



Date: February 4, 2004

Subject: **BD Diagnostics Revised Animal Origin Policy Brief**

Since 1991, BD Diagnostics has continuously worked to limit the BSE risk of our products by stringent safety & traceability requirements for our animal origin raw materials. We work closely with our suppliers to provide extensive documentation of our products, including animal origin information on Certificates of Analysis available at <http://www.bdregdocs.com>, and Certificates of Suitability. We solidified our animal origin policy and practices into a strong quality system in the mid-1990's and implemented formal Quality Policy and Procedure documents in early 1999. Since that time, we have made no changes to our Animal Origin Quality Policy. That policy requires that no bovine materials from BSE countries be used in BD Diagnostics products, as defined in the United States *Code of Federal Regulations*, Title 9, Section 94.18.

On December 23, 2003, the United States Department of Agriculture (USDA) announced their diagnosis of a presumptive positive case of bovine spongiform encephalopathy (BSE) in an adult dairy cow (Holstein) in Washington State that had been slaughtered there on December 9, 2003. That diagnosis was confirmed by the BSE world reference lab in Weybridge, England, on December 25, 2003. By January 5, 2004, both the United States (US) and Canada had confirmed with a high degree of certainty that this 6 ½ year old BSE positive cow, that had been traced to a September 4, 2001 import into Washington State from Canada, originated from a dairy farm in Alberta, Canada. OIE (Office International des Epizooties) subsequently added the US to its list of "Countries/Territories having reported cases of BSE in imported animals only." Because the cow was not native born, and because the US continues to have strong systems in place to prevent a BSE epidemic according to an independent study by Harvard University, the USDA did not add the USA to 9 CFR 94.18, where it maintains a list of countries containing or at risk of containing BSE.

When BSE was announced in Canada in May 2003, in a native born Canadian cow, we excluded Canadian sources of bovine materials from our products following our BD Diagnostics Animal Origin Quality Policy. With the December 2003 news of the BSE-positive cow imported into the US, we have taken the time to re-evaluate our Animal Origin Quality Policy and perform a risk assessment. Based upon this assessment, we have determined that our current animal origin policy and practices for BSE risk reduction, as well as the complement of products and services to meet the requirements of our various customer types, are both ample and sound.

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However, looking to the future, for our current animal origin formulations we have determined that our policy of sourcing only from BSE-free countries becomes untenable if the US status were to change from its current designation. BD Diagnostics offers a portfolio of thousands of finished goods containing bovine origin raw materials, a large number of which include US bovine sourcing. Identifying, contracting and validating raw materials from new suppliers for all of our finished goods made using bovine origin materials would be both a lengthy and costly process. Our evaluation shows that substantially increasing the costs of most of our products in the future by switching to New Zealand and/or Australia only sources is not desirable for the majority of our diagnostic microbiology customers and for many of our other customers as well since it yields only limited risk-reduction and has an insignificant impact on safety for those applications.

In order to make a continuous supply of products available to our varied customers, we are making a change to our Animal Origin Quality Policy that will allow us to manage BSE risks in accordance with a given product's intended use. Specifically, we will continue to source bovine materials only from BSE-free countries **and** the US, Australia and New Zealand, regardless of their designation, for our IVD (*in vitro* diagnostic) labeled products and for our standard "For Laboratory Use" (FLU) labeled products. We will also continue to use multi-use equipment in the manufacture of all formulations, other than those designated "Animal Free" that are produced in our DCM (dehydrated culture media) Plant's dedicated manufacturing suite and equipment. Guidance documents from around the world,<sup>1</sup> which are focused on control of human and animal TSEs, typically exclude IVDs due to their absence of patient and/or user contact. It is generally recognized that products used for *in vitro* diagnostic purposes are not of concern relative to TSE risk.

Those customers that require additional safeguards in the event the US, Australia and/or New Zealand have a change to their BSE status (i.e., producers of drugs, vaccines and medical devices, especially our customers in the field of bioprocessing and those performing media fills) are encouraged to take advantage of the many options for controlled raw material origin or animal-free solutions that are available today from BD Diagnostics.

- Within our regular product portfolio, for many years we have had a number of non-animal formulations and dehydrated ingredients. In the late 1990's, in response to escalating customer interest, we increased our number of non-animal alternatives. First, we have a growing list of non-animal protein hydrolysates and non-animal media formulations. Second, we make available the Media Design Service to identify non-animal formulations that produce desired yields with cell lines and systems. Third, we have dedicated, animal-free equipment and production suite in our DCM Plant in which only the most stringently controlled raw materials may be processed.

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<sup>1</sup> These guidance documents include (a) FDA's Guidance for "Medicinal Devices Containing Materials Derived from Animal Sources (Except for *in vitro* Diagnostic Devices)," and (b) draft ISO standards for animal tissues and their derivatives utilized in the manufacture of medical devices.

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- Regarding controlled raw material origin, custom products can be designed and managed by BD Diagnostics to meet our specific customer needs. For customers who use our products in their manufacture of human or animal therapeutics (i.e., drugs, vaccines and medical devices excluding IVDs), in addition to the non-animal alternatives described above, we have created additional options for reducing BSE risk. These controlled animal origin options include but are not limited to the following: (1) select country of origin sourcing (i.e., Australia and/or New Zealand only), (2) alternative species (i.e., non-bovine) formulations, (3) certified organic bovine (i.e., never fed animal protein) formulations, (4) BSE tested bovine formulations, (5) Category IV<sup>2</sup> (no detectable infectivity) only bovine formulations and (6) other custom products as requested.

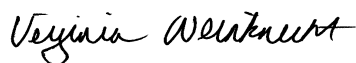
For information on our animal-free or custom products, please send your inquiries by e-mail to [BSE\\_Inquiry@bd.com](mailto:BSE_Inquiry@bd.com). For animal origin information on any of our products, please consult our Certificates of Analysis (COAs), available from the Internet at <http://www.bdregdocs.com>. Included on the COAs are animal species, countries of origin and tissue categories for those BD finished products made using animal materials. For COAs or animal source information that cannot be found at <http://www.bdregdocs.com>, please contact BD by phone at 1-800-638-8663 selection #1 for domestic customers. For international customers, please contact your local BD Representative, or email BD at [cofa@bd.com](mailto:cofa@bd.com).

In summary, aside from two changes, the BD Diagnostics Animal Origin Policy remains as it has been since the early 1990's for bovine materials. The first change is to allow our standard IVD and FLU products to be made using bovine materials originating in BSE-free countries and the US, Australia and New Zealand, regardless of their BSE designation. This designation is being given to the US, Australia and New Zealand due to the strong surveillance, control, reporting, containment and eradication programs in place in these countries for over a decade. The second change is to provide an elevated level of control, including use of certified herds (i.e., either certified organic or tested for BSE), in BD Diagnostics products known to be used in the manufacture of human and animal therapeutics (i.e., drugs, vaccines and/or medical devices excluding IVDs). The three pillars of our Policy continue to be minimizing BSE risk; healthy, food chain sourced animals; and government regulated harvesting facilities. For more details concerning the BD Diagnostics Animal Origin Policy, please see our Animal Origin Position Statement available at <http://www.bdregdocs.com>.



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<sup>2</sup> EMEA/410/01 rev 1, 31 May 2001, "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Human and Veterinary Medicinal Products" from the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) of the European Union. Category IV – No Detectable Infectivity – includes the following: blood clot, feces, heart, kidney, mammary gland, milk, ovary, saliva, salivary gland, seminal vesicle, serum, skeletal muscle, testis, thyroid, uterus, fetal tissue, bile, bone, cartilaginous tissue, connective tissue, hair, skin and urine.