AMERICAN MEAT INSTITUTE

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FSIS Docket Clerk
Docket #03-038IF
Room 102, Cotton Annex
300 12th and C Street, SW
Washington, DC 20250-3700

03-038IF
03-038IF-22
Mark D. 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 Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems. 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.

The first critical element of the interim final rule is that it serve as "a prophylactic measure designed, in part, to prevent human exposure to the bovine spongiform encephalopathy (BSE) agent by ensuring the AMR systems are not a means of introducing central nervous system (CNS) tissue into product labeled as 'meat'." The concepts in this first element should be applied to beef only because cattle are the known source of problematic CNS tissues.

The agency also stated that "[I]n addition to the measures related to BSE, FSIS is finalizing restriction related to bone solids and bone marrow for livestock products." This second element applies more broadly to all meat animals because it involves standards for AMR derived products. Because these two objectives are vastly different, yet important elements of the interim final rule, they should be reviewed separately, recognizing that

certain contemplated requirements in particular are unrelated to pork products.

The agency has regulated meat derived from AMR processes for many years. Use of AMR product has had a significant impact on the meat industry, benefiting consumers through the enhanced availability of usable protein, supporting companies' operations, and making processes safer for the industry's labor force. Indeed, workers have benefited tremendously from the use and development of AMR. In that regard, AMR technology has helped reduce accidents and helped create safer working environments.[1] Similarly, industry has benefited because raw material quality has improved through a consistent reduction in bone chips occasionally present in hand deboned trimmings from beef and pork neck bones. AMR also has improved industry practices concerning removal of the spinal cord from the carcass during the slaughter process.

As FSIS has indicated, AMR products do not present any adverse health, safety, or nutritional effects. Indeed, nutritionists agree that meat and meat products, including AMR, are an excellent source of dietary iron and should be considered an essential source for iron.

Previously submitted comments from AMI indicated that eliminating AMR technology would have significant economic impact on the meat industry. An economic impact study conducted by Sparks in 1999 summarized the costs associated with eliminating AMR technology (Table 1). The agency has incorrectly concluded that, notwithstanding the regulatory requirements included in the interim final rules, "AMR machines will continue to operate." In fact, however, AMR systems have been shut down because of the agency's new regulatory policies on AMR. It is quite likely that, absent certain changes in a final rule, any such final rule would create significant, and likely insurmountable, hurdles to continued use of AMR technology. To that end, the interim final rule has a significant economic impact, in excess of $200 million, and Executive Order 12866 should be observed.

FSIS, the Food and Drug Administration (FDA), and APHIS have implemented effective animal health firewalls, *e.g.* added surveillance of suspect animals and the ruminant-to-ruminant feed ban. The interim final rule policies removing non-ambulatory animals and SRMs from the human food chain in specific ante-mortem situations provide additional safeguards.

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[1] U.S. Department of Labor (2002) published data for Meatpacking and Poultry Processing in 2002 that showed Nonfatal Occupational Injuries and Illnesses have decreased from 21.5 incidents per 100 workers in 1996 to 11.5 incidents per 100 workers in 2002. A portion of this 47% reduction in worker injuries is certainly attributable to the introduction of AMR systems in 1994.

These firewalls and policies provide effective protections for animal health and consumer confidence.

Table 1. Economic impact of AMR systems on the meat industry

Fed Beef Industry	Total Impact for Industry
Spent capital loss	$19,720,000
Capital to restructure	$19,176,000
Additional labor	$36,951,200
Employee medical impact	$7,208,000
Yield reductions	$21,672,210
Fed-Beef Industry Total	$104,727,410
Cow Industry	
Spent capital loss	$10,440,000
Capital to restructure	$6,660,000
Additional labor	$7,722,000
Employee medical impact	$1,590,000
Yield reductions	$8,789,130
Cow Industry Total	$35,201,130
Pork Industry	
Spent capital loss	$9,860,000
Capital to restructure	$6,494,000
Additional labor	$7,979,400
Employee medical impact	$1,643,000
Yield reductions	$42,432,180
Pork Industry Total	$68,408,580
TOTAL COSTS	*$208,337,120*

Additional comments are provided hereafter on specific changes proposed for 9 CFR Parts 301 and 318 in the interim final rule pertaining to Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems.

Part 301 – Terminology

§ 301.2 Definition of Meat

Beef

AMI agrees that consumers should not be misled in their appreciation for meat quality, and agrees that CNS tissues that present a risk of transferring infectious materials from BSE-infected animals should be excluded from meat. The risks from CNS and other animal tissues that present a risk from infectious prions are being managed through processing of carcasses to exclude specified risk materials (SRM) as required by the interim final rule pertaining to Prohibition of the Use of SRM for Human Food published on January 8, 2004. Where there is no known risk of infectious prions, e.g., processing of beef animals that are less than 30 months of age, AMI asserts that FSIS should take a different approach to the production and use of the meat from these livestock.

The interim final rule pertaining to Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems establishes what is essentially a double standard for the definition of meat, allowing bone and its associated tissues in bone-in products (*e.g.* T-bone steaks and porterhouse steaks from cattle less than 30 months old), but excluding the same associated tissues from deboned products, regardless of the age of the animals from which the deboned product is derived. Consumption of bone-in products could easily result in consumer exposure to tissues that are excluded from deboned meat by the interim final rule. The basis for this dual system is not justified clearly by supporting documentation in the interim final rule. AMI respectfully requests that FSIS provide adequate justification for the dual standards for meat, or eliminate this dual standard by allowing the same tissues present in bone-in cuts, to which consumers have exposure, to be allowed in AMR products.

Pork

Where there is no known risk of infectious prions, e.g., processing of hogs, AMI asserts that FSIS should take a different approach to the production and use of the meat from these livestock. The interim final rule pertaining to Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems establishes what is essentially a double standard for the definition of pork, allowing bone and its associated tissues in bone-in products (*e.g.* bone in pork chops), but excluding the same associated tissues from deboned products. Consumption of bone-in products could easily result in consumer exposure to tissues that are excluded from deboned meat by the interim final rule. The basis for this dual system is not justified by supporting documentation in the interim final rule. AMI respectfully requests that FSIS provide adequate justification for the dual standards for pork, or eliminate this dual standard by allowing the same tissues present in bone-in cuts, to which consumers have exposure, to be allowed in AMR products.

The regulatory definition of pork (9 CFR 301.2) has always included portions of bone, skin, sinew, nerve and blood vessels that normally accompany muscle tissue. The CNS-type material that would be prohibited, such as DRG, is often found in bone-in products, *e.g.* bone in pork chops. Nor is the prohibition on CNS-type tissue in AMR pork products necessary to meet consumer expectations. AMI respectfully requests that FSIS supply the consumer research data that has led to its conclusion that consumers understand that meat from bone-in products derived from hand cutting may contain DRG and other CNS-type tissues, but do not expect such materials to be present in meat derived from these same parts of an animal through the use of AMR equipment. If these data are not available or sufficient for the claim, FSIS should remove the requirement excluding CNS tissue from pork AMR.

Specifically for pork, the exclusion of CNS tissue from AMR pork products will not offer any human health benefits, nor prevent human exposure to the BSE agent, and will be very costly for the consumer. Spinal cords are removed from hog carcasses as part of the slaughter operation, with visual verification before the raw material enters the AMR system.

Part 318 – Entry into Official Establishments; Reinspection and Preparation of Products

§ 318.24 Product prepared using advanced meat/bone separation machinery; process control

(a) General

The interim final rule, if finalized as published, will effectively eliminate a wholesome, inexpensive protein source, AMR.

Pork, and pork AMR, has not been associated with any transmissible spongiform encephalopathy (TSE) and there is no scientific base for the purported concern about controlling the presence of CNS-type tissue in AMR pork products. Nervous system tissue is a natural and integral part of any meat of animal origin and CNS-type tissue or various ganglia of pork meat has never been shown to be associated with, or cause, any human diseases and will not affect the prevention of human exposure to the infective BSE agent. Accordingly, there is no scientifically based human health reason to exclude it from pork AMR products.

(b) Process control

Beef

FSIS appears to consider that controls in AMR systems, like controls associated with SRM removal, need to be linked to HACCP systems. Because of the interventions established since 1997 for beef cattle and dairy cows, 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 and even in the consideration of SRM from animals over 30 months of age. Thus, there would be no scientific reason to incorporate controls for prions (and thus, the raw materials for AMR systems and any SRM) in a HACCP plan as suggested in the interim final rule. Controls for raw materials used in AMR processes, as well as in the AMR process itself, would be better covered in an establishment's SSOP, or a pre-requisite program. Thus, this section of the interim final rule should be modified to exclude the reference to HACCP unless a statistical and additional scientific justification is provided to substantiate that prions are hazards likely to occur.

Pork

The same comments that apply to beef above pertain even more specifically to pork where there is no evidence that there is a human health risk from incidental spread of SRMs to pork during processing of carcasses. Thus, prions cannot be rationalized as being hazards reasonably likely to occur during a hazard analysis; there would be no scientific reason to incorporate controls for prions (and thus, the raw materials for AMR systems and any SRM) in a HACCP plan as suggested in the interim final rule.

(c) Noncomplying product

AMI agrees that AMR systems need controls; AMI also believes that the optimal controls for AMR production involve statistical process controls (SPC) where out-of-control conditions with assignable causes can be differentiated from normal process variation. AMI requests that FSIS use SPC to define process control in AMR systems. The use of SPC would allow FSIS inspection staff to recognize out-of-control processes and focus their resources on those instances where assignable causes need to be identified and acted upon.

(i) Bone solids

The application of SPC to define process control could easily be achieved for the calcium performance standard. AMI respectfully requests that any performance standard reflect the upper control limit (UCL) that approximates a three standard deviation spread from the average. If a tighter limit is needed, then an UCL could be set to allow only a two standard deviation spread (e.g., Table 2). As shown in Table 2, and in contrast to the FSIS position reflected in the interim final rule, optimal setting of UCL for calcium in beef and pork AMR products would take into account differences in calcium content in meat and bone due to biological differences between species, differences in physiological maturity due to age at slaughter, and the type of bones processed. The data in Table 2 reflect information collected from three large fed cattle processors and three large cow processors. Additionally, the pork data represent three large butcher pig processors and one sow processor.

Similarly, data collected by another packer using two types of systems from two large hog processing plants operating under HACCP and in accordance with widely accepted Good Manufacturing Practices over a three-year period generated results from 2392 samples. The average calcium level was determined to be 100.96 mg/100g with a standard deviation of 32.12. These data support the FSIS determination that average calcium levels for AMR pork are approximately 100mg/100g, with a wide variation. Based on this data, and using two standard deviations (a conservative process control approach), an appropriate maximum performance standard of 165.2 mg/100g would be appropriate. The conclusions drawn from these data sets are that the proposed standard is inappropriate.

Table 2. Determining Appropriate Calcium Performance Standards

Statistic	Beef (n = 152)	Pork (n = 169)
Mean, Calcium (mg/100 g)	107.4	101.5
Standard Deviation	22.5	33.7
Recommended Performance Standard*	*152.0*	*169.0*

*Calcium Performance Standard = Mean + (2 × Standard Deviation). The proposed method results in approximately 2.5% of all samples exceeding the calcium performance standard.

[a]All product tested was produced in accordance with GMP's outlined by AMI (1997).

(ii) Bone marrow

AMI supports establishing performance standards that limit the introduction of unnecessary soft bone constituents into AMR products.

However, the methods and mechanisms proposed in the interim final rule to measure them are flawed. Specifically, previously submitted data from Agricultural Research Service (ARS) validate the concerns regarding flaws in the excess iron equation proposed in the rule. Implementation of an excess iron performance standard or implementation of a modified performance standard is scientifically unjustifiable for the following reasons.

First, the excess iron equation was incorrectly derived from the relationship of iron content to a histological ranking of assessed bone cell content. Each sample in the study received a rank score of 0-, 1-, 2-, 3-, 4- or 5. The resulting data set was not normally distributed and thus required nonparametric statistical analysis or should have been subjected to a normalization technique. However, neither of these options was used in the statistical analysis, making the conclusions invalid. A proper statistical analysis of the data shows that added iron and the iron:protein ratio only had weak (non-significant) correlations to bone cell content rankings, a position validated by the FSIS technical paper, *"Derivation of excess iron limits for meat products produced by Advanced [Meat] Recovery Systems."* [2] Regardless of the statistical methods applied to the data set, no relationship between iron, excess iron, or any other surrogate for determining bone marrow content is established or documented. The agency's objective is not met through measuring excess iron.

(v) DRG and Other SRM

Specifically, it appears that FSIS views the ELISA test for GFAP as an unacceptable means for determining unacceptable nervous tissue (UNT). However, GFAP is currently the best method for rapidly determining the presence of UNT and can be done in the plant for routine monitoring purposes. Because the immunohistochemical (IHC) "direct" method seemingly favored by FSIS contributes to false negative readings, GFAP testing should be the standard methodology for evaluating presence of UNT.

The agency's proposed measure of dorsal root ganglia (DRG) also is subjective. The agency's procedure has not been peer reviewed nor has it been accepted through a third party collaborative laboratory study; furthermore, the procedure was released three weeks after the interim rule was established. Indeed, FSIS has acknowledged that "Morphologically it is impossible to differentiate the source of fragments of sensory ganglia." This

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[2]This paper states the objective of the 1998 proposed rule was to "provide clear standards...that include adequate markers for bone-related components (levels consistent with defects anticipated when meat is separated by bone by hand)."

acknowledgement raises questions about the legitimacy of the agency's preferred method. In summary, FSIS should accept the peer-reviewed methodology for GFAP detection as a process control method for validation of the removal of CNS tissues.

It is important for FSIS to recognize that histological staining methods are qualitative measures and not quantitative measures. The hematoxylin and eosin staining methods employed in the ARS research should be used only to determine the presence or absence of cellular constituents. Any attempt to quantify cellular components using these staining procedures is outside the scope of their application. Staining methods cannot compensate for the relative density differences in cellular components or the non-random, and non-representative sample examined. Although the staining methods can accurately determine the presence or absence of bone marrow constituents, these techniques cannot be used to determine accurately the amount of bone marrow constituents.

As stated in the interim final rule itself, hand deboned samples also contain bone marrow constituents, which supports the conclusion that *de minimis* amounts of bone marrow cannot be considered an adulterant. Moreover, the data were collected in a manner that does not allow comparison of the presence or absence of bone marrow constituents to the iron content of the samples. Consequently, calculating a hand-deboned iron:protein ratio and using this value as a base ratio for calculating an added iron performance standard are scientifically invalid.

Finally, the desinewing process used in most AMR systems removes a large portion of connective tissue, which concentrates iron and pigment values. Because hand deboned meat has not been passed through a desinewing machine, it is erroneous to directly compare AMR iron values to hand deboned. The interim final rule addresses this fact through the establishment of a correction factor, but the correction factor fails to account for the concentration effect on the iron component.

To establish scientifically justifiable performance standards FSIS should remove the current non-food safety regulatory standards, then republish separate performance standards defining beef and pork AMR products in proposed rules. Such a procedure would allow FSIS to develop a scientific, repeatable, and peer-reviewed procedure for analysis of CNS tissues of concern and provide industry recommendations for performance and analysis for these tissues. FSIS also should conduct a survey to find correct and scientifically justifiable relationships to soft bone constituents. Finally FSIS should develop performance standards that use SPC methodology, which differentiates normal process variation from variation with assignable cause.

Importantly, the interim final rule, if published as a final rule, could undermine consumer confidence in pork by raising unnecessary questions about pork as a potential source of BSE. In addition, the loss of AMR processes and products will have severe detrimental economic effects for pork processors and producers.[3]

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 select cattle and declaring these items as not usable for human food, the rule likely will have unintended consequences by extending its scope to other species.

Sincerely,

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

[3] One industry estimate is that the decrease in value per carcass would approach $0.30, or **$30,000,000** for the industry.