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January 18, 2000

98-027R-25
98-027R
Rosemary Mucklow
Ken Mastracchio

FSIS Docket Clerk
Docket No. 97-027P
Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

Re: Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems Federal Register December 16, 1999

Dear Sir:

National Meat Association (NMA) is an industry organization representing meat packers and processors throughout the United States. Many of our member firms either manufacture meat using advance meat/bone separation equipment and recovery systems and/or use the meat so produced as an ingredient in meat and meat food products.

The December 16, 1999 *Federal Register* proposal, as stated in the summary, reopened the comment period for 30 days to give the public the opportunity to review and comment on the methods and results used by the Agricultural Research Service to ascertain iron values for meat derived from advance meat recovery (AMR) systems. The notice also invites comments on information provided by a meat industry group on economic effects and worker safety issues related to the proposed rule.

NMA appreciates and welcomes the opportunity to provide further comment with regard to the proposed rule referenced above, specifically to comment on the methods and results from a study by the Agricultural Research Service and the safety improvements for workers performing AMR tasks rather than hand deboning. In addition, as several issues in NMA's June 12, 1998 comments to the proposed rule have not been addressed we wish to restate them for the record.

Intermediate Product Issue

As stated in our June 12, 1998 comments, meat recovered in AMR systems is always blended with meat from other sources to produce a final consumable product. AMR product is not consumed exclusively or directly in the form that it is produced. NMA identified AMR product as an intermediate ingredient or, more accurately, a component of a further processed meat and/or meat food product. Products derived from AMR systems are utilized as components whose use rarely exceeds 10% of the finished product. We requested that the proposed rule reflect this *deminimus* use as a meat ingredient and not approach the product descriptors as though consumers would eat this as an end-product. We further stated that the nutritional value of product derived from these systems should be taken into consideration in terms of their nutritional contribution to the finished product, and not evaluated as though they are being consumed as a finished meat or meat food product.

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Central Nervous Tissue
We stated in our June 12, 1998 comments, FSIS Directive 7160.2 dated 4/14/97 assigned PBIS tasks for the specific purpose of ensuring that the producing establishment is completely removing spinal cord from neck and/or back bones before they enter the system. The directive instructs inspectors to sample and submit finished product to FSIS laboratories if they believe spinal cord material is not being removed. Our concern is that the proposal would codify this requirement as a performance standard. In essence, spinal cord should not be expected as an ingredient in raw materials or finished product. It was our recommendation that plants develop standard operational procedures (SOPs) to control and assure the removal of spinal cord from raw materials.

Bone Solids
As stated in our June 12, 1998 comments, the regulation proposes that the finished product's calcium content should be reduced from the current criteria of 150mg/100 grams of product within a tolerance of 30mg to no more the 130.0mg per 100 grams. The Agency's rationale was that "...it's the agency's tentative judgement that the existing calcium limit should be reduced because it is higher than the level that is unavoidable under current good manufacturing practices" and that "...it should be stated as an absolute maximum..." because accounting for analytical (and any other) variability is a production process control question for industry to address. Further, sampling for calcium should be in the final product and not at an interim step.

Generally NMA agreed with the Agency's rationale that, in stating a performance standard, it be expressed in an absolute maximum without a tolerance level. However we pointed out that, simply establishing a performance standard to replace a quality control activity in no way changes the product itself, especially when the Agency's arguments are not based on science, but rather on some form of expediency. We also pointed out that variability will continue and must be considered.

NMA continues to urge the Agency to finalize the performance standard at the current criteria, 150mg/100grams of product which will generally be compatible and accommodative of the existing production capacities and is functionally less than the present requirement which includes a tolerance level. In addition, we stated that the Agency was not in a position, since it had not presented any data, to determine that the proposed performance standard is achievable under current good manufacturing practices.

Bone Marrow
The proposed rule contains a performance standard for bone marrow which is based on determining the product's iron content and the product's protein content using a multiplier of 0.067 for beef or 0.034 for pork. We stated in our June 12, 1998 comments that this was the first such standard of this type that the Agency has ever proposed and that it has no institutional experience. We had serious concerns with the Agency's development of the proposed performance standard. FSIS conceded, in the proposed rule, that the methodology for determining ash "...is known to recover less iron than two other reliable methods for determining iron content: the sulfuric acid wet ash method and the dry ash method." We took this as tacit acknowledgment that the data relied upon to draft the proposal was incorrect and we requested that ARS be asked to review and evaluate the Agency's work and provide it for the record on this issue.

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In order to help facilitate this further research, NMA was signatory to a Cooperative Research Agreement with Agricultural Research Service (ARS) to reanalyze product derived by advanced meat recovery systems which FSIS utilized in the development of its proposed performance standard. The ARS reanalysis used the dry ash method which recovered higher iron values than what was originally recovered by FSIS using the wet ash method. Comparisons were made between the data collected from the analysis of intermediate lean, final lean and hand trim meat.

A review of the data contained in the ARS research project summary dated December 20, 1999 entitled "Soft Bone Constituents in Meat Derived from Advance Meat Recovery Systems" clearly indicates that the proposed rule's performance standards data was flawed. Specifically the ARS data illustrates that the iron values are approximately double those originally used by FSIS to establish the performance standard. For example, the added iron formula in the proposed rule uses the iron:protein ratio of hand boned beef (0.067) as a constant in the equation. The new iron data submitted by ARS illustrates this constant to be 0.134 rather than 0.067.

The ARS data also identifies the following variables which we request be further investigated in consideration of the Agency establishing a performance standard based on calculating iron content to limit bone marrow for products derived by AMR systems:

1) The dry ash analysis of intermediate lean and final lean products derived indicated a significant increase in "dry ash iron and the iron:protein ratio"....due to the desinewing process. ARS researchers attribute this to drum filter which "removes most of the sinew, cartilage and bone chips that are low in iron so it is logical that the iron content of the remaining AMR lean would increase."
2) An increase in iron content could also be attributed to the pressing of the belt in the desinewing process or the bone cannon "removing moisture containing water soluble pigments that are high in iron and this iron becomes part of the recovered meat.
3) A comparative analysis of final lean derived from steer bones and cow bones indicated a significantly higher iron content in product derived from cow bones. Since the added iron equation is based on hand boned meat derived from steer neck bones, a performance standard for cow bones should be based on hand boned meat derived from cow bones.

Ergonomic Advances

The AMR systems offer the industry the best technology available to ensure quality product and significantly reduce repetitive hand work. These systems provide the technology to replace hand or mechanical knife handling labor intensive work with a technology that removes meat from bones under hydraulic pressure. Prior to the introduction of AMR technology, the recovery of meat from carcass bones required the use of hand held mechanical knives which contributed to an incident rate for Carpal Tunnel Syndrome of 38 % over a two year period.

The information submitted by the meat industry group regarding worker safety issues clearly underscores the fact that AMR technology reduced the number of repetitive jobs having the highest rate of Carpal Tunnel Syndrome and Tendonitis. The proposed rule would adversely affect the use of AMR technology at a time when the Occupational Safety and Health Administration has proposed regulations focused on the reduction of worker injuries associated with repetitive motions called cumulative trauma disorders (CTDs).

Our comments submitted on June 12, 1998 recommended that the industry be allowed to develop control procedures in accordance with HACCP that would ensure system control and product safety. Under

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HACCP records generated from these procedures would be available for review by FSIS personnel engaged in verification tasks.

However the proposed rule's performance standards are not compatible with the HACCP risk reassessment process, nor are they compatible with scientific analysis utilized to establish critical limits in a HACCP system. In essence none of the standards identified in the proposed rule have been identified as a safety standard based on scientific analysis.

Economic Impact
The economic impact the proposed rule would have is significant, as reflected in the industry group analysis conducted by Sparks Companies, Inc. and presented to FSIS in July of 1999. The industrys group's analysis is based on the assumption that processing plants would return to previously used systems of auto knives which would result in the following consequences:

1) Meat processors would lose the value of their initial investment which based on the number of systems in use today would be in the area of 40 million dollars.
2) Reconfiguration costs associated with the return to previous systems is estimated to be a total cost of 32 million dollars.
3) Returning to the previous automated knife systems would require the hiring of additional labor and subjecting them to an occupation highly susceptible to the effects of cumulative trauma disorder (CTDs). The total labor cost associated with new hires inclusive of wages and benefits is estimated to be 52 million dollars. The medical expenses based on a conservative injury incidence rate of 20% is estimated to be 10 million dollars.

Conclusion
The proposed regulation introduces performance standards which are clearly not food safety related nor are they based on accurate scientific data. As NMA previously stated in our June 12, 1998 comments, the proposed regulation is too significant to merely adjust numbers and publish the final rule. NMA requests that a thorough investigation be conducted by agency personnel to re-propose the regulation in order to be compatible with the food safety aspects of HACCP.

NMA disagrees with FSIS's determination that the proposed rule is not a significant regulatory action under the criteria set forth in Executive Order 12866. NMA's review of Industry group's analysis of the proposed regulation clearly indicates that the annual economic effect will surely be in excess of 100 million dollars.

We appreciate the opportunity to provide additional comment on this proposed regulation.

Sincerely,

Rosemary Mucklow
Executive Director

Ken Mastracchio
Director of Regulatory Issues