EXCEL

22

RECEIVED
FSIS DOCKET ROOM
00 JAN 18 PM 10:50

January 17, 2000

98-027R-22
98-027R
Dan Schaefer
Scott Eilert

FSIS Docket Clerk
Food Safety and Inspection Service
US Dept of Agriculture
Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

RE: Reopening of comment period on Proposed Rule on Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems, FSIS Docket No. 96-027R, 64 Fed Reg.70200-70201, December 16, 1999.

TO WHOM IT MAY CONCERN:

Excel Corporation is a global meat packing and processing company, which operates six Beef Slaughter facilities in North America with an annual capacity of 7 million head. Excel also operates three Pork Slaughter facilities in North America with an annual capacity of 10 million head. Excel has operated Advanced Meat Recovery (AMR) processes since the implementation of the current rule in December 1994. The production of AMR product significantly impacts our labor force and our business operation. In addition, we have collected and evaluated a substantial amount of data regarding the AMR process and products. We were also involved in the original petition for the AMR in 1994. Therefore, we are qualified to comment on this proposed rule and have a sincere, vested interest in the outcome.

AMR product has been a component of the U.S. food supply since 1994, and has been safely consumed in a variety of products from ground beef to sausages and pizza toppings. Worldwide, recovered meat has been consumed for more than three decades. AMR systems were jointly developed with FSIS over the past five years by conducting research to address FSIS concerns. Throughout the development of this technology, data was openly shared with FSIS. The advent of AMR systems have resulted in:

- Ergonomic Improvements (Improved worker safety)
  - Ergonomic improvement for the worker has been the driving force for development of AMR. Excel has shifted workers away from trimming neckbones with high speed knives to less physically demanding tasks.

- Increased job satisfaction through the replacement of highly monotonous and tedious tasks.

- Improved product quality
  - Product quality has improved through a consistent reduction in bone chips occasionally present in hand deboned trimmings from beef neckbones.

- Maintained consumer acceptance
  - With the use of AMR in a variety of meat products, our quality standards have remained unchanged.

We appreciate the opportunity to provide comments regarding the additional information which has been submitted in response to the proposed rule.

Worker Safety/Ergonomics

We fully agree with the information provided by the United Food and Commercial Workers' Union (UFCW, 1999). Worker safety and ergonomics are the reasons this technology was developed and implemented. The fact that CTD injuries in the meat industry dropped by 38% when this technology was implemented (Dept. of Labor, 1995), is evidence of the impact this technology has on meat industry employees.

Food Safety

We fully agree with FSIS that AMR products do not have any negative health, safety, or nutritional impact. The information from Lester Crawford supports this fact (Crawford, 1999). In addition, we believe meat products, including AMR, have significant positive nutritional benefits, especially in providing iron to the American diet. The typical American diet is deficient in iron (CDC, 1998). Meat and meat products are the best source of dietary iron.

Economics

In previous comments submitted by AMI, it was clearly noted that the elimination of AMR technology would have significant impact on the meat industry. We believe the economic impact study (Sparks, 1999) clearly details the costs associated with elimination of AMR technology. The following table recaps this study and details the specific impact on Excel. We assumed that Excel represents 20% of Federally Inspected Steer and Heifer slaughter and Excel represents 10% of the Federally Inspected Pork slaughter.

	Fed Cattle Industry Impact	Excel Impact
Spent capital loss	$19,720,000	$3,944,000
Capital to restructure	$19,176,000	$5,752,800
Additional labor	$36,951,200	$11,085,360
Employee medical impact	$7,208,000	$2,162,400
Yield reductions	$21,672,210	$6,501,663
TOTAL	$104,727,410	$29,446,223

	Pork Industry Impact	Excel Impact
Spent capital loss	$9,860,000	$986,000
Capital to restructure	$6,494,000	$649,400
Additional labor	$7,979,400	$797,940
Employee medical impact	$1,643,000	$164,300
Yield reductions	$42,432,180	$4,243,218
TOTAL	$68,408,580	$6,840,858

Excel Costs

Fed Beef	$29,446,223
Pork	$6,840,858
Excel TOTAL	**$36,287,081**

Performance Standards

Hard Bone

Excel agrees that the AMR products must have process controls and Calcium is the best objective measure for process control. We disagree with changing the performance standard for Calcium to 130mg/100g. The 130mg/100g standard was arbitrarily based on a limited data set. We propose that the Calcium standard, like any performance criteria, be based on actual process data. We also propose that separate performance standards be established for beef and pork. These species have inherent differences in Calcium content of meat and bone due to:

- Biological differences
- Age at slaughter differences
- Types of bones processed

Our proposal for a performance standard would be to set a maximum Calcium content based on the average Calcium content of AMR products (by species) currently being produced plus two standard deviations to allow for process variation. The following beef data is a compilation of 152 data points from three large fed cattle processors and 3 large cow processors. The pork data is a compilation 169 data points from 3 major butcher pig processors and 1 sow processor (All product was produced in accordance with the GMP; AMI, 1997)

Calcium Performance Standards, mg/100g

	Beef	Pork
N	152	169
Average	107.4	101.5
Standard Deviation	22.5	33.7
Performance Standard*	**152**	**169**

*Performance Standard=Average + (2 x Standard Deviation)

By the statistical nature of this method for process control approximately 5% of all samples will exceed the Calcium performance standard and be out of compliance. In addition, we believe the implementation of industry GMP's (AMI, 1997) has reduced Calcium content prior to gathering this data.

Soft Bone Constituents

Excel agrees with the establishment of performance standards which limit the introduction of unnecessary soft bone constituents into AMR products. It is our sincere hope that the implementation of scientifically based soft bone performance standards would alleviate and prevent further consumer group allegations about "harvesting bone marrow" and prevent future disparagement of AMR products.

While we agree with the established of a performance standard for soft bone, we have some strong oppositions to the methods and mechanisms in the proposed rule. The iron data submitted by the Agricultural Research Service validates our previous position regarding flaws in the proposed Added Iron Equation in the proposed rule. We strongly believe that implementation of the proposed Added Iron performance standard or the implementation of a modified performance standard is scientifically unjustifiable and poorly designed for the following reasons:

- **No AOAC approved procedure for the analysis of iron content in meat products currently exists**. This had led to some confusion about the data and inferences from the 1996 survey. The analysis of minerals in an organic matrix requires complete removal of the organic material through oxidation and/or combustion prior to analysis. Residual organic material will give erroneous results, which are undetectable with internal standards. Typical procedures cited in the literature utilize either wet or dry ashing techniques. Wet ash techniques utilize strong oxidizing mineral acids. Dry ash techniques involve combustion of the sample in muffle furnace (550 degrees C). Hydrochloric acid (HCl) is used as a supplemental acid in some of the ashing procedures. However, in all of the procedures found in the literature HCl is never cited as the sole oxidizing agent, due to the fact HCl does not completely remove the organic matrix. The USDA survey data was generated using HCl as the only oxidizing agent. Therefore the iron values in the survey were dramatically understated (Windham, 1998). We believe this may have led to some false inferences about the survey and the development of the Added Iron Equation. A randomly selected subset (n=22) of the survey data showed the following results (Windham, Personal Communication).

	Average	Std. Dev.
Dry Ash Method	5.61[a]	1.08
HCl Ash Method	3.00[b]	0.99

[a,b]Mean values in same column with different superscripts are significantly different. (P<.05)

Therefore we believe the added iron value equation is based on incorrect data and may have contributed to some incorrect assumptions.

- **The added iron equation was incorrectly derived from the relationship of iron content to a histological ranking of assessed bone cell content.** Each sample received a rank score of 0, 1, 2, 3, 4, or 5. This resulted in a dataset which is not normally distributed and requires nonparametric statistical analysis. When we conducted the proper statistical analysis on the data, we find that neither added iron or the iron/protein ratio has a very strong correlation to the ranking of assessed bone cell content.

- **The histological method used (Hematoxylin and Eosin staining) is a qualitative measure and is not quantitative.** "The purpose of histological stain methods is to visualize and differentiate between tissue components, not to determine their chemical composition" (Lyon, 1994). This method can only determine the presence or absence of cellular constituents. Histological staining cannot be used to determine the amount of any constituent. This is due to the relative density differences in the cellular components and the non-random sample examined. We recognize the ability of this method in determining the presence or absence of bone marrow constituents, but we believe the attempt at determining the amount of bone marrow constituents is incorrect. The following table shows the relationship of the iron content sorted into two groups based on the presence or absence of bone marrow constituents (n=22):

Bone Marrow Constituents	Iron, mg/100g	Added Iron Equation
Present	5.66	3.63
Absent	5.47	3.33

  We believe the correct analysis of this data requires evaluation of the data based on presence or absence of bone marrow constituents and not an estimate of the amount present.

- **The hand deboned samples also contained bone marrow constituents.** The data was collected in a manner which does not allow the comparison of the presence or absence of bone marrow constituents to the iron content of the samples. Therefore, the calculation of a hand deboned Iron/Protein ration and the use of this as a base ratio for calculating an added iron performance standard is invalid. In addition, this supports our premise that *de minimis* amounts of bone marrow cannot be considered adulterants.

- **As shown in the following table, we believe the added iron equation is biased against low fat, high protein products.** A supporting document to the proposed rule (Engeljohn, 1997) states that iron by itself might be biased against low fat, high protein products. REMINDER: This table was developed with the proposed added iron equation (Added Iron=Iron- Protein(Base Iron/Protein Ratio), which was derived using incorrect iron analysis and results in understated iron values.

Protein, %	Max. Iron to meet added iron equation, mg/100g	Iron/Protein Ratio Max. Iron divided by % Protein
13	2.67	0.21
15	2.81	0.19
17	2.94	0.17
19	3.07	0.16

As these data show, with an increase in protein content, the iron:protein ratio declines, which is biased against the high protein samples.

- **The iron content of meat and marrow varies greatly dependent upon animal species, age (Blum and Zuber, 1975), and anatomical location (Calhoun et al., 1998).** Physiologically iron is utilized by heme proteins (hemoglobin and myoglobin) for transporting oxygen from the lungs to muscle tissue. Iron is stored in bone marrow.

- **The desinewing process utilized in most AMR systems removes a large portion of connective tissue, which concentrates iron and pigment values.** Calhoun et al. (1998) reported that the collagen value of pork derived from an AMR system was 5.34 mg/g. Knife trimmed meat from a similar bone source had a collagen value of 12.85 mg/g, and ground pork (80% lean) had a collagen value of 11.58 mg/g. By removing such a large portion of collagen as a component of connective tissue, we have significantly concentrated the pigment and the iron in the AMR product. As hand deboned meat has not been passed through a desinewing machine, it is erroneous to compare AMR iron values to hand deboned.

Conclusion

Our suggestions for establishing a scientifically justifiable performance standards are:

1. Remove the current regulatory performance standard, which subjectively evaluates bone integrity.
2. Develop an AOAC accredited procedure for determining iron content in meat products.
3. Reevaluate the survey data to find correct and scientifically justifiable relationships to soft bone constituents. We recommend that these relationships at the very least have statistically significant correlations.
4. Develop a performance standard which utilizes Statistical Process Control methodology. The proposed standard is set at the average of the data, which does not allow for process or analytical variation. We believe, with the data provided by ARS, it is crucial that process and analytical variation are taken into account. Since this issue does not involve

food safety, it would be irresponsible to eliminate at least 50% of the production by not accounting for variation.

5. Republish the performance standard in a proposed rule. The current added iron equation in the proposed rule contained several flaws. The most notable flaw was inaccurate iron analysis procedures. The data supplied in the reopening of the comment period does not allow the calculation of a new or modified performance standard. We strongly believe that proceeding with a modified performance standard without publishing a new proposed rule would irresponsibly force the industry into an untenable situation.

Excel appreciates the opportunity to comment on the additional data provided for this Proposed Rule. We believe that the adoption of scientifically based performance standards result in consumer confidence, industry benefits, and regulatory equality. However, we feel this performance standard is not scientifically justifiable. Specifically, the performance standard is based on inaccurate iron analysis, inappropriate statistical analysis, and lack statistical process control methods. In addition, the proposed performance standard was derived from a limited data set that does not account for inherent biological differences due to species and age.

Finally, the industry requires publication and comment on the modified performance standard. We will need time to investigate the appropriate process controls needed to meet whatever performance standards are set. In the proposed rule, it is implied that by simply changing machine operating pressures, the industry can meet the proposed performance criteria. Industry testing has shown that within the operating pressures recommended by the manufacturers, we have very little ability to impact calcium or iron values in the finished product. This being the case, it will be necessary for the industry to make extensive capital improvements to meet proposed performance criteria or revert back to hand deboning with high speed knives. At the very least, a period of time will be needed to establish reliable iron analysis methodology and to fully evaluate the capabilities of current equipment. Finally, with the exception of calcium, none of these measurements are performed on a routine basis in most slaughter/fabrication facilities. We would propose an implementation period of 24 months from the time of rulemaking in order to fully meet these requirements.

Thank you for your time and consideration of these comments.

Sincerely,

Dan Schaefer
Director, Beef R&D
Excel Corporation

Scott Eilert
Director, Pork R&D
Excel Corporation