is the European Commission's digital certification and management platform for all sanitary and phytosanitary requirements, supporting the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union Plants and establishments.

The EU requires both EU Member States and third countries to list facilities approved or registered for the handling and manufacture of ABPs and derived products. [36]
Information listed within TRACES includes information concerning category or activity of material handled and types of approval of plants and facilities. In the case of third countries, facilities exporting animal by-products and derived products must also be listed in TRACES.
Consignments may only enter the EU if they have originated from Third Country plants and establishments listed on the approved establishment lists published on the Commission website.

[34] See Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 [lays] down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin

[35] See the World Organisation for Animal Health (OIE) and OIE Bulletin

[36] See Regulation (EU) 2016/429 on transmissible animal diseases, Part V, Chapter 1, Sections 2-4, Articles 230-236

The information held in TRACES is publicly available on the EU's website under the below links:
1. For third country plants and establishments: https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en
2. For plants and establishments in the EU: https://ec.europa.eu/food/safety/animal-by-products/approved-establishments_en

Sections

Third country facilities handling animal derived products are listed in TRACES under one or more of the following 10 sections:

I. Slaughterhouses
II. Dairy plants
III. Other facility for the collection or handling of animal by-products (i.e., unprocessed/untreated materials)
IV. Processing plants
V. Pet food plants (Including plants manufacturing dogchews and flavouring innards)
VI. Game trophies plants
VII. Plants or establishments manufacturing Intermediate Products
VIII. Fertilizer and soil improvers
IX. Storage of derived products
X. Blood and blood products, excluding of equidae, for technical purposes other than feed for animals

The section a facility must be listed under is determined by the commodity, its intended purpose, and/or the certificate/document, which is required for import to the EU. Sections commonly designated for facilities owned by suppliers and manufacturers to our industry sector are sections I, III, VII, IX and X.
Facilities with multiple approvals may be noted in multiple "sections". Facilities who fail to retain the pertinent approval will be removed from TRACES as required by EU authorities. For more information, see Chapter 5.4 Plant Approval and Registration.

Application to be a registered user in TRACES

This offers a number of advantages:

- Tracking of consignments allows the importer to contact the relevant or agent quickly in the event of a problem.
- The ability to check that the correct information has been entered into TRACES, e.g., details of consignor, consignee, intended use etc. allows the importer to ensure that the information is accurate.
- Electronic notification can be performed once Veterinary clearance has been obtained.

The registration process to TRACES is split into two steps.

- Before you can identify yourself in TRACES, please request access to the EU login system
  Note: The EU Login account should be created in the name of a physical person. In TRACES, no collective user accounts can be created. When signing any certificate, the registered of the EU Login account will appear inside the signature boxes. Therefore, please make sure that any person who needs to sign a certificate in TRACES has their own personal account in EU Login AND TRACES.
- Once this is done you can register for a TRACES account.
  Note: All new user requests that are registered in TRACES need to be validated before the user has access to the certificates and the rest of the TRACES functions. Who validates the requests depends on the type of role request and the certificate you will need to use. If in doubt, please contact the competent authority in your country.

To register in TRACES follow the instructions published on the EU webpage:
https://webgate.ec.europa.eu/cfcas3/tracesnt-webhelp/Content/B_Getting%20Started/getting-started.htm.
For support contact the competent authority in your country.

6 Transit and Transhipments

6.1. Transit

Commission Delegated Regulation (EU) 2019/2124 supplements Regulation (EU) 2017/625 as regards rules for official controls of consignments in transit, transhipment and onward transportation through the Union.

Introduction

Transit means the movement from one third country to another third country passing under customs supervision through Union/EEA[37] territory or from one Union/EEA territory to another after passing through the territory of a third country, except in relation to protective measures against pests of plants.[38]

I. Transit from one third country to another third country, passing through Union/EEA territory

The competent authorities of the border control post of introduction into the EU shall only authorise the transit of consignments in compliance with the following conditions:[39]

a) the goods comply with the applicable requirements laid down in the rules referred to in points (d) and (e) of Article 1(2) of Regulation (EU) 2017/625;
b) the consignment has been subjected to documentary checks and identity checks at the border control post with favourable results;
c) the consignment has been subjected to physical checks at the border control post, where non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 was suspected;
d) the consignment is accompanied by the CHED, and leaves the border control post in vehicles or transport containers sealed by the authority at the border control post;
e) the consignment must be directly transported under customs supervision, without the goods being unloaded or split, within a maximum period of 15 days from the border control post to one of the following destinations:
    (i) to a border control post in order to leave the Union territory;
    (ii) to an approved warehouse;
    (iii) to a NATO or US military base located in the Union territory;
    (iv) to a vessel leaving the Union, where the consignment is intended for ship supplying purposes.

Follow-up measures by the competent authorities

The competent authorities of the border control post of introduction into the Union which have not received, within a period of 15 days from the date on which transit was authorised at the border control post, confirmation of the arrival of consignments at one of the destinations referred to in points (e)(i) to (iv) above, shall:[40]

a) verify with the competent authorities at the place of destination whether or not the consignment has arrived at the place of destination;
b) inform the customs authorities of the non-arrival of the consignment;
c) undertake further investigation to determine the actual location of the consignment in cooperation with customs authorities and other authorities in accordance with Article 75(1) of Regulation (EU) 2017/625.

[37] The European Economic Area (EEA) consists of the Member States of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland).
[38] Regulation 2017/625/EU Article 3(44)
[39] Regulation 2124/2019/EU, Article 19
[40] Regulation 2124/2019/EU, Article 20

Transportation of consignments to a vessel leaving the Union territory

Where a consignment of goods is destined to a vessel leaving the Union territory, the competent authorities of the border control post of introduction into the Union shall, in addition to the CHED, issue an official certificate in accordance with the model laid down in Annex to Commission Implementing Regulation (EU) 2019/2128 which shall accompany the consignment to the vessel. In the case where several consignments of products are delivered together to the same vessel, the competent authorities of the border control post of introduction into the Union may issue one single official certificate which shall accompany such consignments to the vessel, provided that it has indicated the reference of the CHED for each consignment.[41]

Official controls at the border control post where goods leave the Union territory

The competent authorities of the border control post where goods leave the Union territory shall perform an identity check to ensure that the consignment presented corresponds to the consignment referred to in the CHED or in the official certificate accompanying the consignment. In particular, they shall verify that the seals fixed on the vehicles or transport containers are still intact.
The competent authorities of the border control post where goods leave the Union territory shall record the outcome of official controls in part III of the CHED or part III of the official certificate in accordance with the model set out in Annex to Implementing Regulation (EU) 2019/2128. The competent authorities of the border control post responsible for checks shall record the outcome of these controls in the IMSOC.[42]

Derogations for consignments in transit

By way of derogation, the competent authorities of the border control posts of introduction into the Union may authorise transit of animal by-products and derived products through the Union territory of the following consignments:[43]

- Transit by road or by rail through the Union between border control posts in Latvia, Lithuania and Poland, coming from and destined to Russia, directly or via another third country.
- Transit by road through Croatia coming from Bosnia and Herzegovina, entering at the road border control post of Nova Sela and exiting at the port border control post of Ploče.

The authorisation shall be subject to compliance with the following conditions:
The competent authorities of the border control post of introduction into the Union shall:

- perform documentary checks and identity checks;
- stamp the official certificates accompanying the consignments intended for the third country of destination ‘ONLY FOR TRANSIT VIA THE EU’;
- retain copies or electronic equivalents of the certificates at the border control post of introduction into the Union;
- seal the vehicles or transport containers transporting the consignments.

The operator responsible for the consignment shall ensure that consignments are directly transported under customs supervision, without being unloaded, to the border control post where consignments are to leave the Union territory.

The competent authorities of the border control post where the goods leave the Union territory shall:

- perform an identity check to confirm that the consignment covered by the accompanying CHED actually leaves the Union territory. In particular, they shall verify that the seals fixed on the vehicles or transport containers are still intact;
- record the outcome of the official controls in the IMSOC.
- The competent authorities of the Member States shall carry out risk-based controls to ensure that the number of consignments and the quantities of animals and goods leaving the Union territory match the number and quantities entering the Union territory.

[41] Regulation 2124/2019/EU, Article 21
[42] Regulation 2124/2019/EU, Article 33
[43] Regulation 2124/2019/EU, Article 34

Transit of goods refused by a third country after their transit through the Union

The competent authorities of the road or of the rail border control post of introduction into the Union may authorise further transit through the Union territory of products of animal origin, germinal products, animal by-products, derived products, hay and straw and composite products subject to compliance with the following conditions:[44]

a) the consignment of goods was refused entry by a third country immediately after their transit through the Union or the seals placed by the competent authorities on the vehicle or transport container are still intact;
b) the goods comply with the applicable requirements laid down in the rules referred to in points (d) and (e) of Article 1(2) of Regulation (EU) 2017/625;
c) the consignment has been subjected to documentary checks and identity checks at the border control post with favourable results;
d) the consignment has been subjected to physical checks at the border control post, where non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 was suspected;

The competent authorities of the road or of the rail border control post of introduction into the Union shall re-seal the consignment after the documentary and identity checks with favourable results.

The operators shall directly transport the consignment to one of the following destinations:

a) the border control post which authorised transit through the Union; or
b) the warehouse where it was stored before refusal by a third country.

II. Transit from one part of the Union territory to another part of the Union territory, and passing through the territory of a third country

The competent authorities of the Member States shall ensure that consignments, which are moved from one part of the Union territory to another part of the Union territory, passing through the territory of a third country are transported under customs supervision.

The operators responsible for consignments which have passed through the territory of a third country shall present the consignments when they are re-introduced into the Union territory to:[45]

a) the competent authorities of a border control post designated for any category of the goods; or
b) a location, indicated by the competent authorities referred to in point (a), which is in the close vicinity of the border control post.

The competent authorities of the border control post of re-introduction into the Union shall:

a) perform a documentary check to verify the origin of the animals and goods comprising the consignment;
b) where required by the rules referred to in points (d) and (e) of Article 1(2) of Regulation (EU) 2017/625, verify the animal health status of the third countries through which the consignments have transited and the relevant official certificates and documents accompanying the consignments;
c) where required by the rules referred to in points (d) and (e) of Article 1(2) of Regulation (EU) 2017/625, perform an identity check to verify that the seals put on the vehicles or transport containers are still intact.

When non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 is suspected, the competent authorities of the border control post of re-introduction into the Union shall perform in addition identity checks and physical checks.

The competent authority at the exit point from the Union shall:

a) perform the checks where required by the rules referred to in points (d) and (e) of Article 1(2) of Regulation (EU) 2017/625;
b) stamp the official certificate accompanying the consignment with the following wording ‘ONLY FOR TRANSIT BETWEEN DIFFERENT PARTS OF THE EUROPEAN UNION VIA [third country name]’.

[44] Regulation 2124/2019/EU, Article 36

[45] Regulation 2124/2019/EU, Article 37

6.2. Transhipment

Introduction

'Transhipped consignments' means consignments of animals or goods entering the Union by sea or by air transport from a third country, when those animals or goods are moved from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward travel.[46]

Documentary, identity and physical checks[47]

The competent authorities of the border control post of transhipment shall perform documentary checks on originals or copies of official certificates or documents that are required to accompany transhipped consignments of products of animal by-products and derived products in the following cases:

a) for goods subject to the animal health requirements and the rules for the prevention and minimisation of risks to human and animal health arising from animal by-products and derived products where the transhipment period:
   (i) at the airport exceeds 3 days;
   (ii) at the port exceeds 30 days;
b) for goods other than those referred to in point (a), where the transhipment period exceeds 90 days.

The competent authorities shall return to the operator responsible for the consignment the official certificates or documents on which they performed documentary checks to allow such official certificates or documents to accompany the consignment for onward travel.

Where the competent authorities of the border control post of transhipment suspects non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625, they shall perform documentary checks, identity checks and physical checks on the consignment. Those documentary checks shall be performed on original official certificates or documents where such official certificates or documents are required to accompany the consignment.

Where a consignment intended for dispatch to third countries exceeds the time period and where it does not comply with the rules referred to in Article 1(2) of Regulation (EU) 2017/625, the competent authorities of the border control post shall order the operator either to destroy the consignment or to ensure that it leaves the Union territory without delay.

The competent authorities of the border control post of introduction into the Union shall perform the documentary, identity and physical checks of goods intended to be placed on the Union market, except where documentary checks, identity checks and physical checks have been performed at another border control post.

Storage of transhipped consignments[48]

The operator responsible for consignments of animal by-products and derived products shall ensure that those consignments are only stored during the transhipment period either in:

(i) the customs or free zone area of the same port or airport in sealed containers; or
(ii) commercial storage facilities under the control of the same border control post. [49]

[46] Regulation 2124/2019/EU, Article 2(2)

[47] Regulation 2124/2019/EU, Article 13

[48] Regulation 2124/2019/EU, Article 14

[49] in compliance with the conditions laid down in Article 3(11) and (12) of Commission Implementing RL (EU) 2019/1014.

Notification of information before the transhipment period expires[50]

For consignments intended for transhipment, the operator responsible for the consignments shall provide notification before the arrival of the consignments to the competent authorities of the border control post of transhipment through TRACES or another information system designated by the competent authorities for that purpose, indicating the following:

a) the information necessary for the identification and location of the consignment in the airport or port;
b) the identification of the means of transportation;
c) the estimated time of arrival and departure of the consignment;
d) the destination of the consignment.

In addition to the prior notification, the operator responsible for the consignment shall also notify the competent authorities of the border control post of transhipment by completing and submitting the relevant part of the CHED in TRACES in the following cases:

a) the transhipment period has expired; or
b) the competent authorities of the border control post of transhipment inform the operator responsible for the consignment of their decision to perform documentary checks, identity checks and physical checks based on a suspicion of non-compliance.

[50] Regulation 2124/2019/EU, Article 16

APPENDIX 1
Glossary of Terms and Definitions

This glossary of terms and definitions comprises direct quotations from cited EU regulations plus other words or terms mentioned in the regulations for which no official definition was provided but which were sufficiently obscure or ambiguous that they needed defining. Such definitions were either taken from cited reference sources or are generally accepted terms within the serum industry and which have been endorsed by the ISIA as being officially recognized as such.

Entries in *italics* are direct quotations from EU Regulation.
To access hyperlinks (usually indicated by being underlined text): "Control + click".

'adult bovine serum' (ABS) is defined as the liquid fraction of clotted blood derived from healthy, slaughtered cattle 12 months of age or older deemed to be fit for human consumption by ante- and/or post- mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.
Serum industry standard. ISIA approved

'altered serum'. See 'Modified serum'.
Serum industry standard. ISIA approved

'animal' *means any invertebrate or vertebrate animal*
Regulation 1069/2009/EC, Article 3(5)

'animal by-products' *means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen.*
Regulation 1069/2009/EC, Article 3(1)

'animals used in a procedure or procedures' (formerly 'experimental animal') – *means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.*
This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition but excludes the killing of animals solely for the use of their organs or tissues.
Directive 2010/63/EU Article 3

'**antisera'** means a serum containing antibodies, such as one obtained from an animal that has been subjected to the action of antigen either by injection into the tissues or blood or by infection; also called immune serum.
Miller-Keane Encyclopaedia and Dictionary of Medicine, Nursing, and Allied Health,

'approval number' means that an establishment or plant has been approved by the competent authority having been inspected and/or deemed appropriate to handle animal by-products and/or derived products for certain purposes according to the provisions of Article 24 of Regulation 1069/2009/EC.
Regulation 1069/2009/EC, Article 24

Note: As evidence of this, an approval number has been allocated and this number is shown in Box reference 1.11 and 1.12 and 1.28 on health certificates and other model declarations

'approval of establishments or plants' means plants or establishments (as above) that have received approval by the competent authority where such establishments or plants carry out various processes as covered in Regulation 1069/2009/EC, which includes storage of animal by-products and/or derived products for certain purposes;

Regulation 1069/2009/EC Article 24(2) states that: *approval referred to in paragraph 1 shall specify if the establishment or plant is approved for the operations with animal by-products and/or derived products of:*

- *a) a particular category referred to in Articles 8, 9 or 10; or*
- *b) more than one category referred to in Articles 8, 9 or 10, indicating if such operations are carried out:*
  - *(i) permanently under conditions of strict separation which prevent any risk to public and animal health; or*
  - *(ii) temporarily under conditions which prevent contamination, in response to a shortage of capacity for such products arising due to:*
    - *a widespread outbreak of an epizootic disease, or*
    - *other extraordinary and unforeseen circumstances.*

Regulation 1069/2009/EC, Article 24

'artiodactyla' means an order of mammals that comprises the even-toed ungulates (see 'ungulates').
https://www.lexico.com/definition/artiodactyla

'batch' *means a unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit.*
Regulation 142/2011/EU Annex I Point 50

'**blood**' *means fresh whole blood.* Note: see also 'whole blood'.
Regulation 142/2011/EU Annex I Point 2

'**blood products'** *means derived products from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures.*
Regulation 142/2011/EU Annex I Point 4

'Border Control Post' (BCP) *means a place, and the facilities belonging to it, designated by a Member State for the performance of official controls*.
Regulation 2017/625/EU, Article 3(38)

'bovine calf serum' (BCS) is defined as the liquid fraction of clotted blood derived from healthy, slaughtered bovine calves, aged from 20 days up to 12 months, deemed fit for human consumption by ante-and/or post- mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.
Serum industry standard. ISIA approved

'bovine serum albumin (BSA)' means protein manufactured from serum or plasma by manipulating solvent concentrations, pH, salt levels and temperature. It has numerous biochemical applications.
https://medical-dictionary.thefreedictionary.com/serum+albumin

'carcase' *means the body of an animal after slaughter and dressing.*
Regulation 853/2004/EC Annex I point 1.9

'**category'** or 'categories' are covered under Appendix 2 Categorisation of Animal By-Products & Derived Products.

'CITES' *(the Convention on International Trade in Endangered Species of Wild Fauna and Flora) is an international agreement between governments. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival.*
Because the trade in wild animals and plants crosses borders between countries, the effort to regulate it requires international cooperation to safeguard certain species from over-exploitation. CITES was conceived in the spirit of such cooperation.
https://cites.org/eng/disc/what.php

'clarified Fetal Bovine Serum' is semi-processed FBS, obtained as described above, that has been thawed, pooled and subjected to some level of filtration before being dispensed into final packaging. No further processes, treatment, additions or deletions are allowed. Clarified FBS is stored frozen pending further treatment.

Serum industry standard. ISIA approved

'collection centres' *means premises other than processing plants in which the animal by-products referred to in Article 18(1) of Regulation* 1069/2009/EC *are collected with the intention to be used for feeding to the animals referred to in the same Article.*

Regulation 142/2011/EU Annex 1 point 53

This definition of 'collection centre' outlines collection centres whose focus is on animal by-products for specific feeding purposes and is, therefore, not directly relevant to this sector. Within the Sector**,** 'collection centre' is interpreted as premises other than processing plants where animal by-products (such as blood products and tissues) are harvested and stored. Note: Collection centres may not have the same registration or approval number as processing facilities.

'colour-coding' *means the systematic use of colours as set out in point 1(c) of Chapter II of Annex VIII for displaying information as provided for in this Regulation on the surface or on part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them.*

Regulation 142/2011/EU Annex I Point 44

Note: Colour-coding is a labelling requirement to indicate the Category of ABP or derived product on the packaging, container or vehicle during transport or storage. The requirement for colour-coding is applicable for material for any movement between EU Member States. However, national law may require colour coding for transportation within the Member State. (for more information, see Chapter 5.3 Labelling)

'Commercial Document' *must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other. Member States may require that proof of the arrival of the consignments is provided by the TRACES system or by a fourth copy of the commercial document which is sent back by the receiver to the producer.*

A commercial document, must specify:

(a) the description of the material and the animal species of origin;
(b) the category of the material;
(c) the quantity of the material;
(d) the place of origin and/or the place of dispatch of the material;
(e) the name and the address of the consignor;
(f) the name and the address of the consignee and/or user.

Regulation 142/2011/EU Annex VI Section 1(1)

A model of a commercial document appears in Annex VIII, Chapter III of Regulation 142/2011/EU. Note: A Commercial Document as used and described in this Guidance does not constitute any other document of a commercial nature such as an invoice. See 'commercial invoice' below.

'commercial invoice' *is a record or evidence of the transaction between the exporter and the importer. Once the goods are available, the exporter issues a commercial invoice to the importer in order to charge him for the goods. The commercial invoice contains the basic information on the transaction, and it is always required for customs clearance.*

https://trade.ec.europa.eu/access-to-markets/en/content/customs-clearance-documents-and-procedures

'commodity code' (HS Code or HTS Code in the US) indicates to Customs Authorities the content or intended use of a product and is required at point 1.19 on EU health certificates. The Harmonized Commodity Description and Coding System (HS) of tariff nomenclature is an internationally standardized system of names and numbers for classifying traded products developed and maintained by the World Customs Organization (WCO), an independent intergovernmental organization based in Brussels, Belgium with over 170 member countries. Note: Each commodity falls under a 'parent group' e.g., animal vegetable and food, mineral products, chemicals; for example, '3002' antibodies, human or animal, blood, blood products, immunological products, toxins and micro-organisms. Many different types of product may be listed under the same HS code but require different levels of documentation.
See Section 5.1 Tariff Codes/Commodity Codes.

'country of origin' (often abbreviated to COO) could be defined differently depending on the regulatory framework, e.g., on EU health certificates I.7 they ask for country in which the finished products were produced, manufactured or packaged, in II.5 they ask for the country where the blood was collected. Other jurisdictions have different definitions (e.g., country of slaughter, collection, manufacturing).

'CHED' (The **C**ommon **H**ealth **E**ntry **D**ocument) shall be issued as a result of the inspection at the border control post by national competent authorities. Customs authorities shall only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED. The CHED shall be used by:

- The operators in order to give prior notification to the competent authorities of the border control post of arrival of the consignments
- The competent authorities of the border control post, on order to:
  - Record the outcome of the official controls performed and any subsequent decisions
  - Communicate this information referred to through Implementing Regulation (EU) 2019/1715 (the IMSOC Regulation).

  https://trade.ec.europa.eu/access-to-markets/en/content/health-and-consumer-protection-animal-and-plant-product

'derived products' *means products obtained from one or more treatments, transformations or steps of processing of animal by-products.*

Regulation 1069/2009/EC, Article 3(2)

Note: See definitions for 'treated', 'transformation' and 'processing methods'.

'destination' see 'place of destination'.

'donor serum': Donor-sourced serum is defined as the liquid fraction of clotted blood derived from healthy animals from controlled donor herds 12 months of age or older from controlled donor herds whose health status is confirmed by regular inspection by competent, legally authorized veterinarians.
There are no deletions or additions (including preservatives) allowed.

Serum industry standard. ISIA approved

'end point' *means that the derived products referred to in Article 33 of Regulation (EC) 1069/2009 which have reached the stage of manufacturing regulated by the Community legislation have reached the end point in the manufacturing chain, beyond which they are no longer subject to the requirements of this Regulations.*

Regulation 1069/2009/EC, Article 5

'end user' means an individual or entity who uses a product after it has been fully developed and/or marketed. See definition for 'user'.

'establishment or plant' *means any place where any operation involving the handling of animal by- products or derived products is carried out, other than a fishing vessel.*

Regulation 1069/2009/EC, Article 3(13)

'experimental animals' means animals used in procedures for experimental or other scientific purposes or educational purposes as defined in Directive 2010/63/EU. Animals killed solely for the use of their organs and tissues are NOT considered experimental animals.

'facilities' or 'premises' means 'establishment or plant' (see definition above).

'farmed animal' *means:*

a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes;
b) equidae;

Regulation 1069/2009/EC, Article 3(6)

Note: These include 'laboratory' animals bred specifically for purpose even if these are not destined for experimental purposes.

'fetal bovine serum' (FBS), also known as **'fetal calf serum' (FCS)**
Semi-processed fetal bovine serum is obtained from the blood of fetuses of healthy, pre-partum bovine dams that have been deemed fit for human consumption through ante- and/or post-mortem veterinary inspection. It is collected in abattoirs inspected by the competent authority in the country of origin. Fetal blood is collected aseptically using cardiac puncture, thereby reducing the risk of microbial contamination and resultant endotoxins. Collection occurs in an area of the abattoir specifically set aside for this purpose to minimize the risk of contamination by other fluids.
Fetal blood is allowed to clot and is then centrifuged. Semi-processed FBS is the liquid fraction of the clotted fetal blood. After separation by centrifugation, no further processing or treatment of the semi- processed FBS is allowed. Also, no additions (including preservatives) or deletions are allowed.
Semi-processed FBS is stored frozen pending further processing.
Serum industry standard. ISIA approved

'fresh whole blood' is an animal by-product, is not modified, treated or processed and contains no additives.
Note: Blood collected in this state will have a very short shelf life and will start to clot after a short period of time exposed to air.
Serum industry standard. ISIA approved

'health certification' is documentation required to accompany certain ABPs as laid down in Annex XV of Regulation 142/2011/EU.

'hemoglobin' is the iron-containing oxygen-transport metalloprotein in the red blood cells of all vertebrates (except the fish family Channichthyidae) and the tissues of some invertebrates. In mammals the protein makes up about 97 % of the red blood cells' dry content, and around 35 % of the total content (including water). Hemoglobin and hemoglobin-like molecules are also found in many invertebrates, fungi, and plants.
http://medical-dictionary.thefreedictionary.com/hemoglobin
Note: hemoglobin extracted from bovine or other vertebrate blood is a blood derived product.

'HGPs - Hormonal Growth Promotants' *is any veterinary medicine containing either natural or synthetic hormones sold for the purpose of increasing muscle tone, growth rate, weight gain, or feed efficiency of animals.*
https://www.mpi.govt.nz/animals/growth-hormones/using-hormonal-growth-promotants/
The use of such material in farmed animals is prohibited in the EU. Material derived from animals treated with HGPs is classified as Category I as in Article 8 (c) Regulation 1069/2009/EC.
Note: HGPs are regulated by Directive 96/22/EC and Regulation 2017/625/EU (Directive 96/23/EC)

'hydrolysed proteins' *means polypeptides, peptides and amino acids, and mixtures thereof, obtained by the hydrolysis of animal by-products.*
Regulation 142/2011/EU, Annex I, Point 14

'Illegal treatment' means the use of beta-agonists and certain substances having a hormonal or thyrostatic action, which is prohibited in stock farming in the EU.

'implantable device' *means any device, including those that are partially or wholly absorbed, which is intended:*

- *to be totally introduced into the human body, or*
- *to replace an epithelial surface or the surface of the eye,*

by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;
Regulation (EU) 2017/745, Article 2(5)

'incoterms' International Commercial Terms means a series of international sales with terms, published by International Chamber of Commerce (ICC) and widely used in international commercial transactions.
These are accepted by governments, legal authorities and practitioners worldwide for the interpretation of most commonly used terms in international trade. This reduces or removes altogether uncertainties arising from different interpretation of such terms in different countries. Scope of this is limited to matters relating to rights and obligations of the parties to the contract of sale with respect to the delivery of goods sold.

'intermediate operations' *means the operations other than the storage referred to in Article 19 (b)*

Regulation 142/2011/EU, Annex I, Point 45

Note: Not to be confused with any activity concerning 'intermediate products'. This is not considered to have direct relevance to our industry sector but may be applicable to suppliers.

'***intermediate product'*** *means 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 products;

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 the product on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical or veterinary purposes, active implantable medical device, in-vitro diagnostic medical device for medical and veterinary purposes, laboratory reagent or cosmetic products.

Regulation 142/2011/EU, Annex I, Point 35

'in-vitro **diagnostic medical device'** *means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*

- *concerning a physiological or pathological state, or*
- *concerning a congenital abnormality, or*
- *to determine the safety and compatibility with potential recipients, or*
- *to monitor therapeutic measures.*

Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in-vitro diagnostic examination.
Products for general laboratory use are not in-vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in-vitro diagnostic examination;

Directive 98/79/EC Article 2(b)

'**laboratory animal'** could be an '**experimental animal**' or a '**farmed animal'** are *distinguished from other animals by their intended use in research, teaching, or testing and in some cases, because they possess specialized anatomic, genetic, physiologic or metabolic conditions that differ from other members of the same species.*

http://www.iaclam.org/lav.html

Note: this is a complex issue. From a veterinary point of view within the scope of Regulation 1069/2009/EC the fact that an animal is kept or bred in or for laboratory use is not sufficient to determine the category. Other considerations include whether it is deemed fit for human consumption, post-mortem inspection, symptoms of diseases, hormones and contaminants plus the intended purpose (including experimental use) or mode of killing.

'laboratory reagent' *means 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.*

Regulation 142/2011/EU Annex I, Point 36

'medical device' *means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- *— devices for the control or support of conception;*
- *— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.*

Regulation (EU) 2017/745, Article 2(1)

'medicinal product' *means:*

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Directive 2001/83/EC Article 1(2)

'model declaration' is documentation required to accompany certain ABPs as laid down in Annex XV of Regulation 142/2011/EU.

'modified serum' is Sterile Filtered Bovine Serum that has been subjected to additional chemical, biochemical or mechanical processing beyond that described for sterile filtered FBS such that the original serum has undergone a transformation by the addition or removal of material.

Serum industry standard. ISIA approved

'monoclonal antibodies' means antibodies produced from single hybridoma.
Note: Monoclonal antibodies produced using cell culture technologies under controlled conditions are considered to be outside the scope of this legislation.

'neo-natal bovine calf serum' is defined as the liquid fraction of clotted blood derived from new-born calves that have not suckled from the mother cow. There are no deletions or additions (including preservatives) allowed.

Serum industry standard. ISIA approved

'new-born calf serum' (NBCS) is defined as the liquid fraction of clotted blood derived from healthy, slaughtered bovine calves aged less than 20 days, deemed fit for human consumption through ante- and/or post- mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.

Serum industry standard. ISIA approved

‘OIE‘ (World Organisation for Animal Health) is an *intergovernmental organisation responsible for improving animal health worldwide. The need to fight animal diseases at global level led to the creation of the Office International des Epizooties through the international Agreement signed on January 25th, 1924. In May 2003 the Office became the World Organisation for Animal Health but kept its historical acronym OIE.*
It is recognised as a reference organisation by the World Trade Organization (WTO) and in 2018 has a total of 182 Member Countries. The OIE maintains permanent relations with nearly 75 other international and regional organisations and has Regional and sub-regional Offices on every continent.
https://www.oie.int/en/who-we-are/

‘operator’ *means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users;*
Regulation 1069/2009/EC Article 3(11)

Note: The preamble of Regulation 1069/2009/EC also sets out to clarify the responsibilities of the operators with the following statement: ‘The primary responsibility for carrying out operations in accordance with this regulation should rest with operators’. For full text see Obligations of Operators Regulation 1069/2009/EC Article 21 (Collection and identification as regards category and transport) and Article 22 (Traceability).

‘origin’ see ‘'country of origin' ’ above

‘other types of bovine serum’ can be provided as ‘semi-processed, clarified or sterile filtered as described above. They can also be provided screened for suitability in a specific application (pre-qualified or screened) or subjected to specific modification, treatment, enhancement or alteration (specialty)
Serum industry standard. ISIA approved

‘parts of slaughtered animals’ are not precisely defined and comprises:
Blood, which is the first product of ‘slaughter’.
The carcass is the body of an animal after slaughter and dressing (Regulation 853/2004/EC, Annex I point 1.9), and may fall within the scope of Regulation 1069/2009/EC if used as a source of animal by-products and derived products.

‘pathogenic’ (agent) means *any disease-producing agent, especially a virus, bacterium, or other microorganism.*
Pathogen | Definition of Pathogen at Dictionary.com

’perissodactyla’ means *an order of nonruminant ungulate mammals (as the horse, the tapir, or the rhinoceros) that usually have an odd number of toes, molar teeth with transverse ridges on the grinding surface, and posterior premolars resembling true molars.*
https://www.merriam-webster.com/medical/Perissodactyla

‘placing on the market’ *means any operation the purpose of which is to sell animal by-products or derived products to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party.*
Regulation 1069/2009/EC Article 3(14)

'place of destination or establishment of destination' means the establishment where the products are sent for final unloading, or for transit the warehouse in a free zone, the customs warehouse or the ship supplier.

- Box I.12. of model health certificate: except in the case of storage of products in transit, this information is optional.
  - For the placing on the market: the place where the animals or products are sent for final unloading. Give the name, address and approval number of the holdings or establishments of the place of destination, if applicable.
  - For storage of products in transit: the name, address and approval number of the warehouse in a free zone, the customs warehouse or the ship supplier.
- Box I.13. of model commercial document:
  - products subject to Article 48(3) of RL (EC) No 1069/2009 only a storage plant, incineration or co-incineration plant registered in accordance with Art 23(1)(a); an establishment or plant approved in accordance with Art 24 of RL (EC) No 1069/2009

Regulation 142/2011/EU, Annex XIV

'**plasma'** is the liquid fraction of un-clotted blood. After the addition of an anticoagulant to fresh whole blood, plasma is prepared by centrifuging the mixture until the red and white blood cells separate from the liquid phase. Plasma is a derived product of blood according to Regulation 142/2011/EU.

Serum industry standard. ISIA approved

'polyclonal antibodies' means antibodies that are obtained from different B cell populations. They are a combination of immunoglobulin molecules secreted against a specific antigen, each identifying a different epitope. These antibodies are typically produced by inoculation of a suitable mammal, such as a mouse, rabbit or goat. Larger mammals are often preferred as the amount of serum that can be collected is greater.

'premises' see 'establishment or plant'

'pre-qualified or screened fetal bovine serum' is sterile-filtered FBS that has been screened or qualified for suitability for a variety of specific applications. Examples may include Hybridoma screened, Stem Cell screened, Insect Cell screened, Low Endotoxin tested, or Low IgG tested. Pre-Qualified or Screened FBS may be labelled according to the application for which it has been qualified.

Serum industry standard. ISIA approved

'**processed animal protein'** *means animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.*

Regulation 142/2011/EU, Annex I, Point 5

Note: This is not relevant for the serum industry sector.

'processed serum': This term is to be avoided for reasons of ambiguity. Instead see 'modified serum'.

Serum industry standard. ISIA approved

'processing methods' *means the methods listed in Chapters III and IV of Annex IV* of Regulation 142/2011/EU.

Regulation 142/2011/EU, Annex I, Point 49

Note: The term 'processing methods' should not be confused with 'treated'.

‘**processing plant’** *means premises or facilities for the processing of animal by-products as referred to in Article 24(1)(a) of Regulation (EC) No* 1069/2009*, in which animal by-products are processed in accordance with Annex IV and/or Annex X.*

Regulation 142/2011/EU, Annex I, Point 58

Note: This definition is not relevant for material covered under this guideline for the sector although this could affect suppliers of material into the industry.

‘product used for in-vitro diagnosis’ *means a packaged product, ready for use, containing a blood product or another animal by-product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used in vitro for the examination of samples of human or animal origin, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents; it does not include donated organs or blood.*

Regulation 142/2011/EU, Annex I, Point 37

Note: CE marking of product reflects that the material is in full compliance with the IVD Directive 98/79/EC and is therefore outside the scope of the ABP regulatory framework.
The IVD Regulation (EU) 2017/746 will repeal and replace the IVD Directive (EC) 98/79 from the date of application of the IVD Regulation: 25 May 2022. From that date, references in the Animal By-Products legislation shall be understood as referring to the IVD Regulation.

‘**products of animal origin’** *means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004.*

Regulation 1069/2009/EC, Article 3(3)

Note: Some of these products may be source material for our Sector by law or by choice (see preamble Regulation 1069/2009/EC, Point 12).

‘**prohibited substances’** see definition of ‘HGPs - Hormonal Growth Promotants’.

‘registration’ (of operators, establishments or plants) means the authorisation by the competent authority for an operator, establishment or plant to handle animal by-products or derived products.
The competent authority will issue a registration number to authorised facilities (see **‘**approval number’).

Regulation 1069/2009/EC, Article 23

Note: ‘registration’ does not constitute ‘approval’.

‘research and diagnostic samples’ *mean 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.*

Regulation 142/2011/EU, Annex I, Point 38

Note: These types of samples are not for commercial purposes. See Chapter 4.3 Samples.

‘scrapie’ *is a TSE* (Transmissible Spongiform Encephalopathies) *in small ruminants (sheep and goats) and it can be divided into classical scrapie and atypical scrapie. First recognised more than 250 years ago, it has been known for centuries. It is assumed that scrapie can be transmitted horizontally, from one animal to another or via environmental routes, or vertically, from ewe to lamb / from goat to kid. The clinical signs of scrapie are found predominantly in animals aged from 2 to 5 years and include weight loss, salivation, pruritus and associated hair loss and skin abrasions, incoordination of hind limbs and altered behaviour such as observed nervousness, depression, excitability or aggressiveness. On the basis of the available scientific data scrapie is not considered to be transmissible to humans.*

https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse_en

‘serum’ is the liquid fraction of clotted blood. It is depleted of cells, fibrin and clotting factors. Serum differs from plasma in that anti-coagulant is never added to the blood after collection from the animal. Serum is prepared by centrifuging until the clot is separated from the liquid phase. The serum is then removed and stored frozen pending further processing. Serum is a derived blood product under Regulation 142/2011/EU.

Serum industry standard. ISIA approved

Serum may be derived from the blood of any animal, (terrestrial, aquatic, avian, human, or insect), but is most commonly derived from the blood of bovine, equine, caprine or ovine animals.

‘site’ means a contiguous geographic area containing one of more establishments or plants. Note: the word ‘site’ may also be used as ‘place’ within the text of regulations.

'**slaughtering**' *means the killing of animals intended for human consumption.*

Regulation 1099/2009/EC Article 2(j)

‘specialty Fetal Bovine Serum’ is semi-processed FBS or sterile filtered FBS that has been subjected to one or more modification processes, or that has been enhanced or altered in any way. Examples are Dialysed, Charcoal Stripped, IgG stripped, Gamma Irradiated, Heat Inactivated, Performance Enhanced, Dehydrated and Reconstituted. Specialty FBS must be labelled in a manner that clearly identifies it as having been modified, treated, enhanced or altered.

Serum industry standard. ISIA approved

‘sterile filtered Fetal Bovine Serum’ (FBS) is semi-processed FBS, obtained as described above, that has been thawed, pooled and subjected to filtration (usually through a series of membrane filters culminating in a sterile 0.1 micron filter) before being aseptically dispensed into its final packaging, labelling and placing on the market. No further processes, treatment, additions or deletions are allowed. Sterile filtered FBS is stored frozen.

Serum industry standard. ISIA approved

‘Specified Risk Material’ (SRM) *means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001.*

Regulation 1069/2009/EC, Article 3(18)

‘**starting point’** *means the point in the life cycle of animal by-products from which the requirements of this Regulation should apply. Once a product has become an animal by-product, it should not re-enter the food chain.*

Regulation 1069/2009/EC, from Preamble Point 21

‘storage plant’ is an establishment approved for storage of specified animal by-products and derived products.

‘technical plant’ is a term that no longer exists under Regulation 1069/2009/EC.

'technical product' is a term which is not defined or mentioned in the legally binding text of Regulation 1069/2009/EC.

'technical use' is a term used in section 1.25 on certain model certificates in Annex XV of Regulation (EU) 142/2011 for products destined for any use other than for animal consumption.

Regulation 142/2011/EU, Annex XV

‘**traceability**’ means the ability to trace the history, application or location of an entity by means of recorded unique identifiers. This is also referred to in Annex VIII of Regulation 142/2011/EU. Note: ISIA Traceability Standard – Any customer or auditor, whether government regulatory agents or ISIA-approved inspectors, reviewing traceability-standard-compliant-members are assured that the geographic origin represented on the product is, in fact, accurate, true, and traceable to the abattoir(s) or donor farm(s) from whence the raw blood was collected and that the type of serum (species and age) represented is correct. Each compliant member is responsible for keeping proper records which demonstrate traceability and serum type accuracy from the abattoir(s) or donor farms(s) through one step forward of their position in the supply chain. The integrity of the document chain is tested by third party independent audit.

'TRACES' (**TRA**de **C**ontrol and **E**xpert **S**ystem) is a multilingual online management tool which notifies, certifies and monitors trade in animals, products of animal origin, feed and food of non-animal origin, plants, seeds, propagating material, goods of organic origin and woods. TRACES is an e-government system, following the requirements of the EU Digital Agenda towards dematerialisation of health documents, traceability (monitoring movements, both within the EU and from non-EU countries); information exchange (enabling trade partners and competent authorities to easily obtain information on the movements of their consignments, and speeding up administrative procedures); risk management (reacting rapidly to health threats by tracing the movements of consignments and facilitating the risk management of rejected consignments).
What's Traces? (europa.eu)

'**trade'** *means trade in goods between Member States as referred to in Article 28 of the Treaty on the Functioning of the European Union.*
Regulation 142/2011/EU, Annex I, Point 48

'trade samples' *means animal by-products or derived products intended for particular studies or analyses authorised by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment.*
Regulation 142/2011/EU, Annex I, Point 39

'**transformation**' means an irreversible change in form, nature, or appearance caused by a chemical, biochemical, mechanical and/or physical process.
Note: Freezing or chilling are not transformational as the original material remains unchanged

'transit' *means movement from one third country to another third country passing under customs supervision through Union/EEA territory or from one Union/EEA territory to another after passing through the territory of a third country, except in relation to protective measures against pests of plants.*
Regulation 2017/625/EC, Article 3(44)

*'***transmissible spongiform encephalopathies (TSEs)**' *means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001.*
Regulation 1069/2009/EC, Article 3(17)

Note: These include Bovine Spongiform Encephalitis of cattle (BSE or Mad Cow Disease) and classical scrapie in sheep and goats. For a full set of definitions and further information please refer to SRMs/GRMs in this document.

''transhipped consignments' *means consignments of animals or goods entering the Union by sea or by air transport from a third country, when those animals or goods are moved from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward travel.*
Regulation 2124/2019/EU, Article 2(2)

'treated' means the animal by-product or derived product has been subjected to one of a number of processes designed to inactivate adventitious agents. The nature of the treatment depends on the material concerned. In the case of blood products, these treatments may include heat inactivation, change of pH or gamma irradiation. Please see Appendix 7 How to Complete Health Certificates 4(A), 4(C), 4(D).
Serum industry standard. ISIA approved

Note: The above-mentioned treatments may affect the biological performance of the material.

'treatment' – see 'treated'

'treated serum' is serum that has been subjected to one of a number of processes designed to inactivate adventitious agents, the details of which may vary according to species.
Serum industry standard. ISIA approved

‘ungulates’ *means the animals listed in Annex III* to Regulation (EU) 2016/429.
Regulation (EU) 2016/429, Article 4(45)

‘user’ *means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes;*
Regulation 1069/2009/EC, Article 3(12)

‘veterinary legislation’ *means laws, regulations and all associated legal instruments that pertain to the veterinary domain.*
OIE Terrestrial Animal Health Standards Commission / September 2010

'veterinary medicinal product' means
(a) any substance or combination of substances presented as having properties *for treating or preventing disease in animals or,*
(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Directive 2001/82/EC, Article 1(2)

‘whole blood’ is an animal by-product that contains an anticoagulant and has not been depleted of any of its components.
Serum industry standard. ISIA approved

APPENDIX 2
Categorisation of Animal By-Products & Derived Products

This chapter discusses the types of material that can fall into the various Categories as defined in Regulation 1069/2009/EC, Articles 7, 8, 9 & 10.

Article 7 of Regulation 1069/2009/EC states that:
Animal by-products shall be categorized into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.

Derived products shall be subject to the rules for the specific Category of animal by-products from which they have been derived, unless otherwise specified in this Regulation, or provided for in measures for the implementation of this Regulation which may specify the conditions under which derived products are not subject to those rules adopted by the Commission.

NOTE: Border Control Posts (BCPs) may allow materials being imported with certification for human consumption to be downgraded for other uses on a case-by-case basis.

This table should be used in conjunction with the definitions as shown in Appendix 1 Glossary of Terms and Definitions

Category 1 material

Regulation 1069/2009/EC, Article 8

Category 1 material shall comprise the following animal by-products:	**Comments**
a) entire bodies and all body parts, including hides and skins, of the following animals:	
(i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed	Not applicable
(ii) animals killed in the context of TSE eradication measures	Not applicable
(iii) animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals	Not applicable

Category 1 material shall comprise the following animal by-products:	**Comments**
(iv) *animals used in a procedure or procedures defined in Article 3 of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, in cases where the competent authority decides that such animals or any of their body parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;*	Materials from experimental animals are viewed as Category 1 material only, where serious health risks to humans or other animals can be expected. This is generally not the case with materials from live animals bred for purpose such as polyclonal antibodies or special serum components.
(v) wild animals, when suspected of being infected with diseases communicable to humans or animals	Not applicable
b) the following material: *(i) specified risk material* *(ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal*	The risk depends upon the type of material and the geography of origin. For example, some by-products of slaughter of cattle from certain geographical areas such as the EU are considered as SRM. The parts classified as specified risk material (SRM) are set out in point 1 of Annex V of Regulation (EC) 999/2001 (as amended).
c) *animal by-products derived 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 *Note: Directive 96/23/EC repealed and replaced by Regulation (EU) 2017/625*	Material from animals treated with EU prohibited hormones (Hormonal Growth Promotants (HGPs)). While these animal by-products may not enter the human or animal food chain, the importation of certain derived products from Category 1 material for the bio-pharmaceutical industry has been permitted by the EU since 2008.
d) animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, *if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation* *Note: Directive 96/23/EC repealed and replaced by Regulation (EU) 2017/625*	Materials exceeding the limits for residues of certain non-prohibited substances or contaminants, e.g., PCBs are not permitted. This is a permitted source of material for the import of material using 4C and 4D certificates.

Category 1 material shall comprise the following animal by-products:	**Comments**
e) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27: *(i) from establishments or plants processing Category 1 material; or* *(ii) from other establishments or plants where specified risk material is being removed*	Not applicable
f) catering waste from means of transport operating internationally	Not applicable
g) mixtures of Category 1 material with either Category 2 material or Category 3 material or both	Any mixture is determined by the Category of highest risk of the component.

Category 2 material

Regulation 1069/2009/EC, Article 9

(Material that is neither Category 1 nor Category 3)

Category 2 material shall comprise the following animal by-products:	**Comments**
a) manure, non-mineralized guano and digestive tract content	Material may be imported using an Import Permit and/or as a Research Sample. This material can only be imported for research or diagnostic applications (not for commercial resale)
b) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27: *(i) from establishments or plants processing Category 2 material; or* *(ii) from slaughterhouses other than those covered by Article 8(e)*	Not applicable
c) *animal by-products containing residues of authorized substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of* Directive 96/23/EC *Note: Directive 96/23/EC repealed and replaced by Regulation (EU) 2017/625*	Material exceeding the limits for residues of certain non-prohibited substances or contaminants, e.g., antibiotics or veterinary pharmaceuticals is not permitted
d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products	Not applicable
e) products of animal origin, other than Category 1 material, that are: *(i) imported or introduced from a Third Country and fail to comply with Community veterinary legislation for their import or introduction into the Community except where Community legislation allows their import or introduction subject to specific restrictions or their return to the Third Country; or* *(ii) dispatched to another Member State and fail to comply with requirements laid down or authorized by Community legislation except where they are returned with the authorization of the competent authority of the Member State of origin*	This material must be destroyed or returned.

Category 2 material shall comprise the following animal by-products:	**Comments**
f) animals and parts of animals, other than those referred to in Article 8 or Article 10, *(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes*	It must be clear that this concerns material that may not be covered as either Category 1 or Category 3 material. This material must either comply with one of the sub paragraphs to this clause and not have been killed/ slaughtered for human consumption This is a permitted source of material for Intermediate Products
(ii) foetuses;	The comments as above apply. Note: This does not include fetal bovine serum, since the fetus is considered as a part of a slaughtered animal unfit for human consumption (Regulation 854/2004/EC, Annex I, Section 2, Chapter 5, Point 1 c). Material from a dead-born calf would, however, fall under this point. This is a permitted source of material for Intermediate Products. *Note: Regulation (EC) 854/2004 repealed and replaced by Regulation (EU) 2017/625*
(iii) oocytes, embryos and semen which are not destined for breeding purposes; and	This is a permitted source of material for Intermediate Products.
(iv) dead-in-shell poultry	Not applicable
g) mixtures of Category 2 material with Category 3 material. *Any mixture is determined by the Category of highest risk of the component*	Any mixture is determined by the Category of highest risk of the component
h) animal by-products other than Category 1 material or Category 3 material	This is a permitted source of material for Intermediate Products Example: Snake venom

Category 3 material

Regulation 1069/2009/EC, Article 10

Category 3 material shall comprise the following animal by-products:	**Comments**
a) carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons	There are three principal criteria: 1.) The animal was slaughtered with the intention of human consumption. 2.) The material is fit for human consumption and has been sourced from animals that have successfully undergone an ante-mortem and post mortem inspection in a slaughterhouse. 3) the material is sourced from animals fit for human consumption but not intended for human consumption due to commercial reasons. This includes material from any species slaughtered in a slaughterhouse and meeting the above criteria. This is a permitted source of material for Intermediate Products and for products covered under health certificates 4A, 4C, 4D, 11, 12
b) carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation	There are two principal criteria: 1.) The animal was slaughtered with the intention of human consumption. 2.) The material is fit for slaughter for human consumption and has been sourced from animals, which have successfully undergone an ante-mortem inspection in a slaughterhouse. This could include material that failed post-mortem inspection. This includes material from any species slaughtered in a slaughterhouse and meeting the above criteria. This is a permitted source of material for Intermediate Products and for products covered under health certificates 4A, 4C, 4D, 11, 12
(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals	The animal was intended to be slaughtered for human consumption, but the material may then be considered unfit for human consumption due to stress or other physical trauma. This is a permitted source of material for Intermediate Products and for products covered under health certificates 4A, 4C, 4D, 11, 12

Category 3 material shall comprise the following animal by-products:	**Comments**
(ii) heads of poultry	This is a permitted source of material for Intermediate Products
(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of: – *animals, other than ruminants requiring TSE testing, and*	This does not apply to material from ruminants, e.g., skin (bovine) for the production of collagen, cholesterol (from sheep wool). This is a permitted source of material for Intermediate Products and material covered under Certificates 11 and 12.
– *ruminants which have been tested with a negative result in accordance with Article 6(1) of* Regulation 999/2001/EC	This applies only to material originating in the EU and therefore this paragraph is absent on import documents.
(iv) pig bristles	This is a permitted source of material for Intermediate Products.
(v) feathers	This is a permitted source of material for Intermediate Products.
c) animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation 853/2004/EC, which did not sho*w any signs of disease communicable to humans or animals*	Not applicable
d) blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation:	The blood referred to here must meet two criteria: 1) The animal was slaughtered with the intention of human consumption 2) The animal has successfully undergone an ante- mortem inspection in a slaughterhouse. This seems to be a special case of paragraph (b) in so far as that for a particular material (blood) the question of fitness for human consumption remains unaddressed.
(i) animals other than ruminants requiring TSE testing; and	This paragraph includes blood from all species except ruminants e.g., horse, pig, rabbit, chicken etc. plus blood from ruminants that are not required to be tested, e.g., age < 24 months* * See Bovine Spongiform Encephalopathy | FDA

Category 3 material shall comprise the following animal by-products:	**Comments**
(ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation 999/2001/EC	This applies only to material originating in the EU and therefore this paragraph is absent on import documents
e) animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and separator sludge from milk processing	This may cover remnant material fit for human consumption and which may undergo further transformation. This is a permitted source of material for Intermediate Products.
f) products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal risk arise	This may cover remnant material fit for human consumption but which, for a variety of reasons (commercial or otherwise), is no longer destined for human consumption. This is a permitted source of material for Intermediate Products and material covered under Health Certificates 11, 12 and 15.
g) petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;	This is a permitted source of material for Intermediate Products.
h) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals	This includes material from animals of any species that were alive at the moment of collection of the by-product. Typical examples are blood from donor animals or dairy products. This is a permitted source of material for Intermediate Products and material covered under Health Certificates 2, 4A, 4C, 4D.
i) aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals	This is a permitted source of material for Intermediate Products.
j) animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption	This covers fishery by-products arising from the further transformation of fish e.g., fish gelatin. This is a permitted source of material for Intermediate Products and material covered under Health Certificate 11 and 12.
k) the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals	
(i) shells from shellfish with soft tissue or flesh	This is a permitted source of material for Intermediate Products.

Category 3 material shall comprise the following animal by-products:	**Comments**
(ii) the following originating from terrestrial animals: hatchery by-products, eggs, egg by-products, including egg shells,	This is a permitted source of material for Intermediate Products
(iii) day-old chicks killed for commercial reasons;	This is a permitted source of material for Intermediate Products
l) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals	This is a permitted source of material for Intermediate Products
m) animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g)	This is a permitted source of material for Intermediate Products
n) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article	Not applicable
o) adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation	Not applicable
p) catering waste other than as referred to in Article 8(f)	Not applicable

We are aware that there are groups of material not covered by the above. We have been advised that in order to ascertain the method of importation into the EU for this type of material advice should be sought, in the first instance from your local competent authority.

APPENDIX 3
Scientific Names of Certain Animal Species

Order	Family	Genus	Species	Scientific Name	Common Name
Artiodactyla, Ruminantia	Bovidae, Bovinae	Bos	Taurus	Bos taurus	Cattle (Bovine)
		Bison	Bison	Bison bison	American Bison
	Bovidae, Caprinae	Ovis	Aries	Ovis aries	Sheep (Ovine)
		Capra	Aegagrus	Capra aegagrus hircus	Goat (Caprine)
Artiodactyla	Suidae	Sus	Scrofa	Sus scrofa domesticus	Swine, Pig, Minipig (Porcine)
Perisodactyla	Equidae	Equus	Ferus	Equus ferus caballus	Horse (Equine)
			Africanus	Equus africanus asinus	Donkey
Lagormorpha	Leporidae	Oryctolagus	Cuniculus	Oryctolagus cuniculus	Rabbit
Rodentia	Muridae	Rattus	Norvegicus	Rattus norvegicus	Brown Rat
			Rattus	Rattus rattus	Black Rat
		Mus	Musculus	Mus musculus	Mouse
		Meriones	Unguiculatus	Meriones unguiculatus	Gerbil (Mongolian)
	Caviidae	Cavia	Porcellus	Cavia porcellus	Guinea Pig
	Cricetidae	Mesocricetus	Auratus	Mesocricetus auratus	Golden (Syrian) Hamster
		Cricetulus	Griseus	Cricetulus griseus	Chinese Hamster
Didelphimorphia	Didelphidae	Didelphis	Virginiata	Didelphis virginiana	Opossum
Carnivora	Felidae	Felis	Catus	Felis catus	Cat
	Canidae	Canis	Lupus	Canis Lupus familiaris or dingus	Dog
	Mustelidae	Mustela	Putorius	Mustela putorius furo	Ferret (domestic)
Primates	Cercopithecidae	Macaca	Fasicularis	Macaca fascicularis	Crab-eating (or long tailed) Macaque
			Mulatta	Macaca mulatta	Rhesus monkey/Macaque
	Callitrichidae	Callithrix	jacchus	Callithrix jacchus	Marmoset
	Chlorocebus	Chlorocebus	sabaeus	Chlorocebus sabaeus	African Green Monkey
Galliformes	Phasianidae	Gallus	Gallus	Gallus gallus	Chicken
		Meleagris	Gallopavo	Meleagris gallopavo	Turkey
Columbiformes	Columbidae	Columba	Livia	Columba livia domestica	Pigeon
Psitticaformes	Psittacidae	Melopsittacus	undulatus	Melopsittacus undulatus	Budgerigar
Salmoniformes	Salmonidae	Salmo	Salar	Salmo salar	Salmon (Atlantic)
		Oncorhynchus	-	Oncorhynchus *spec.*	Salmon (Pacific)
Clupeiformes	Clupeidae	Brevoortia	Tyrannus	Brevoortia tyrannus	Menhaden (Atlantic)
		Clupea	Harengus	Clupea harengus	Herring (Atlantic)
Cypriniformes	Cyprinidae	Cyprinus	Carpio	Cyprinus carpio carpio	Common Carp
		Danio	Rerio	Danio rerio	Zebra fish
Anura	Pipidae	Xenopus	Laevis	Xenopus laevis	African clawed frog
	Ranidae	Rana	Pipiens	Rana pipiens	Northern leopard frog
Hymenoptera	Apidae	Apis	Mellifera	Apis mellifera	European Bee
		Bombus	Terrestris	Bombus terrestris	European Bumblebee
	Vespidae	Vespula	Vulgaris	Vespula vulgaris	European Wasp
			Pensylvanica	Vespula pensylvanica	Western yellow jacket US Wasp
			Maculifrons	Vespula maculifrons	Eastern yellow jacket US Wasp
Coleoptera	Lampyridae	Photuris	Lucicrescens	Photuris lucicrescens	Firefly
Archaeogastropoda	Fissurellidae	Megathura	Crenulata	Megathura crenulata	Keyhole Limpet

APPENDIX 4
Specified Risk Material

Specified Risk Materials (SRMs) are materials classified based on the risk associated with certain tissues, organs or body parts of those animals from which the material is collected. Specifically, for bovine, ovine and caprine material, these concerns centre on infection with Transmissible Spongiform Encephalopathies (TSEs) and the country of origin of the animal from which the material is a by-product or is derived. Other factors influencing the level of risk include the age of the animal (i.e., age at slaughter under 30 months), since BSE is a very slow developing disease and the method of stunning prior to slaughter since this may also be considered a contributory risk factor.

The definition as published by DG SANCO in Regulation 1069/2009/EC, Preamble 18, states:
'Specified Risk Material' (SRM) means specified risk material as defined in Article 3(1)(g) of Regulation 999/2001/EC *(laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies).*
Regulation 1069/2009/EC further states that SRMs should be considered as Category 1 material and that import, transit and export, all fall under Regulation 999/2001/EC.

Regulation 999/2001/EC contains listings of all those products that must be accompanied by an SRM declaration in accordance with Annex IX of Regulation 999/2001/EC (as amended). An SRM statement has been included in the Veterinary Health certificate models in Regulation 142/2011/EU and is summarized below.

SRM statements are not required for:

- cosmetic or medicinal products or medical devices, or their starting materials or Intermediate Products
- products which are not intended for use in human food, animal feed or fertilizers, or to their starting materials or Intermediate Products
- products of animal origin intended for exhibition, teaching, scientific research, special studies or analysis, provided those products are not eventually consumed or used by humans or by animals other than those kept for the research projects concerned

Model health certificates from Regulation 142/2011/EU		**SRM declaration**
Chapter 4A	Blood products from equidae	Not applicable
Chapter 4C	Untreated blood products, excluding of equidae	II.10
Chapter 4D	Treated blood products, excluding of equidae	II.11
Chapter 8	Animal by products	II.1.10
Chapter 20	Intermediate Products	No requirement

APPENDIX 5
Geographical TSE Risk by Country and Region

While the incidence of BSE has declined significantly in recent years, there are still isolated cases of the disease and control measures continue to be in force. Regulation 999/2001/EC, Article 5.1 states:
The BSE status of Member States or third countries or regions thereof shall be determined by classification into one of the following three categories:

- negligible BSE risk,
- controlled BSE risk,
- undetermined BSE risk.

The rating system is under the control and direction of the OIE (Office Internationale de Epizooties). A detailed categorization of TSE risk by country can be found at https://www.oie.int/en/what-we-do/animal-health-and-welfare/official-disease-status/.

However, the above list differs slightly from the Commission's list and the Commission is likely to prefer its own list to that of the OIE.
Please refer to: Commission Decision 2007/453/EC

And also to: Commission Implementing Regulation (EU) 2021/404/EU [lays] down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted.

Factors influencing the risks associated with various body parts have also been prioritized in Article 3(1)(g) of Regulation 999/2001/EC.
Current EU guidelines for human or animal drug manufacturing for TSE transmittal minimalisation products should be sourced from the lowest category countries.
https://eur-lex.europa.eu/search.html?scope=EURLEX&text=EMA%2F410&lang=en&type=quick&qid=1621843020965

With regard to Regulation 142/2011/EU the following applies for countries from which material may be imported into the EU:

Annex XIV Chapter II Section 1 Table 2 row 14 of Regulation 142/2011/EU:
In the case of animal by-products for the manufacture of pharmaceuticals: countries as set forth in Annex II Part 1 of Regulation 206/2010/EU (see also 144/2011/EU*), Annex I Part I of Regulation 798/2008/EC* and Annex I Part 1 of Regulation 119/2009/EC**.*
Plus: Japan, Philippines, Taiwan.
In the case of animal by-products for the manufacture of products for use outside the feed chain for farmed animals, excluding for pharmaceutical purposes: countries as set forth in Annex II Part 1 of Regulation 206/2010/EU, from which fresh meat of the animal species concerned may be imported (see also 144/2011/EU*, Annex I Part I of Regulation 798/2008/EC* and Annex I Part I of Regulation 119/2009/EC** or Annex II of Decision 2006/766/EC*** in the case of material from fish).*

* repealed by Commission Delegated Regulation (EU) 2020/692
** repealed and replaced by Regulation (EU) 2017/625
*** repealed by Commission Implementing Regulation (EU) 2021/405

Please note that these Regulations change frequently. For updates, please refer to the ISIA homepage.

APPENDIX 6
Treatment with Illegal Substances

A Hormone Growth Promotant (HGP) is a naturally occurring hormone, or synthetic alternative that is used to promote weight gain and improve the typically slow rate at which cattle convert grass into meat.

Regulation 1069/2009/EC preamble point 33 states that the use of certain substances and products is unlawful under Regulation 2377/90/ECC which is repealed by Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin and Directive 96/22/EC which concerns the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of ß agonists in the EU.

Relevant to this sector, Regulation 1069/2009/EC, Article 8(c) defines some Category 1 materials as being derived 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*.

* Note: Directive 96/23/EC repealed and replaced by Regulation (EU) 2017/625.

Annex XIV, Chapter II, section 1 table 2.2 of Regulation 142/2011/EU allows for the importation of blood products that have been treated with HGPs.

Annex XII Point 1(b) of Regulation 142/2011/EU allows for the importation of Intermediate Products originating from animals that have been treated with HGPs.

APPENDIX 7
How to Complete Health Certificates 4(A), 4(C), 4(D)
Guidance for the completion of Health Certificates by Veterinary Authorities in the Exporting Country

Introduction

These Health Certificates each comprise two parts.

Part I contains boxes numbered I.1 to I.28, the completion of which is entirely at the discretion of the supplier and is essentially data entry. Notes at the end of Part II give guidance on the completion of some of these boxes. This Guidance also offers (below) some further advice where appropriate.

Part II is the actual declaration, which is signed by the competent authority. The declaration contains a variety of options, which are deleted or struck-out as appropriate. Practice varies from country to country but while some of these strikeouts are the responsibility of the supplier, e.g., source, treatment, packaging etc., disease statements etc. are at the discretion of the competent authority. In all cases, such strikeouts or deletions are subject to oversight by the competent authority.

While the Model Health Certificate Chapter 4C and 4D are used for the same type of species and blood products in their untreated (Chapter 4C) or treated (Chapter 4D) form, Chapter 4A Health certificate must be used for both treated or untreated blood and blood products from equidae. For this reason, there is a significant difference in the certification content of Part II between Certificates Chapter 4C and D and Certificate Chapter 4A.

A special requirement exists for imported material from equidae. The country of collection must be eligible to export fresh meat and live animals for breeding to the EU in order for derived products to be imported without “treatment”. If the country of collection can only export fresh meat, but not export live animals for breeding, then treatment will be required. This condition does not exist for material from species imported under certificates Chapter 4C and 4D.

ANNEX XV of Commission Regulation 142/2011/EU of 25 February 2011 states:

The model health certificates in this Annex shall apply to the importation from third countries and to the transit through the European Union of the animal by-products and the derived products referred to in the respective model health certificates.

Notes

(a) Veterinary certificates shall be produced by the exporting country, based on the models in this Annex, according to the layout of the model that corresponds to the animal by-products or derived products concerned. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.

(b) Where the model certificate states that certain statements shall be kept as appropriate, statements, which are not relevant may be crossed out and initialed and stamped by the certifying officer, or completely deleted from the certificate.

(c) The original of each certificate shall consist of a single sheet of paper, both sides, or, where more text is required; it shall be in such a form that all sheets of paper needed are part of an integrated whole and indivisible.

(d) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, accompanied, if necessary, by an official translation.

(e) If for reasons of identification of the items of the consignment, additional sheets of paper are attached to the certificate, these sheets of paper shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, on each of the sheets of paper.

(f) When the certificate, including additional schedules referred to in e), comprises more than one page, each page shall be numbered — (page number) of (total number of pages) - at the bottom of the page and shall bear the code number of the certificate that has been designated by the competent authority at the top of the page.

(g) The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC* are followed.

* repealed and replaced by Regulation (EU) 2017/625

(h) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

(i) The original of the certificate must accompany the consignment at the EU border control post.

(j) If health certificates are used for consignments in transit, box No I.5 (Consignee) of the relevant health certificate shall be completed with the name and address of the border control post through which the consignment is intended to leave the European Union.

General Guidance as issued by the EU community states:

General: Please complete the certificate in capitals; to positively indicate any option, please tick or insert an X.
Where mentioned, the ISO codes use the two-letter country code in compliance with the international standard ISO 3166 alpha-2.[51]

Part I — Information on the consignment shipped

Country: Please indicate the third country issuing the certificate

Box I.1 Consignor:
Please give the name and address (street, town and region/ province/state, as applicable) of the physical or legal person who sends the consignment. It is recommended that telephone and fax numbers or the e-mail address be given**.**

Box I.2 Certificate reference No:
The certificate reference number is the number that the competent authority of the third country must assign in accordance with its own classification.

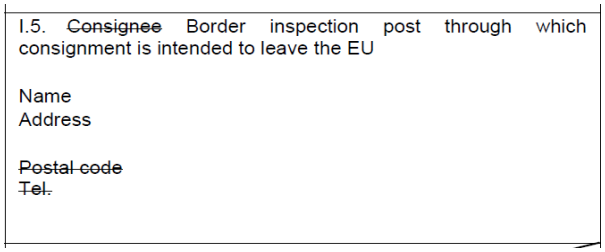
Box I.2a:
Reserved for TRACES notification. The TRACES number of the certificate is a unique reference number assigned by the TRACES system – crossed out, not to be filled in.

Box I.3 Central competent authority:
The name of the central authority of the country of dispatch, which is responsible for certification.

Box I.4 Local competent authority:
If applicable, the name of the local authority responsible at the place of origin or place of dispatch in the country which is responsible for certification.

[51] International standard two-letter code for a country in accordance with the ISO 3166 alpha-2 international standard; https://www.iso.org/iso-3166-country-codes.html.

Box I.5 Consignee:
Consignments to the EU (Consignee): Please enter full name, address, and telephone number of consignee (entity receiving the product in the EU). The postal code is only required if it is part of the address of the consignee (some EU member countries do not yet have postal codes as part of addresses). For consignments that are only transiting the EU, it is acceptable to prepare section I.5 of the Health Certificates as follows:


I.5. ~~Consignee~~ Border inspection post through which consignment is intended to leave the EU

Name
Address

~~Postal code~~
~~Tel.~~

Note regarding transit shipments: The person responsible for the consignment while it is in the EU (the person listed in section I.6) is required to prepare a Common Health Entry Document (CHED) prior to release of the shipment from the BCP through which the consignment enters the EU. The identity of the BCP through which the consignment will leave the EU must be identified on the CHED.

Box I.6 Person responsible for the load in the EU:
1: for products in transit through the EU: Please give the name and address (street, town and post code). It is recommended that the telephone and fax numbers or the e-mail address be given. This person is responsible for the consignment when it is presented at the border post and makes the necessary declarations to the competent authorities on behalf of the importer.
2: for products, animals or semen, embryos or ova imported into the EU: Reserved for TRACES notification. Please give the name and address (street, town and post code). It is recommended that the telephone and fax numbers or the email address be given.

Box I.7 Country of origin:
Please give the name of the third country in which the finished products were produced, manufactured or packaged or in which the animals were kept during the required period. Example: if the exported product originates from a country different from the country of exportation and has not undergone any handling other than further shipping the original country of origin remains unchanged. If the product has undergone any handling like filtration or other treatment prior to exportation the country of origin is same as the country of exportation.

Box I.8 Region of origin:
If applicable: This is only for species or products affected by regionalisation measures or by the setting up of approved zones in accordance with European Union legislation. The approved regions or zones must be indicated as described in the Official Journal of the European Union. Code: as indicated in the relevant regulations.

Box I.9 Country of destination:
Please give the name of the Member State of destination of the animals or products. If the products are in transit, please give the name of the Third Country of destination. Third Countries may correct typographical errors in Chapter 4C at II.5.4, II.5.4.1, II.5.4.2.

Box I.10 Region of destination:
see Box I.8.

Box I.11 Place of origin:
Please give the place from which the animals or products come.
For animals: an agricultural holding or any other officially monitored agricultural, industrial or commercial establishment, including zoos, amusement parks, wildlife and hunting reserves where animals are regularly kept or bred.
For semen, embryos and ova: collection or storage centres for semen, and embryo and ova collection or production teams.
For products or by-products of animal origin: any unit of a company in the food sector or animal feed sector. Only the establishment shipping the products or by-products is to be named and the country of dispatch if different from the country of origin.
Please give the name, address (street, town and region/province/state, as applicable) and the approval or registration number of these structures, if the latter is required by the regulation.

Box I.12 Place of destination:
To be filled out for storage of products in transit only: give the name, address (street/town and postcode) and the approval or registration number of the warehouse in a free zone, customs warehouse or ship chandler.

Box I.13 Place of loading:
For animals: please give the place where the animals are loaded and, if they are assembled beforehand, the details of the assembly centre: this applies to official assembly centres for animals before shipping. They must be approved by the official authority or must be placed under their supervision.
For products, semen and embryos please indicate the place of loading or the port of embarkation.

Box I.14 Date of departure:
For animals: please give the date and time at which the animals are scheduled to leave.
For products, semen, embryos and ova, please give the date of departure.

Box I.15 Means of transport:
Please give all the details on the means of transport: the type of transport (aeroplane, ship, railway wagon, road vehicle, other).
Identification of the means of transport: by air, the flight number, by ship, the name of the ship, by rail, the number of the train and the rail car and by road the number plate of the road vehicle and the number of the trailer if applicable.
Others: means of transport not listed by Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations. If the means of transport is changed after the certificate has been issued, the consignor must inform the BCP of entry into the EU.
Documentation references: optional: please indicate the number of the airway bill, bill of loading, or the commercial number of the train or road vehicle.

Box I.16 Entry BIP[52] in EU:
Please give the name and the number of the BIP (Border Inspection Post)[52] as it appears in the Official Journal of the European Union. This information can be changed until the Common Health Entry Document is completed.

Box I.17:
Box I.17 is an unfilled field in health certificate models 4A, 4C, 4D, and 8.

Box I.18 Description of commodity:
Give a veterinary description of the goods or use the titles as they appear in the World Customs Organisation's Harmonised System included in amended Regulation 2658/87/EEC. This customs description shall be supplemented, if necessary, by any information required to classify the goods in veterinary terms (species, processing, etc.). Example: "Fetal Bovine Serum"

[52] Border Inspection Posts (BIPs) were renamed to Border Control Posts (BCPs) https://ec.europa.eu/food/animals/veterinary-border-control/contact-details-bcps-veterinary_en

Box I.19 Commodity code (HS code):
Please give the appropriate code as it appears in the World Customs Organisation's Harmonised System included in amended Regulation 2658/87/EEC**.**

Box I.20 Quantity:
For animals and animal products (semen, ova, embryo), please give the number of heads or straws expressed as units. For aquaculture animals and products, please give the total gross and net weights in kg (Not relevant for our sector).

Box I.21 Temperature of product:
Please tick the appropriate temperature for transport/storage of the product (ambient, chilled, frozen).

Box I.22 Number of packages:
Indicate the total number of boxes, or the number of packages (e.g., pallets) for products.

Box I.23 Seal/Container No:
Number of seals and number of containers if applicable (for sea freight shipments and airfreight shipments where a container is used).

Box I.24 Type of packaging:
For example, boxes or jugs or bottles or vials or pallets as indicated in I.22.

Box I.25 Commodities certified for:
For this sector, always select technical use.

Box I.26 For transit through EU to third country:
It is only for the transit of products of animal origin through the EU/EEA from a third country and to a third country: Give the name and the ISO code of the country of destination (this box appears only in the certificates for transit and storage, including storage for ships chandlers).

Box I.27 For import or admission into EU:
For import or temporary entry into the EU (specific box for certificates for import and entry).
Final import: This option features only for the import of animal species also authorized for re-entry or temporary entry (such as registered equidae).
Re-entry: This option features only in the context of import of animal species authorized for re-entry, such as registered equidae for races, shows or cultural events after temporary export (Commission Decision 93/195/EEC). Not relevant to our sector.
Temporary entry: This option features only in the import of species of animals authorized for temporary entry (such as registered equidae for a maximum period of 90 days). Not relevant to our sector.

Box I.28 Identification of the commodities:
Please give the requirements specific to certain animal species and types of products. The information required, which is listed exhaustively below, is set out in each specific certificate.
Species must be identified by scientific name.
21.4.2007 EN Official Journal of the European Union L 104/47
For products: Species (scientific name), nature of commodities, approval number of establishments (manufacturing plant), number of packages, net weight, batch number.
NOTE: a batch number is not required on the certificate 4A but advisable for the purposes for traceability.

Part II — Certification

Box II. Health information:
Please give the information in compliance with the relevant regulation.

Box II.a. Certificate reference No:
Reference number: cf. Box 1.2.

Box II.b.
TRACES reference number: cf. Box 1.2a – crossed out, not to be filled in.

Official veterinarian: Please give name, qualification and title and the date of signature.
In cases covered by the relevant legislation, the veterinary inspector may be replaced by an official inspector.

APPENDIX 8
How to Complete Chapter 20 Model Declaration
for the import of intermediate products

Introduction

The Chapter 20 model declaration (Chapter 20) provides a "declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices, *in-vitro* diagnostics and laboratory reagents". The importer and not the third country authorities are responsible for preparing and signing the model declaration. Essential information about the supplier (e.g., TEC reg number), product- and shipment-information typically is filled in by the supplier.
It is a requirement that importers/agents notify the Border Control Post (BCP) at the point of entry into the EU of the arrival of consignments at least 24 hours before the estimated time of arrival at the Border Control Post. The Chapter 20 provided at the time of entry must be in a language that is acceptable to the BCP.

Text passages that are indicated with superscript "(2)" in Section II of Chapter 20 require the importer resp. the supplier to delete by crossing out those indents which do not apply to the consignment.

Overview of Chapter 20

- Part I (Details of dispatched consignment) asks for general information concerning the consigner and consignee, the consignment and its transportation. It is fairly straightforward to complete. The information listed here will be used for the electronically generated CHED (TRACES).

- In Part II (Certification)(1) the importer declares that the intended purpose for the intermediate product is to be used in the manufacture of medical devices / laboratory reagents and/or one or more of several product types according to Article 33 of regulation 1069/2009/EC.

- Part II(2) confirms that the material complies with the definition of an intermediate product[53]

- In Part II(3) the importer specifies details of the origin of the intermediate products being imported.

- Part II(4) confirms that the outer packaging of the material is correctly labelled.

- Section II(5) confirms that the consignment will be transported directly to a registered and or approved plant or establishment.[54] (See Chapter 5.4 Plant Approval and Registration). Depending on the understanding of the BCP either and / or can remain or the option which is not applicable should be crossed out

- The importer signs the Chapter 20 declaration.

Additional information on completing sections I, II(1) and II(3) is below.

[53] See definition under Appendix I, Glossary, 'intermediate product'
[54] In accordance with Regulation (EU) 142/2011, Annex XII, 3.

Completing Part I – details of dispatched consignment

(please note that the guidance for Part I also applies to the certificates in Regulation 142/2011/EU)

box I.2	The reference number of the declaration is usually issued by the competent authorities of the third country according to their own system. However, since Chapter 20 is being filled out and signed by the consignee (unlike health certificates), any unique reference can be used (e.g., an AWB number or invoice number is sufficient). Please note that the reference number must be indexed with an additional letter or number if more than 1 Statement is issued for different articles of the same consignment.
box I.3	Central competent authority: currently there are no requirements set out. You may state the national authority of the country of export or import (different from health certificates, where the name of the competent authorities of the third country of shipping is required) - it is advisable to check with the BCP of entry or the Member States national authority, who might request to state the national authority of the importing country.
box I.4	Local competent authority: currently there are no requirements set out. Depending on the local BCP requirements you can leave it blank or state the local authority of the country of export or import (different from certificates, where the name of the local authorities of the third country of shipping is required) - it is advisable to check with the BCP of entry or the Member States national authority, who might request to state the local competent authority for the consignee.
box I.6	Person responsible for the load in EU: Person in the importer's establishment that can give information about the consignment especially in cases when the importer and the BCP are located in different Member States.
box I.7	Country of Origin: Name of country in which the intermediate product was manufactured (NOT the country of origin of the raw materials contained in the intermediate product). ISO-Codes (international standard codes for countries, consisting of 2 letters according to the international norm ISO 3166 alpha-2)[51]
box I.8	Region of origin: (where the intermediate product has been produced). Check with the Member States national authority, whether this needs to be filled in).
box I.11	Place of origin: Name, full address and approval number or registration number of the establishment where the Intermediate Products originate from (NOT the place of origin of the raw materials contained in the intermediate product).
box I.12	Place of destination: Place of destination of the consignment. Tick the box "Custom Ware-house" only if the place of destination is a custom warehouse for commodities in transit.
box I.13	Place of loading: Name/location of shipping harbour or airport.
box I.14	Date of departure: of the consignment from the country of origin.
box I.15	Means of transport and documentation references: name the means of transport including the flight number (airplane), ship name (ship), train- and freight car number (rail).
box I.16	EU-Border Control Post: Name resp. place and, if required, number of the BCP.
box I.18	Description of commodity: Name, together with a description of goods (i.e., component xy or OEM-intermediate product for IVD, containing BSA with or without information about quantity of content like 4%).
box I.19	Commodity code (HS-Code): see Chapter 5.1 Tariff Codes/Commodity Codes.

box I.20	Quantity: Gross weight and net weight (in kg).
box I.22	Number of packages: number of shipping boxes/internal packages.
box I.23	Seal/Container No: For sea or airfreight shipments where a sealed container is used, please enter the container number. This information can be provided by the shipping company or by the exporter.
box I.28	Species: scientific name of the species the intermediate product contains or originates from. (See Appendix 3 Scientific Names of Certain Animal Species). Approval number of establishments, Manufacturing plant: Approval number of the establishment from where the intermediate product has been exported or approval number of the establishment where the intermediate product was manufactured.

Completing Part II – Certification

Under II(1) the intended use of the intermediate products consignment is to be specified by crossing out non-relevant uses:

either	[- medicinal products,]
and/or	[- veterinary medicinal products,]
and/or	[- medical devices for medical and veterinary purposes,]
and/or	[- active implantable medical devices,]
and/or	[- in vitro diagnostic medical devices for medical and veterinary purposes,]
and/or	[- laboratory reagents,]
and/or	[- cosmetic products,]

Importing intermediate products of category 1 and/or 2 for the production of medicinal products or veterinary medicinal products or active implantable medical devices is only possible where the intended use of the intermediate products is considered justified by the competent authority with regard to protection of public or animal health. Importers are advised to contact the competent authority of the importing country prior to the importation of category 1 or category 2 products.

II(3) comprises a list of all allowed sourcing materials for intermediate products. The importer must specify the origin of the intermediate products being imported by deleting those indents that do not apply.
The importer should choose the indent which best applies to the intermediate product being imported. Importers are advised to obtain all required information from their supplier outside of the EU.

When deciding on the applicable indent, the importer will need to ignore occasional inconsistencies, repetition and apparent redundancy in the text of II(3), which stems from the necessity to precisely mirror the text of the legislation. Should there be any confusion over which indent to select, the importer is advised to contact their BCP.

Summary of the indents:
Note: the respective paragraphs under Point 3 of Chapter 20 have been numbered (see attached excerpt of Chapter 20 on the following page) starting with "**1**". For reference, corresponding articles of Regulation 1069/2009/EC are listed for each paragraph.

1. This paragraph (3) allows all the material in the following indents (except for the final indents numbered 15 and 16) to be either category 3 or 1 material (delete treatment-alternative as appropriate). Material is classified as category 1 material if it originates from animals, which have been submitted to treatment with illegal substances. (Category 2 material is listed in the two final indents of II(3), numbered 15 and 16. Therefore crossing out these indents indicates that the material being imported is either category 3 or category 1).
   The imported derived products have been derived from or produced by materials, listed in the following indents:

2. **(see Article 10 a)** must be selected for material generated according to the EU food legislation requirements, but not intended to be used as food.
   This indent usually applies to the import of intermediate products such as bovine serum albumin.
3. **(see Article 10 b)** animal by-product by law. Different from the preceding indent (2) the material has been derived from animals fit for human consumption but consists of animal parts that are not considered fit for or rejected as unfit for human consumption.
4. **(see Article 10 d)** concerns blood from animals other than ruminants which have been considered fit for human consumption. Please note that the wording differs from that of Article 10 d). Clarification is currently sought to resolve this issue.
5. **(see Article 10 e)** by-products of food production.
6. **(see Article 10 f)** former foodstuff
7. **(see Article 10 g)** former pet food and feeding stuff – not considered applicable for our Industry.
8. **(see Article 10 h)** material from live animals, this indent applies to blood products such as antibodies, antiserum as well as milk products.
9. **(see Article 10 i)** aquatic animals, and their parts **(see Article 10 j)** Aquatic animals and their parts which originated from food plants.
10. **(see Article 10 k)** eggs, shell/-fish
11. **(see Article 10 l)** invertebrates (such as insects, worms, clams, crabs, octopus, snails)
12. **(see Article 10 m)** Rodentia and Lagomorpha and parts thereof. Importers are advised to contact their authorities in order to make sure the right selection is made.
    This indent applies mostly to imported mouse antibodies and rabbit antisera or antibodies.
13. **(see Article 10 i, l, m**) indent focusing on products generated by a range of animal species (aquatic non-mammals, and non-pathogenic invertebrates, rodents and Lagomorpha).
    This indent differs from the preceding indent only by the distinction in Article 10 of Regulation 1069/2009/EC between “parts derived from” and “products generated by” certain animals.
14. **(see Article 9 f)** Certain category 2 materials; please note that fetal calf serum is considered Category 3”.
15. **(see Article 9 h)** category 2 material not grouped under category 1 or 3, other than that mentioned in the preceding indent.

The following paragraph lists common examples of frequently used intermediate products and the crossing-out pattern of indents in II.3 of Chapter 20.

Materials, containing or consisting of:

Antisera, Antibodies, blood products from live animals: (e.g., goat, sheep, bovine)

- All indents of II.3 are crossed out except indent No 8

Antisera, Antibodies, blood products from live animals: (Rodentia, rabbits)

- All indents of II.3 are crossed out except indent No 8 and 13 Bovine materials (e.g., bovine serum albumin)
- All indents of II.3 are crossed out except indent No 3 (in case of e.g., bovine material that is being considered Category 1 material)[55]
- All indents of II.3 are crossed out except indent No 2 (in case of Cat. 3 Material)

Materials, containing 2 or more different animal-derived materials as components:

e.g., bovine materials (e.g., bovine serum albumin) **and** e.g., antisera or antibodies

- Combine deletion-pattern of each animal-derived material, contained in the respective intermediate product

[55] Chapter 20 statements for Intermediate products that consist of or contain animal-derived materials that are classified as Category 1 materials due to illegal treatment according to article 8(c) or 8(d) of Regulation 1069/2009/EC may prove difficult to fill out correctly since the Chapter 20-template does not provide a straight-forward solution:
Indents 2, 3 and 4 allow only material that originates from animals that are fit for human consumption “…in accordance with Community legislation”, which is not the case with Category 1 – material.
For Intermediates with animal-derived products that might have undergone illegal treatment as listed in (1) It is recommended to leave open the indent (3) (”rejected as unfit for human consumption…”) which is in agreement with the current opinions of several border control posts.

Excerpt from C20 importers declaration see below:

Section II(3) of CHAPTER 20 Model Declaration
Available choices to delete as applicable (consecutively numbered for clarity)

Numbering for Section II(3), Model Declaration Chapter 20 of Regulation 142/2011/EU

II(3) it has been derived from

(2)either **1** it has been derived from the following material which 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(2) *
* Note: Directive 96/23/EC repealed and replaced by Regulation (EU) 2017/625.

(2)and/or **2** [-carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons],

(2)and/or **3** [-carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2)and/or **4** [-blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation];

(2)and/or **5** [-animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2)and/or **6** [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

(2)and/or **7** [-petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2)and/or **8** [-blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2)and/or **9** [-aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2)and/or **10** [-animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

[(2)]and/or **11** [-the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals: hatchery by-products, eggs, egg by-products including egg shells,

(iii) day-old chicks killed for commercial reasons;]

[(2)]and/or **12** [-animal-by products from aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

[(2)]and/or **13** [-animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation 1069/2009/EC;]

[(2)]and/or **14** [-products derived from or generated by:

- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals,
- aquatic and terrestrial invertebrates other than species pathogenic to humans or animals,
- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation 1069/2009/EC;]

[(2)]and/or **15** [-animals and parts of animals, other than those referred to in Article 8 or Article 10 of Regulation 1069/2009/EC,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;

(ii) foetuses;

(iii) oocytes, embryos and semen which are not destined for breeding purposes; and

(iv) dead-in-shell poultry;]

[(2)]and/or **16** [-animal by-products other than Category 1 material or Category 3 material

APPENDIX 9
Useful Links

The following index includes all regulations referred to in this document, listed chronologically, together with the regulation Title and Website address (URL). Click on the URL and it will link to the website or enter the URL into your web browser.

76/768/EEC	No longer in force, Date of end of validity: 11/07/2013; Repealed by 1223/2009/EC
2658/87/EEC	on the tariff and statistical nomenclature and on the Common Customs Tariff
90/385/EEC	No longer in force, Date of end of validity: 25/05/2021
2377/90/EEC	No longer in force, Date of end of validity: 05/07/2009; Repealed by 470/2009/EC
93/42/EEC	No longer in force, Date of end of validity: 25/05/2021
93/195/EEC	No longer in force, Date of end of validity: 30/09/2018; Repealed by 2018/659/EU repealed by 2021/404/EU
96/22/EC	concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists
96/23/EC	No longer in force, Date of end of validity: 13/12/2019; Repealed and replaced by 2017/625/EU
98/79/EC	on in vitro diagnostic medical devices
2001/82/EC	on the Community code relating to veterinary medicinal products
2001/83/EC	on the Community code relating to medicinal products for human use
999/2001/EC	laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
1831/2003/EC	on additives for use in animal nutrition
853/2004/EC	laying down specific hygiene rules for food of animal origin
854/2004/EU	No longer in force, Date of end of validity: 13/12/2019; Repealed and replaced by 2017/625/EU
1/2005/EC	on the protection of animals during transport and related operations
2006/766/EC	No longer in force, Date of end of validity: 13/12/2019; Repealed by 2019/626/EU repealed by 2021/405/EU
2007/275/EC	No longer in force, Date of end of validity: 20/04/2021; Repealed by 2021/632/EU
2007/453/EC	establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk

798/2008/EC	No longer in force, Date of end of validity: 20/04/2021; Repealed by 2020/692/EU
119/2009/EC	No longer in force, Date of end of validity: 20/04/2021; Repealed by 2016/429/EU
470/2009/EC	laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin
1069/2009/EC	laying down health rules as regards animal by-products and derived products not intended for human consumption
1099/2009/EC	on the protection of animals at the time of killing
1223/2009/EC	on cosmetic products
2010/63/EU	on the protection of animals used for scientific purposes
206/2010/EU	No longer in force, Date of end of validity: 20/04/2021; Repealed by 2020/692/EU
142/2011/EU	implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text
144/2011/EU	No longer in force, Date of end of validity: 20/04/2021; Implicitly repealed by 2020/692/EU
2016/429/EU	on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’)
2017/625/EU	on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
2017/745/EU	on medical devices
2017/746/EU	on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
2019/1014/EU	to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points
2019/1715/EU	laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)
2019/2007/EU	No longer in force, Date of end of validity: 20/04/2021; Repealed by 2021/632/EU
2019/2124/EU	supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transhipment and onward transportation through the Union
2019/2128/EU	establishing the model official certificate and rules for issuing official certificates for goods which are delivered to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers, or to NATO or a United States’ military base

2020/692/EU	supplementing 2016/429/EU as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin
2021/404/EU	laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with 2016/429/EU
2021/405/EU	laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption
2021/632/EU	laying down rules for the application of Regulation (EU) 2017/625 as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC
APHA	United Kingdom (UK) Animal & Plant Health Agency (APHA)
BCP	Border Control Post – Contact details of BCPs – veterinary
CITES	The Convention on International Trade in Endangered Species of Wild Fauna and Flora
EU approved establishments	lists of approved facilities in EU Member States
ICC	International Chamber of Commerce
ISIA	International Serum Industry Association
ISO Country Codes	ISO 3166 Country Codes
MedTech Europe	MedTech Europe
Non-EU approved establishments	lists of approved facilities in non-EU countries
OIE	World Organisation for Animal Health (OIE)
TRACES	TRAde Control and Expert System (New Technology)