

# Glossary of Terms and Definitions



INTERNATIONAL SERUM  
INDUSTRY ASSOCIATION

**'active implantable medical device'** means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

[Directive 90/385/EEC](#) Article 1(2)(c)

**'altered serum'**. See 'Modified serum'.

Serum industry standard. ISIA approved

**'animal'** means any invertebrate or vertebrate animal

Regulation (EC) No 1069/2009 Art 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 (EC) No 1069/2009 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](#). See Chapter 8



Miller-Keane Encyclopedia 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 (EC) No 1069/2009.

Regulation (EC) No 1069/2009 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 (EC) No 1069/2009 Article 24 (1) (i) and which includes storage of animal by-products and/or derived products for certain purposes;

Regulation (EC) No 1069/2009 Article 24(2) states that:

*the approval referred to in paragraph 1 shall specify if the establishment or plant is approved for 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.

**'artiodactyla'** means an order of mammals that comprises the even-toed ungulates (see 'ungulates').  
<http://oxforddictionaries.com>

**'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 (EU) No 142/2011 Annex I Point 50 page 37

**'blood'** means fresh whole blood.

Regulation (EU) No 142/2011 Annex I Point 2 page 33

Note: see also 'whole blood'.

**'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 (EU) No 142/2011 Annex I Point 4 page 33

**'Border Inspection Post' (BIP)** means point of entry for animal derived product into the European Union

**'bovine serum albumin (BSA, also known as Cohn Fraction V)'** means [albumin](http://en.wikipedia.org/wiki/Bovine_serum_albumin) protein manufactured from serum by manipulating solvent concentrations, pH, salt levels and temperature. It has numerous biochemical applications.

[http://en.wikipedia.org/wiki/Bovine\\_serum\\_albumin](http://en.wikipedia.org/wiki/Bovine_serum_albumin)

**"bovine serum – other types"** can be provided 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). See Fetal bovine serum for further definition

Serum industry standard. All definitions are ISIA approved

**"neo-natal bovine calf serum"** (NNBCS) is defined as the liquid fraction of clotted blood derived from newborn calves that have not suckled from the mother cow. It is collected in abattoirs inspected by the competent authority of the country of origin. There are no deletions or additions (including preservatives) allowed.

**"newborn bovine 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.

**'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.

**"Donor-sourced Bovine Serum"** (DBS) is defined as the liquid fraction of clotted blood derived from healthy cattle 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.

**“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.

**“Adult Bovine Serum Analog”** (ABSA) is defined as the product obtained by treatment of Adult Bovine Plasma by the addition of calcium and subsequent dialysis, or by freezing. Both these methods result in clotting of fibrin and its removal. The plasma must be 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.

**‘carcase’** means the body of an animal after slaughter and dressing.  
(EC)853/2004 Annex I point 1.9

**‘category’ or categories’** these are covered in [‘Categories’](#) section. See page **Error! Bookmark not defined.**

**‘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.  
<http://www.cites.org/eng/disc/what.php>

**‘collection centers’** means premises other than processing plants in which the animal by-products referred to in Article 18(1) of Regulation (EC) No 1069/2009 are collected with the intention to be used for feeding to the animals referred to in the same Article  
Regulation (EU) No 142/2011 Annex 1 point 53

This definition of ‘collection center’ outlines collection centers whose focus is on animal by-products for specific feeding purposes and is, therefore, not directly relevant to this sector. Within the Sector, ‘collection center’ is interpreted as premises other than processing plants where animal by-products (such as blood products and tissues) are harvested and stored.

Note: Collection centers may not have the same registration or approval number as processing facilities

**‘country of origin’** (often abbreviated to COO) means the country of manufacture, production or slaughter where a product comes from, i.e. where the animal that was the source of the ABP or derived product was raised or slaughtered.

Note: The ISIA defines the country of origin to be determined by where the animal was slaughtered. According to the ISIA Traceability program, Certificates of Analysis must reflect all origins present (if in fact a mixture of sources exists) and also reflect the percentages of each. ISIA discourages using mixtures of sources except in specific instances such as Central American serum. However in complex Intermediate Products containing two or more derived products of differing origins, the country of manufacture of the completed intermediate product is applicable.  
Serum industry standard. ISIA approved

**‘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 (EU) No 142/2011 Annex I Point 44 page 37

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. (see [Labelling](#) page **Error! Bookmark not defined.**)

**‘Commercial Document’** *this 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 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 (EU) No 142/2011 Annex VI Section 1(1)

A model of a commercial document appears in Annex VIII Chapter III of Regulation (EU) No 142/2011 on page 96

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. See also page **Error! Bookmark not defined.** of this document for information on completing [Commercial Documents](#).

**‘commercial invoice’** means a list of goods sent or services provided, with a statement of the sum due for these; a bill. A commercial invoice may be accepted as a commercial document by the member state authorities.

<http://oxforddictionaries.com>

**‘commodity code’** (HS Code or HTS Code in the US) (see also ‘Tariff Number’) 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) (formerly the Customs Co-operation Council), an independent intergovernmental organization with over 170 member countries based in [Brussels, Belgium](#).  
<http://en.wikipedia.org/wiki/Harmonized>

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.

<http://hscode.org/>

Many different types of product may be listed under the same HS code but require different levels of documentation.

**‘CVED’** (The Common Veterinary Entry Document) is the certificate is issued by the Border Inspection Post for all consignments presented, whether they are for consignments presented as meeting EU requirements and are for free circulation, consignments that will be subject to channelling or those consignments not meeting EU conditions and destined for transshipment, transit, or their placing in free zones, free warehouses or customs warehouses or for ship suppliers (chandlers). Channelling refers to consignments accepted under the conditions laid down in Article 8 of Directive 97/78/EC but that remain under veterinary control until a specified final destination is reached, usually for further treatment.

<http://www.food.gov.uk/multimedia/pdfs/blankcved.pdf>

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

Regulation (EC) No 1069/2009 Article 3(2)

Note: See definition for ‘treatment’, ‘transformation’ and ‘processing’

**'destination'** see 'place of destination'.

**'end point'** means that the product or material has been processed or transformed in such a way that it is considered not to pose significant risk to human or animal health and may be removed from the scope of Regulation (EC) No 1069/2009.

Material can reach an 'end point' once it is a 'commercial product', i.e. the intended use has been defined and it may be demonstrated that there is no risk involved if the product is used as intended. Précis of Regulation (EC) No 1069/2009 Preamble point 22

**'end user'** this is an individual or entity who uses a product after it has been fully developed and/or marketed.

See definition for 'user' below.

**'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 (EC) No 1069/2009 Article 3(13)

**'experimental animals'** see 'Animals used in a procedure or procedures' (above)

**'facilities' or 'premises'** means a plant, site or establishment; a place where a process is carried out

Note: Facilities may also be used to describe catering or sanitary areas within a plant or establishment. See also 'site'.

*Facility: a place, amenity, or piece of equipment provided for a particular purpose*

*Premises: a house or building, together with its land and outbuildings, occupied by a business or considered in an official context*

<http://oxforddictionaries.com>

**'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 (EC) No 1069/2009 Art 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 FBS"** 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. All following definitions are ISIA approved

**"Clarified FBS"** 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 processing.

**"Aseptically filtered 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, labeling and

placing on the market. No further processes, additions or deletions are allowed. Sterile filtered FBS is stored frozen.

Sterile filtered FBS may be treated using gamma irradiation or heat inactivation and additionally labeled to indicate the treatment method used.

**“Pre-Qualified or Screened FBS”** 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 labeled according to the application for which it has been qualified.

**‘Specialty FBS’** 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, pH treated, Performance Enhanced, Dehydrated and Reconstituted. Specialty FBS must be labeled in a manner that clearly identifies it as having been modified, enhanced or altered.

**‘fresh whole blood ’** is not defined in the Regulation.

It is an animal by-product and 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

**‘GBR (Geographical BSE-Risk)’** is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE (Bovine Spongiform Encephalopathy), pre-clinically as well as clinically, at a given point in time, in a country. Where its presence is confirmed, the GBR gives an indication of the level of infection.

SSC/ 11/01/2002/ 6.2.c.1 (Scientific Steering Committee)

Note: This terminology is no longer to be used in conjunction with Regulation (EC) No 1069/2009 since this document relies on OIE classification. See also Regulation (EC) No 1069/2009

**‘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://en.wikipedia.org/wiki/Hemoglobin>

Note: hemoglobin extracted from bovine or other vertebrate blood is a blood derived product.

**‘HGP - Hormonal Growth Promotants’** are a group of veterinary drugs that mimic the hormones that influence cattle growth.

[http://www.dpi.qld.gov.au/4790\\_6473.htm](http://www.dpi.qld.gov.au/4790_6473.htm)

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 (EC) No 1069/2009.

Note: HGPs are regulated by Directives [96/22/EC](#) and [96/23/EC](#)

**‘hydrolyzed proteins’** means *polypeptides, peptides and amino acids, and mixtures thereof, obtained by the hydrolysis of animal by-products.*

Regulation (EU) No 142/2011 Annex I Point 14 page 34

**‘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. As of January 1, 2011 the eighth edition, Incoterms 2010 have effect. The number of Incoterms® rules has been reduced from 13 to 11. The new terms apply to all modes of transport.

<http://en.wikipedia.org/wiki/Incoterm>

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

Regulation (EU) No 142/2011 Annex I

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’** is a derived product with specific intended uses as listed in the Regulation.

An intermediate product requires some further handling for final use in the bio-medical sector.

The text states:

(a) which is intended for the manufacture of medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, in vitro diagnostic medical devices or laboratory reagents;

(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 that purpose;

(c) which however requires some further handling or transformation, such as mixing, coating, assembling, packaging or labelling to make it suitable for placing the product on the market or putting it into service, as applicable, as a medicinal product, veterinary medicinal product, medical device, active implantable medical device, in vitro diagnostic medical device or laboratory reagent.

Regulation (EU) No 142/2011 Annex I Point 35 See [‘Intermediate Products’](#)

**‘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 1(b)

**‘laboratory animal’** could be an **‘experimental animal’** or a **‘farmed animal’** and is an animal bred for purpose or maintained for purpose. These include rats, mice, rabbits and guinea pigs. In special-use laboratories additional animal species can be added, e.g. hamsters, non-human primates, amphibians, fowl, sheep and pigs.

<http://medical-dictionary.thefreedictionary.com>

Note: this is a complex issue and a detailed explanation will be given in the Laboratory Animal section (which is yet to be completed, subject to input from Member States). However, from a veterinary point of view within the scope of Regulation (EC) No 1069/2009, 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.

ISIA

**'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 (EU) No 142/2011 Annex I Point 36 page 36

Note: 'Laboratory reagents' are regarded as finished products (see Preamble Regulation (EU) No 142/2011 Point 30) with specific intended use and may therefore be deemed to have reached 'end point'.

See '[Finished Products](#)' on page **Error! Bookmark not defined..**

**'medical device'** [Comment: This definition has been amended by Directive 2007/47/EC] therefore see definition given in 2007/47/EC, means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes:

diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

See Directive 93/42/EEC Article 1(2)(a) as amended by Directive 2007/47/EC

See '[Finished Products](#)' on page **Error! Bookmark not defined..**

**'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) See '[Finished Products](#)' on page **Error! Bookmark not defined..**

**'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 should be 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 newborn calves that have not suckled from the mother cow. There are no deletions or additions (including preservatives) allowed.

Serum industry standard. ISIA approved

**'newborn 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

**'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 (EC) No 1069/2009 Article 3(11)

Note: The preamble of Regulation (EC) No 1069/2009 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 please see Obligations of Operators Regulation (EC) No 1069/2009: Article 21 (Collection and identification as regards category and transport) and Article 22 (Traceability)

**‘place of destination or establishment of destination’** means the plant, establishment, operator or user as specified in Box 1.12 of model certificates and declarations and Box 1.13 of the model Commercial Document.

The note to these indicates that this may require the “approval number or registration number” as appropriate.

Regulation (EU) No 142/2011 Annex XV

**‘premises’ see ‘facilities’**

**‘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’** is 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 (EC) 853/2004 Annex I point 1.9), and may fall within the scope of Regulation (EC) No 1069/2009 if used as a source of animal by products and derived products. Other parts of animals slaughtered which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons.

**‘pathogenic’** (agent) means any disease-producing agent, especially a virus, bacterium, or other microorganism.

<http://dictionary.reference.com/browse/pathogen>

**‘perissodactyla’** means an order of mammals that comprises the odd-toed ungulates and includes equidae (horses and donkeys).

<http://oxforddictionaries.com>

**‘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 (EC) No 1069/2009 Article 3(14)

Note: If not stated otherwise this includes the importation of products

**‘plant’ or ‘establishment’** see ‘establishment’ above

**‘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. The plasma is then removed and may be stored frozen pending further use or processing.

Plasma is a derived product of blood according to Regulation (EU) No 142/2011

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.

Wikipedia

**‘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

**'process'** means a systematic series of mechanized or chemical operations that are performed in order to produce something.

<http://oxforddictionaries.com>

Note: one or more treatments, transformations or steps of processing of animal by-products, such that the processed material is different to the original material by the addition or removal or transformation of material by a chemical, bio-chemical, mechanical or other procedure/s.

Chilling or freezing, packaging and/or labelling are not considered 'processes' but are considered 'activities'.

**'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 feeding stuffs, 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, gelatin, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.

Regulation (EU) No 142/2011 Annex 1 Point 5 page 33

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 (EU) No 142/2011.

Regulation (EU) No 142/2011 Annex 1 Point 49

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

**'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 (EU) No 142/2011 Annex 1 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 (EU) No 142/2011 Annex I Point 37 page 36

Note: CE marking of product reflects that the material is in full compliance with the IVD Directive EC78/97 and therefore is outside the scope of this 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 (EC) No 1069/2009 Article 3(3)

Note: Some of these products may be source material for our Sector by law or by choice (see Preamble Regulation (EC) No 1069/2009 Point 12)

**'prohibited substances'** see definition of 'HGPs'

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

Regulation (EC) No 1069/2009 Article 23

Note: registration does not constitute 'approval'

**'research and diagnostic samples'** means 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 (EU) No 142/2011 Annex I Point 38 page 36

Note: These types of samples are NOT FOR COMMERCIAL PURPOSES

See ['Samples'](#) on page **Error! Bookmark not defined..**

**'scrapie'** means a disease of sheep involving the central nervous system, characterized by a lack of coordination causing affected animals to rub against trees and other objects for support, and thought to be caused by an infectious agent such as a prion. See 'TSE'

<http://oxforddictionaries.com>

**'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 (EU) No 142/2011

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 or more establishments or plants.

Note: the word 'site' may also be used as 'place' within the text of the regulation.

**'slaughter'** means causing the death of an animal by bleeding

[Directive 93/119/EC](#) Article 2(7)

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

Regulation (EC) No 1069/2009 Article 3(18))

Note: for details on [SRMs](#)/GRMs refer page **Error! Bookmark not defined..**

**'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 (EC) No 1069/2009 from Preamble Point 21

**'storage plant'** is a term that no longer exists under Regulation (EC) No 1069/2009

**'suidae'** means an omnivorous domesticated hooved mammal with sparse bristly hair and a flat snout for rooting in the soil, kept for its meat (e.g. pig, warthog, boar, babirusa).

<http://oxforddictionaries.com>

**'technical plant'** is a term that no longer exists under Regulation (EC) No 1069/2009

**'technical product'** is a term which is not defined or mentioned in the legally binding text of Regulation (EC) No 1069/2009

**'technical use'** is a term used in section 1.25 on certain model certificates in Annex XV of 7066 for products destined for any use other than for animal consumption.

Regulation (EU) No 142/2011

**'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 (EU) No 142/2011 .

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.

ISIA

**'TRACES'** (**TR**AdE **C**ontrol and **E**xpert **S**ystem) the EU Trade Control and Expert System, is an internet-based service initially set up to provide traceability of live animals. Through TRACES information between all relevant national and Community authorities is coordinated, to provide a rapid reaction in case of animal diseases outbreak. Movements for live animals, animal products and germ plasma within the EU are also monitored, so that traders can be provided with the equivalent certificates. TRACES assists in the management of intra and extra community trade of live animals and animal products

<http://ec.europa.eu/idabc/en/document/5377/5637.html>

*The purpose of the integrated computerised veterinary system 'TRACES' is to provide assistance in the certification for all veterinary authorities within an informatics network to improve the sanitary protection in the EU: sanitary control of animals and animal products, tracing back and forth of outbreaks of diseases, integration of EU, EFTA/EEA and Third Country competent veterinary authorities.*

<https://sanco.ec.europa.eu/traces/security/privacy.do>

See also [2002/459/EC](#)

**'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 (EU) No 142/2011 Annex I Point 48 page 37

**'trade samples'** means animal by-products or derived products intended for particular studies or analyses with a view to carrying out a production process or developing feeding stuffs or other derived products, including testing of machinery, for use in an establishment or plant which is:

- (a) producing feeding stuffs, or products for uses other than food and feed; or
- (b) processing animal by-products or derived products

Regulation (EU) No 142/2011 Annex I Point 39

Note: The sector believes that Trade Samples as defined above are not relevant to our industry sector

**'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 through the Community from the territory of a Third Country to the territory of another Third Country, other than by sea or by air;

Regulation (EC) No 1069/2009 Article 3(15)

**'transmissible spongiform encephalopathies (TSEs)'** means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation ([EC](#)) [999/2001](#).

Regulation (EC) No 1069/2009 Article 3(17)

Note: For a full set of definitions and further information please refer to SRMs/GRMs in this document

**'TSEs'**: *means all transmissible spongiform encephalopathies with the exception of those occurring in humans.*

(EC) No 999/2001 Article 3(1)(a)

Note: These include Bovine Spongiform Encephalitis of cattle (BSE or Mad Cow Disease) and classical scrapie in sheep and goats. For further information please see Specified Risk Material ([SRM](#)) section on page **Error! Bookmark not defined.** of this document

**'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 notes on model Health Certificates 4(a) and 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 hoofed mammals

Oxford English Dictionary

**'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 (EC) No 1069/2009 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 fresh blood"** is not modified, treated or processed and contains no additives.

Serum industry standard. ISIA approved

**'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