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Dan Schaefer

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: Advanced Meat Recovery, Interim Final Rule, FSIS Docket No. 03-038IF, 69 Fed Reg. ppg.1874-1885, Jan 12, 2004.

TO WHOM IT MAY CONCERN:

Excel Corporation is a global meatpacking and processing company, which together with its affiliated companies, operates eight Beef Slaughter facilities in North America with an annual capacity in excess of 7 million head. Excel also operates two Pork Slaughter facilities in North America with an annual capacity in excess of 9 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 involved in the original petition for AMR in 1994. Consequently, we are highly qualified to comment on this proposed rule and have a sincere, vested interest in the outcome. We appreciate the opportunity to provide comments regarding this topic.

BACKGROUND

AMR product has been a component of the U.S. food supply since 1994, and has been safely consumed in a variety of products including ground beef, sausages, and pizza toppings. Worldwide, recovered meat has been safely consumed for more than three decades. AMR systems were jointly developed by the meat industry and FSIS 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 Work Safety

Ergonomic improvement for the worker has been the driving force for development of AMR. AMR systems have led to reduced accidents and ultimately safer working environments. The U.S. Department of Labor (2002) published data for Meatpacking and Poultry Processing in 2002 that showed Nonfatal Occupational Injuries and Illnesses have decreased from 21.5 incidents per 100 workers in 1996 to

11.5 incidents per 100 workers in 2002. We are confident that a significant portion of this 47% reduction in worker injuries was a direct result of the introduction of AMR systems in 1994. Moreover, AMR systems have enabled Excel to shift workers away from trimming neckbones with high-speed knives to less physically demanding tasks. This has resulted in increased job satisfaction through reassignment to more meaningful tasks that are less tedious and monotonous.

Improved raw material quality

Raw material quality has improved through a consistent reduction in bone chips occasionally present in hand deboned trimmings from beef neckbones. We also believe that AMR has improved industry practices since 1994 due to the removal of the spinal cord from the carcass during the slaughter process.

Increased consumer demand

As a result of the high quality, safe, and nutritional products provided by the meat industry, per capita consumer demand for beef has risen from 61.0 lbs. per capita consumption in 1993 to 63.1 lbs. per capita consumption in 2001 (US ERS, 2003). This 3.5% increase is directly attributable to the consumer demand and satisfaction currently enjoyed with beef.

We appreciate the opportunity to provide the following general comments to the interim final rule:

1. ***Ergonomics/ Worker Safety***

   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 cumulative trauma injuries in the meat industry dropped by 47% since this technology was implemented (US Dept. of Labor, 2002) is evidence of the benefits this technology provided to meat industry employees.

2. ***Food Safety/Nutrition***

   We fully agree with the FSIS position that AMR products do not have any negative health, safety or nutritional impact. The information provided by Lester Crawford supports this fact (Crawford, 1999). Moreover, CDC (1998) data indicates that iron deficiency is one of the most widespread nutritional concerns regarding the typical American diet. Nutritionists agree that meat and meat products, including AMR, are the best source of dietary iron and should be considered an essential source for iron.

3. ***Economics***

   In previous comments submitted by AMI (1997), it was clearly noted that the elimination of AMR process would have significant economic impact on the meat industry. The economic impact study conducted by Sparks (1999) clearly illustrates the costs associated with elimination of AMR technology. Table 1 recaps the findings of the Sparks (1999) study and details the specific impact on Excel.

Table 1. Economic impact of AMR systems on the meat industry

	Total Impact for Industry	Total Impact for Excel
Fed Beef Industry[a]		
Spent capital loss	$19,720,000	$3,944,000
Capital to restructure	$19,176,000	$3,835,200
Additional labor	$36,951,200	$7,390,240
Employee medical impact	$7,208,000	$1,441,600
Yield reductions	$21,672,210	$4,334,442
Fed-Beef Industry Total	**$104,727,410**	**$20,945,482**
Cow Industry[b]		
Spent capital loss	$10,440,000	$1,044,000
Capital to restructure	$6,660,000	$666,000
Additional labor	$7,722,000	$772,200
Employee medical impact	$1,590,000	$159,000
Yield reductions	$8,789,130	$878,913
Cow Industry Total	**$35,201,130**	**$3,520,113**
Pork Industry[c]		
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
Pork Industry Total	**$68,408,580**	**$6,840,858**
TOTAL COSTS	***$208,337,120***	***$31,306,453***

[a]Calculations for the economic impact of AMR were interpolated using the assumption that Excel-Beef accounts for approximately 20% of Federally Inspected Fed Steer and Heifer slaughter.
[b]Calculations for the economic impact of AMR were interpolated using the assumption that Excel's affiliated companies account for approximately 10% of the Federally Inspected Cow slaughter.
[c]Calculations for the economic impact of AMR were interpolated using the assumption that Excel-Pork accounts for approximately 10% of Federally Inspected Pork slaughter.

Although FSIS disagrees with the findings of the Sparks (1999) report, Excel finds Spark's conclusions to be very accurate, particularly when the additional burdens of the interim final rule are factored in. Specifically, Excel disagrees with the following conclusions surmised by FSIS regarding the Sparks (1999) report:

3.1. "*AMR machines will continue to operate.*" The interim final rule is written with constraints that do not impact human food safety, but create significant, likely insurmountable, hurdles to continued use of AMR technology. For this reason, we believe the loss of current capital assets outlined in the Sparks (1999) report to be accurate.

3.2. "*Costs of auto-knives should be depreciated over several years.*" Basis our experience, auto-knives have a very high maintenance cost and must be frequently replaced because

of OSHA vibrational requirements. We believe the useful, amortizable lifespan of these knives is one year and therefore agree with the conclusions in the Sparks (1999) report.

3.3. "*Executive Order 12866.*" The interim final rule has significant economic impact, on the order of $200 Million, and portions of this rule ***are not*** associated with imminent food safety hazards. Portions of the interim final rule not associated with imminent food safety hazards must be dealt with separately through open, prudent, and judicious rulemaking processes.

Excel disagrees with the April 2004 FSIS BSE economic impact estimates. The simple removal of cow vertebral bones will result in a product loss of 3lbs of meat per head on an estimated FI slaughter of 5.6 Million head will result in over $15 Million of direct losses, which exceeds the entire FSIS estimate for the impact on AMR. Product loss, equipment utilization/alternative processes, additional laboratory testing, and regulatory compliance exceeds the agency's estimate by at least 4 fold. We believe that this study grossly underestimates the economic impact on the industry.

We have separated our remaining comments into two parts: Section 4-Measures appropriate in preventing human exposure to the BSE agent in the United States, and Section 5-Measures included in the interim final rule, not related to human exposure to the BSE agent in the United States:

4. Measures appropriate to preventing human exposure

In the United States, BSE is an animal health issue that has been sensationalized as a perilous threat to human health – clearly this is not the case. Consumer confidence in the safety of the U.S. food supply remains high (NPD, 2004) and research has determined that the risk to humans in the U.S. is negligible, with or without AMR products in the food supply (Cohen et al., 2003).

Excel applauds and commends the combined efforts of USDA, FDA, and APHIS in implementing animal health firewalls, such as surveillance of suspect animals, and the ruminant-to-ruminant feed ban. Additionally, the interim policies removing specific non-ambulatory animals and Specific Risk Materials from the human food chain in specific ante-mortem situations have some merit as additional animal health safeguards. Undoubtedly, these firewalls and policies are the most effective protections for both animal health and consumer confidence. Likewise, these practices have ensured that any animals identified as being infected with BSE will be limited, isolated, sporadic, and eventually non-existent.

Excel agrees with FSIS in general principle, that central nervous tissue (**CNT**) is not meat and the ultimate goal should be to remove these materials from the food chain, subject to obvious practical constraints. Currently, our facilities are equipped with mechanical devices to thoroughly remove spinal cord and other associated tissues from the vertebral channel, we expect that as technology improves so will our ability to remove these materials. The removal of these tissues is continually monitored by multiple visual inspections. Finished product is tested for the presence of Glial Fibrillary Acidic Protein (**GFAP**) to validate effective removal of CNT (Schmidt et al., 2002). Current GFAP technology is capable of detecting CNT at 1 part per million, however, we expect that improvements in this test will increase sensitivity by 10 to 1000 fold.

Excel disagrees with some of the details regarding implementation of these measures and the supporting documents referenced in the interim final rule.

4.1. In the reference document "*Analysis of 2002 FSIS Bovine AMR Products Survey Results*" (USDA/FSIS, 2002), FSIS compared an immunohistochemical (IHC) analysis method for detecting Unacceptable Nervous Tissue (UNT) to an ELISA based method that detected GFAP. Based upon the conclusions, it appears FSIS views the ELISA test for GFAP as an unacceptable means for determining UNT. **Excel disagrees** with this position. We believe that GFAP is currently the best method for rapidly determining the presence of UNT. As stated in the USDA/FSIS (2002) document "discrepancies between results of the ELISA tests and the direct UNT tissue determination could be caused in part by sampling and measurement errors; matched or paired samples may actually be different with respect to the presence of UNT, or there may be amounts of UNT that are below the (direct) method's sensitivity contributing to a false negative result for the direct method." This IHC method (USDA/FSIS/OPHS, 2004) has a detection limit of 0.25% spinal cord, while the current colorimetric GFAP test (R-bioPharm, 2001) has a detection limit of 0.03% spinal cord (0.6 ng/mg GFAP). Therefore the IHC "direct" method readily contributes to false negative readings. We believe that GFAP testing should be the standard methodology for evaluating presence of UNT. We do not believe the current, direct method identified by USDA is a "gold standard" method by which to judge all other methods due to sampling and measurement error, in addition to the subjective decision of any given pathologist. In addition, the GFAP methodology, while not stated in the methodology, is an old fluorometric version of the GFAP test. We believe that FSIS should recognize the current colorimetric GFAP test as an acceptable method for qualitative determination of CNT.

4.2. We are concerned that the measurement of dorsal root ganglia is also highly subjective. The details of this procedure have not been published, peer reviewed, or accepted by a third party collaborative laboratory study and were released three weeks after the interim rule was established. As stated in USDA/FSIS/OPHS (2004), "Morphologically it is impossible to differentiate the source of fragments of sensory ganglia". Again, we believe this highly subjective procedure establishes imprecise and inconsistently attainable goals.

4.3. We believe that specifying dorsal root ganglia component of meat product is incorrect. DRG from cattle under is not a Specified Risk Material and is present in many products that contain the vertebral column. If the agency continues to consider DRG an unexpected component of meat, we believe the agency should commission the Harvard Risk Group to reevaluate their findings and include new assumptions, such as the entire removal of DRG from the food supply, to provide consumers and industry with full support and assurance in AMR products.

We applaud the quick action taken by USDA to maintain consumer confidence in the U.S. food supply and the goal of preventing human exposure to the BSE agent. We strongly believe that FSIS should accept the peer-reviewed methodology for GFAP detection (Schmidt, et al., 2002) as a process control method for validation of the removal of central nervous tissues.

5. *Measures included in the interim final rule, not related to or appropriate for preventing the human exposure to the BSE agent in the United States.*

5.1.Performance Standards

5.1.1. **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 from the current level of 150 mg/100 g to 130mg/100g. The 130 mg/100 g standard is 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 because these species have inherent differences in Calcium content in meat and bone due to:

- Biological differences
- Differences in age at slaughter (i.e., differences in physiological maturity)
- 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 normal process variation. The data shown in Table 2 reflect information collected from three large fed cattle processors and three large cow processors. Additionally, the pork data represents three major butcher pig processors and one sow processor.

Table 2. Determination of appropriate Calcium Performance Standards

Statistic	Beef (n = 152)	Pork (n = 169)
Mean, Calcium (mg/100 g)	107.4	101.5
Standard Deviation	22.5	33.7
Recommended Performance Standard*	***152.0***	***169.0***

*Calcium Performance Standard = Mean + (2 × Standard Deviation).

[a]All product tested was produced in accordance with GMP's outlined by AMI (1997).

Based upon simple statistics, our proposed method results in approximately 2.5% of all samples exceeding the Calcium performance standard and thus would be out of compliance.

5.1.2. **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 will alleviate and prevent further "special interest group" allegations regarding "harvesting bone marrow" and prevent future disparagement of AMR products.

While we agree with the establishment of a performance standard for soft bone, we hold strong oppositions to the methods and mechanisms in the interim final rule. The iron data, submitted by the Agricultural Research Service, cited in the rule and supporting documents

validate our previous position regarding flaws in the Excess Iron Equation proposed in the rule. We strongly believe that implementation of an Excess Iron performance standard or the implementation of a modified performance standard is scientifically unjustifiable and poorly designed for the following reasons:

5.1.2.1. **Excess iron is not a human health issue nor does the establishment of an excess iron standard have any impact on preventing human exposure to the BSE agent in the United States.** We agree with the statement in the rule that bone marrow is not considered an infective or specific risk material and that the only concern about Calcium levels as a means of ensuring that an excess amount of bone solids is not introduced into the product. Through FSIS acknowledgement of these facts, we strongly believe that any regulations regarding product quality and/or performance standards for Excess Iron and/or Calcium must be dealt with through open, prudent and judicious rulemaking. Forcing these burdens on the industry under the guise of emergency rulemaking does not have any impact on the risk of human exposure to the BSE agent and is not appropriate to address through this interim final rule.

5.1.2.2. **The excess iron equation was incorrectly derived from the relationship of iron content to a histological ranking of assessed bone cell content.** Each sample in the study received a rank score of 0-, 1-, 2-, 3-, 4- or 5. The resulting data set was not normally distributed and thus required nonparametric statistical analysis or should have been subjected to a normalization technique, unfortunately, neither of these options were used in the statistical analysis making all conclusions invalid. We conducted the proper statistical analysis on the data, and found that added iron and iron:protein ratio only had weak (non-significant) correlations to bone cell content rankings. Our position is validated by the FSIS technical paper, "*Derivation of excess iron limits for meat products produced by Advanced [Meat] Recovery Systems*" (USDA/FSIS, 1999). This paper states the objective of the 1998 proposed rule was to "provide clear standards...that include adequate markers for bone-related components (levels consistent with defects anticipated when meat is separated by bone by hand)." Regardless of the statistical methods applied to the dataset, no relationship between iron, excess iron or any other surrogate for determining bone marrow content is established or documented. Cleary the objective of the 1998 proposed rule is not met through measurement of excess iron. We fail to recognize any evidence indicating a relationship between bone marrow and iron content, iron:protein ratio or excess iron.

5.1.2.3. **Histological staining methods are qualitative measures and not quantitative measures.** Lyons (1994) stated, "the purpose of histological stain methods is to visualize and differentiate between tissue components, not to determine their chemical composition." The Hematoxylin and Eosin staining methods employed in the ARS research should only be used to determine the presence or absence of cellular constituents. Any attempt to quantify cellular components using these staining procedures falls outside the scope of their application. Staining methods cannot compensate for the relative density differences in cellular components or the non-random, and non-representative sample examined. We recognize that the staining methods can accurately determine the presence or absence of bone marrow constituents, however, we

do not believe that these techniques can be used to accurately determine the amount of bone marrow constituents. Using the data from Hasiak and Marks (1997), table 3 shows the iron content of samples sorted into two groups based on the histological presence or absence of bone marrow constituents.

Table 3. Iron contents of samples with and without bone marrow constituents present

	Bone Marrow Constituents (n = 22)	
Traits	Absent	Present
Iron, mg/100g	5.47	5.66
Added Iron Equation	3.33	3.63

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.

5.1.2.4. **Hand deboned samples also contain bone marrow constituents.** This supports our position that *de minimis* amounts of bone marrow cannot be considered an adulterant. Moreover, data were collected in a manner that does not allow comparison of the presence or absence of bone marrow constituents to the iron content of the samples. Consequently, the calculation of a hand deboned iron:protein ratio and the use of this as a base ratio for calculating an added iron performance standard is scientifically invalid.

5.1.2.5. **No AOAC approved procedure for the analysis of iron content in meat products currently exists**. 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 that are undetectable with internal standards. Typical procedures cited in the literature utilize either wet or dry ashing techniques. Wet-ashing techniques utilize strong acids and/or oxidizing agents to remove organic material, whereas dry-ashing techniques use combustion of the sample in a muffle furnace (550°C) to remove organic material. 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, because HCl does not completely remove the organic matrix. USDA survey data were generated using only HCl as an oxidizing agent. Consequently, the iron values published in the survey were dramatically understated (Windham, 1998). We believe these procedural errors make the Excess Iron Equation invalid and probably allowed incorrect conclusions to be drawn from the study. A randomly selected subset (n = 22) of the survey data showed the following results (Table 4;Windham, Personal Communication).

Table 4. Methodological differences in iron determination

	Method	
	Dry Ash	HCl Ash
Mean	5.61[a]	3.00[b]
Standard Deviation	1.08	0.99

[a,b] Means within the same row lacking common superscripts are different ($P < 0.05$).

Therefore we believe the added iron value equation is based on incorrect data and may have contributed to some incorrect assumptions. Manipulation of the existing dataset with a correction factor is an unsound basis for rulemaking decisions.

5.1.2.6 The excess iron equation is biased against low fat, high protein products. A supporting document to the interim final rule (Engeljohn, 1997) states that iron by itself might be biased against low fat, high protein products. As shown in Table 5, as protein content increases, the iron:protein ratio decreases, which is biased against high protein samples, such as AMR. The interim final rule mentions, but fails to support any logic regarding this topic.

Table 5. Allowable iron contents and iron:protein ratios for samples containing different levels of protein

Protein content (%)	Maximum allowable iron[a] (mg/100 g)	Iron:Protein ratio[b]
13.0	5.47	0.420
15.0	5.78	0.385
17.0	6.08	0.360
19.0	6.38	0.335

[a]Maximum amount of allowable iron in finished product to meet the Added Iron Equation.
[b]Maximum allowable iron divided by protein content.

5.1.2.7. **Iron content of meat and marrow varies greatly depending upon animal species, age, and anatomical location.** Physiologically iron is utilized by heme proteins (hemoglobin and myoglobin) for transporting oxygen from the lungs to muscle tissue. Iron is also stored in bone marrow. Blum and Zuber (1975) and Calhoun, et al. (1999) reported variations in iron content. Lacking specific knowledge of these factors and the ability to assign detailed adjustment factors for age, species, and location, iron content is not a suitable surrogate for marrow and is not a functional process control marker.

5.1.2.8. **Distribution of iron stores within the body varies greatly under different environmental factors.** Human data shows 3% of the population is anemic which increases with age, childbearing age, gestation, and lactation. Between 50-100% of humans experience anemia during pregnancy. We believe these environmental conditions cause extreme variations in the iron content of muscle tissue relative to protein level especially in the slaughter cow population. Mobilization of iron stores to accommodate gestation, lactation or plane of nutrition makes establishment of a baseline iron protein value difficult. We believe the derivation of excess iron values fails to recognize any of these potential factors.

5.1.2.9. **Hemoglobin represents 70% of the total iron in the body.** Incomplete blood drain could contribute to excess iron values in the highly vasculated tissues typically found in AMR raw materials.

5.1.2.10. **"Dry Lab" production of iron results using a correction factor to compensate for inaccurate lab procedures from a small subset of results is flawed**. We conducted a more complex adjustment utilizing regression techniques for the AMR and Hand

Deboned samples separately. This analysis resulted in low R^2 values, 0.22 and 0.04, respectively. Obviously a simple mean shift by multiplying 2.12 by the wet ash values results in a less accurate adjustment. The only appropriate practice would be to analyze the entire set of samples with proper laboratory procedures.

5.1.2.11. **This data was collected as part of a survey and was never statistically designed for development of process control procedures.** Development of process control procedures from this data is inherently flawed.

5.1.2.11.1. The number of hand-deboned samples is too low to provide statistical power.

5.1.2.11.2. Hand deboned and AMR samples were not collected in the same facility or on the same population of cattle. Moreover, the theoretical excess iron value is being applied to all species and ages of animals without any testing or sample collection.

5.1.2.11.3. Iron determinations for hand-deboned samples were based on an individual carcass, whereas, iron determinations for AMR products were based on composites of many carcasses. If the true objective was to determine if iron values for AMR product were different from hand-deboned product the appropriate design would have utilized paired sides and developed "composites" of 50-100 carcasses for hand-deboned and AMR product, respectively, and replicated to provide statistical significance.

5.1.2.12. **The desinewing process utilized in most AMR systems removes a large portion of connective tissue, which concentrates iron and pigment values.** Calhoun et al. (1999) 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 directly compare AMR iron values to hand deboned. The interim rule addresses this fact through the establishment of a correction factor based on the 1996 Survey Results (Hasiak and Marks, 1997). This correction factor accounts for a 0.5% protein change between pre- and post-desinewing (Note: This average protein change is inclusive of one establishment that did not desinew and was included as a 0% change in the calculation of the average), but fails to take into account the concentration effect on the iron component.

6. ***Conclusion***

Our suggestions for establishing scientifically justifiable performance standards are:

6.1. Remove the non-food safety related measures from the interim final rule and republish the performance standard in a proposed rule. The current excess iron equation in the interim rule contains several flaws. In addition to inaccurate iron analysis procedures, the interim rule and supporting data fails to establish any relationship of iron to bone marrow constituents. The current derivation of excess iron methodology has not been proposed in previous rulemaking or allowed for comments. We strongly believe that

FSIS should not proceed with a modified performance standard without publishing a new proposed rule. Proceeding without open rulemaking on the non-food safety related measures is unnecessarily burdensome and rash.

6.2. Develop a scientific, repeatable, and peer-reviewed procedure for analysis of central nervous tissues of concern and provide industry recommendations for performance and analysis for these tissues.

6.3. Remove the current regulatory performance standards, which subjectively evaluates bone integrity.

6.4. Re-conduct the survey data to find correct and scientifically justifiable relationships to soft bone constituents. We expect that these relationships will, at the very least, have statistically significant correlations before they are considered for performance standards.

6.5. 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.

Excel appreciates the opportunity to comment on this interim final rule. We agree, in principle, with the removal of potentially infective central nervous tissues from the human food chain. However, it is unfortunate that embedded within the rule are non-emergency related measures. These performance standards were proposed by the agency in 1996 and regardless of the BSE situation can be dealt with through open rulemaking, since they are admittedly not an imminent food safety risk.

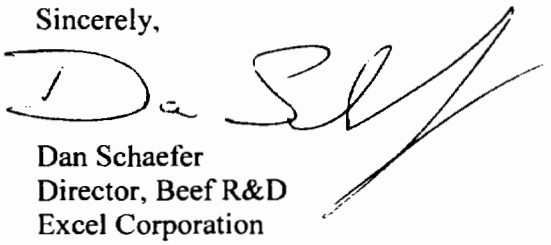
We believe that the adoption of scientifically based performance standards result in consumer confidence, industry benefits, and regulatory equality. However, we feel the proposed performance standard is not scientifically justifiable. Specifically, the performance standard is based on inaccurate iron analysis, inappropriate statistical analysis, and lacks 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 interim 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.

Thank you for your time and consideration of these comments. We look forward to the removal of the current performance standards from the interim final rule.

Sincerely,



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