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Animal Tissues and Product Safety

When Dr. Lee founded Standard Process in 1929, the first whole food supplement he introduced was Catalyn®. Catalyn and many other Standard Process products contain animal tissues (organs, glands, or extracts thereof). Dr. Lee believed that, "The quality of a whole food supplement is dependent on the quality of the manufacturing process." This remains the foundation of our doctrine today, and it is applied to the animal tissues that are used in many Standard Process products.

Standard Process whole food supplements are manufactured in our facility in Palmyra, Wisconsin. The animal tissues that we use are supplied by U.S. Department of Agriculture (USDA)-inspected facilities and approved based on the laws and regulations of the USDA. They are derived from animals that were found sound and healthy and received pre- and post-mortem inspection. Standard Process products are labeled with the source species and name of each gland or organ contained in each product.

Standard Process' manufacturing facility is inspected by the Wisconsin Department of Agriculture, Trade and Consumer Protection Division, as well as the Food and Drug Administration (FDA). These inspections occur on a regular basis and include both our farm and our manufacturing facility. Standard Process cooperates fully with these agencies with respect to their inspections and the integrity of the tissues used in our products.

Animal Diseases and BSE

There have been news reports about animal diseases and how these diseases affect human health. Reports in the past have focused on Foot and Mouth disease, a disease of cattle; and scrapie, a neurological disease of sheep and goats. According to the USDA, there is no specific evidence that either of these diseases poses a risk to humans.

The most recent news reports have focused on BSE (bovine spongiform encephalopathy), also known as "mad cow" disease. The U.S. Department of Health and Human Services (DHHS) describes it as follows:

> *BSE is a fatal disease that causes progressive neurological degeneration in cattle. Similar to BSE, Creutzfeldt-Jakob disease (CJD) is a rare disease that occurs in humans. In 1996, following outbreaks of BSE among British cattle, scientists found a possible link between BSE and a variant of CJD (vCJD). While it is not certain how BSE may be spread to humans, evidence indicates that humans may acquire vCJD after consuming BSE-contaminated cattle products.*

Since the discovery of BSE in the United States, the USDA's Food Safety and Inspection Service (FSIS) has implemented a number of policies that will strengthen protection against BSE, including immediate banning of non-ambulatory (downer) animals from the human food supply. To view the complete list of updates that have been made by the USDA, along with the most up-to-date information on BSE, please visit the following websites:

www.fda.gov/oc/opacom/hottopics/bse.html

www.cdc.gov/ncidod/dvrd/bse/

www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml

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Department of Agriculture Programs to Protect Against BSE

The USDA's Food Safety and Inspection Service (FSIS) examines all cattle before they can be approved for use as human food. The use of cattle with unidentified neurological diseases is prohibited.

In 1989, the USDA issued restrictions prohibiting the importation of live ruminants (cows, sheep, and goats), as well as certain ruminant products from countries where BSE is known to exist in native cattle. In late 1997, the USDA took further steps to stop the importation of live ruminants and most ruminant products from all countries in Europe.

USDA rules: limit the use of certain "specified risk materials" from animals over 30 months of age; expand the prohibition of central nervous system tissues in advanced meat recovery products; and prohibit air-injection stunning of cattle. These rules also prohibit ambulatory animals, which have been targeted for BSE surveillance testing, to go to market until negative results are obtained.

Standard Process relies on USDA-inspected slaughterhouses for its animal tissue raw materials. Because of shortages in recent years with respect to some animal tissue, Standard Process' USDA-inspected suppliers sometimes purchase animal tissues that are in short supply domestically from non-BSE-affected countries. When these suppliers import animal tissue raw materials, the USDA requires that each shipment be accompanied by an original certificate endorsed by a veterinarian employed by the non-BSE exporting country's animal health agency. They must certify that the animal tissues are from animals that passed pre- and post-mortem examinations and that the animal tissues were treated in a specific manner prior to shipment.

Department of Health and Human Services Programs to Protect Against BSE

FDA regulations prohibit the use of most mammalian protein in the manufacturing of animal feed given to cattle. This prohibition is a preventative measure designed to protect animals from potential transmissible degenerative neurological diseases, such as BSE, and to minimize any potential risk to humans.

Since 1992, the FDA has instructed manufacturers of FDA-regulated products not to use certain bovine materials from countries affected by BSE. Bovine products from non-BSE countries are considered safe for use as ingredients in conventional foods as well as in dietary supplements. Dietary supplements are regulated as a subcategory of foods, and the import alerts and guidance documents on BSE apply equally to bovine ingredients used in conventional foods or in dietary supplements. Gelatin, which is used as a raw material for capsules and perles, was also the subject of a 1998 FDA guidance document stating:

> *At this time there does not appear to be a basis for objection to the use of gelatin produced from bovine hides and bones in FDA-regulated products for human use if the gelatin is produced in the United States from U.S.-derived raw materials or from cattle born, raised, and slaughtered in other countries that have no reported BSE cases and that meet OIE BSE standards.*

When Standard Process received the FDA's November 1992 letter to dietary supplement manufacturers regarding BSE and imports, we promptly instituted further procedures to assure that our USDA-inspected suppliers were aware of and adhering to the FDA's instructions not to use bovine materials from BSE-affected countries. Standard Process was inspected by the FDA with respect to this issue and the FDA was satisfied that our company had proper procedures in place. To this day, we continue to meet all of their requirements.

Dietary Supplement Trade Association Programs to Protect Against BSE

Standard Process is a member of several industry trade associations. These represent the dietary supplement industry and work together to ensure the safety of dietary supplements. These organizations do this by cooperating with the FDA and the USDA to provide the government and the public with information about the steps companies have taken to ensure that dietary supplements are in compliance with the FDA's guidance relating to BSE. The industry will continue to help government agencies by gathering data on the industry practices that are followed to ensure compliance.

Standard Process®

800-848-5061 | www.standardprocess.com

1200 West Royal Lee Dr. | Palmyra, WI 53156