FAQs

New regulations for importing animal by-products and animal derived products into and within the European Union

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What is the purpose of legislation controlling the movement of animal derived material?

The purpose of legislation to control the movement of animal by-products through the European Community is primarily to protect human and animal health within the Community.

The legislation also requires full traceability of animal derived material which is not for human or animal consumption in order to prevent material imported into the EU from re-entering the human or animal food chain.

Following the 1986 outbreak of Mad Cow Disease (Bovine Spongiform Encephalitis, BSE) in the UK and a dioxin contamination event in Belgium in 1992, new regulations were devised by the European Union in an attempt to control the import of potentially diseased or otherwise contaminated animal derived material. This Regulation (EC) 1774/2002 was rushed into existence and subsequently required numerous amendments or derogations.

In 2009 a new Regulation (EC) No 1069/2009 passed into European law with the intention of clarifying some of the issues raised by Regulation (EC) No1774/2002 and its derogations, and to give a clear framework based on a risk assessment philosophy. Regulation (EU) No 142/2011 has been developed to provide clarity and detailed provisions for the implementation of Regulation (EC) No 1069/2009.

Will this legislation affect me?

If you import animal derived materials into the EU, or supply such materials to someone who then imports into the EU, you will almost certainly be impacted by these regulations

What regulations and what is their focus?

Regulation (EC) No 1069/2009 is the basic outline regulation covering the import of animal derived material not for human or animal consumption and Regulation (EU) No 142/2011 is the document providing the implementing rules. Together these documents address both animal by-products and animal derived products and cover all aspects of the collection, processing and transport of these materials both into and within the European Community.

Here are the official titles and descriptions of both of these regulations together with links to both:.

REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

http://www.serumindustry.org/documents/Regulations-EC10692009.pdf

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF

COMMISSION REGULATION (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council 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

http://www.serumindustry.org/documents/142-2011.pdf

http://europa.Lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:054:0001:0254:EN:PDF

What is DG SANCO?

DG SANCO is the acronym for the Directorate General for Health and Consumer Affairs of the European Community. It forms part of the European Commission, and is the regulatory body of the European Union. As such, it takes guidance and comment from the competent authorities in each European Community member state. In turn, each European Community member state has a team dedicated to resolving any issues with DG SANCO and can provide support as required.

DG SANCO is directly responsible for:

- the preparation and implementation of EU Law governing food and related products
- legislation concerning consumer rights and the protection of public health.
- the development of amendments and derogations of legislation.

What is TRACES?

TRACES stands for TRAde Control and Expert System, a system which has been providing traceability for material entering the European Community since 2004.

On March 4, 2011 the EU launched a new section of their electronic TRACES database. The EU now requires third country facilities exporting animal by-products under Regulation (EC) No 1774/2002 (or its successors, Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011) to be listed in TRACES.

Animal derived products entering the European Community must come from, and go to, establishments which are listed in TRACES both in the European Community and in 3rd countries (there are exceptions - see Guidance Document). The consignment must be recorded in TRACES so that its whereabouts may be established at any time while the product falls under the animal by products regulations.

Does my facility require approval / registration?

If your facility or establishment handles, stores, or processes any animal by-products intended for export to the European Community, then you will need to be approved and/or registered by the competent authority of the member state or 3rd country of your establishment's location. Care must be taken to ensure that the facility is listed in the appropriate section(s) under TRACES.

What is meant by "sections under TRACES"?

'Sections" refers to the type of facility being listed. These include Slaughterhouses, Dairy plants, other facilities, Processing plants, Plants manufacturing intermediate products and Storage (facilities) of derived products. There are also other plants or establishments referred to under TRACES but which are not in this sector. For more details, refer to the ISIA/EDMA Guidance Document.

How do I apply for registration?

We suggest that initial contact should be through your local competent authority for the appropriate application forms and advice.

How do I import an animal by-product for technical use?

Technical use means any use other than for human or animal consumption. There is no quick and simple answer to this but general requirements include:

- needing to source from a facility registered in TRACES

- being registered yourself, which means complying with a variety of sanitary and administrative requirements

Detailed information may be found in the ISIA/EDMA Guidance Document.

What types of product are covered by the legislation?

Most animal by-products or derived products not intended for human or animal consumption, with the exception of pet food, are covered by the regulation.

What are Categories?

Animal by products and derived products covered by this legislation are categorised as Category 1, 2 or 3; each successive category being assessed as presenting a decreasing risk to animal or human health with Category 1 being of higher perceived risk and Category 3 a lower risk.

Regulation (EC) No 1069/2009 (see link above) details the criteria for the categorisation of material and this is also covered fully within the ISIA/EDMA Guidance Document.

What Category is Fetal Bovine Serum?

Fetal Bovine Serum (FBS) is to be considered as Category 3 material. A recent comment from DG SANCO stated: The fetal bovine blood harvested from fetuses, which have been obtained from bovine animals slaughtered in the slaughterhouse should be Category 3 material. If the fetus is aborted as a result of a particular disease or stillborn that material should be considered Category 2 material.

Do I need a Veterinary certificate?

Veterinary Health certificates are required for certain materials falling under certain categories. Full details of the types of certificates required and how these should be completed are shown in the ISIA/EDMA Guidance Document.

How do I complete a certificate?

Carefully and correctly! This is very important since minor errors may result in a shipment being rejected.

Your local Veterinary office or Border Inspection Post (BIP) of entry into the European Community will be able to offer advice as to the paperwork required. This is important since there is still local interpretation as to current requirements.

The ISIA/EDMA Guidance Document gives much additional information on this subject.

What are Harmonised Tariff Codes?

Harmonised Tariff Codes are codes devised to enable products to be easily assessed for customs duty (hence 'Tariff') and also serve as an indicator to customs and veterinary officials as to whether a consignment requires veterinary inspection.

What happens to a consignment on import?

Shipments are assessed by customs to ascertain if the material requires veterinary inspection by the Border Inspection Post (BIP) at which time, the paperwork (such as health certificate and/or commercial document) must be correct.

Following approval by the BIP, the importer or their shipping agent may take delivery of the shipment for immediate transport to the nominated establishment of destination.

What is Traceability? Why is Traceability important?

Traceability is the paper trail that establishes the provenance of a product. This covers movement from the establishment of origin all the way to the final facility within or (for goods in transit) outside of the European Community until the material is ready to be placed on the market. At any point in the supply chain, the establishment having control of the product must be able to satisfy an audit to demonstrate the ultimate origin(s) of the material in an unbroken chain.

Are there special requirements for packaging?

In general terms, there are no specific additional packaging requirements driven by this legislation. However, the relevant health certificate under which the material is imported specifies certain packaging requirements, further details of which are listed in the governing regulations and which are also dealt with in the ISIA/EDMA guidance document.

Is there a special requirement for labelling?

Yes, depending upon the Category, processing and final use of the material, there are various labelling requirements (e.g. colour coding and specific wording) that must be met. Full details of these requirements are given in the relevant section of the ISIA/EDMA Guidance Document.

Can I CE mark my product to avoid Veterinary inspection?

NO!

The manufacturer of an IVD product must CE mark the product if the intention is to sell the product within the European Community. The legal term of 'manufacturer' is defined in Article 1 of the IVD Directive 98/79/EC as the person or company that places the IVD or IVD kit on the market under their own name.

A third party manufacturer or supplier of product intended for IVD use cannot be considered the manufacturer.