

Guidance for Industry
Use of Material from BSE
Positive Cattle in Animal Feed

Comments and suggestions regarding this guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. All written comments should be identified with Docket No. 2004D-0438.

For questions regarding this guidance, contact Burt Pritchett, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6860. E-mail: burt.pritchett@fda.gov

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/cvm>.

Paperwork Reduction Act Public Burden Statement

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. This guidance does not contain any new collections of information.

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Use of Material from BSE-Positive Cattle in Animal Feed

This guidance represents the Food and Drug Administration's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

FDA's BSE (bovine spongiform encephalopathy) feed regulation (21 CFR 589.2000) prohibits from use in ruminant feed any protein-containing portion of mammalian animals with the exception of certain products. FDA took this action to minimize the potential for any undetected BSE infectivity in animal feed to spread to ruminants via their feed. This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from cattle that test positive for BSE.

II. Background

In the Federal Register of June 5, 1997 (62 FR 30936), FDA published a final rule prohibiting material defined as protein derived from mammalian tissues from inclusion in ruminant feed because they could potentially contain infectious agents that cause TSEs (transmissible spongiform encephalopathies). Although BSE, a TSE of cattle, had not been identified in the United States at that time, the 1997 regulation was put in place to prevent the establishment and amplification of BSE in the United States through animal feed and thereby minimize risk to humans and animals.

¹ This guidance has been prepared by the Division of Animal Feeds in the Center for Veterinary Medicine (CVM) at the Food and Drug Administration.

CONTAINS NON-BINDING RECOMMENDATIONS

BSE was first diagnosed in 1986 in the United Kingdom and in 2003 in North America when it was diagnosed in a dairy cow in Canada. The disease was subsequently diagnosed in a dairy cow in Washington state that had been imported from Canada.

Epidemiologic evidence has strongly suggested an association between the outbreak in the United Kingdom of BSE and feeding to cattle protein derived from other cattle infected with BSE. In addition, the consumption of beef products contaminated with the BSE agent has been linked to a form of human TSE known as new variant Creutzfeldt-Jakob disease (vCJD).

TSE's are fatal, progressively degenerative central nervous system diseases of man and other animals. TSE's include, among other diseases, BSE in cattle, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease (CJD) in humans. There is no known treatment for these diseases, and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for BSE that can be used to test for the disease in live animals.

III. Use in animal feed of material from BSE-positive cattle

Pursuant to Sec. 402(a)(5) of the Federal Food, Drug, and Cosmetic Act, animal feed and feed ingredients containing material derived from a BSE-positive animal are considered adulterated. Therefore, material from BSE-positive animals may not be used in any animal feed or feed ingredients. FDA recommends that any such adulterated feed or feed ingredient be recalled or otherwise removed from the marketplace.