Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 02N–0273]

RIN 0910–AC37

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (we) is soliciting information and views on some potential changes to its current regulation prohibiting the use of certain proteins in ruminant animal feed. We put this regulation in place to prevent the spread through animal feed of the agent of bovine spongiform encephalopathy (BSE) were it to enter the United States. In this regulation we determined that protein derived from mammalian tissues for use in ruminant feed is a food additive under the Federal Food, Drug, and Cosmetic Act (the act), and that use of certain mammalian proteins in ruminant feed causes the feed to be adulterated under the act. We are considering revising this regulation, and therefore we are asking the public for comment on certain possible modifications to the rule. This information may be used to help draft a proposed rule in the near future.

DATES: Submit written or electronic comments by February 4, 2003.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Linda Huntington, Executive Secretariat, Office of the Commissioner (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4443.

SUPPLEMENTARY INFORMATION:

I. Background

We published the regulation, ''Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,'' (21 CFR 589.2000) in the **Federal Register** of June 5, 1997 (62 FR 30936).

On October 30, 2001, we held a public hearing in Kansas City, MO to hear views from the public on the adequacy of the present BSE feed regulation. We specifically invited comments, both oral and written, on 17 questions about ways the rule and its enforcement might be improved to achieve its original objectives of preventing the establishment and amplification of BSE in the United States. We appreciate the efforts of the many organizations and individuals who took the time to express the views of various segments of the animal feed industry, regulatory agencies, concerned consumers, and consumer organizations on the adequacy of the present feed rule.

Shortly after the public hearing, the U.S. Department of Agriculture (USDA) released a report prepared by the Harvard Center for Risk Analysis (*http://www.aphis.usda.gov/oa/bse/*) on the findings of a major 3-year initiative to develop a risk assessment model that allows evaluation of the impact of various risks and potential pathways for exposure of U.S. cattle and U.S. citizens to the BSE agent. The assessment of the present situation in the United States using this model concluded that, due to control measures already in place, the risk to U.S. cattle and to U.S. consumers from BSE is very low. The model also demonstrated that certain new control measures could reduce the small risk even further.

USDA's BSE surveillance program supports the findings of the Harvard study that measures implemented by the U.S. Government, such as early import restrictions and the feed ban, have been effective in preventing the entrance and establishment of BSE in the U.S. cattle population. The USDA surveillance program, which has been in place since May 1990 and which targets the highest risk cattle population, has found no cases of BSE to date. Although BSE has not been detected in the United States, the U.S. Government's response to BSE has always been proactive and preventive. Therefore, USDA and FDA are interested in exploring measures that could further reduce the already small risk that BSE will enter and become established in the United States. To that end, FDA is once again asking for information from the affected industries and the public on several ways that the animal feed regulation could be strengthened.

II. Agency Request for Information

We are soliciting information and comments from those with interest and expertise in any of the following five aspects of the BSE feed regulation:

1. Excluding Brain and Spinal Cord From Rendered Animal Products

The Harvard risk assessment identified removal of high risk tissues, such as brain, spinal cord, gut, and eyes, from human food and rendered material for animal feed, as a way to dramatically reduce the potential exposure of cattle and humans to the BSE agent. In response to the Harvard study, USDA's Food Safety Inspection Service is considering rulemaking to ban high risk tissues obtained from certain populations of cattle (also called specified risk materials or SRMs) from use in human food. Should USDA publish such a proposal, FDA may also propose that SRMs be prohibited from going into rendered material. Therefore, FDA is asking for comments on the following questions:

- Should high risk materials, such as brain and spinal cord from ruminants 2 years of age and older, be excluded from all rendered products?
- How feasible would it be for the rendering industry to implement such an exclusion?
- What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from a brain and spinal cord exclusion?

2. Use of Poultry Litter In Cattle Feed

In some parts of the country where cattle are raised in proximity to large poultry production areas, poultry litter, composed of excreta, bedding, spilled feed, and feathers, may be used as a feed ingredient for cattle. The Harvard risk assessment said that the risk from the use of poultry litter as a feed supplement should be investigated

further. For example, if the spilled feed contained ruminant protein, would this practice represent a significant break in the feed regulations? In order to further investigate possible risk, FDA is seeking information on the following questions:

- How extensive is the use of poultry litter in cattle feed in the United States?
- What is the level of feed spillage in poultry litter?
- What are the methods used to process poultry litter before inclusion in animal feed?
- What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from banning poultry litter in ruminant feed?

3. Use of Pet Food In Ruminant Feed

Under the current regulation, pet food for retail sale is exempt from the labeling requirement and need not bear the caution statement ''Do not feed to cattle or other ruminants.'' However, if the pet food products are sold or are intended for sale as distressed or salvage items, then, under § 589.2000(d)(4), such products must state, ''Do not feed to cattle or other ruminants.'' In order to assure that salvaged pet food is not used in ruminant feed despite the requirement that it be labeled with the caution statement, FDA is asking for comments on the following questions.

- Should pet food for retail sale be labeled with the statement ''Do not feed to cattle or other ruminants.''?
- What would be the adverse and positive impacts (economic, environmental, health, etc.) of such a labeling requirement?

4. Preventing Cross-Contamination

The Harvard risk assessment and the FDA public hearing identified cross-contamination of feed and facilities as a possible BSE risk. The current animal feed regulation permits feed and feed ingredients for ruminant animals to be processed in facilities that also process prohibited proteins. The rule requires that those firms handling both prohibited and nonprohibited material have a system in place and a written plan to prevent cross-contamination. We provided suggestions in the preamble to the final rule and in the small entity compliance guides on ways to prevent carry-over in shared equipment. Small entity compliance guides include: No. 67—Renderers; No. 68—Protein Blenders, Feed Manufacturers, and Distributors; No. 69—Feeders of Ruminant Animals With On-Farm Feed Mixing Operations; No. 70—Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations; and No. 76—Questions and Answers, BSE Feed Regulation. You may see the small entity compliance guides on the Center for Veterinary Medicine (CVM) Internet site at *http://www.fda.gov/cvm* or by calling the CVM Communications Staff at 301–594–1755. For feed mills, these suggestions were based on medicated feed good manufacturing practices (GMPs) and included physical cleaning, flushing, or sequencing. For renderers, we suggested flushing, using one complete change of operating volume of the entire system.

The rule requires that those firms handling both prohibited and nonprohibited material have a system in place and a written plan to prevent cross-contamination. The only way to be sure that there is absolutely no potential for carry-over of, or cross-contamination with, prohibited material is to use completely separate facilities. We are interested in information on control measures, other than dedicated facilities, that apply specifically to transmissible spongiform encephalopathy (TSE) agents and in information on whether such measures can prevent carry-over of prohibited material. The agency is asking for comments on the following questions:

- Are there practical ways, other than dedicated facilities, for firms to demonstrate that the level of carry-over could not transmit BSE to cattle or other ruminants? If so, what is the safe level of carry-over in a feed mill; and
- What is the scientific rationale used to establish this safe level?
- What steps are firms currently taking to prevent cross-contamination of prohibited protein into ruminant feed, and what are the costs of those steps?

5. Elimination of the Plate Waste Exemption

The current regulation contains an exemption that permits ''inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings)'' to be fed to ruminants. Although the Harvard study concluded that plate waste posed a minimal risk, FDA wishes to reconsider this exemption and is seeking information on the following questions.

- To what extent is plate waste used in ruminant feed?
- What is the composition of plate waste, and what are its sources?
- How is plate waste processed before inclusion in ruminant feed?
- What would be the adverse and positive impacts (economic, environmental, health, etc.) from excluding plate waste from ruminant feed?

III. Comments

You may submit written or electronic comments regarding the advance notice of proposed rulemaking (ANPRM) by February 4, 2003, to the Dockets Management Branch (see **ADDRESSES**). Please submit two copies of any comments, except that individuals may submit one copy. Identify your comments with the docket number found in brackets in the heading of this document. You may see received comments in the Dockets Management Branch reading room between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

You may submit comments electronically on the Internet at: *http://www.fda.gov/dockets/ecomments*. On this Internet site, select ''02N–0273'' and follow the directions.

This ANPRM is issued under sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, and 371) and under the authority of the Commissioner of Food and Drugs.

Dated: November 4, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–103777–02]

RIN 1545–BA54

User Fees for Processing Offers to Compromise

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed amendments to the regulations relating to user fees to provide for the imposition of user fees for the processing of offers to compromise. The charging of user fees implements the Independent Offices Appropriations Act (IOAA). This document also contains a notice of public hearing on these proposed regulations.

DATES: Written and electronic comments must be received by February 4, 2003. Outlines of topics to be discussed at the public hearing scheduled for Thursday, February 13, 2003, must be received by Thursday, January 23, 2003.