



August 11, 2004

1771 01 15 11 100

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket No. 2004N-0257; Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; 69 FR 42275 (July 14, 2004)

Dear Sir or Madam:

John R. Cady
*President and
Chief Executive Officer*

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5917
Fax: 202-637-8464

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA appreciates this opportunity to offer comments to minimize the unnecessary burden that would be created by this proposed rulemaking.

General Comments

- NFPA strongly supports the intent of the related FDA interim final rulemaking (69 FR 42256) that prohibits the use in foods, dietary supplements and cosmetics of cattle materials that might carry the Bovine Spongiform Encephalopathy (BSE) infective agent. We will submit separate comments on some of the more detailed specifics of that rule at a later date. Our comments herein are directed toward implications of the proposed recordkeeping requirements on manufacturers of FDA-regulated food products.

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

The scope of the products and firms impacted by the recordkeeping proposal is much broader than necessary. The proposed regulation applies to all manufacturers who use "cattle materials," a term which is undefined in the

2004N_0257

C3

Dockets Management Branch
August 11, 2004
Page Two

rule itself and is not clearly delineated in the preamble to the rule. NFPA members who utilize meat and meat food products in the manufacture of FDA-regulated food products utilize only USDA-inspected meat items from which specified risk materials (SRM) have already been removed as mandated by FSIS regulations (9 *CFR* 310.22 - Specified risk materials from cattle and their handling and disposition). Foreign meat and poultry establishments are also required to meet these same requirements. NFPA finds it totally unwarranted that FDA intends to require new recordkeeping (to be maintained for a period of two years) for such products that bear the USDA mark of inspection or are produced under any inspection system that has been determined by FSIS to be equivalent. Any new recordkeeping should apply only to firms that use or handle certain specific cattle materials that have not been inspected and passed by USDA. Thus, we urge that inspected and passed cattle materials as well as materials that are not a risk for transmitting the BSE agent, (i.e., dairy products) should be specifically exempted from the recordkeeping requirement.

Scope of the rule is unnecessarily broad.

NFPA believes that the rule is much broader than needed and impacts more firms than is warranted. The scope should be narrowed providing certain exemptions discussed later in these comments. Furthermore, the applicability of the rule should be limited to the initial user of certain specific cattle materials.

As noted, we believe that the interim final rule prohibiting use of SRMs and other uninspected cattle materials is appropriate. However, we do not believe that the minor incremental protection that will be afforded by the recordkeeping requirement will justify the burden it will impose on the food industry. The fact is that under the new FSIS and FDA prohibitions it is illegal to use SRMs or uninspected cattle materials in the prepared products that our members manufacture.

Considering that extensive BSE testing has resulted in only one BSE positive animal (of Canadian origin), the risk of transmitting the BSE agent would be a very minor regulatory consideration for a firm that would willingly utilize banned materials in the manufacture of food products for human consumption. If there are such unscrupulous operators in existence, they are unlikely to be deterred by the need for a statement that incoming ingredients contain no prohibited materials; rather, they must be uncovered by diligent investigative actions by FSIS and FDA personnel and prosecuted to the full extent of the law. Under the proposed rule, 99.99% of the industry would be burdened by a virtually useless need to create and maintain documentation of the obvious – they use only legal cattle ingredients in their products.

Thus, unless there are specific cattle materials that could reasonably be expected to create some confusion or raise some issue about whether or not they are prohibited materials, they should not be included in the scope of this recordkeeping requirement. Certainly boxed beef is not such a material, nor are any other meat ingredients or meat food products that leave an inspected establishment bearing the USDA mark of inspection. Some may be concerned about carcasses

Dockets Management Branch
August 11, 2004
Page Three

or cuts of beef from which SRMs have not yet been removed that are allowed to leave an inspected establishment bearing the USDA inspection legend. FSIS regulations and policy are very clear that the receiving establishment must document the removal of the remaining SRM in its HACCP plan, SSOPs or prerequisite program.

USDA inspected and passed products and dairy products should be exempted.

FSIS conducts continuous inspection of cattle slaughter operations. Detailed regulations mandate the removal of SRMs. Other regulations dictate that SRMs and other materials that are deemed unfit for human food are classified as inedible and are either denatured or must be handled under rigid controls. We believe that an FDA requirement for inspected slaughter establishments to affirm that the materials they produce do not contain prohibited cattle materials is redundant and fails to acknowledge the very rigorous controls that FSIS has in place. The burden of this proposal rule would unnecessarily impact not only FDA-regulated facilities, but also the USDA establishments that must supply the records.

Recordkeeping requirement should not apply to secondary and tertiary users of cattle materials.

FDA staff indicate that the Agency intends this recordkeeping rule to apply not just to manufacturers that directly use cattle materials, but also to subsequent processors that might utilize an ingredient that contained any amount of cattle material. For example, we understand that not only beef extract manufacturers, but also further processors that utilize any amount of beef extract in their formulations would have to comply with the rule. We believe that such an extension would significantly expand the impact of the rule with little or no benefit. As noted above, the focus of the rule should be on direct, not indirect, users of certain specified cattle materials.

It does not appear that the Agency's benefit-cost assessment has captured the recordkeeping costs for these secondary and tertiary indirect users of cattle materials. For example, in Table 2 on page 42281 of the proposal, the Agency has assessed costs for 32 facilities that manufacture flavoring extracts. We cannot comment on the accuracy of that estimated number of extract manufacturers, but it is obvious that a much larger number of facilities utilize flavoring extracts in their products. The costs imposed on such facilities have not been considered.

Dockets Management Branch
August 11, 2004
Page Four

Suggestion to narrow the scope of the proposed rule.

One means of narrowing the scope of the recordkeeping requirement would be to exempt cattle materials that should not be covered, such as the following:

- a) Dairy products and other cattle materials that pose no risk of transmitting the BSE agent.
- b) Meat and meat food products bearing the USDA mark of inspection.
- c) Secondary and tertiary products manufactured from covered cattle materials.

The proposed record retention period is longer than necessary.

In the absence of substantial justification, we believe FDA requirements should be consistent with those of FSIS. FSIS requires (*CFR* 310.22 (d)(4)(iii) that inspected establishments retain records of SRM removal, segregation and disposition for at least one year.

When recordkeeping is required, a continuing guarantee should suffice.

Preamble discussion of Agency expectations for recordkeeping includes the following:

“A signed and dated affirmation (with contact information) by the slaughter establishment that cattle material supplied by that establishment in a particular shipment does not contain prohibited cattle materials.” (underline added)

The words underlined above strongly suggest FDA’s intent to require lot-by-lot documentation that no prohibited cattle materials have been used. In the event that recordkeeping is required in some limited circumstances, we believe that a continuing guarantee, rather than lot-by-lot documentation, should be deemed adequate. Clearly lot-by-lot certification grossly expands the amount of documentation that must be obtained and maintained - without any significant added benefit to the Agency. Continuing guarantees of compliance with FDA and FSIS regulatory requirements would greatly simplify the recordkeeping burden and significantly reduce the costs involved.

We appreciate this opportunity to comment on the proposed rulemaking.

Regards,



John R. Cady

cc: OMB