



16

January 18, 2000

FSIS Docket Clerk
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 102, Cotton Annex
300 12th St., S.W.
Washington, DC 20250-3700

98-027R-16
98-027R
Mark Dopp

RECEIVED
FSIS DOCKET ROOM
00 JAN 19 PM 7:25

Re: Docket No. 98-027R, Reopening of Comment Period for the Proposed Rule Published April 13, 1998, Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems (63 FR 17959)

Dear Sir/Madam:

The American Meat Institute (AMI), the national organization representing the meat and poultry industries, appreciates this opportunity to comment on the above-referenced proposed rule. AMI has a significant interest in this proposal because a number of AMI members use Advanced Meat Recovery (AMR) technology.

Throughout the 30-year history of meat products derived by machine separation it has been almost universally agreed that no food safety issues are associated with meat derived from using AMR technology. AMI applauds the conclusions set forth in the paper presented by Dr. Lester Crawford, Georgetown University Center for Food and Nutrition Policy, and commends them to the agency's attention as additional evidence of that fact.

AMI expressed its concerns about the proposal in comments filed June 12, 1998. Those concerns remain.¹ The comments provided herein further refine and reinforce AMI's previously articulated concerns, and can be summarized as follows:

- The proposal would have an adverse effect on industry ergonomic efforts;
- The technical basis underlying the proposal is inadequate;
- The proposal is based on an antiquated regulatory foundation that is fraught with inconsistencies; and
- The proposal underestimates the economic impact on the industry.

The Proposal would have an Adverse Effect on Industry Efforts to Minimize Ergonomic Problems

AMI's earlier comments emphasized the significant impact the proposal would have with respect to the meat and poultry industry's efforts to address ergonomic problems. It is beyond dispute that the proposal, if adopted, would force many companies to abandon the use of the AMR technology. That abandonment, in turn, would result in more extensive manual trimming to recover the meat currently being retrieved through the AMR technology.

The meat and poultry industry has been a leader in the practice of ergonomics to improve worker safety and, in that regard, has almost universally adopted voluntary ergonomic guidelines. The adoption of those guidelines has yielded a notable decrease within the industry in certain types of musculoskeletal disorders (MSDs), in particular those involving cumulative trauma disorders. Regrettably, the supplemental documents now on file with FSIS affirm the adverse effects the proposed rule would have on such programs.

It is ironic, and inappropriate, that FSIS has proposed a regulatory change that could have an adverse health effect on meat and poultry industry employees in order to regulate a product that is safe and wholesome. That irony is heightened when, at the same time, the Occupational Safety and Health Administration has proposed a sweeping regulation regarding a wide array of ergonomic issues, asserting a pressing need for such regulation because of the growing concerns about MSDs.² Because of the possible adverse health impact alone FSIS should abandon this proposed rulemaking.

¹ AMI's comments supported certain components of the proposal and the support set forth in that correspondence remains. In those comments AMI suggested the alternative use of a moisture/protein ratio (MPR) of 0.36 for pork and 0.52 for beef from AMR systems. AMI continues to support those values.

² See 64 *Fed. Reg.* 65768 (Nov. 23, 1999).

The Technical Basis for the Proposal is Unsound and Inadequate

It is beyond dispute that the data underlying the proposal were flawed. Indeed, that problem has been acknowledged by FSIS. Furthermore, data submitted to FSIS after the proposal was published rectified the problem with the analytical methodology used initially. Moreover, those data, coupled with the appropriate methodology, demonstrate that, should a performance standard be established, the parameters of such a standard must be notably greater than the values provided in the proposal. More importantly, however, the recent data provided by USDA's Agricultural Research Service (ARS) show that several other variables significantly affect the quantity of iron in final AMR-derived product.

Specifically, the new ARS information demonstrates that more than a dozen variables affect the composition of AMR-derived product and neither AMI nor the agency knows if this list is inclusive. Nor is the impact of each of these more than dozen variables known. For example, factors such as type and age of animal and type of bones used have an effect on the total iron content of AMR-derived product. In that regard, recent research indicates that final lean from cow bones is notably higher in iron, iron:protein ratio, and added iron than that from steer bones. Establishing a performance standard based on data derived from steer bones only or even partially, skews the standard inappropriately, prejudicing those establishments that primarily slaughter cows. This data demands that the agency, if it establishes a performance standard for a non-food safety related issue, must, as it has done for other components of its regulatory system, establish standards that account for the notable differences between cows and steers.³

In addition to the legitimate concerns about one standard applying to all cattle, there is also evidence that the extra heme-containing water from the AMR process also increases the total iron content in the AMR-derived product when compared to hand-deboned product. AMI also is concerned that the proposal would provide a disincentive to improve the quality of AMR-derived product by removing connective tissue. Removing a significant portion of connective tissue during the latter stages of processing enhances product quality, but increases the iron concentration in the remaining product. Traditionally, FSIS policies with respect to the quality of any product for consumer purchase have either been neutral or encouraged improvements. The proposal would deviate from such an approach and encourage companies to produce lesser quality products in order to meet the iron criteria.

All of the above-discussed factors highlight a fundamental point made in AMI's previous comments – what affects the iron content, the substance apparently chosen by FSIS to serve as the measure regarding AMR, in AMR-derived product is

³ The agency has, in several other performance standards, established different parameters for cows and bulls versus steers and heifers. See, e.g. the *Salmonella* performance standard and the generic *E. coli* criteria in slaughter plants.

much more complicated than originally contemplated in the proposal. Those factors must all be considered by the agency because, as the preceding discussion demonstrates, compliance with the proposal would be much more complex than turning dials on AMR machines.

The Proposal is based on an Antiquated Regulatory Foundation

The basic definition of meat is approximately 100 years old and is, in effect, an anatomical description. For the last 50 years, at least, that definition has not been suitable or accurate for constituents of processed products and the above-referenced proposal is an ill-advised effort to amend an antiquated definition of meat.

FSIS recognized this problem 25 years ago in its effort to revise the definition of meat. Ironically, the agency's 1994 AMR rulemaking recognized this fact and articulated excellent reasons not to apply old regulatory constraints to AMR-derived product.⁴ Rather, in 1994 the agency appropriately recognized and relied on newer mechanisms, such as nutrition labeling routinely used by consumers to make purchase selections, to help define meat. The reasoning and analysis utilized by FSIS in that rulemaking remains valid today.

The proposal is an ill-informed attempt to relate a selected chemical constituent of AMR-derived product to a library reference, such as USDA Handbook 8, for regulatory purposes and, in that regard, conflicts with longstanding agency policies regarding other meat product constituents. For example, USDA Handbook 8 lists three types of ground beef -- Regular, Lean, and Extra Lean -- and the chemical constituents for each are mathematical averages. Significantly, the analytical values used to derive those averages would show a broad range. Yet, by current FSIS rules any meat, as currently defined, may be ground and labeled as "ground (specie)," regardless of how much the chemical constituents of such "ground (specie)" may vary from values listed in Handbook 8 for that same product.

In the proposal the agency fails to recognize, or chooses to ignore, that meat is not just a set of chemical constituent values. The compositional values for meat used in preparing the thousands of processed meat products for consumer consumption are different than the values in USDA Handbook 8, and in some cases "less than" than the compositional values of AMR-derived product. Yet, the use of such meat is permitted and the finished products made therefrom are widely accepted in the marketplace.

The proposal suggests that AMR-derived product is somehow unique or different from these other components, and therefore, should be separately regulated. Such a concept is outdated and conflicts with other agency actions and policies, particularly when weighed against other more pressing concerns raised by

⁴ 59 *Fed. Reg.* 62552-53.

FSIS Docket Clerk
January 18, 2000

this proposal, such as the adverse health effect the rule could have on meat and poultry industry workers and the significant economic impact the proposal likely would have on the industry generally.

The Proposal's Economic Impact is much Greater than Initially Acknowledged by the Food Safety and Inspection Service

AMI's previous comments demonstrated the proposal's economic impact would be major and significant. Comments from others presented similar information. The more recent, and independent, analysis done by Sparks Companies, Inc., also demonstrates the adverse impact on the industry to be major and significant. Accordingly, FSIS must conduct an economic impact analysis with respect to the proposal and consider the results of that analysis when contemplating any rulemaking. Indeed, the significant adverse economic impact of the proposal should be a prominent consideration in favor of abandoning the proposal.

Conclusion

The technical basis for the proposal is unsound and inadequate. Furthermore, the proposal fails to account for serious flaws in the statistical validity of the data utilized by the agency. Moreover, the proposal conflicts with the agency's longstanding policies concerning meat and processed products' constituents. These reasons alone are sufficient for the agency to abandon the proposal. Compounding those problems is the fact that there are serious economic and ergonomic problems associated with the proposal, which also, standing alone, warrant abandoning the proposal. For the foregoing reasons AMI strongly recommends that FSIS terminate the proposed rulemaking.

AMI appreciates the opportunity to submit these additional comments regarding this very important issue. Please contact me if you have questions about anything provided in these comments or in AMI's previously submitted comments.

Respectfully submitted,



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

cc: J. Patrick Boyle
Jim Hodges
Bill Dennis