CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

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August 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

Enclosed are comments to proposed rules on federal measures to mitigate BSE risks (Docket 2004N-0264) and recordkeeping requirements for foods and cosmetics produced with cattle material (Docket 2004N-0257). We appreciate the opportunity to submit comments on these issues.

Sincerely,

Stephen Watkins

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Research Associate
Program on Food Safety

2004N-0257

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CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

August 11, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Comments on Proposed Rule: Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; Docket No. 2004N-0257

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to submit written comments on FDA's proposed record keeping and record maintenance rule relating to human food and cosmetics made from, processed with or containing cattle materials. CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition and alcohol issues. CSPI is supported principally by the 890,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

Under the proposed rule, manufacturers and processors must keep records demonstrating the absence of prohibited cattle materials in their products as a way to assure compliance with the

ban on SRMs.[1] We support the proposed rule and believe that it is a long-overdue step in assuring the safety of food and cosmetic items made from cattle parts. However, we believe the rule could be strengthened in the following ways.

1. The Rule Should Impose Specific Recordkeeping Requirements

A. Certification Should Be A Mandatory Recordkeeping Requirement

FDA recognizes that once material is removed from cattle, it may be unable to determine the source of the material, whether it was from an animal over 30 months of age at slaughter, or whether the animal was inspected and passed. As a result, manufacturers and suppliers "must depend" on records from their suppliers of cattle materials to ensure that the source material does not contain prohibited cattle materials.[2]

Under the proposed rule, manufacturers and processors must maintain records "sufficient to demonstrate" that the food is not made from or does not contain prohibited cattle materials. However, the rule not define what records are "sufficient" for this demonstration. In the preamble, FDA lists only one type of record that it "would expect" a manufacturer or processor of FDA-regulated food containing cattle material to have – a signed and dated affirmation by the slaughter establishment. The FDA does not, however, make such an affirmation a mandatory record that manufactures and processors must keep.

Given FDA's recognition of the difficulty in tracking cattle parts once removed from the animal, FDA should go beyond merely stating its expectation that manufacturers and processors will have signed affirmations. The agency should require every facility handling cattle materials

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[1] 69 Fed. Reg. 42,255 (July 14, 2004). Under the interim final rule, prohibited cattle materials include specified risk materials from cattle 30 months and older, the small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated beef.

[2] 69 Fed. Reg. at 42,278.

to provide an independent audit to the FDA certifying annually that the facility is in compliance with the rule's requirements.[3] Imposing a certification requirement as an element of adequate recordkeeping would also enhance FDA's ability to enforce compliance with the rule. In addition, we suggest that FDA specify the actual wording of the certification or affirmation in order to avoid ambiguity. This could be similar to the SRM statement that must be typed in the "Remarks" section of the export certificate required for ruminant meat and meat products exported to the European Union.[4]

B. FDA Should Impose Recordkeeping Requirement Sufficient for Traceback and Recall

In the preamble to the proposed rule, FDA recognizes that the records concerning the source of cattle parts used in human food and cosmetics are important for traceback and recall purposes.[5] Yet, the proposed rule does not include any specific recordkeeping requirements that would assist the agency in conducting a traceback or recall.

For all products produced from cattle parts, manufacturers and processors should be required to maintain records sufficient to identify the source of each cattle part that is used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products. FDA should require manufacturers and processors to keep records not only relating to the source of their materials but to the distribution of any products containing cattle parts throughout the food supply chain. At a minimum, these records should include:

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[3] We agree with FDA that a national animal identification system should making maintaining information about source animals less burdensome. For that reason, we encourage FDA to work with USDA to implement such a program as soon as possible.

[4] USDA, Food Safety and Inspection Service, Export Library: *Export Requirements for the European Union* (July 28, 2004), available at *<http://www.fsis.usda.gov/ofo/export/euregs.htms>*.

[5] 69 Fed. Reg. at 42,277.

- sale and shipping records covering outgoing shipment of product to wholesalers, distributors, and customers, and sale/shipping invoices and records covering incoming shipments from suppliers for the shelf life of the product; and
- records indicating the receipt date of the shipment of source material and what and how much received; and lot number or lot codes received if available.

In addition, manufacturers and processors should be required to have written plans for notifying FDA in the event of a recall of any human food or cosmetic products that are discovered to contain prohibited cattle materials. Manufacturers and processors should also have an affirmative duty to notify FDA where they have information that human food and cosmetic products may contain prohibited cattle materials.

II. The Rule Should Impose Specific Recordkeeping Requirements on Renderers

FDA should impose specific recordkeeping requirements on facilities, both packer-renderers and independent renderers, that render cattle for use in human food and cosmetics. Renderers recycle a wide-range of cattle parts that are used in a wide range of products.

As part of their quality (and safety control), renderers should be required to keep records of any checks, tests or other procedures performed to assure that prohibited cattle materials are kept separate from other cattle materials that can be used for human food or cosmetics.[6] Such records should include procedures used to disinfect equipment and sites where prohibited materials are removed, where prohibited materials are kept, and how and when prohibited materials are used or disposed of. In addition, they should be required to keep records that are

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[6] According to the National Renderers Association, renderers typically incorporate Good Manufacturing Processes, hazard analysis and critical control point (HACCP), or ISO 9000 in their processes to assure that their products are made in a sanitary and wholesome fashion. National Renderers Association, *North American Rendering: A Source of Essential, High-Quality Products*. Accordingly, renderers could maintain the required records as part of their GMPs or HACCP systems.

sufficient to trace the movement of the prohibited cattle materials.

III. FDA Should Impose A Minimum Three Year Recordkeeping Requirement

FDA has proposed that required records be kept for two years, although the USDA only requires records to be kept for one year under its BSE interim final rule. We strongly support a longer record-retention requirement and believe that records showing the absence of prohibited materials should be kept for at least three years. As FDA has noted, many FDA-regulated foods have longer shelf lives, and it is important that records are kept during the shelf life of such products.[7] These records would be critically important in the event that FDA needs to conduct a traceback. These justifications support a longer, three-year record keeping requirement.

IV. FDA Should Strengthen the Recordkeeping Requirements for Importers

In the preamble, FDA acknowledges that it does not necessarily have access to records maintained at foreign facilities. For that reason, it is proposing to require that importers must electronically affirm their compliance with the recordkeeping requirements. This provision must be considerably strengthened.

First, importers should be required to certify that the products do not contain prohibited material – not just that they have records documenting the absence of prohibited materials. Because FDA does not necessarily have access to the records themselves, then it has no way of assuring compliance with the ban on prohibited materials in the absence of an affirmative certification.

In addition, the rule is unclear on whether the certification requirement applies for each shipment of product. FDA should require certifications for each separate lot of food or cosmetic

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[7] 69 Fed. Reg. at 42,277.

items containing cattle parts coming into the United States from each separate manufacturer or processor. These could be included as part of the prior notice notification required for food importers.

CONCLUSION

The proposed recordkeeping requirements are a necessary part of FDA's efforts to assure compliance with the ban on the use of prohibited cattle materials in human food and cosmetics and to conduct a traceback in the event that potentially contaminated products are distributed in the market place. However, FDA cannot assure compliance unless it considerable strengthens the proposed rule by imposing more specific recordkeeping requirements, particularly on importers.

Respectfully submitted,

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