



STATE OF WASHINGTON
DEPARTMENT OF AGRICULTURE

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Docket No. 2002N-0273
Division of Dockets Management [HFA-305]
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

As the director of the Washington State Department of Agriculture (WSDA) Pesticide Management Division, I wish to comment on the FDA's proposal to amend the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals.

The Washington State Department of Agriculture (WSDA) supports strengthening rules preventing the spread of BSE and commends FDA for its work on this difficult task. However, I have the following concerns and issues with the current proposal.

On December 23, 2003 the first BSE positive animal in the United States was found in Washington State. Federal and state agencies in concert with industry responded promptly and professionally to address the related food safety and animal health issues. The rendering industry in Washington responded thoroughly and unequivocally by rapidly identifying suspect raw material sources, disposing of hundreds of tons of processed product and implementing complete clean out of their entire plants.

USDA identified and recalled edible product that could contain meat from the BSE positive animal. Some stores put the recalled meat without any special identifying markings in the bins for rendering instead of the bins for disposal. This resulted in rendering recalled meat that could not be used in animal feed. For a second time renderers had to dispose of tons of processed product and for a second time cleaned out their plants. The proposed rule creates two bins and Washington renderers need verification that the firms filling the bins will segregate the material and mark the bins correctly.

Real gains in human and animal health require a systems approach to overcome gaps resulting from industry specialization and government jurisdictional boundaries. FDA, in its own Animal Feed Safety System (AFSS) initiative, is using a systems approach to identify and address gaps that can result in contaminated feed. FDA has provided the scientific and cost/benefit foundation for the proposed BSE rule. However, FDA does not show how existing jurisdictional gaps will

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be managed to achieve a verifiable health benefit within a regulatory framework that provides certainty rather than uncertainty for the affected industries.

Although there is a need to develop and refine safe and effective alternative large animal disposal methods, WSDA believes that the existing modern rendering infrastructure currently provides the only safe and regulated method with the capacity to handle the national animal mortality and animal slaughter by-product burden. Elements in the proposed rule adversely and unnecessarily inhibit the flow of raw material into this current best option.

WSDA disagrees with FDA that the critical control point for separating Cattle Materials Prohibited in Animal Food or Feed (CMPAF) from material suitable for use in animal feed resides solely or even principally within the rendering industry. This critical control point occurs whenever and wherever CMPAF is first removed from the animal, separated and identified. Renderers do convert raw material to feedable form but content as well as form is the issue. Slaughter facilities as well as renderers must have required verifiable separation and identification procedures in place so that renderers are assured that material picked up for animal feed is free of CMPAF and that CMPAF awaiting non-feed disposal is clearly identified.

Both WSDA and USDA FSIS regulate custom exempt slaughter facilities but the emphasis is on sanitation, labeling and records - not the proper disposal of inedible materials. Normal inspection frequency for both agencies is only once or twice a year. WSDA currently licenses seventy-seven Mobile Custom Farm Slaughter firms and eleven Stationary Custom Slaughter Establishments. Due to this infrequent and limited inspection focus, reliable CMPAF separation by custom slaughter operations is of great concern and will require increased technical assistance and regulatory time.

WSDA believes physical inspection of written procedures, records, and a percentage of materials to be rendered for animal feed, will be necessary at all slaughter facilities and renderers. This regulatory verification of CMPAF removal creates new work load requirements for FDA and state inspectors. FDA states, and WSDA agrees, that the current rule, 21 CFR 589.2000, is the primary tool for preventing the spread of BSE. For this reason a change in inspectional emphasis away from feed manufacturers is not justified and will not offset the additional work created by the proposed 21 CFR 589.2001.

Although some animal mortalities and slaughter by-products are currently disposed of in municipal solid waste facilities the proposed rule will create a new, continuous and higher volume waste stream. There is a lack of uniformly available municipal solid waste facilities for non-feed disposal of dead stock and slaughter by-products - especially a concentrated waste stream that is composed of the material most likely to carry the infectious agent for variant CJD in humans and BSE in cattle. FDA should provide clear guidance on approved methods for disposal of the CMPAF to ensure that they will not contaminate any animal feed and that they do not accumulate in the environment to become a source of contamination in the future.

Each year in Washington State thousands of calves that have not been inspected and passed for human consumption are rendered. The proposed rule would require that the brain and spinal

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cord be removed from these animals before rendering for animal feed. It is unlikely that the value of rendered product derived from young (low weight) cattle will justify the labor to remove and dispose of CMPAF materials. It is likely that renderers will not accept calves resulting in the need for producers to find alternative disposal for thousands more animal mortalities. The removal of brain and spinal cord from calves is not consistent with the science offered by FDA and USDA in rulemaking relating to SRM's for human food, dietary supplements and cosmetics.

WSDA does not agree with the rationale that the lack of established cattle aging capability within the rendering industry is sufficient reason for this costly and unscientific requirement. Is documentation that brain and spinal cord are being adequately removed (a new process for renderers) any more or less plausible than documentation that accepted aging criteria is utilized (also a new process for renderers)? WSDA believes that FDA should include in rule an alternative to brain and spinal cord removal by allowing renderers willing to invest in training personnel to age animals according to accepted criteria. FDA should engage USDA, industry and veterinary or other qualified experts in aging cattle to develop criteria in addition to dentition, such as obvious size or weight indicators by breed, that can be used by renderers.

Currently the BSE rules in Canada and the United States, and the relative BSE risks, are similar. It is important that FDA work closely with Canada to keep the rules as consistent as possible if trade is to remain free between the two countries. Consistency between the two countries is also necessary for effective enforcement within the United States.

WSDA conducts inspections for compliance with 21 CFR 589.2000. Once 21 CFR 589.2001 is finalized, WSDA would appreciate receiving both educational and enforcement guidance documents to aid in achieving compliance by all responsible parties.

Thank you for the opportunity to provide the above comments for your consideration.

Sincerely,

PESTICIDE MANAGEMENT DIVISION



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