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STATE OF WEST VIRGINIA
DEPARTMENT OF AGRICULTURE
CHARLESTON 25305

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COMMISSIONER

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On behalf of the State of West Virginia, I am submitting our comments on the interim final rule on *Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle*, as promulgated by the Food Safety and Inspection Service in the *Federal Register* of January 12, 2004.

We support most of the measures taken to strengthen safety of the beef supply and to limit the potential exposure of humans to the agent that causes bovine spongiform encephalopathy (BSE). At the same time, we would like to offer comments intended to modify the interim rule. Our comments are limited only to those sections of the interim rule which, in our judgment, need to be revised. In addition, we are requesting clarification from USDA, Food Safety and Inspection Service (FSIS) on the applicability of the rules to custom animals.

SECTION 309.2

We suggest a revision to the proposed language of this section to make a distinction between crippled livestock resulting from recent, acute injuries, as opposed to non-ambulatory livestock due to an underlying pathological condition. We realize that non-ambulatory cattle, due to undiagnosed reasons, are more likely to be affected by BSE. However, this assumption does not apply to cattle that were clinically healthy and were injured. Such animals do not pose a greater risk to public and animal health and do not warrant condemnation. We would be in favor of defining crippled livestock due to recent leg or pelvis injuries and limit the maximum allowable time elapsing between the acute injury and slaughter (e.g., twelve hours). It is difficult to find a scientific rationale for condemnation of an animal injured in transportation to the slaughterhouse or during unloading. We understand it may be condemned as a result of antemortem inspection but not before it is examined by a government veterinarian. Further, we would anticipate that FSIS will issue, in the form of a FSIS directive, a set of guidelines that will contain objective criteria for FSIS veterinarians for differentiation between these two classes of non-ambulatory livestock.

SECTION 309.3

We propose three (3) revisions to the interim rule:

1. Designate as Specified Risk Materials (SRMs) *all* the anatomical parts listed under (a)(1), (except for the vertebral column), *regardless* of the age of slaughtered cattle, and prohibit their use for human food.

   We all realize that our knowledge of BSE, including infectivity during the poorly defined incubation period, is still very limited. The relationship between human exposure to the BSE agent and the likelihood of developing variant Creutzfeldt-Jacob Disease (vCJD) is unknown. We do know, however, that the brain and spinal cord of cattle with clinical signs of BSE are estimated to contain nearly 90% of the total infectivity of the animal. Scientific literature shows that BSE infectivity has been demonstrated in the distal ileum six (6) months after post oral exposure to the BSE prion, and in the tonsils ten (10) months after exposure. Our current limited knowledge of BSE indicates that the BSE prion is primarily replicated in the neural tissue. Thus, it appears plausible to assume that the BSE agent is present in the brain and spinal cord very early. Allowing for consumption of the brain and spinal cord from cattle of any age carries an unjustifiable high risk that can be easily avoided. Therefore, we propose designation of the brain, skull, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, tonsils and the entire small intestine of all cattle as SRMs, *regardless* of the age of the cattle.

2. Designate the spleen as a SRM. The FSIS interim final rule quotes the European Commission's Scientific Steering Committee which estimated that the spleen contains about 0.3% of the infectivity in BSE-affected animals. In the interim final rule, the spleen is the only organ that, in spite of its infectivity, was not included as a SRM. Economic impact of the spleen designation as SRM would be negligible.

3. Remove the designation of the major portions of the vertebral column as a SRM. We realize that the main reason for such a designation is the fact that the dorsal root ganglia (DRG) of cattle are well attached to the bones of the vertebral column and are not removed along with the loosely attached spinal cord. However, the designation of the vertebral column as a SRM only due to a strong attachment of DRG is not scientifically justifiable. FSIS has a regulatory authority to require the inspected establishment to fully remove the spinal cord and the adjacent ganglia before the carcass leaves the slaughter house, instead of declaring the major portions of the vertebral column as inedible parts.

We are aware that in 1997, the United Kingdom (the U.K.) banned bone-in beef after some studies showed that in experimentally inoculated cattle, dorsal root ganglia contained the prion, considered the causative agent for BSE. However, just two years later, the U.K. lifted the ban on the sale of bone-in beef because British scientists working on the BSE mode of transmission concluded that the potential risk of human exposure to the BSE prion from bone-in beef was insignificant.

The Harvard study, frequently cited in *Supplementary Information* preceding the interim final rule, reported bone-in beef as one of the less likely routes for potential human exposure to the BSE prion. The interim final rule elaborates on this subject on page 1867 in the *Federal Register: "However, as stated in the Harvard study report, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. For example, the reported quantity for potential exposure to infectivity in bone-in beef reflects the presence of spinal cord and DRG in a fraction of cuts like T-bone steaks, although the spinal cord and DRG may never be consumed in these cuts of meat."* Please note that the short-lived ban on bone-in beef in the U.K. was lifted after 200,000 cattle tested positive for BSE and after destruction of 4.5 million cattle, during which prolonged and severe declines of beef consumption and wide-spread uncertainty, sometimes bordering on hysteria, about the safety of British beef resulted. We doubt that such a drastic reversal in the U.K. regulation would have taken place if any doubts about potential exposure to the BSE prion in bone-in beef had existed. Imposing such a ban in the United States cannot be scientifically or even psychologically justified. Thus, we propose that FSIS remove any references to the vertebral column as a specified risk material, and simply require that the spinal cord and dorsal root ganglia are completely removed by the slaughter establishment.

Finally, the State of West Virginia requests a revision to the interim final rule or another form of clarification which would state that the new provisions amending Section 309.2 are not amendable to personal slaughtering and custom slaughtering for personal, household, guest, and employee uses as exempted by the Federal Meat Inspection Act, Section 623. *Exemptions from inspection requirements*. Our representative participated in a few FSIS conference calls on this subject and our impression is that the issue has not been clarified. FSIS top officials conducting the conference calls maintained that *every* crippled custom animal delivered for slaughter to a custom plant is automatically considered "adulterated" and, therefore, condemned. We disagree with this interpretation due to the following reasons:

1. The Federal Meat Inspection Act, section 601(m) reads: *"The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:"* and further defines the term: *"(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food."* We believe that since the FMIA so clearly states that *"The term 'adulterated' shall apply to any carcass, part thereof, meat or meat product..."* it is not applicable to live animals. A live animal, injured or not, cannot be determined "adulterated." It can be condemned as a result of antemortem inspection but it cannot be arbitrarily determined "adulterated" in the absence of such examination.

2. Custom animals are exempt from provisions requiring antemortem and postmortem inspection by FMIA. Section 623: *Exemptions from inspection requirements* states: *"The provisions of this subchapter requiring inspection of the slaughter of animals and the preparation of the carcasses, parts thereof, meat and meat food products at establishments conducting such operations for commerce shall not apply to the slaughtering by a person of animals of his own raising, and the preparation by him and transportation in commerce of*

the carcasses, parts thereof, meat and meat food products of such animals exclusively for use by him and members of his household and his nonpaying guests and employees; nor to the custom slaughter by any person, firm, or corporation of cattle, sheep, swine or goats delivered by the owner thereof for such slaughter... " Thus, in a custom establishment, an animal with an injured leg cannot be condemned since no livestock inspection is mandated by government.

3. A custom-exempt animal, raised by a farmer, and brought to a custom-exempt establishment for slaughter and/or processing, remains the property of the farmer. Thus, such an animal cannot be condemned just because it was injured en route to the slaughter house. Certainly, it raises a broader constitutional issue whether the government can seize the farmer's property due to such a trivial reason.

4. In states designated for exclusive Federal inspection, FSIS has no system of granting custom exemptions, licensing or registering the existing custom-exempt establishments. FSIS District Offices are not aware of the number of custom-exempt establishments located in their districts, where they are located, what kind of operations they conduct, or the volume of slaughtered animals. Thus, who would determine if an injured cow was "adulterated" and how? We do not believe that FSIS would be able to enforce condemnations of recently injured animals in custom plants in States designated for exclusive Federal inspection.

5. If FSIS declares that the provisions of the interim final rule are also applicable to custom plants, exempt by FMIA from antemortem and postmortem inspection, then we may expect that most injured animals will be illegally slaughtered on farms, under grossly unsanitary conditions. In terms of broad public health protection, the final effect will be just the opposite as intended.

We hope the above comments will receive proper consideration in order to prevent potential human exposure to the BSE agents.

On behalf of the State of West Virginia,

Gus R. Douglass
Commissioner

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