

WORLD TRADE ORGANIZATION

G/TBT/N/USA/67/Add.1
21 July 2004

(04-3150)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 16 July 2004, is being circulated at the request of the delegation of the United States.

Use of Materials Derived From Cattle in Human Food and Cosmetics; and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; Final Rule and Proposed Rule

The Food and Drug Administration (FDA) is issuing an interim final rule (interim final rule) to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef). Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. FDA is taking this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington. This action is consistent with the recent interim final rule issued by the U.S. Department of Agriculture (USDA) declaring specified risk materials and the carcasses and parts of non-ambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire small intestine be removed and disposed of as inedible. This action will minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. Also in this issue of the Federal Register, FDA is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain material from cattle establish and maintain records sufficient to demonstrate that the food and cosmetics are in compliance with this interim final rule.

DATES: The interim final rule is effective on July 14, 2004. Submit written or electronic comments by October 12, 2004. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 189.5 and 700.27 as of July 14, 2004.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0081, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>.
Follow the instructions for submitting comments on the agency Web site.

E-mail: fdadockets@oc.fda.gov.
Include Docket No. 2004N-0081 and or RIN number RIN-0910-AF47 in the subject line of your e-mail message.
FAX: 301-827-6870.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section V in the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Rebecca Buckner,
Center for Food,
Safety and Applied Nutrition (HFS-306),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
301-436-1486.
