



AMERICAN
SOCIETY FOR
MICROBIOLOGY



Public and Scientific Affairs Board

January 4, 2002

FSIS Docket Room
Docket #00-023N
Room 102 Cotton Annex
300 12th Street, SW.
Washington, DC 20250-3700

Re: [Docket No. 00-023N]; *Federal Register*, Vol 66, 55912-55913; Availability of and Request for Comment on FSIS Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef, Notice.

The American Society for Microbiology (ASM) would like to comment on the draft Risk Assessment for *Escherichia coli* (*E. coli*) O157:H7 in ground beef published November 5, 2001, in the *Federal Register*.

The ASM is the premier educational and scientific society dedicated to the advancement of microbiological research and its application for the common good. The Society represents more than 42,000 microbiologists, including scientists in academic, industrial and government institutions, working in a variety of areas, including medical, genomic, molecular, environmental and food microbiology, and public health. The following comments were proposed by the ASM's Public and Scientific Affairs Board Committee on Agricultural and Food Microbiology.

The ASM commends the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) for conducting a Risk Assessment for *E. coli* O157:H7 in beef with a focus on ground beef. The Society supports the concept of quantitative microbiological risk assessments of foods, when appropriately modeled, as a science-based approach to providing risk managers needed information for reducing human illness from foodborne pathogens.

In general terms the draft is clearly constructed and well documented. However, after providing background information on the various classes of *E. coli* that have the ability to cause disease in humans, it unfortunately limits the value of this study by restricting the scope and findings to only O157:H7 rather than all Shiga Toxin-Producing *Escherichia coli* (STEC) that cause human disease. The draft Risk Assessment should expand the assessment to include other strains of STEC (e.g. O111:H-, O104:H21, and non-typables) that are frequently the cause of hemorrhagic colitis (HC) and Hemolytic Uremic Syndrome (HUS). The HC and HUS strains, while historically a problem outside the United States, are becoming more common in the United States.

The assessment suggests that STEC in general and O157:H7 in particular, can induce thrombotic thrombocytopenic purpura (TTP). This is in fact misleading since TTP is a very distinct clinical syndrome with different epidemiological, clinical and laboratory abnormalities, and has a different response to therapy than HC or HUS caused by STEC. All suggestions that O157:H7 can cause TTP should be removed in order to avoid confusion and over reporting of human disease by this or other STEC. If the occurrence of TTP was used in estimating the risk of O157:H7 infection, FSIS should recalculate the assessment's findings.

The "Production" portion of the report focuses on breeding and feedlot cattle but fails to account for other sources of ground beef, most notably culled dairy cattle and immature cattle (veal). This omission should be reconsidered if conclusions concerning the overall risk to the public are to be correct. At the very least, the ASM recommends that the report limit its risk assessment conclusion to ground beef actually evaluated in the assessment.

While the "Production" module simulates cattle entering the slaughter process, it fails to account for the final and significant step of transporting the cattle to the slaughter facility. Production related risk does not end on the farm and restart as the cattle enter the slaughter facility. On the contrary, cattle spend a significant amount of time in crowded and stressful conditions during transit and at the slaughter facility in holding pens. As a result, the contamination rate of cattle entering the "slaughter" phase may be substantially underestimated and a critical control point overlooked. The ASM recommends that the Production section be revised to account for this processing time. The ASM also encourages FSIS to conduct an analysis of the risk/benefit relationship between intervention at the production and processing steps.

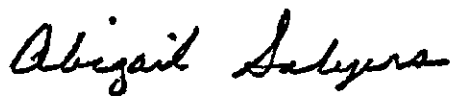
Throughout the Risk Assessment it appears that the estimated accuracy of the detection method used in determining the presence of O157:H7 has not been included as a factor. This omission should be corrected. The detection method may be the most important factor in documenting the relative risk, as well as in measuring the successfulness of any control method. It is very clear that the sensitivity and specificity of the various methods used to identify O157:H7 vary greatly in their results. The methods used when examining feces, water, surfaces, and ground beef are also not equal and may result in a substantially flawed risk estimate. The ASM suggests that any conclusions include this information, and further recommends that additional research be conducted in this area.

In the "Preparation" section of the assessment a statement is made that suggests that granulated ground beef and intact beef products essentially have the same surface area and as such, are "generally considered to be safe after cooking". This statement is incorrect. The surface to volume ratio for granulated ground beef is greater than that of intact beef cuts and as such, granulated ground beef cooks much faster than ground beef or intact cuts. Intact beef is only considered safe in relation to ground beef because the risk of surface-contamination and cross-contamination caused by mixing and processing is considerably greater for ground beef.

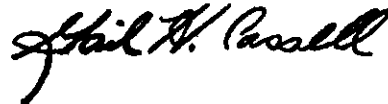
In the “Hazard Characterization” portion of the report a case is made that beta-Poisson is an accurate representation of the O157:H7 dose-response relationship because the organism operates independent of the host. While this may be a correct assumption to model the interaction of O157:H7 in cattle, it is not correct for humans. *E. coli*. O157:H7 disease causing ability is primarily dependent on direct interaction with the human host (STEC have evolved a unique mechanism for this purpose), which causes a host response at the attachment site (attaching effacing lesion) and produces toxins that bind to a specific cell surface receptor (Gb3). Furthermore, host factors (most notably age) are important factors that influence the virulence potential of STEC. As such, the selection of the beta-Poisson function, which is the foundation for the Risk Assessment, may be incorrect. At a minimum, the Risk Assessment’s calculations should be redone using the alternative assumption of bacteria-host dependent interactions.

The ASM is pleased to have the opportunity to provide comments in response to the draft Risk Assessment for *Escherichia coli* O157:H7 for ground beef and hopes that these comments and recommendations are of assistance to FSIS.

Sincerely,



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President, ASM



Gail Cassell, Ph.D
Chair, Public and Scientific Affairs Board



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