AMERICAN MEAT INSTITUTE

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FSIS Docket Clerk
Docket #03-025IF
Room 102, Cotton Annex
300 12th and C Street, SW
Washington, DC 20250-3700

03-025IF
03-025IF-621
Mark Dopp

Dear Sir/Madam:

This letter responds to the interim final rule published by the Food Safety and Inspection Service (FSIS or the agency) on January 8, 2004, requesting public comment about the rule pertaining to Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle. The American Meat Institute (AMI) is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. AMI member companies account for more than 90 percent of U.S. output of these products. AMI appreciates the opportunity to provide comments regarding several topics in the interim final rule.

Comments are provided herein on selected changes for 9 CFR Parts 309 and 310 provided in the interim final rule.

Part 309 – Post-Mortem Inspection

§ 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise

The language in the interim final rule with respect to nonambulatory livestock is overly broad and must be amended not cause the unnecessary condemnation of animals for reasons wholly unrelated to food safety or animal health. It is clear that the rule's focus is to address concerns raised by the case of bovine spongiform encephalopathy (BSE) in December 2003. The rule, however, reaches well beyond those concerns and captures

unnecessarily other species not affected by that disease.

The change in the regulations replacing "seriously crippled animals commonly termed "downers" in 309.2 (b) with "non-ambulatory disabled livestock " unnecessarily and inappropriately broadens the rule's scope. The interim rule, as written, includes not only non-ambulatory disabled and diseased cattle but swine and, otherwise healthy swine that have suffered injuries such as a broken appendage or severed tendons and or are subject to temporary fatigue or metabolic conditions that are specific to swine.

The interim rule's objective is to "minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease." As the discussion that follows demonstrates, the rule overreaches even with respect to cattle. There is no reason, however, to apply that standard, "livestock that cannot rise from a recumbent position or that cannot walk, including those with broken appendages, severed tendons, or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions," to swine when there is no scientific link between swine and BSE.

In the alternative, FSIS should consider species-specific language that recognizes that swine or other amenable species can be "temporarily disabled" and still be suitable for slaughter and use as human food. For example, swine can become "temporarily disabled" through stress or fatigue, yet they are not "diseased" and should be eligible for use as food.[1] Under the interim rule language such animals could be construed as nonambulatory and be subject to condemnation. For the foregoing reasons, FSIS should amend the language interim final rule to recognize the differences in species and the conditions that may warrant the condemnation of those animals on a species by species and case-by-case basis.

Before January 12, 2004, FSIS regulations required aggressive ante-mortem inspection of all livestock destined for slaughter and has prohibited for human food any livestock exhibiting clinical signs of central nervous system (CNS) disorders (9 CFR 309.4) and any livestock that are in a dying condition or that die otherwise than by slaughter (9 CFR 309.3). Other non-ambulatory livestock have also undergone rigorous ante-mortem inspection and are identified as "US Suspects" (9CFR 309.2(b)). USDA veterinarians carry out ante-mortem inspection and a record of the veterinarian's findings is transferred with the animal through slaughter to the carcass inspection level. The "US Suspect" animal is slaughtered separately and undergoes a

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[1] Porcine Stress Syndrome (PSS) is a genetic-based, metabolic stress condition that occurs in a small proportion of animals in the swine population and can cause *temporary* ambulatory interruption and dysfunction.

rigorous post mortem inspection by USDA Veterinarians before a determination is made that the carcass is fit for human consumption. This system has long been proven effective at providing appropriate safeguards to protect human health.

Given the recent discovery of Bovine Spongiform Encephalopathy (BSE) in an imported Canadian dairy cow in the U.S., AMI is not opposed to additional regulatory actions regarding certain cattle that may present a higher risk for testing positive for BSE. AMI supports the condemnation of cattle that exhibit clinical signs consistent with CNS disorders, including BSE. AMI is also supportive of an inspection system that identifies and condemns cattle that fit certain scientifically based measures indicative of clinical BSE. However, AMI does not support wholesale condemnation of cattle based on a broad definition of non-ambulatory disabled status. Cattle may become non-ambulatory for a variety of reasons, both chronic and acute. Recognizing that BSE is a very rare disease, even in the country with the highest prevalence in the world (i.e., the United Kingdom), certain factors associated with non-ambulatory condition may be valid indicators of early signs of this very rare condition, BSE. However, there are myriad conditions that may render a bovine non-ambulatory disabled that are unrelated to neurological disease. These conditions could include broken appendages, fatigue, stress, obesity, severed tendon or ligaments, and dislocated joints. In many of the cases in which a bovine has become non-ambulatory, the causes are completely unrelated to neurological conditions or BSE, e.g., a steer that breaks a leg while being unloaded from a trailer.

A publication from the University of Zurich by U. Braum, U. Kihm, N. Pusterla, and M. Schonmann (http://www.bse.unizh.ch/pdf/clinicalexamination.pdf) provides detailed guidance on establishing the clinical signs consistent with cattle suspected of BSE (Table 1). These veterinarians have extensive experience dealing with cattle positive for BSE. While the authors point out that clinical signs of BSE are subtle, the document establishes clear and objective guidelines for determining clinical risk factors.

Table 1: Clinical signs of BSE

Characteristic symptoms with an insidious course. The following clinical signs may occur:
1. Disturbances in behaviour • Fearfulness, nervousness, increased alertness and panic-stricken behaviour • Fear of traversing the manure gutter and of passing through doorways and of small obstacles such as a pole on the ground • Aggressiveness e.g., violent kicking at people or during milking • Frequent licking of the nose • Bruxism • Tremors: Trembling or muscle twitching involving lips, muzzle, ears, neck, cranial body, flank or entire body
2. Disturbances in locomotion • Gait becomes progressively stiffer, ataxia and hypermetria in the hindlimbs and occasionally also in the forelimbs. Recumbency in terminal stages.
3. Disturbances in sensitivity • Easily startled, sometimes to the point of collapsing after minor disturbances such as noise or movement of people or animals • Hypersensitivity to touch, particularly in the head and neck regions; manipulation of the head and neck areas results in cow tossing her head sideways, wrinkling her nose, salivating and snorting • Hypersensitivity to light: easily startled when the light is suddenly turned on in a dark room • Hypersensitivity to noise: easily startled by noise e.g., door slamming
4. Slow weight loss • Slow weight loss and decrease in milk production despite normal feed intake

Braun et al. (1997) state, "generally, disturbances in behaviour, locomotion or sensitivity must be interpreted with caution when they are limited to one clinical category. In such cases, BSE is not likely the problem." They also cite a recent study (Schicker, 1997) involving 50 cows known to be positive for BSE; all had positive findings in at least two of the three clinical

categories; and 43 of the cows had positive findings in all three of the clinical categories. None of the 50 BSE positive cows had only one clinical symptom. Table 2 describes the Swiss Health of Animal Regulations. Group II describes the clinical findings of cattle that have no symptoms of BSE, or only mildly positive findings in one clinical category; and in Switzerland, these cattle are treated equally with respect to not requiring additional BSE control measures.

While it has been cited in the interim final rule that epidemiological data from the EU suggest that animals that generally fit the description of "non-ambulatory" are more likely to test positive for BSE, there remain significant differences between countries concerning the definition of this general class of cattle. AMI agrees that there may be evidence to indicate that a certain subset of cattle that are non-ambulatory may represent an appropriate target class for additional BSE control measures, such as targeted surveillance. However, examination of recent data from Switzerland, where they conduct a very robust BSE surveillance program, is instructive (Table 3).

These data suggest there is no difference between the BSE prevalence rate of cattle in the "sick slaughtered" category and those from the general "healthy population" within the Swiss cattle herd in 2002. While the interim final rule cites data from the EU to support condemnation of all cattle determined by U.S. definition to fit a "non-ambulatory disabled" classification, the actual data from Switzerland, a country believed to have very well developed and globally recognized BSE control measures in place, do not support such a position. By using the precautionary logic in the interim final rule, all U.S. cattle should be condemned, and of course, this is not logical or supported by any form of risk benefit analysis. The SRM removal portions of this interim final rule are appropriate to mitigate the risk posed by any cattle that may test positive within the general healthy cattle population.

Table 2. Clinical diagnosis and measures provided by Swiss Health of Animal Regulations

Group	Clinical diagnosis	Clinical findings	Health of Animal Regulations
I	BSE	• all typical symptoms present (disturbances in behaviour, locomotion and sensitivity) **or** • distinct positive findings in 2 clinical categories (e.g. panic-stricken and ataxic or nervous and hypersensitive to sound)	• Report to cantonal veterinary authorities, euthanatise animal, submit brain for histological examination, incinerate carcass
II	No BSE	• no typical symptoms of BSE, **or** • a single mildly positive finding in 1 clinical category (e.g. mildly hypersensitive to sound or to manipulation of neck) **or** • disturbance in locomotion without abnormalities in behaviour and sensitivity	• No further measures necessary with regard to BSE
III	Suspicious of having BSE	• Severe disturbances in behaviour (e.g. nervous, fearful, panic-stricken) **or** • Severe disturbances in sensitivity (e.g. hypersensitive to manipulation, sound, light)	• Repeat clinical examination 1 to 2 weeks later, possibly more than once • Animal must not be slaughtered • Report to cantonal veterinary authorities • If suspicion persists, euthanatise animal, submit brain for histological examination, incinerate carcass
IV	BSE cannot be ruled out	• mildly positive findings in 2 clinical categories (e.g. mildly panicky and mild sensitivity to sound) **or** • a distinct positive finding in 1 clinical category (e.g. panic-stricken by sound). The remaining clinical categories yield clearly negative findings	• See Group III

Table 3. BSE cases in Switzerland according to category, 2002

Category	Tests conducted	Positive for BSE	Percent positive
Clinical BSE suspects	57	8	14%
Fallen stock (dead on farm)	10,032	8	0.08%
Sick slaughtered	8,317	2	0.02%
Healthy slaughtered	5,895	1	0.02%
Voluntary healthy slaughter	143,757	5	0.002%

Furthermore, the interim final rule provides no distinction of age within the "non-ambulatory disabled" classification. It has been clearly established in the scientific literature, and referenced in other sections of this interim final rule, that the infective agent for BSE accumulates to the point of being detectable in the animal after 30 months of age. Over 99.99% of cattle that have tested positive for BSE worldwide, are older than 30 months of age. In the interim final rule, FSIS discusses the 21- and 23- month of age cattle found by the Japanese to be BSE positive. AMI asks FSIS to investigate these findings further and publicly clarify that these results were reached using inadequate methodology (e.g., using phosphotungstate in the analysis of the concentrated Western Blot preparation for the test sample but not for the control sample) and that the tissue samples, originally reported to be positive by the Japanese, were later confirmed as negative by the International Reference Laboratory in Weybridge, England.

New measures proposed in the interim final rule that require all cattle presented for slaughter that are non-ambulatory disabled to be condemned must recognize that some of these non-ambulatory cattle will be under 30 months. The interim final rule must also recognize that cattle may become non-ambulatory disabled for an acute reason that has absolutely no association with the very rare disease, BSE. For instance, it is illogical and without any scientific merit, to condemn a 20 month old fed steer that has severed a tendon or broken an appendage, out of precaution that it may be infected with BSE.

AMI recommends that FSIS reconsider the definition of non-ambulatory disabled cattle to be more specific to the subgroup of this class of cattle that are most likely to be at higher risk for testing positive for BSE. Cattle that are younger than 30 months of age, and cattle that have experienced an acute injury that is not accompanied by other clinical signs of BSE should not automatically be condemned, but should proceed through the normal FSIS slaughter inspection procedures. Cattle that have become non-

ambulatory for reasons related to stress or fatigue, and have no other clinical signs associated with BSE, should be given the opportunity to recover from the fatigue to determine if they can become ambulatory.

Thus, the consideration that all non-ambulatory disabled livestock are at risk for BSE is an overly conservative approach to control of risks associated with SRMs. AMI agrees with FSIS that "data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle." AMI agrees that such observations should be the basis for surveillance programs for BSE. However, the statement that "non-ambulatory disabled cattle present a risk of introducing the BSE agent into the human food supply" without any consideration given to the cause of the non-ambulatory disabled condition, or to existing and new risk mitigation measures is an overly conservative and unnecessary position.

Comparing the human health risks associated with BSE in the U.S. with those in Europe, and basing the role of non-ambulatory disabled animals in human health risks in Europe with their role in the U.S. does not take into account the significant differences in BSE prevalence rates on the two continents and the risk control measures, e.g., the feed ban, that have been in place in the U.S. for years.

Although the statement by FSIS that "permitting the carcasses of non-ambulatory cattle to be used for human food if the animal tests negative for BSE will not provide the same level of protection against human exposure to the BSE agent that prohibiting these cattle from entering the human food supply will," states an obvious fact, it does not consider the extremely low prevalence of BSE in the U.S., nor does it consider the many other factors such as additional reasons an animal may be non-ambulatory and the age of the non-ambulatory animal.

References:

Schicker, E. (1997). Untersuchungen bei Kuhen mit boviner spongiformer Enzephalopathie (BSE). Dissertation, Universitat Zurich.

Braun, U., Schicker, E., Pusterla, N., Schonmann, M. (1997). Klinische Befunde bie 50 Kuhen mit boviner spongiformer Enzephalopathie. In Vorbereitung.

Braun, U., Kihm, U., Pusterla, N., Schonmann, M. Clinical examination of cattle with suspected bovine spongioform encephalopathy (BSE). (http://www.bse.unizh.ch/pdf/clinicalexamination.pdf)

Part 310 – Post-Mortem Inspection

§ 310.22 Specified Risk Materials From Cattle and Their Handling and Disposition

(a) Identification of Specified Risk Materials (SRMs)

AMI supports the designation of certain tissues from cattle that have demonstrated BSE infectivity as SRM. It must be recognized however that various tissues possess different levels of infectivity starting from the time an animal is infected to the time clinical signs of the disease are observable in the animal. For example, the brain of an animal 30 months of age or older is appropriately designated as SRM, while the brain of an animal less than 30 months of age should not be designated as a SRM.

Also, the amount or weight of the various tissues and level of infectivity that certain tissues can harbor directly influences the proportion of infectivity contained in the animal. The Spongiform Encephalopathy Assessment Committee (European Community, 1998), assigned "Relative Infectivity" of BSE-SRMs using "Infectivity Density" and "Percent of Total Infective Load Per Animal" (Table 4).

Table 4. Relative Infectivity of BSE-SRMs[1]

Tissue	**Infectivity Density**	**Weight (kg) Per Animal of 537 kg**	**ID 50 Per Animal**	**Percent of Total Infective Load Per Animal**
Brain	10	0.5	5,000	64.0
Spinal Cord	10	0.2	2,000	25.6
Trigeminal ganglia	10	0.02	200	2.6
Dorsal root ganglia	10	0.03	300	3.8
Ileum	$3.2*10^{-2}$	0.8	256	3.3

[1]European Community. 1998. Relative infectivity of specified risk materials. Report of the Spongiform Encephalopathy Assessment Committee.

Clearly, removal of the brain and spinal cord from animals over 30 months of age provides the most significant human health protection. In a country, such as the U.S., that has not diagnosed an indigenous case of BSE, removal of all known SRM may not be warranted. Experts agree that the public health risk in the U.S. from exposure to the BSE infective agent is extremely small. In comparison, an estimated four million cattle were infected in Great Britain. More than 180,000 cases of BSE have been diagnosed since 1986. Widespread human exposure to BSE infectivity occurred, yet less than 150 cases of nVCJD have been diagnosed in Great Britain. Future estimates of nVCJD cases have been drastically reduced from earlier estimates and the number of nVCJD cases diagnosed each year continues to decline. Precipitous actions to reduce a perceived human health threat should be avoided.

A study conducted by the Harvard Center for Risk Analysis outlined steps that could reduce possible human exposure to BSE infectivity if the disease was introduced into the U.S.; the study, however, was not a human health risk assessment. It did not quantify the probability that BSE will be introduced into the U.S.; it did not estimate how many people will contract nVCJD; and it did not estimate the reduction in illnesses and deaths that would occur as a result of implementing certain mitigation steps. Any actions to prevent human exposure to the BSE infective agent, such as removing all SRM prescribed by USDA in the interim rule should be evaluated based on its public health outcome. AMI suggests a human health risk assessment be conducted to determine the extent of public health protection SRM removal provides before publishing a final rule.

Furthermore, the OIE International Animal Health Code outlines recommendations for managing the risks associated with the presence of BSE in cattle. OIE standards are developed to assure the safety of international trade in animal and animal products. The U.S. has the coveted designation of a "provisionally BSE free" country under OIE guidelines. SRM removal is not required under a "provisionally BSE free" designation. USDA has taken extraordinary steps to protect public health by extending the list of SRMs well beyond what would be required for a "minimal" risk country. For countries designated as "minimal" risk, OIE requires that fresh meat and meat products do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age. AMI suggests that USDA requirements for SRM removal be harmonized with OIE standards to the maximum extent possible.

Protection of public health should be the U.S. government's top priority. Policies should be based on technical facts and science. Actions that may be perceived as beneficial yet provide no measurable benefit should be avoided. Removal of certain tissues from the food supply, such as the entire small intestine and the vertebral column may not be warranted.

AMI agrees that removal of the distal ileum (DI) of the small intestine and the dorsal root ganglia contained in the vertebral column is appropriate when sourced from animals that are likely to harbor the infectious prions. We do not agree, however, that removal of the entire small intestine and the vertebral column from older animals is justified. Significant economic costs are associated with declaring these tissues as SRM, yet the potential reduction in human health risk that will result from removing these tissues is extremely small.

AMI suggests that the regulatory language be changed to permit the removal of the only the DI. The current language "to ensure effective removal of the DI, the establishment shall remove the entire small intestine..."should be deleted. Only the DI has been shown to harbor infectivity in experimentally infected animals and experience dictates that the DI can be effectively removed from the small intestine. This is discussed in greater detail below.

Additionally, any regulation prohibiting the use of DRG should be stated as such, and not written to require the removal of the vertebral column itself. Removing the vertebral column from animals over 30 months of age prohibits the production of bone-in rib eye steaks, T-bone steaks, or other cuts that contain bone from the vertebral column. AMI is confident that technologies can be developed to effectively remove DRG yet allow the vertebral column from older animals to remain in the food supply.

Specific Recommendations on the Distal Ileum

The expansion of the category of SRM to include the entire small intestine is overly broad and not scientifically sound. The scientific evidence and past agency practice support the separation and removal of the DI only. Throughout the preamble to the interim final rule FSIS repeatedly references the research and scientific evidence that the DI can be a source of the infective agent of BSE. Indeed, in announcing several new regulatory measures that have been taken, the agency clarified that the scope of the designation as a SRM would be limited to the DI. Specifically, at a briefing held by FSIS and Animal and Plant Health Inspection Service (APHIS) the

day after the Secretary's December 30, 2003, announcement of the new safeguards, the agency's Dr. Dan Englejohn clarified that the SRM identification was limited to the distal ileum.

> **DR. DAN ENGELJOHN:** Good morning. I'd like to identify that we have some clarifications from our information that was released yesterday. We are going to clarify that in the policies we're working on, instead of the entire small intestine that will be identified as a risk material it will be only the distal ileum. And we're making some clarifications to the actions that would be taken with the vertebral column of beef and that would be that we will be following closely the information that Canada put out on how they defined what would or would not be allowed from the vertebral column. (Transcript of Technical Briefing, December 31, 2003)

The body of scientific evidence supports the conclusion that the DI may pose a risk of infectivity. In that regard, the infective agent has been found in certain lymph-reticular system tissues, called the Peyer's patches, which are concentrated in the distal ileum of the small intestine.

Research indicates, however, that the infective agent is not found in gastrointestinal tissues other than the DI. Specifically, the infective agent is not present in the duodenum and the jejunum portions of the small intestine even when the agent is found in the ileum. Moreover, the infective agent for BSE has only been found in the DI of cattle that were inoculated with the BSE infective agent. The infective agent has not been reported to have been found in the DI of animals that have succumbed to the disease naturally.

Thus, the research and science indicate that the DI of the small intestine may be a risk material for the BSE infective agent, albeit a small risk. That scientific work also supports a conclusion that the DI contains the only tissues in the gastrointestinal tract containing the infective BSE agent in artificially infected animals. Therefore, the remaining portion of the small intestine should be allowed to remain as an accepted, edible product for human consumption.

Significantly, there is precedence within FSIS regulatory requirements to allow meat packers to separate the DI from the remainder of the small intestine and allow that remainder to be used for human food purposes. Specifically, before December 23, 2003, FSIS officials signed export certificates "certifying" the removal of the DI from small intestines being sold and exported to Japan. In that regard, at least one procedure was presented to FSIS to separate and remove the DI, which was acceptable to FSIS such

that certificates were signed and small intestines exported. Indeed, the FSIS Export Library provided that:

> If requested by the exporter, FSIS can provide the following certification statement for beef and beef products that do not contain the indicated specific risk material: *"The product does not contain brain, eye, spinal cord, or distal ileum."* This statement can be included in the Remarks section of FSIS 9060-5 or as an FSIS Letter Head Certificate: Blank certificates are found at http://www.fsis.usda.gov/OFO/export/JapanBeefCert.pdf. (Emphasis added)

In short, FSIS has recognized the scientific issues concerning the DI and has recognized and acknowledged at least one method for separating and removing the DI from the small intestine and allowed such procedures to be used. The discussion that follows provides at least one process for removing the DI and allowing the small intestine to be used for human food purposes. AMI encourages FSIS to allow this procedure, as well as other procedures, to effectively remove DI tissue that potentially could be infective.

General Description and Processing Procedure for the Distal Ileum

The discussion below describes a method that would be an appropriate guideline for removing and separating the DI from the remaining edible portion of the gastrointestinal tract of bovine animals.

The beef small intestine processed for export to international market is comprised of the small intestine beginning at the stomach, including the duodenum, and the jejunum anterior to a point commonly referred to as the "flange" (Figure 1). The ileum of a beef animal will, on average, be 15 to 24 inches in length (dependent on age and size of animal). The ileum is very distinguishable as it is a very straight portion of the intestine (Figure 3). The anterior portion begins where the cranial mesenteric artery ends and the ileum terminates at the cecum and colon (Figures 2 and 3).

The distal portion of the ileum can be generically defined as the portion, or half, of the ileum that is adherent to the cecum, estimated at one to one and one-half feet in length. The proximal portion of the ileum being defined as the portion, or half, of the ileum which is adherent to the jejunum, estimated at one to one and one-half feet in length.

The flange is located in the distal jejunum, estimated at one and one-half to two feet from the end of the cranial mesenteric artery and the anterior

ileum depending on the size of the animal. Removal at this point would include the entire ileum and a portion of the jejunum (Figure 1).

The portion of the intestine removed would include the entirety of the ileum, thus including the DI, along with a short portion of the distal jejunum; the removed items would equal approximately three to six feet in length depending on the age and the size of the animal (Figures 2 and 3).

(a) Processing Procedures for the Distal Ileum

1. The small intestine is removed from the abomasum.
2. Separate the small intestine from the cecum at the ileocecal orifice. Separate the ileum from the jejunum at a point commonly referred to as the flange. The entire portion being three to six feet in length (36 to 72 inches; dependent on age and size of animal). Separation would be monitored by FSIS personnel prior to transfer of products to inedible rendering (ileum) and for processing (remaining jejunum and duodenum of small intestine).
3. Flush out and clean the remaining portion of the small intestine

(b) Alternative Removal Procedures for the Distal Ileum

1. Remove small intestine from abomasum
2. Leaving small intestine attached to the cecum, measure a 36 to 80 inch section back through the entire ileum and into the jejunum, and make separation at that point.

Leaving the DI attached to the cecum provides an easy point of reference for on-line verification by USDA. The 80 inches is an ultraconservative severance, for which precedent exists, i.e., Japan product specifications before December 23, 2003.

(c) Verification (options)

1. Plant management will monitor procedure according to approved SSOPs to verify proper procedures. Removal of the DI would be verified directly by FSIS personnel. The process would be completed on the evisceration table in sight of FSIS personnel.
2. Plant management will monitor the procedure according to pre-requisite programs. This procedure would be verified by FSIS.
3. FSIS would oversee the process and verify that the procedure was correctly completed. However, the procedure would take place in a location that was not within site of FSIS personnel.

Note: The figures provided and referred to herein were taken from an approximately 1500 pound Holstein cow. Thus, the measurements shown would be, on average, larger than most animals slaughtered in the United States.

Figure 1. Relevant anatomy and terminology

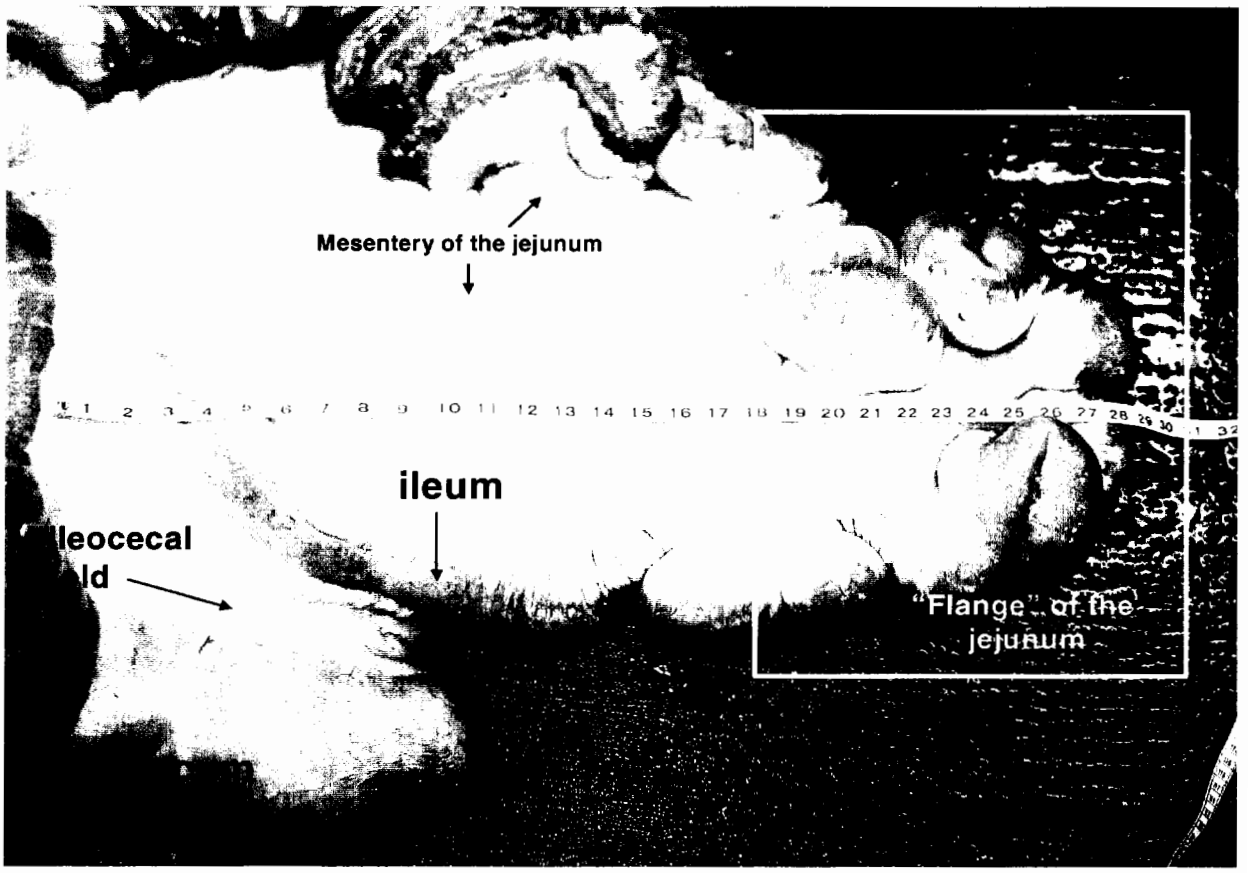

Figure 2. The junction of the jejunum and ileum is the point where the cranial mesenteric artery ends, and the cranial limit of the ileocaecal fold. The cranial limit of the ileocecal fold is labeled as point "A" in the picture below. This is this author's definition of the junction between the jejunum (intestine to the right) and the ileum (intestine to the left).

Figure 2 from Weaver AD, Bovine Surgery and Lameness. London: Blackwell Scientific Publications, 1986, p. 68.

Figure 3. The ileum is defined as the terminal part of the small intestine, from the free edge of the ileocecal fold to the ileocecal orifice. Its cranial [distal] part is adherent to the cecum and colon [brackets mine.] By this definition, the ileum would be contained within the brackets as shown in the photograph below:

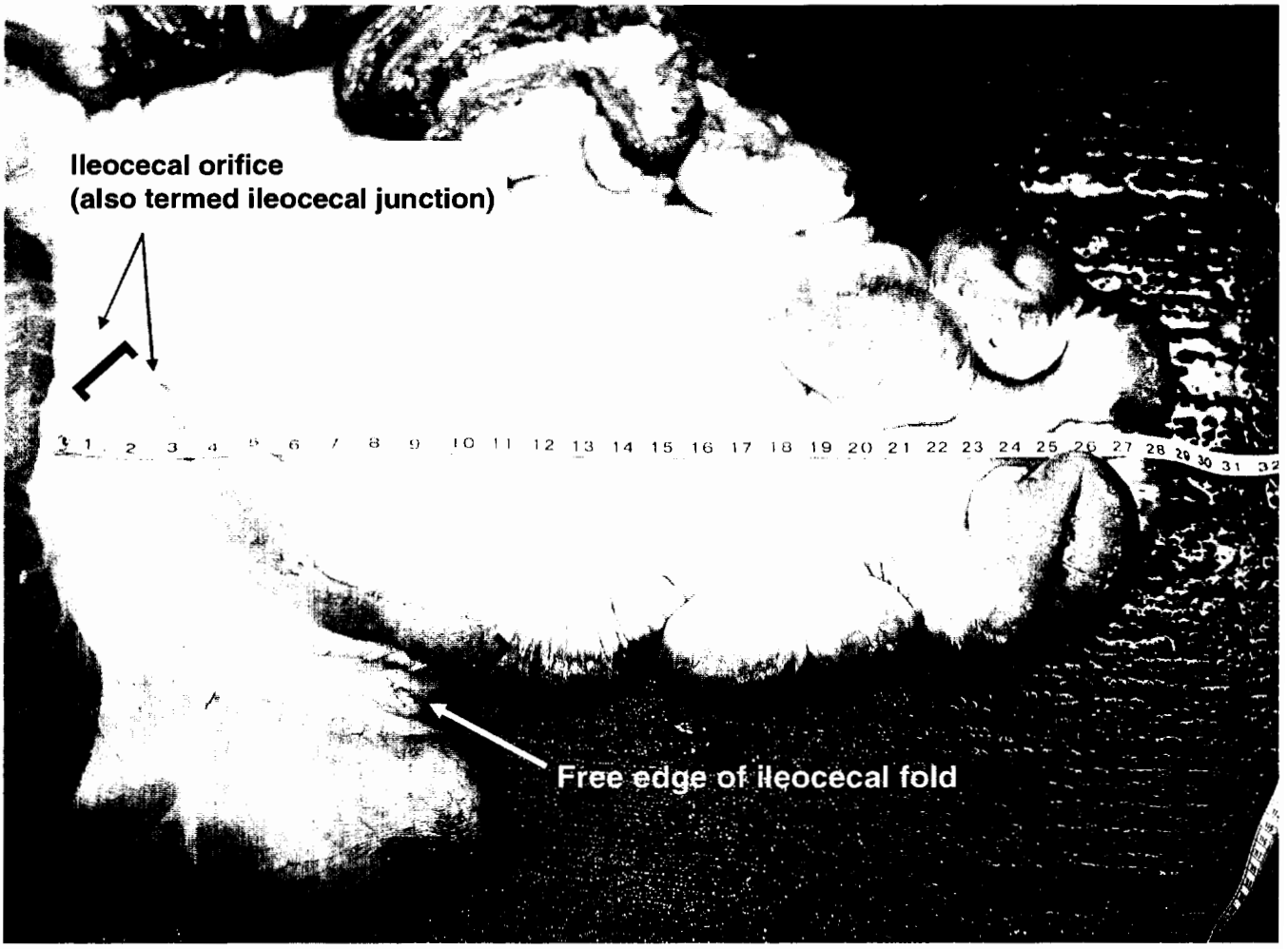

Figure 3 from Habel RE. Ruminant digestive system. In: Getty R, ed., The Anatomy of the Domestic Animals. Ed. 5, Philadelphia: WB Saunders Co., 1975, p. 904.

§ 310.22 Specified Risk Materials From Cattle and Their Handling and Disposition

(d) (1) SRM Protocols in HACCP, SSOP or Pre-requisite Programs

Because of the interventions established since 1997, no use of earlier BSE-propagating feeding and production practices, and U.S. BSE surveillance data, prions cannot be rationalized as being hazards reasonably likely to occur during a hazard analysis, even in SRM from animals over 30 months of age. Thus, there would be no scientific reason to incorporate controls for prions (and thus, the SRM) in a HACCP plan. Removal of SRM would be better covered in an establishment's SSOP, or a pre-requisite program. Sanitation of equipment used in slaughter would be covered in the SSOPs. Thus, this section of the interim final rule should be modified to exclude the reference to HACCP unless a justification is provided to substantiate that prions are hazards likely to occur.

In summary, public health policy regarding SRM in the human food supply should be based on using the best available science, recognizing the existing very low public health risk, demonstrating a measurable public health benefit, avoiding SRM designation for products that pose minimal risks, and avoiding unwarranted costs.

FSIS requested comments as to whether it has chosen measures that are most appropriate for preventing human exposure to the BSE infective agent in the U.S. Although FSIS is fulfilling its responsibilities to protect public health by identifying SRM from selected cattle and declaring these items as not usable for human food, the rule requires additional changes to more accurately reflect the factors that both contribute to, and mitigate the risk associated with, BSE in the U.S.

Sincerely,

Mark D. Dopp
Senior Vice President, Regulatory
Affairs and General Counsel