

BSE/TSE Raw Material Certification

The note for guidance EMA/410/01 Rev. 3 of the EC considers the requirements of raw materials used for human and veterinary medicinal products and introduces risk assessment into the regulatory compliance process for products derived from TSE/BSE-relevant animal species.

Worthington Biochemical Corporation, an ISO9001 Certified producer of enzymes and related biochemicals, certifies that all lots and types of bovine pancreas starting materials are sourced from the following minimizing the risks of potential BSE/TSE contamination:

- 1) USDA or equivalent approved suppliers.
All of the bovine raw materials supplied to Worthington for further processing originate from certified United States Department of Agriculture (USDA) or equivalent approved facilities, where all slaughtered animals are given ante- and post-mortem inspections and certified to be free of disease and suitable for human consumption and/or exportation.
- 2) Tissue Source
The pancreas tissue is categorized as IB, Lower infectivity tissues, no detected BSE transmission.
- 3) Source Animal Age
The pancreas tissue is sourced from younger animals not older than 30 months.
- 4) Risk Classification
According to Resolution No. 20 (81st General Session May 2013) the World Organization for Animal Health (OIE) has upgraded the United States' risk classification for bovine spongiform encephalopathy (BSE) to negligible risk in accordance with Chapter 11.5 of the Terrestrial Code.
- 5) Cross Contamination
During processing the product(s) sourced from bovine pancreas is highly purified and does not come in contact with any other animal or specified risk materials.

Signed: ____ Signature on file _____ Date: ____ 5-Sept-2017 ____

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