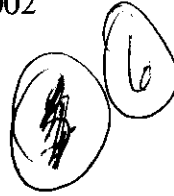




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Docket Clerk
USDA Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street S.W.
Washington, DC 20250-3700



RE: Docket No. 00-023N: "Draft Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef"

The American Meat Institute (AMI) is the nation's oldest and largest meatpacking and processing industry trade association. Our members slaughter and process over 90 percent of the nation's beef, pork, lamb, veal and nearly 75 percent of the turkey produced in the United States. AMI appreciates the opportunity to comment on the review of the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) Draft Risk Assessment of the Public Health Impact of *E. coli* O157:H7 in Ground Beef (the draft). AMI has and continues to support the use of scientifically based risk assessment as the foundation for regulatory programs for inspection of the U.S. meat and poultry supply. The risk assessment team of FSIS is to be commended for the logical and structured approach taken in compiling the data, constructing the draft model and presenting the findings. A critical aspect of this approach is the peer review process. The review currently being conducted by the National Academy of Sciences Committee is a valuable part of the process.

Ground beef is a major component of the U.S. diet. The U.S. beef industry produces approximately eight billion pounds of ground beef annually, which accounts for approximately \$12 billion (wholesale) in annual sales. Since the original identification of *E. coli* O157:H7 as a food borne hazard and human pathogen associated with cattle and subsequently beef, the industry has taken this issue very seriously. Significant strides have been made by the industry to reduce and eliminate this microorganism from beef products. As indicated in the draft, the implementation of multiple interventions in the slaughter process has proven to be an effective means to reduce both the prevalence and density of this organism on carcasses and subsequently, ground beef. New interventions continue to be studied and implemented when proven effective. The continuing improvement in the ability to detect *E. coli* O157:H7 provides new opportunities to understand where the organism resides and to further understand the effectiveness of control methods. Ongoing research on pre-harvest interventions may one day prove effective. The draft risk assessment model has the potential to provide another tool to assist USDA and the industry in further understanding the effectiveness of current and future control strategies.

AMI advocates a food safety system that is risk-based, achievable, measurable, and applied throughout the food chain. Risk assessment should be the foundation of a food safety system and food safety policy. This draft risk assessment is appropriate and should provide the basis by which current and future food safety regulatory policies are evaluated for improving

public health. The following comments address specific components of the draft that we feel require further clarification or additional study prior to finalization. We also strongly recommend that the document not be finalized until the recommendations from the NAS committee charged with reviewing the draft have been fully addressed.

Exposure Assessment

The three modules of the exposure assessment; production, slaughter and preparation are logical and appropriate. This approach recognizes the importance of assessing the risk throughout the food chain.

The production module provides recognition of differences in steer/heifer vs. cow/bull inputs, which is appropriate based on intuition about the production systems and is supported by the available data. Furthermore, it is important that the draft recognizes a seasonal effect in the prevalence of *E. coli* O157:H7.

Recent data collected on prevalence and quantitative values of *E. coli* O157:H7 may improve the production and slaughter modules

The input data in the production module uses a compilation of several published studies. One of these studies, Elder et al. 2000, is a key reference because of the presumption that the methodology used to prepare and enrich the samples and the laboratory techniques described in this paper, provide a greater level of sensitivity for *E. coli* O157:H7. AMI suggests that new and additional data collected by the researchers with the Agricultural Research Service at the Clay Center (the same laboratory that conducted the Elder et al. 2000 research) be considered for inclusion in the final risk assessment. While the data is not published, AMI suggests that the risk assessment should not be finalized until these new data are considered. These data should provide additional insight on the effects of season, without the burden of adjusting for differences in study methodology and test sensitivity. Additionally, the research from Clay Center may provide valuable insight about quantitative levels of *E. coli* O157:H7 which are lacking in the current draft.

The effect of cross contamination needs clarification

The draft states that a high within-herd prevalence of *E. coli* O157:H7 would result in a higher incidence of end-product contamination. This does not recognize the handling of carcasses as individual units in the slaughter process. Transferring contamination from carcass to carcass should be no greater in a high-prevalence herd than a low-prevalence herd. Barkocy-Gallagher, et al. 2001 (Applied and Environmental Microbiology, Sept. 2001, p. 3810-3818) demonstrated that most carcass contamination occurs very early during processing and that most carcass contamination occurs within the same lot and not from cross-contamination between lots. This new information, not included in the draft, may provide valuable insight into the mechanisms for cross-contamination within a processing facility. Additionally, data cited in the last paragraph on page 54 of the draft supports the assertion that cross contamination typically

occurs within the lot; “Isolation of Biotype I *E. coli* from carcasses was not significantly different, whether the herd was highly contaminated or not.”

AMI recommends that the modeling of cross-contamination in the final risk assessment consider the data presented in Barkocy-Gallagher, et al. (2001).

Calculation of Transformation Ratio (TR) did not utilize certain prevalence data and the calculation appears to have data transfer inaccuracies

One of the research needs identified was additional information on *E. coli* O157:H7 contamination of carcasses following dehiding. However, the draft references a study by Bacon et al. 2000 (p. 63) in which 12 commercial beef slaughter facilities participated to provide data on the prevalence of *E. coli* O157:H7 on hides, carcasses immediately after dehiding but before intervention treatment, carcasses post intervention treatment, and in ground beef. Data was collected during the high prevalence season, in both steer-heifer slaughter plants as well as cow-bull slaughter plants located throughout the U.S. Samples were taken from 2254 carcasses, making this one of the most extensive carcass prevalence studies conducted to date. Unfortunately, the draft provides no explanation of the reasons that this data was not used in calculating the TR. Subsequently, the draft states that additional data on carcass prevalence is needed.

The data used in the calculation of TR does not match data from the original source cited, Elder et al. 2000. The draft states “91 of 307 cattle (30%) and 148 of 312 carcasses at dehiding (47%) were *E. coli* O157:H7 positive.” A review of Elder et al. 2000 indicates the following data for samples testing positive for *E. coli* O157:H7: feces, 91/327 (28%); hide 38/355 (11%); pre-evisceration 148/341 (43%); post-evisceration 59/332 (18%); and post-processing 6/330 (2%). The incongruence between these two statements must be clarified, as this is likely to have an impact on the value of TR.

Carcass chiller data should be clarified

There are assumptions made in the slaughter module that should be clarified. First, at Step 6, Chiller (p. 67) the draft states that there are specific FSIS regulations regarding carcass chilling. While suggestions from the National Advisory Committee for Microbiological Criteria for Foods were discussed during the finalization of the HACCP rule, a requirement for carcass chilling was not codified in the final regulations. During that process, industry submitted a significant amount of quantitative time-temperature data on carcass chilling. This is one of the additional research needs identified in the draft document; however, significant time-temperature data should be available to FSIS. If additional data are required, AMI and member companies will assist in collection of additional information on carcass chilling.

The assumptions made in the modeling for change in *E. coli* O157:H7 populations as a result of carcass chilling are not well described. The sensitivity analysis indicates that carcass chilling is a significant correlated factor in the model, yet the data behind the assumption are not well documented, and the draft clearly states that this is an area that needs additional research.

Assumptions in the preparation module and estimation of the effect of storage temperature on growth may overestimate *E. coli* O157:H7 in ground beef

The assumption (p.77) that imported beef is equivalent to domestic trim in prevalence and density of *E. coli* O157:H7 is not supported by industry data. This assumption does not take into account the unique geographical considerations of the countries from which that trim originates and the fact the imported trim is rapidly frozen after slaughter and prior to distribution.

The assumption (p. 79) that the reduction in lag period for *E. coli* O157:H7 is cumulative throughout the farm to table continuum may be flawed. Estimating the varied temperatures that the organism may be exposed to would be challenging; however, the final risk assessment should account for the fact that this assumption is likely to overestimate the ultimate growth of the organism.

Also in the preparation module, the modeling of temperature and time needs clarification. The Audits International (1999), Cold Temperature Survey, which the AMI Foundation co-funded, was designed to only look at temperatures in the retail / supermarket distribution channel, and into the home (R. Daniels, personal communication). It appears that the draft has extrapolated this temperature data to include ground beef that is distributed through the foodservice or HRI channels (p. 81). These two distribution channels, foodservice and retail, handle ground beef very differently. The majority of ground beef sold through retail / supermarket channel is produced and distributed in a non-frozen state. The vast majority of ground beef that is distributed through foodservice / HRI is produced frozen and distributed frozen. The draft addresses the effects of freezing; however, an estimate of the proportion of ground beef sold frozen was modeled with a uniform distribution of 20 – 80%. The uncertainty in this estimate is high and the most likely value of 50% is likely to underestimate the proportion of foodservice ground beef that is distributed frozen. AMI suggests that this component should be studied more closely and more appropriate estimates should be made.

The anchoring approach seems logical

The anchoring approach used to validate the exposure assessment portion of the model seems appropriate, given the available data. Using the routine FSIS monitoring data from FY 2000 is logical since these data would have been collected after the increase in sample size and improvements to detection methodology utilized by FSIS.

Risk Characterization

AMI agrees with the statement in the draft (p. 139) that data is needed on the seasonal consumption patterns of ground beef. Intuitively, it could be predicted that seasonal differences in ground beef might be related to illness patterns, as a greater percentage of ground beef consumption occurs during warmer months of the year. This factor should be modeled in the final risk assessment.

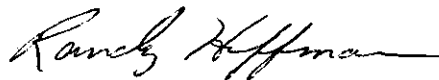
The scope of the draft is limited to *E. coli* O157:H7 in ground beef. However, due to the dramatic rise in human cases of *E. coli* O157:H7 infections from sources other than undercooked ground beef, e.g. drinking water, unpasteurized fruit juices, swimming pools, etc., it seems prudent from a public health and policy perspective that emphasis must be placed on research to reduce prevalence of the organism in cattle and other domestic animals.

AMI strongly suggests that assumptions and estimates made in this risk assessment must be confined to ground beef and extrapolation of these results to other non-ground beef products should be avoided. As the agency contemplates the risk of *E. coli* O157:H7 in non-ground beef products, full consideration must be given to the unique differences in production, fabrication, packaging and distribution of non-ground beef products through a formal risk analysis process.

Again, we appreciate the opportunity to provide comment on this draft. The draft provides an overall analysis of the risk of human illness from *E. coli* O157:H7 in ground beef. Given the conclusions provided in the Sensitivity Analysis and Dependency Analysis sections, additional regulatory actions seem unwarranted at this time. Once finalized, the risk assessment model should be used to not only assess the potential impact of future regulatory actions, but more importantly in a retrospective manner to assess the effectiveness of regulatory actions that have already been instituted. For instance, the model should be used to provide an estimate the effect that routine FSIS testing of ground beef at retail for *E. coli* O157:H7 has had on improving public health. Additionally, the model should be used to explain the public health impact of the adulterant policy for *E. coli* O157:H7 in ground beef. The quantitative estimates of the impact of these policies would be valuable. FSIS should consider these potential uses of the model as part of a continuing plan to improve the effectiveness of regulatory programs relative to *E. coli* O157:H7 in ground beef.

Thank you for consideration of the comments provided above. If there are any questions about the comments provided above, please do not hesitate to contact me.

Sincerely,



Randall Huffman, Ph.D.
Vice President, Scientific Affairs

cc: J. Patrick Boyle
Jim Hodges