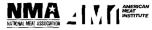


January 18, 2000

FSIS Docket Clerk Docket No. 98-027R Room 102, Cotton Annex 300 Twelfth Street S.W. Washington DC 20250-3700 FSIS DECRET ROOM

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98-027R-1 98-027R Harold T. Hodges

Re: Proposed Rule on Advanced Meat Recovery

The Better Food Development (BFD) Corporation wishes to comment on this proposed rule.

OVERVIEW

BFD is a major manufacturer/distributor of Advanced Meat Recovery (AMR) Systems which are subject to both current and proposed FSIS regulations. We are strongly opposed to changing the current regulation.

The current regulation (9 CFR 301.2 (m) subparagraph 2) is clear, concise and easily applied. FSIS deserves to be congratulated.

Firstly, BFD wishes to categorically refute the rumor that reduced pressure will allow current or future systems to comply with proposed iron standards. We have conducted tests from 100 BARs to 220 BARs coupled with short dwell times and iron relatively remains the same. Whereas at pressures lower that 180 BARs, yield is substantially impacted. The yield impact renders the system(s) economically impractical. We will be most happy to demonstrate this to FSIS meat scientists.

In addition, FSIS should understand that MS(s) poultry is a commodity at the very low end of a limited market. If a market could be developed for MS(s) beef/pork, it would be sold as pet food in competition with rendering.

Meat produced by AMR Systems is of substantial quality and generally has a chemical lean of 70% or more. This high quality meat is blended with other meat requiring an increase in the lean to fat ratio.

Meat produced by AMR Systems does not present a public health concern nor is it a Food Safety Issue. The real issue is pure economics i.e., a competitor desirous of near complete market share.

Simply stated, BFD believes that FSIS's proposals of April 13, 1998 and December 16, 1999 are based on political pressures and innuendo coupled with certain FSIS misconceptions and known flawed science.

BFD firmly and respectfully requests FSIS to withdraw it's proposal(s) and vigorously defend it's original rule of December 6, 1994.

UNWARRANTED LEGISLATION

Before addressing the narrow perspective of Docket No. 98-027R, it is imperative to address the underlying facts, propositions and influencers that are promulgating additional regulation of meat produced by Advanced Meat Recovery Systems.

59 FR 62551 of December 6, 1994, codified in CFR 301.2 (rr) and subparagraph 2 is sound and succinctly stated. It is without confusing language. It is easily understood and applied.

Numerous USDA and FSIS policy makers have attested to the fact – that meat produced by AMR technology is not a public health or food safety issue. In addition, the nation's leading meat scientists from academia and industry have continuously reaffirmed that meat produced by AMR Systems is not a public health or food safety issue.

In fact, there has never been a single documented case where meat produced by AMR Systems presented a public health or food safety issue.

Meat produced by AMR Systems has been subjected to intense and often unwarranted FSIS scrutiny. The question is – why is there a need for additional scrutiny and regulation?

One could question the tactics of a lone competitor employing Low Temperature Rendering producing a product known as Lean Finely Textured Beef (LFTB) – who has enjoyed the good graces of Washington DC based advocacy groups and the largess of their political influence.

It must be noted for the record this single competitor and these advocacy groups clamor for additional regulation of AMR produced meat, whilst LFTB, a USDA approved product for the school lunch program, continues to escape the scrutiny of FSIS.

USDA's loose description of LFTB in TDS-136, dated June 22, 1999, forces the question – why does this product escape FSIS rulemaking and public scrutiny? (Attachment 1)

Another USDA-AMS publication A-A-20256, dated July 16, 1997, titled Commercial Item Description, paragraph 3.1.2 closes with the following sentence,

"Beef deboned utilizing the Advanced Meat Recovery (AMR) System shall not be used." What science was used to justify that sentence? Does the intent of that sentence reflect a policy maker's predisposition? (Attachment 2 Commercial Item Description 7/16/97, (Attachment 3 Beef Products, Inc. Advertisement, Attachment 4 Beef Products, Inc. Advertisement, Attachment 5 CSU Analysis LFTB)

USDA and FSIS officials have repeatedly stated that meat produced by AMR Systems is safe and wholesome. Whereas, FSIS's proposed rule of April 13, 1998 under the title "Supplementary Information" takes considerable liberty with it's implication that meat produced by AMR Systems is unwholesome, adulterated or misbranded. These placards bring into question, where is the scientific corroboration? The second question being, how do these charges in the "Supplementary Information" comply with the Administration's May 1997 emphasis on the use of science based HACCP principles arrived at through a collaborative process with industry and stakeholders alike? How does this proposed rule comply with Executive Order 13100 of August 28, 1998? (Attachment 6)

Based on these charges, lacking scientific foundation, FSIS now believes the provisions adopted on December 6, 1994 are confusing and need revision to prevent misbranding or economic adulteration. Therefore, the Agency is proposing to clarify the "scope" of bone as used in the definition of meat . . .

9 CFR 301.2 (rr) clearly identifies meat and subparagraph 2 clearly and concisely defines meat produced by AMR Systems. 9 CFR 301.2 (rr) Meat. (1) "The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart or the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats

(2) The product derived form the mechanical separation of the skeletal muscle tissue from the bones of livestock using the advances in mechanical meat/bone separation machinery and meat recovery systems that do not crush or grind, or pulverize bones, and from which the bones emerge comparable to those resulting from hand deboning (i.e., essentially intact and in natural physical conformation such that they are recognizable, such as loin bones and rib bones, when they emerge from the machinery) which meets the criteria of no more than 0.15 percent or 150mg/100gm of product for calcium (as a measure of bone solids content) within a tolerance of 0.03 percent or 30mg."

The Agency's proposal to clarify the "scope" of bone as used in the definition of meat is beyond the scope of understanding. (Definition of scope: meaning the extent of mindful perception) It is extremely hard to understand what FSIS means by "clarify the scope of bone as used in the definition of meat". This is of contentious jurisdiction.

The state of confusion referenced in the Agency's proposed rule of April 13, 1998, requiring clarification, is the direct result of FSIS's politically induced attempts to apply unprecedented special definitions and characteristics to "only" that meat produced by AMR technology.

Referring to 9 CFR 301.2 (rr) subparagraph 2 and FISI Directive 7160.2 dated April 14, 1997, note the clever difference in the comparison of bones.

9 CFR 301.2 (rr) subparagraph 2 states that bones emerging from the machinery are comparable to those of hand deboning (i.e., essentially intact and in natural physical conformation such that they are recognizable, such as loin bones and rib bones, when they emerge from the machinery) . . .

Whereas, FSIS Directive 7160.2 reads: "FSIS's purpose in adding subparagraph 2 to 9 CFR 301.2 (rr) was to supplement the definition of meat so that meat includes product derived by recovery systems that remove muscle from bones by a mechanical means that results in product that has the functional and chemical characteristics of meat. In other words, the product is comparable to product derived by hand deboning . . ."

The foregoing underlined words from 7160.2 when compared to 9 CFR 301.2 (rr) subparagraph 2 represent a newly imposed "gold standard" i.e., meat produced by AMR Systems must now subjectively look like hand trimmings to be meat.

FSIS cannot utilize a directive to change the meaning or intent of a code. Furthermore FSIS, in their directives to inspectors should exclude clever language which purports any meaning other than that which is in the code.

Based on this FSIS action – one must ask the question – what prompted that subtle change and how did it become policy without going through rule making? From our perspective, based on the foregoing, for meat to be meat, it must be removed by a hand held knife. The question that must be asked is – how can a low temperature rendered by-product (LFTB) be meat?

The real intent of 7160.2 was a directive to remove spinal cord from neck/back bones prior to processing. The industry lauded the efforts of FSIS regarding the removal of spinal cord and spent hundreds of thousands of dollars investing in new equipment for that very purpose. However, the industry failed to notice the delicately introduced "new gold standard".

Per FSIS's proposed rule of April 13, 1998 under the title "Summary"; it is not enough for FSIS to suggest the following

"In future rule makings, the Agency expects to apply the process control performance standards approach of this proposal to other types of operations for manufacturing meat and poultry trimmings."

FSIS must develop and apply uniform rules on industry as a whole as opposed to the rule of exception. Should FSIS consider the proposed rule of April 13, 1998 to be an application of a process control performance standards approach – it's thinking is seriously flawed or else FSIS has been overwhelmed with the abundant rhetoric of the proponents of this additional unwarranted regulation.

Considering that FSIS questioned the science the proposed rule was based on and the fact they chose to forge ahead with rule making, makes their reasoning suspect. It seems the Agency is desirous of setting inappropriate boundaries to establish that meat produced by AMR Systems is misbranded or adulterated.

The process employed by FSIS to date is most unusual and it is clear that FSIS is advocating the imposition of new substantive and onerous requirements echoed by the National Consumers League; as opposed to "clarifying" the rule.

When one considers the tentative commitment of FSIS to the National Consumers League (NCL) for a negotiated intermediate or mid-process calcium measurement in a December 27, 1995 letter to NCL – numerous questions are raised.

Why and how can FSIS rule making be negotiated outside of public purview? In fact, the Administrative Procedures Act, section 553 speaks to this specific point.

It is more than evident that FSIS has been unusually responsive to the National Consumers League continued echoing of a competitor's objections.

FSIS must categorically recognize this is and has always been – an issue between competitive processes. FSIS must allow market forces to determine process viability and market share.

This has never been a public health concern or a food safety issue except in the eyes of a competitor who with innuendo enflamed Washington's advocacy groups.

FSIS must disassociate itself from this strife and stand by it's original rule. A sound and clearly stated rule that industry has relied on and applied.

FSIS should carefully consider it's good reputation in the eyes of the American Public before making judgements and decisions based on imaginary science that will "effect economic discrimination".

RE: FSIS Docket No. 98-027R, Reopening of Comment Period.

9 CFR 301.2 (rr) subparagraph 2 is a good, sound and clearly stated rule. It is succinct, easily understood and applied. The meat industry, based on this precisely defined rule has invested heavily to lessen worker injuries whilst improving profits in a profit short industry.

AMR BENEFITS

The only objector registered to date and for approximately five years in duration – is that of a competitive process and specific advocacy groups and their consultants who echo his comments on a continuing basis.

9 CFR 301.2 (rr) was accepted and judiciously applied by industry. The beneficiaries of this rule are many.

Our producers of cattle and hogs, (over 97% are categorized as small business) achieve increased payback due to higher animal unit yields generated by AMR Systems.

The American Consumer – who has never heard of NCL and cares less of their boisterous echoes – is desirous of an abundant and continuing supply of nutritious and wholesome ground meat at an economical price – they have directly benefited from the implementation of AMR Systems.

Most importantly, the workers formerly employed on hand held vibratory air knife deboning lines are now employed in less injurious jobs where AMR Systems have been implemented. Note, this is an employee short industry.

The PROPOSAL WOULD HAVE AN ADVERSE IMPACT ON INDUSTRY EFFORTS TO MINIMIZE MUSCULOSKELETAL DISORDERS (MSD's)

In "Job Safety and Health Quarterly/Fall 1990", the Secretary of Labor announced the Agency's new Ergonomics Program Management Guidelines for Meat Packing Plants – emphasizing repeated trauma now referred to as MSD's. The Secretary identified the meat industry near the top of the list of high hazard industries – being second to shipbuilding. (Attachment 7)

The National Institute for Occupational Safety and Health (NIOSH) on January 6, 1995 reported that disorders due to repeated trauma in the meat packing industry was nearly 75 times that of industry as a whole in the 1980's. While the meat packing industry is struggling to correct this problem – ergonomic injuries continue to extract a tremendous toll on packing house workers. (Attachments 8&9)

On November 23, 1999, the Occupational Safety and Health Administration (OSHA) published a proposed rule requiring employers to establish a basic ergonomics program to address the risks of musculoskeletal disorders (MSD's).

A United Food and Commercial Workers (UFCW) bulletin regarding MSD's, outlines the following:

"Other elements that contribute to MSD's are cold temperatures, slippery floors, poor grips on handles and vibrating tools." (Attachment 10)

An example being hand held air driven vibratory knives in a cold environment.

In addition, it has been reported by numerous industry human resource executives that a low of 60% to a high of 80% of the workers employing hand held air driven vibratory knives are recently arrived ethnic groups including women. A population least able to obtain less injurious jobs and dependent on government health programs.

Industry quickly recognized in 1994-1995 and to-date, the benefits of implementing AMR Systems. They invested millions of dollars to help protect these workers.

Per the public record, the Coalition for Advanced Meat Recovery with the assistance of Labor, submitted a white paper titled "Worker Safety Issues Related to Advanced Meat Recovery". (Attachment 11)

It is a travesty that FSIS has proposed an unwarranted regulatory change that would severely impact the health of recently arrived ethnic groups including women operating air driven vibratory knives on deboning lines, in order to further regulate a product that has been proven to be safe and wholesome.

This regulatory imposition is in direct opposition to OSHA's proposed rule and cuts the heart out of industry's efforts to minimize ergonomic problems.

PROPOSED RULE'S ECONOMIC IMPACT DAMAGES INDUSTRY AND INDUSTRIES WORKERS.

Based on USDA's Economic Impact Analysis of November 30, 1994, Docket No. 94-003F, the Coalition for Advanced Meat Recovery, per the public record, sought the assistance of Sparks Companies, Inc. to review USDA's data and to review the economics of AMR abandonment caused by inappropriate and arbitrary rule making.

FSIS has in error determined this proposed rule is not significant under Executive Order 12866. How FSIS could arrive at this conclusion is beyond comprehension. Their November 30, 1994 Economic Analysis strongly refutes this as does the Sparks Companies "very conservative" analysis. (Attachments 12 & 13)

Therefore, FSIS must conduct an economic Impact Analysis and consider the results when considering any rule making. (Attachment 14)

FOOD SAFETY

Food Safety is of primary concern to everyone in the meat industry. Our families are consumers. We, members of the industry, are consumers.

Nearly every American Consumer enjoys a good hamburger – in fact hamburger (ground beef) and breakfast sausage are found in nearly every American diet in substantial quantities.

Meat produced by AMR Systems is not a consumer end or finished goods product. Meat produced by AMR Systems is blended at a rate of 5 to 15% in ground beef. Meat produced by AMR Systems is also utilized in breakfast sausage, ethnic fresh and smoked sausages, taco meat, pizza toppings, etc., where additional (market short) lean meat is required.

Meat produced by AMR Systems assists the entire industry from producer to processor. It benefits nearly every American household. In fact, it is a safe, wholesome and nutritious source of lean meat.

Attached for your reading is a white paper titled "Advanced Meat Recovery Systems" by Dr. Lester Crawford of the Center for Food and Nutrition Policy, Georgetown University, found in the public record. (Attachment 15)

Dr. Crawford is respected through out America as one of the foremost meat scientists – his refutation of Public Health Concerns or Food Safety Issues with AMR Systems is complete and should be carefully considered by FSIS prior to any unwarranted decision making – or – to support their <u>warranted</u> decision of December 6, 1994.

SCIENCE BASED DECISION MAKING

In their decision making process, FSIS must consider two seldom addressed topics.

- 1. The splitting, quartering and/or breaking down by saw into roasts, chops and steaks introduces marrow into meat.
 - How does one know when and where the marrow was introduced when testing ground or AMR produced meat?
- 2. Worker introduced microbial/pathogenic contamination.
 - AMR Systems substantially reduce the number of workers retrieving very small, high surface area pieces of meat, highly susceptible to personnel introduced contamination.

AMR Systems virtually eliminate this occurrence.

Attached for your convenience is the USDA-ARS report. This report adequately refutes FSIS's allegations and establishes that iron variability in meat may be affected

by more that a dozen variables and of which the iron impact for these variables either separately or in combination is unknown. (Attachment 16)

USDA has been consistent in it's remarks that policy decisions must be science based. Recently the FSIS Administrator, Mr. Thomas Billy, stated "We must see that science wins out over rhetoric - that science guides our food safety decisions." Similar statements have been expressed by Secretary Glickman and Under Secretary Woteki.

Based on the foregoing statements reflecting policy, why would FSIS <u>arbitrarily</u> lower the calcium standard to where only 90% of the samples analyzed in the 1996 survey would have been in compliance.

CONCLUSION

We have previously stated our suspicions of political pressure and FSIS's apparent willingness to accommodate a political decision as opposed to a science based decision supported by the haste to publish, based on flawed science and innuendo.

It is our firm conviction that FSIS must remove itself from politically induced decision making and forcefully support it's original decision of December 6, 1994.

FSIS must not be a party to effecting economic discrimination. (Attachment 17)

There are other far more serious issues that should consume FSIS's budget and limited time.

BFD Corporation (BFD)

Harold T. Hodges

<u>APPENDIX</u>

Attachment	1	TDS-136 dated June, 1999
Attachment	2	A-A 20256 Commercial Item Description
Attachment	3	Beef Products Advertisement
Attachment	4	Beef Products Advertisement
Attachment	5	Colorado State University Analysis-LFTB
Attachment	6	Executive Order 13100
Attachment	7	Red Meat, Ergonomics Program
Attachment	8	NIOSH, Ergonomics
Attachment	9	NIOSH, Carpal Tunnel Facts
Attachment	10	United Food Commercial Workers MSD's Bulletin
Attachment	11	Worker Safety White Paper
Attachment	12	USDA 1994 Economic Impact Analysis Meat & Bone Separation
Attachment	13	Sparks Companies, Economic Impact Of Proposed Rule
Attachment	14	Executive Order 12866
Attachment	15	Advanced Meat Recovery White Paper Food Safety
Attachment	16	USDA-ARS Soft Bone Constituents Study
Attachment	17	USDA announce addressing Market Concentration