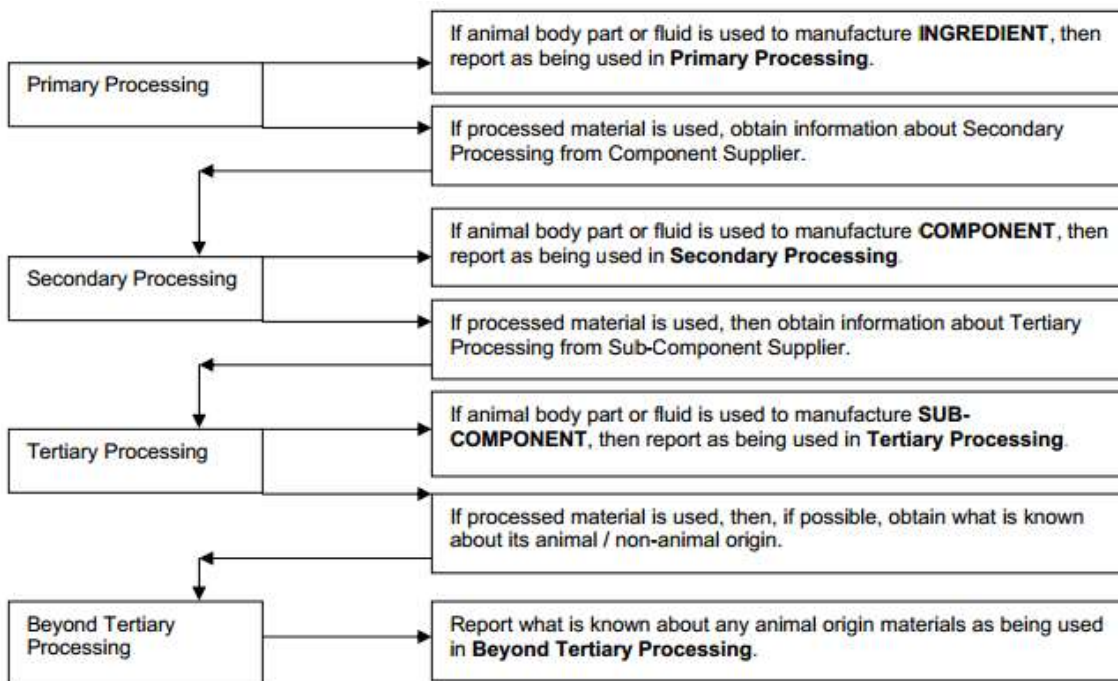




Animal Origin Position Statement

It is the policy of **BD Life Sciences – Integrated Diagnostic Solutions** (hereafter referred to as BD) to inform customers of animal origin materials used in the manufacture of BD finished products and in the manufacture of any of the materials used by BD, using Certificates of Analysis (COA) available from the Internet at www.bd.com/regdocs. This animal origin information is obtained either directly from the BD suppliers of animal body parts and fluids ('animal tissues') or from the BD suppliers of pre-processed ingredients.

If an animal source table is provided on a BD COA, then those animal tissues were used either in Primary Processing or Secondary Processing. If animal tissues are used in Tertiary Processing or Beyond Tertiary Processing, then this information is shown as a statement on the BD COA below the animal source table. It is important to note that for materials manufactured by cell culture or fermentation, BD considers the cell's intracellular processes as a level of processing in the schema shown below.



Animal Origin Position Statement (Continued)

A. BD Traceability System

1. Since 1991, BD has continuously worked to limit the Bovine Spongiform Encephalopathy (BSE) risk of our products by stringent safety & traceability requirements for our animal origin materials. We work closely with our international and domestic suppliers in order to provide our customers with extensive documentation of our products, including animal origin information on Certificates of Analysis (www.bd.com/regdocs), and Certificates of Suitability.
2. BD requires our suppliers to complete a detailed questionnaire titled "Safety & Traceability Questionnaire for Suppliers of Ingredients & OEM Products" in order to assess the origin, traceability and safety of our purchased materials. The questionnaire is re-sent to existing suppliers of animal sourced raw materials, and certain non-animal materials, approximately every three years in order to verify existing information and to obtain new information as regulations and customer requirements change.
3. The questionnaire includes, but is not limited to, questions about the following: country of origin (i.e., where the tissues are obtained directly from the animals), slaughter method, animal health status, regulatory body for the processing facility that determines animal health, age of animals, animal tissues used, processing performed that may reduce biobload, equipment cleaning, and genetic modification of any plant, animal, or microbe components used.
4. Information obtained from the questionnaire is incorporated into our Buy Specifications, incoming inspection procedures, and material origin databases. BD's supplier specifications require suppliers to notify BD in advance of making any changes to both the materials purchased by BD and the practices that affect the information provided to BD in the BD Safety & Traceability Questionnaire.
5. Each animal origin material purchased by BD requires a Certificate of Origin from the BD supplier stating animal species, country of animal origin, and country of material manufacture. Typically these must be lot-specific for each lot of animal origin material supplied to BD. In some instances, an Annual Supplier Certificate of Origin is acceptable as long as it provides the animal species, country of animal origin, and country of material manufacture that will be used exclusively for every lot provided to BD during the calendar year in question.

B. BD Animal Related Product Definitions

1. **Animal Origin Ingredient:** A material used by BD in a finished product formulation where either the material itself is an animal tissue, or it is made using an animal tissue, or one or more of the ingredient's components is made using an animal tissue. In the latter case, the BD supplier certifies to BD information obtained from the ingredient component's supplier.
2. **Animal Component Free Product:** These products have no animal tissues used as ingredients in the manufacture of the BD finished product.
3. **Animal Free Product:**

NOTE #1: If BD learns from an ingredient supplier that an animal tissue was used in a tertiary processing step, then the involved BD finished product(s) may continue to be designated as Animal Free. However, such BD finished products must be designated Animal Free Level I and may not be manufactured in either dedicated BD Animal Free equipment (Level II) or facilities (Level III).

NOTE #2: For information about the specific Animal Free Level of a non-animal BD product, send your e-mail inquiry to BDDS.Customer.Questionnaires@bd.com.

- a. **Level I - Animal Free / Multi-Use Facility & Equipment Product.** None of the ingredients or ingredient components is made using animal tissues. Manufacturing, blending and packaging equipment may be used for Animal Free and Animal Origin Products, but this equipment must have been cleaned following a procedure validated to remove product residue.
- b. **Level II - Animal Free / Dedicated Process Product.** None of the ingredients, ingredient components, ingredient sub-components, or product contact packaging material is made using animal tissues. For **final BD product**, the manufacturing, blending and packaging equipment must be dedicated to, and exclusively used for, Animal Free Products.
- c. **Level III - Animal Free / Dedicated Process & Facility Product.** None of the ingredients, ingredient components, ingredient sub-components, or product contact packaging material is made using animal tissues. For **final BD product**, the manufacturing, blending and packaging equipment must be dedicated and exclusively used for Animal Free Products in facilities dedicated to, and exclusively used for, Animal Free Products.

Animal Origin Position Statement (Continued)

C. Animal Sources for Raw Materials

1. BD sources ruminant-origin materials primarily from Australia, New Zealand, and the USA. Non-ruminant animal origin materials are sourced from a variety of countries.
2. BD suppliers must meet BD standards for safety and traceability. BD has standards for traceability, animal health, regulatory body determining/monitoring animal health, tissue and country of tissue origin.
3. BD's sourcing policy for each acquired material is based upon assessments (A) of tissue/country risk for any and all Transmissible Spongiform Encephalopathy (TSE)-relevant species tissues used, and (B) of supplier equipment exposure to tissue/country risk for any and all TSE-relevant species used. Sourcing priority is given to countries with BSE/TSE OIE Negligible or OIE Controlled Risk status, and countries that have an active veterinary disease surveillance program. (OIE = World Organization for Animal Health)
4. In addition to products of animal origin, BD provides a number of non-animal products.
 - a. We designate products as "Animal Free" if, at a minimum, all ingredients and ingredient components have been certified by our suppliers to not be made using animal tissues.
 - b. For Animal Free Level I Products, animal tissues may be used in tertiary processing only (i.e., in the manufacture of ingredient sub-components). Such products are manufactured in BD's multi-use facility using BD's multi-use equipment that has been validated to remove product residue.
 - c. For Animal Free Level II Products, animal tissues may be used in beyond-tertiary processing only. Manufacturing must take place in an animal-free suite.
 - d. For Animal Free Level III Products, animal tissues may be used in beyond-tertiary processing only. Manufacturing must take place in an animal-free facility.
5. Those customers that require additional safeguards are encouraged to take advantage of the following BD options for controlled raw material origin or animal-free solutions:
 - a. Non-animal media formulations.
 - b. Possible controlled animal origin options include the following:
 - Country of origin sourcing from select countries
 - Formulations using materials from non-TSE species
 - Formulations using lower risk category tissues
6. The animal tissues used in the manufacture of culture media are harvested from animals that are free of symptoms of infections or contagious diseases. For animal tissues sourced from slaughterhouses, the animals are deemed healthy by ante and post-mortem inspection in USDA licensed facilities, or the foreign government equivalent, where animal tissues are sourced outside the United States. For donor herd materials (e.g., milk, blood), the animals are either deemed fit for human consumption or deemed clinically healthy.
7. No guarantee can be made concerning the feeding practices followed for the specific animals used in BD products. BD relies on the respective governments in the source countries to control animal feed importation, animal importation, animal feeding practices, and rendering industry processes, and, thereby, prevent the introduction of BSE and other TSEs into their animals.
8. The vast majority of animal tissues are sourced from animals older than 6 months of age.

Animal Origin Position Statement (Continued)

D. BIC, SIC and ABC Tissue Categories for Animal Tissues

In order to provide information to our customers concerning animal tissues used, and yet not divulge proprietary ingredient information, BD provides tissue categories rather than tissue names on our Certificates of Analysis that contain an Animal Source table. BD applies these tissue categories to all animal and human origin materials used, and to all animal tissues used, and not just to bovine, ovine, or other TSE-relevant species. For the specific categories and their respective animal tissues, please see table below, "BD Tissue Categories, Based on the Three Published Reference Sources." Those references are as follows:

- BIC: Tissues listed as High Infectivity (BIC I), Medium Infectivity (BIC II), Low Infectivity (BIC III), and No Detectable Infectivity (BIC IV) originated from Executive Summary of the November 21, 1997 meeting of the European Community's Scientific Steering Committee Working Group on SRM (Specified Risk Materials). Categories were designed to reflect BSE infectivity.
- SIC: Tissues listed as High Infectivity (SIC I), Medium Infectivity (SIC II), Low Infectivity (SIC III), and No Detectable Infectivity (SIC IV) originated from *Biologicals*, 1992, Volume 20, Pages 155-158, article entitled, "EEC Regulatory Document, Note for Guidance." Categories were designed to reflect relative scrapie infectivity titers.
- ABC: Tissues listed as High Infectivity (ABC - IA), Lower Infectivity (ABC - IB) and No Detectable Infectivity (ABC - IC) originated from EMA/410/01 Rev 3, the European Commission's "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products", effective July 1, 2011. Categories were designed to reflect TSE infectivity in TSE-relevant species.

BD Tissue Categories, Based on the Three Published Reference Sources								
Tissue	BIC	SIC	ABC		Tissue	BIC	SIC	ABC
Adipose Tissue, discrete	IV	IV*	IB		Milk - Bovine Health Uncertain	IV	IV	IB
Adrenal or Adrenal Gland	II	II	IB		Milk - Non-Bovine	IV	IV	IB
Albumin	IV*	IV*	IB*		Nasal Mucosa	III	III	IB
Amniotic Fluid	IV*	IV*	NDF		Nasal Mucus	NDF	NDF	IC
Appendix	NDF	NDF	IB		Nictitating Membrane	NDF	NDF	IB
Ascites Fluid	IV*	IV*	NDF		Olfactory Mucosa	III	III	IB
Autonomic Ganglia	II	II	IB		Optic Nerve	I	I	IA
Bile	IV	IV	IC		Ovary	IV	IV	IB
Blood	IV*	IV*	IB		Pancreas – Gland and/or Enzyme	III	III	IB
Blood Clot	IV	IV	IB*		Peptic Enzyme	II*	II*	IB
Blood Vessels	NDF	NDF	IB		Peripheral Nerves	III	III*	IB
Bone	III	IV	IC		Pineal Gland	I	II	NDF
Bone Marrow	III	III	IB		Pituitary Gland	I	II	IA
Bone with Vertebrae	I	IV	IC		Placenta	II	II	IB
Brain	I	I	IA		Placenta Fluids	II	II	IC
Cartilaginous Tissue	IV	IV	NDF		Plasma	IV*	IV*	IB
Cerebrospinal Fluid	II	II	IB		Prostate	IV*	IV*	IC
Colon / Caecum	II	II*	IB		Proximal Colon	II	II	IB
Colostrum	IV	IV*	IC		Rectum	II	III	IB
Connective Tissue	IV	IV	NDF		Retina	I	I	IA
Cord Blood	NDF	NDF	IC		Saliva	IV	IV	IB

Animal Origin Position Statement (Continued)

BD Tissue Categories, Based on the Three Published Reference Sources							
Tissue	BIC	SIC	ABC	Tissue	BIC	SIC	ABC
Cornea	I	I	IB	Salivary Gland	IV	IV	IB
Dental Pulp	NDF	NDF	IC	Sciatic Nerve	III	III	IB*
Distal Colon	II	III	IB*	Seminal Testis	IV	IV	IC
Dorsal Root Ganglia	I	I	IA	Seminal Vesicle	IV*	IV	IC
Duodenum	II	II*	IB	Semen	IV*	IV	IC
Dura Mater	I	II	IA	Serum	IV	IV	IB
Eggs	IV	IV*	NDF	Shell	IV*	IV*	NDF
Embryos	II*	IV*	IC	Skeletal Muscle	IV	IV	IB
Enteric Plexuses	II	II*	IB	Skin	IV	IV	IB
Epididymus	IV*	IV*	IC	Skull	I	IV	IC
Esophagus	II*	II*	IB	Sperm	IV	IV	IC
Eye	I	I	NDF	Spinal Cord	I	I	IA
Feces	IV	IV	IB	Spinal Ganglia	I	I	IA
Fat	IV	IV*	IB	Spleen - Bovine and Other Species	II	II	IB
Feathers	IV*	IV*	NDF	Spleen - Ovine & Caprine	I	II	IB
Fetal Blood	II	IV	IB	Stomach / Abomasum,	II*	II*	IB
Fetus	II	IV	IC	Stomach Linings	II*	II*	IB
Fetal Tissue	II	IV	IC	Sweat	IV*	IV*	IC
Fore-Stomach	II*	II*	IB	Tears	IV*	IV*	IC
Gingival Tissue	IV*	IV*	IC	Tendon	IV	IV	IC
Hair	IV	IV	NDF	Testis	IV	IV	IC
Heart / Pericardium	IV	IV	IB	Thymus	III	III	IB
Hooves	IV*	IV*	NDF	Thyroid Gland	IV	IV	IC
Ileum	II	II	IB	Tongue	IV*	IV*	IB
Intestinal Mucosa	II	II*	IB*	Tonsil	II	II	IB
Intestine , Total	II	II*	IB*	Trachea	IV*	IV*	IC
Jejunum	II	II*	IB	Trigeminal Ganglia	I	I	IA
Kidney	IV	IV	IB	Umbilical Cord	II*	II*	IB*
Large Intestine	II	III*	IB*	Urine	IV	IV	IB
Liver	III	III	IB	Uterus (non-gravid)	II	IV	IB
Lung	I	III	IB	Vertebral Column	I	IV	IC
Lymph Nodes	II	II	IB	Whole Animal	I*	I*	IA*
Mammary Gland / Udder	IV	IV	IB	Wool	IV*	IV*	NDF
Milk - Bovine Healthy	IV	IV	MLK**				

KEY:
 * = Category assigned by BD due to such tissues being used by BD suppliers, originating from any animal species, and needing tissue code(s) in order to be represented on BD Certificates of Analysis. Code assignment was based upon BD decisions about similarities to tissues found in the respective regulatory documents.
 ** = BD assigned "MLK" code to the ABC category for bovine milk from healthy animals due to the Note for Guidance indicating that this tissue is in compliance with the Note for Guidance and yet listing all milk as Category IB. This code will best ID this tissue on BD COAs. Milk of any other sort is listed by BD as IB for the ABC category.
 NDF = Tissue not listed in the regulations associated regulations in Section 4.3.4 above, and BD chose to ID these exclusively as not defined (i.e., NDF).

Animal Origin Position Statement (Continued)

E. Processing

1. No manufacturing procedures are validated to remove or inactivate infectious agents such as those procedures recognized in *EC Guidelines for Minimizing the Risk of Transmission of Agents Causing Spongiform Encephalopathies via Medicinal Products*, III/3298/91.
2. No cleaning procedures are validated to remove, inactivate or reduce infectious agents.
3. All US BD Life Sciences – Integrated Diagnostic Solutions finished product manufacturing facilities are ISO 13485 certified. FDA Establishment Registrations exist for facilities that manufacture IVD products.

F. Certificates of Suitability: Ph. Eur. 1483 Products with Risk of Transmitting Agents of Animal Spongiform Encephalopathies.

1. Certificates of Suitability are applicable to products that contain TSE-relevant (e.g., cow, sheep, goat) materials that are used in the manufacture of medicinal products.
2. *In vitro* diagnostic devices, unless they are subsequently used to prepare medicinal products (such as starter cultures or seed cultures), do not require a Certificate of Suitability.
3. Dossiers for the Certificates of Suitability are submitted to EDQM, based upon customer request, for our products that are covered by this monograph.
4. Certificates of Suitability list TSE-relevant species, tissues and countries of origin. They do not list this information for non-TSE-relevant species used in the product, or for bovine milk collected from healthy animals under the same conditions as milk for human consumption. Therefore, a Certificate of Suitability should not be used as a batch specific Certificate of Origin.
5. BD currently has active Certificates of Suitability.
6. BD will provide information (non-proprietary) to our customers, to assist with regulatory submissions.

G. Contact Information

1. BD Certificates of Analysis (COAs) are available from the Internet at www.bd.com/regdocs.
2. BD Technical Services at 800.638.8663, selection 2.
3. For additional information regarding Animal Origin, please contact bdds.customer.questionnaires@bd.com.



Katana Webb
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May 15, 2020
Date