



**NATIONAL CATTLEMEN'S BEEF ASSOCIATION**

1301 Pennsylvania Ave., N.W. • Suite 300 • Washington, DC 20004-1701  
Phone 202-347-0228 • Fax 202-638-0607 • Web Site www.beef.org • E-mail cattle@beef.org

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

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01/04/02 10:15 AM

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

On behalf of the National Cattlemen's Beef Association (NCBA) I want to express our appreciation for the opportunity to comment on Docket No. 00-023N: "Draft Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef".

Producer-directed and consumer-focused, NCBA is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

NCBA supports the USDA's utilization of the science of risk assessment in an effort to better understand the sources of risk from *E. coli* O157:H7 in ground beef, and to estimate the occurrence and extent of *E. coli* O157:H7 contamination at points along the farm to table continuum.

We also feel it is important to note that there may be other Shiga toxin producing *E. coli*, such as *E. coli* O16 and O111, that may present a risk, particularly on or in imported beef and trimmings.

The risk assessment is based on a combination of current scientific data and scientific assumptions. The risk assessment must rely upon these assumptions until additional scientific data is generated. At the conclusion of this risk assessment, FSIS lists future research needs that are designed to generate data to fill the existing gaps. As more data becomes available, a more detailed picture of the risk of illness from *E. coli* O157:H7 in ground beef within the U.S. population can be developed. However, we feel very strongly that much additional research and continued fine tuning of the risk analysis model is needed before this will be useful in reducing risk.

We have identified several areas of weakness in the risk analysis and included data to illustrate our concern.

1. The model estimates that the prevalence of O157:H7 in combos during the low prevalence season is 77% (ranging from 55% to 97%) containing no *E. coli*

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O157:H7. During the high prevalence season, an average of 57% of combos (ranging from 42% to 83%) contains no *E. coli* O157:H7. Therefore, an average of 23% and 43% of combo bins contain 1 or more *E. coli* O157:H7 organisms during the low and high prevalence seasons, respectively.

We have attached several studies documenting that even when a combo with a presumptive positive *O157:H7* is found, in most cases, even under exhaustive testing the organism cannot be detected again.

This indicates to us that the model is overestimating the prevalence of O157:H7 in combo bins.

The fact that more than 2,624,093 samples of ground beef from selected establishments, with relatively higher risk, indicate a prevalence of O157:H7 of 0.319 percent, is further evidence the prevalence estimates in the model are too high.

2. The model indicates that a 0.33 log increase occurs as a result of the temperature during fabrication, and thus contamination levels entering combo bins are more than doubled.

We have also enclosed data indicating that O157:H7 was unable to grow in packages of ground beef stored at either 4 or 10 degrees C for periods of up to 49 days. This brings into question the assumption of a doubling of O157:H7 during fabrication.

A study (included) also illustrates a decline of .40 logs O157:H7 in ground products during periods of storage at temperatures of just under 10 degrees C. This is not referenced as an potential mechanism reducing risk in the model.

3. The risk assessment model does not consider the potential for recontamination of cooked ground beef products with *E. coli* O157:H7 in a commercial setting, or by the consumer in the home. Nor does it consider the potential for cross contamination of other food items from contaminated fresh beef (i.e. cross contamination of watermelon or mayonnaise with *E. coli* O157:H7.) Currently there is a lack of data to accurately determine the risk in these two areas. However, each represent potential problems and warrant concern.
4. Seasonal effects modeled in this risk assessment utilize data on the prevalence of *E. coli* O157:H7 within infected herds. An increased seasonal incidence of *E. coli* O157:H7 infections in both U.S. cattle and human populations occurs in the warm months of June to September. However, it should be noted that the data used to estimate the breeding herd prevalence and within herd prevalence of *E. coli* O157:H7 in breeding herds comes from studies in which the experimental protocols vary (see Table 3-1 and Table 3-2). The time period when the animals were sampled throughout the year varied during the year, as did the isolation methodology, which varied in sensitivity. It appears that fecal samples rather than hide samples were used in these studies. There was no indication as to the sample size, which can impact on the results.

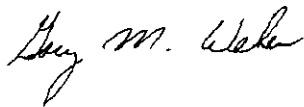
As these were the only studies available to FSIS for the risk assessment, FSIS used this data in their mathematical models. However, it is not desirable to composite data from studies using different experimental protocols.

An important benefit of conducting a risk assessment is the identification of data gaps. On page 154 of the "Draft Risk Assessment", the FSIS has listed a number of potential research projects that should be conducted in order to fill some of the existing gaps related to *E. coli* O157:H7 in ground beef. More data on *E. coli* O157:H7 at slaughter is required. We fully support the need for additional research to more fully understand this issue and to develop a more accurate model.

I have included several research reports that illustrate areas of concern mentioned in these comments. If additional discussions would be helpful, please let me know.

Thank you for your consideration of these points and continual examination of both existing and upcoming data.

Sincerely,

A handwritten signature in black ink that reads "Gary M. Weber". The signature is written in a cursive style with a large, stylized 'G' and 'W'.

Gary M. Weber, Ph.D.  
Executive Director, Regulatory Affairs