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April 5, 2004

FSIS Docket Clerk
Food Safety and Inspection Service
US Dept of Agriculture
Room 102, Cotton Annex
30012th Street SW
Washington, DC 20250-3700

03-025IF
03-025IF-592
Warren J. Dorsa
Angela L. Siemens
Ronald W. Easterday

RE: Advanced Meat Recovery, Interim Final Rule, FSIS Docket No. 03-0381F, 69 Fed Reg. Ppg. 1874-1885, Jan 12, 2004

To Whom It May Concern:

Smithfield Foods, Inc., Smithfield, Va. operates 8 pork slaughter establishments within our Farmland Foods, Gwaltney of Smithfield, Ltd., John Morrell & Co., and Smithfield Packing Co. operating companies. These operating companies have a combined annual slaughter capacity of about 28 million head. Our slaughter operations have operated Advanced Meat Recovery (AMR) processes since 1989. We have estimated that the value of these systems to our business is in excess of $8,000,000 per year. Thus, the production of AMR meat product significantly impacts our labor force and business operations. Over the years of operating AMR systems we have collected a significant amount of data and operational knowledge. Consequently, we are highly qualified to comment on this interim final rule.

To put it simply, we are strongly ***opposed*** to the interim regulation as regards advanced pork recovery systems – there is no justification for the regulatory change in terms of either public health or consumer expectations. All the rule will do is effectively eliminate a wholesome, inexpensive protein source.

The interim final rule clearly states its' principal objective in the first paragraph of the summary (pg. 1874). The two central elements are stated as:

Item (1) "This new regulation is 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 tissue (CNS) into product labeled as "meat" (emphasis added).

Item (2) "In addition to the measures related to BSE, FSIS is finalizing restrictions related to bone solids and bone marrow for livestock products."

Generally, we feel **Item (1)** should only be applied to beef, since as the interim final rule clearly establishes, cattle are the known source of the problematic CNS, and **Item (2)** should be the only section that relates to all meat animals since it concerns the standards of identity for AMR meat products. It is our general feeling that unexpected detrimental consequences will occur if the agency allows wording in the interim final rule to move the rule away from these stated objectives and affect other non-risk causing meats. Since there are two central, but different, elements of the interim final rule we would like to separately address them as they relate to pork products.

Item (1)
On page 1877 of the interim final rule, the agency states "Furthermore, FSIS...believes the lack of process control regarding the presence of CNS-type tissues in pork product recovered from AMR systems also may be a concern". However, there is no basis for any concern from either a public health perspective or consumer expectations.

Since pork has never been associated with any Transmittable Spongiform Encephalopathy (TSE), there is no scientific base for FSIS concern with controlling the presence of CNS-type tissue in pork meat recovered from AMR systems. Nervous system tissue is a natural and integral part of any meat of animal origin. Since CNS-type tissue or various ganglia of pork meat has never been shown to be associated with, or cause any human diseases and will certainly have no impact on the prevention of human exposure to the Bovine Spongiform Encephalopathy agent, there is no scientifically based human health reason to exclude it from pork AMR meat products. This is especially true since CNS-type tissue, trigeminal and dorsal root ganglia, and other Specified Risk Materials (SRM) as defined in §310.22(a) from cattle is the real issue. We feel the inclusion of §318.24(a) (i.e. "other than skulls or vertebral column bones of cattle 30 months of age and older") as well as §310.22(b) declaring these items of cattle origin inedible and not usable for human food, adequately and appropriately addresses the concerns of protecting human health as related to SRMs from cattle.

We conclude §318.24(a)(2) and §318.24(c)(1)(v) do nothing to achieve the FSIS stated objective and should be removed from the final rule. Additionally, all verbiage throughout the regulation & supplementary information regarding CNS-type tissues other than spinal cord and those from beef should be removed since there is no scientific basis for inclusion.

With the above mentioned regulatory controls in place we do not feel there is any scientific basis for changing the FSIS current definition of meat to exclude specific nervous system tissues from the definition of all animal meats as is done in §301.2(ii). With the agencies declaration in §310.22(b) that cattle SRMs are inedible and not usable for human food, the change in §301.2(ii) is unwarranted and unnecessary. Nothing is gained toward achieving the major objective of keeping cattle SRMs from human food. In fact, prior to the realization of cattle CNS tissues being associated with vCJD the agency had no concerns about these materials being present in animal meat. The agency **correctly** took the position that these were natural-normal constituents of animal meat. While there is now a scientific basis for excluding cattle SRMs from entering the meat supply intended for food, the exclusion of these nervous system tissue from pork AMR meat will not offer any human health benefits, nor prevent human exposure to the BSE agent, and will be implemented at an exorbitant cost to the pork industry with no benefits to public health. The changing of this definition will impose an unjustified and unproductive economic burden on the pork industry.

Likewise, the application of the prohibition on CNS-type tissue to pork AMR is not necessary to meet consumer expectations. Let us be clear up front – there is no spinal cord in our products; not only do we remove spinal cords as part of the slaughter operation, we visually verify removal before the raw material enters the AMR system. Our concern is with the prohibition as it relates to other CNS tissue, such as dorsal root ganglia.

The regulatory definition of meat has always included "the portions of bone, skin, sinew, **nerve** and blood vessels which normally accompany the meat, 9 CFR § 301.2. The CNS-type of nerves prohibited in pork AMR, such as dorsal root ganglia, may be found in the muscle of bone-in products regardless of the species (e.g. T-bone steaks and porterhouse steaks from animals less than 30 months old, bone in pork chops, lamb chops, various chicken cuts, etc.). It is illogical to

conclude that if the consumer knew that meat from bone-in products derived from hand cutting may contain dorsal root ganglia and other CNS-type tissues the public would not also expect these materials to be present in meat derived from these same areas of an animal through AMR equipment. To be sure, there is the additional issue of BSE with regard to beef AMR, but as discussed above, that does not relate to pork AMR.

We propose USDA return to the current definition for meat as applied to pork AMR; at the very least §301.2(ii) should be removed.

Item 2

We **agree** with the FSIS position stated in the interim final rule supplementary information on pg. 1878, that "The presence of small amounts of calcium does not affect the qualitative characteristics of the product and only trivially affect its compositional aspects". Therefore we see no reason to change the performance standard for calcium to a regulatory maximum of 130mg/100g from the presently implemented and acceptable level of 150mg/100g. However, if a change is to be made, we propose it would be more appropriate to set a calcium standard based on the average calcium content of AMR products currently being produced, plus two standard deviations above and below the mean to allow for plant specific process variation. Two standard deviations, which is less than the normally accepted process control of three standard deviations above and below the mean, allows for tighter controls in systems that have inherently high standard deviations. This should be done by species.

Data collected from two types of systems and two major hog processing plants operating under HACCP and in accordance with widely accepted GMPs 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 what FSIS data determined; that average calcium levels for AMR pork are approximately 100mg/100g and have a wide range of variation. Based on our data, and using two standard deviations (a conservative process control approach), we would submit a maximum performance standard of 165.2 mg/100g.

We propose USDA adapt the original levels that have been successfully implemented to date. If a change is to be made, than using statistical process control method is more appropriate and will enable both the establishment and FSIS to remove product that falls outside the upper control limit.

In conclusion, Smithfield Foods, Inc. appreciates the opportunity to comment on the interim final rule. We feel that while attempting to address the objective of preventing human exposure to the BSE agent through AMR systems, FSIS has arbitrarily and inappropriately involved pork AMR meat. This was done through unnecessary wording in 301.2(ii) and 318.24(2), discussed above, that has no scientific bases and only serves to create an economic hardship to our company, the pork industry in general, and our consumers. We estimate the FSIS changes in the interim final rules discussed in our comments will cost Smithfield Foods, Inc. in excess of $8,000,000 annually since they will in effect eliminate our ability to profitably run AMR systems. The result will be the removal of the systems and elimination of associated jobs. Moreover, consumers will be denied this low cost, wholesome protein source. Nothing else is accomplished by these changes. The involvement of pork in this rule does nothing to advance the strategic objective of USDA since no public health benefits are gained (i.e. the cost to the industry is high while the benefit to public health is zero). Good, wholesome meat will be lost for no reason. The source of bovine SRM and elimination of them as a part of human food through ARM systems is adequately addressed in other sections of the new interim rules.

We also feel the changes made for calcium requirements would be better served to include maximum calcium content set by plants own operating data utilizing two standard deviations as opposed to a regulatory maximum of 130mg/100g. This would adequately "ensure that the production process was in control, and that the characteristics and composition of the resulting product is those of meat".

Thank you for your time and consideration of these comments.

Sincerely,

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