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

97-068N
97-068N-46
Robert G. Hibbert

Re: Notice on Beef Products Contaminated With *Escherichia Coli* 0157:H7, FSIS Docket No. 97-068N, Fed. Reg. 2803, January 19, 1999

TO WHOM IT MAY CONCERN:

The Eastern Meat Packers Association (EMPA) represents primarily small to medium size family owned businesses in the northeastern United States. Our membership includes slaughterers of beef animals as well as a large number of processors of the beef products at issue in the above-captioned notice. As a result, our membership's interest in this issue is direct and substantial.

Procedural Issues

It would be difficult to imagine a more confusing procedural setting within which to file a written comment. In sequence FSIS has (1) announced, without any formal or informal notice or precipitating emergency, a drastic change in its policy regarding *E. coli* 0157:H7 in beef products, blatantly mischaracterizing such an announcement as a "clarification;" (2) made the "clarification" effective upon the date of the announcement; (3) demonstrated an inability to provide answers to the host of technical, legal, practical and other questions which the announcement predictably and inevitably generated; (4) announced that it would withhold enforcement of the "clarification" pending a public meeting and completion of comment process; (5) conducted the public meeting where the focal point was an industry-led presentation of a proposed plan to address agency concerns through a carcass-based sampling program; (6) reacted non-committally but favorably to such a presentation; (7) both during and after the public meeting, led all interested parties to believe that it would establish a mechanism whereby comments could be withheld until this industry proposal was reduced to writing; and (8) subsequently contradicted these representations in an informal document which stated that no decisions regarding extensions had been reached and that, therefore, comments needed to be filed prior to the original deadline.

We assume that this is not the case, but would note that if FSIS had somehow set for itself the goal of creating a process which maximized public confusion and minimized the public's ability to provide informed comment to this initiative, it would have engaged in this very same process.

EMPA's membership is generally supportive of the industry's carcass-based sampling program. We obviously need, however, and hereby request, the opportunity to provide comments upon a specific written proposal once it becomes available. Under such circumstances, it is difficult to determine exactly what can be commented upon at the present time. It may be most productive to therefore comment upon the broader issues of substance and procedure raised by the original January 19 announcement.

Scope of FSIS Authority

In this regard, we believe that regardless of the ultimate mechanics of this particular issue, it is essential for FSIS to clarify, on the public record, (1) its conclusions as to the scope of its authority to determine that raw products containing pathogenic substances are adulterated within the meaning of the Federal Meat Inspection Act and Poultry Products Inspection Act, and (2) identify and commit to the procedures it will employ in the future reaching such determinations.

In the substantive area, despite the agency's inexplicable desire to cling to the fiction that its January 19 policy announcement was only a "clarification," it is clear that the announcement is a major substantive change with considerable potential impact upon both the industry and the public as a whole. Under such circumstances, FSIS must specify, on the public record, its authority for such action, and its reasons for specifically taking this action at the present time. This is important, not only for the issue of *E. coli* 0157:H7 in beef products, but also to inform the public on the broader questions of FSIS'purported authority to determine that raw products, which have heretofore been allowed to be lawfully marketed regardless of the presence of any pathogens, can be considered as adulterated as a matter of law.

The "clarification" at issue has been characterized as an extension of existing FSIS policies regarding the presence of *E. coli* 0157:H7. The original FSIS policy announcement of *E. coli* 01587:H7 on ground beef, however, was precipitated by a specific emergency situation resulting from consumption of undercooked ground beef products. At present, there does not appear to be any comparable situation confronting the public through these other products. Also, when challenged, the agency defended its original policy for ground beef based upon particular characteristics of ground beef. More specifically, FSIS observed that in ground beef processing the surface of a contaminated carcass could wind up in the center of an individual patty and that it was also common for ground beef patties, at their center, to be served rare or otherwise undercooked.

Through the present notice, the agency appears to be extending this policy to encompass any situations where the materials on the surface of a beef carcass even theoretically could be transferred into the carcass. Is there any data indicating the presence of *E. coli* in such products? Is there any data to support the implicit suggestion that such products are routinely undercooked? The FSIS needs to address these and all other related questions and otherwise explain its basis for this extension of its policy before it begins to enforce it.

Even more importantly, the policy announcement must be reconciled with what we assume is a continuation of the general policy that raw meat and poultry products containing pathogens are not deemed to be adulterated. Could this policy be "clarified" or otherwise further extended at some later date? If so would it only apply to beef products? Would it only apply to *E. coli* 0157:H7? FSIS should not attempt to skirt such questions by suggesting that they lie outside the scope of this proceeding. What is in fact central to this proceeding is the core question of the scope of FSIS' authority to determine when products are and are not adulterated.

Future Proceedings

FSIS is also obligated to clarify its procedural approach to such issues in the future. EMPA believes that conventional notice and comment rulemaking procedures are the proper vehicles for resolving such questions. In fact, the chaos created by FSIS' efforts to circumvent this procedural model provides perhaps the strongest argument for its utilization in the future. If, in the future, FSIS wishes to make policy departures of a similar nature, it should propose to do so and seek public comment on the issue before making any final decision. If it wishes to obtain public input on an issue before issuing a proposal, it can utilize an advance notice or use some other similar procedural technique. If, on the other hand, it believes it is confronted with a genuine emergency situation which provides good cause for dispensing with normal notice and comment requirements, it can at least attempt to proceed accordingly by stating any alleged basis for emergency action on the public record. We would therefore respectfully request that FSIS commit itself to a process of uniformly addressing such actions in this fashion in the future.

We appreciate being provided with this opportunity to provide comment on this issue. We also hope, as requested above, that we will be afforded the opportunity to comment in further detail on the substance of future industry proposals once they are submitted.

Sincerely

Robert G. Hibbert
Counsel to EMPA