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[Docket No. 03-025F] Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; 69 *Federal Register* 1862; January 12, 2004

Dear Ms. Riley:

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 the opportunity to comment on this rulemaking, which was one of several interim rulemakings undertaken in the wake of the finding of the first BSE positive animal in the United States. NFPA commended USDA for its prompt response to this situation, which helped to retain the confidence of our consuming public and which will, eventually, help to restore the world export market for US beef and beef products. While we broadly support the intent of this regulation, we offer the following comments intended to provide additional flexibility for meeting the requirements while maintaining an equivalent level of protection. Our comments are focused on the following issues:

- Consideration of human food use for non-ambulatory disabled cattle whose condition results solely from certain known conditions that have no relationship to symptoms potentially consistent with BSE.
- Redefinition of specified risk materials to allow for alternative methods for identification and removal of potentially infectious materials when they can be scientifically documented as affording an equivalent level of risk reduction.

- Rewording of one section to more clearly define that SRM removal responsibilities apply to establishments that slaughter and to establishments that handle carcasses or parts of cattle from which SRM have not yet been removed.
- Support for the ban on the use of mechanically separated beef for meat food products or for edible rendering.

Non-ambulatory, disabled cattle

NFPA supported the Secretary of Agriculture's decision on December 30 to ban "... all downer cattle from the human food chain." This was an expedient measure to help avoid unnecessary risk from animals that might be considered at higher risk of carrying the BSE infective agent. However, given the opportunity to more closely evaluate the broad scope of this ban, NFPA members would not oppose FSIS reconsideration of the need to include certain categories of animals under the purview of this policy. In particular, FSIS could, based on science, determine to remove from the definition of non-ambulatory disabled cattle those animals whose condition results solely from defined circumstances that have no relationship to symptoms potentially associated with BSE, e.g., broken legs, etc. It may be appropriate to limit this redefinition to animals under 30 months of age, which are unlikely to pose a risk of BSE. We note that the preamble discussion (69 *FR* 1870) of a Swiss study that showed an increased likelihood of detecting BSE in targeted testing of fallen stock and emergency-slaughtered animals compared to the general population of healthy animals looked only at animals over 24 months of age.

Animals meeting the specific requirements to be established by FSIS would be suitable for use as human food. Such a measure could safely minimize to some degree the considerable financial loss to producers or owners of such stock that would be incurred if the otherwise healthy animal had to be disposed of for non-human use and yet pose no increased risk to public health. NFPA believes that such an exemption could be more appropriately handled by the regulatory process than by legislation which has recently been proposed.

Specified risk material (SRM)

NFPA strongly supports the identification, removal and disposal of specified risk materials (SRM) as perhaps the most important element of a larger strategy to minimize, to the extent possible, the chance of exposure of humans or ruminants to the BSE agent. However, in several instances, we believe that the regulatory definition of SRM could be amended to allow flexibility for industry to utilize alternative methods for SRM removal that can be scientifically determined to be just as effective as the procedures specified in the interim final rule. NFPA consistently urges that regulations not be made any more prescriptive than necessary to achieve a defined regulatory objective. Such a policy allows maximum flexibility for firms to comply using the methods most suited for their individual situation.

Vertebral column

At 9 CFR 310.22 (a)(1), FSIS identifies the following among a list of specified risk materials:

> 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 of age and older;

NFPA notes that the vertebral column itself is in fact a bony process, which FSIS, in preamble discussion of this interim final rule, acknowledges has never been demonstrated to carry BSE infectivity. FSIS explains that since the vertebral column contains the spinal cord and dorsal root ganglia (DRG), inclusion of the vertebral column in the definition of SRM ensures that spinal cord and DRG for animals over 30 months will be removed.

[However, NFPA suggests that regulatory intent can be fully met by correctly listing spinal cord and DRG as specified risk materials and adding an additional sentence at the end of §§310.22(a)(1) regarding removal of the vertebral column and worded as follows: "Unless the establishment can demonstrate through scientific methods that the spinal cord and DRG have been completely removed, the entire vertebral column (with appropriate exclusions as listed in the current interim final rule) shall be removed."]

This regulatory option might encourage firms to explore and, with adequate documentation, to utilize alternative procedures for spinal cord and DRG removal that might safely salvage for human consumption certain cuts of meat that are effectively prohibited under the interim final rule.

Distal Ileum

At 9 CFR 310.22 (a)(3), FSIS also identifies the following as specified risk materials

> The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with §§ 314.1 or 314.3 of this subchapter.

In the same vein as our comments above on the vertebral column, NFPA suggests rewording the second sentence of this section. (The second phrase within that sentence regarding disposal of this SRM is entirely and unnecessarily duplicative of specific disposal requirements found at 9 CFR 310.22 (c) and therefore should be deleted.) As acknowledged in the preamble, the only portion of the intestine that has been identified as carrying BSE infectivity is the distal ileum. Thus, it is appropriate that this is the portion of the intestine identified as SRM.

Analogous to our comments above for the vertebral column, we believe firms should be provided flexibility to remove just the distal ileum rather than the entire small intestine if it can be done effectively. Thus, we suggest rewording the second sentence as follows: "Unless the establishment can provide scientific documentation that the procedures used effectively remove the entire distal ileum, the entire small intestine shall be removed." Certainly, if procedures can be documented to be just as effective in complete removal of the distal ileum without sacrificing the entire small intestine, that option should be allowed.

Establishments responsible for SRM removal

Section 9 CFR 310.22 (d) delineates the requirements for establishments that are responsible for SRM removal. The wording of this section has led to some confusion or ambiguity, during implementation of this interim final rule, regarding any obligation of further processing establishments to address SRM removal. We suggest the following changes to streamline this section and to eliminate any remaining confusion.

The phrase "Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle ....." is repeated four times in this section. The problem noted above derives from the fact that any further processing facility for beef could be considered to be an establishment that "processes carcasses or parts of cattle." Any confusion can be easily remedied by clarifying that the only establishments impacted by this rule are those establishments that slaughter cattle or which process carcasses or parts of cattle from which specified risk materials have not yet been removed. Alternatively, the wording could be "or which process specified risk material-containing carcasses or parts of cattle."

In order to streamline this section, we suggest the following rewording:

(d) Procedures for the removal, segregation, and disposition of specified risk materials by establishments that slaughter cattle and establishments that process carcasses or parts of carcasses from which specified risk materials have not yet been removed.

(1) Develop, implement, and maintain .....
(2) Take appropriate corrective action .....
(3) Routinely evaluate the effectiveness .....
(4) *Recordkeeping requirements.* ....

Such rewording should make clearer that establishments that receive only meat and meat items from which SRM has already been removed are not subject to these provisions.

Mechanically separated species

NFPA supports the new regulatory provision declaring mechanically separated (beef) to be inedible and prohibited for use as human food.

Defining SRM

NFPA understands that the current definition of SRM is based on scientific evidence that certain tissues may carry the infective agent for BSE. We have also heard speculation by knowledgeable experts that other tissue types may eventually be shown to be infective and if this happens the Agency should reconsider its definition of SRM. By the same thought process, we believe that the Agency should also consider revising the definition of SRM if science proves that certain tissues now considered to be SRM do not pose a risk.

We wish to note that the regulatory delineation of certain materials from cattle as SRMs does not de facto mean that in all cases they are hazardous materials that pose a danger to animals or to humans. It is important to keep in mind that it is only in the event that SRM is derived from an animal that is infected with BSE, that these materials will present any risk.

To date, the expert community has not used the results of BSE testing of animals as a factor in defining SRM. This has been rationalized by questioning whether any test can detect a low level of infectivity, i.e., "How do we know that an animal that tested negative is not infected?" However, as we have observed in other areas of testing, especially for chemical residues, the ability to detect lower and lower levels of an agent increases markedly as new techniques are developed. Without a doubt, this will occur with BSE testing methodologies as well. In the event that a test is developed that is sensitive enough to provide adequate assurance that animals testing negative pose negligible risk to humans or animals, we would urge the Agency to consider as an option, redefining SRM based on validated test results rather than on age or tissue type alone.

Respectfully submitted,

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President & Chief Executive Officer