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October 3, 2002 00-022N
00-022N-12
Denis W. Stearns

Gary McKee, Administrator
Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Re: Petition for Amendment of 64 Fed. Reg. 2803

Dear Mr. McKee

Pursuant to 5 U.S.C. 553(e) and 7 C.F.R. 1.28, I hereby petition the FSIS to amend the "policy statement" issued on January 19, 1999 in 64 Fed. Reg. No. 11, pages 2803-05 to expressly exclude any intact cut of meat intended for further processing at retail.

In that statement, the FSIS explained that:

> The public health risk presented by beef products contaminated with E. coli O157:H7 is not limited ...to raw ground beef products. Given the low infectious dose of E. coli O157:H7 associated with foodborne disease outbreaks and the very serious consequences of an E. coli O157:H7 infection, the Agency believes that the status under the FMIA of beef products contaminated with E. coli O157:H7 must depend on whether there is adequate assurance that subsequent handling for the product will result in food that is not contaminated when consumed.

64 Fed. Reg. 2803. It then went on to state that:

> FSIS believes that in evaluating beef products contaminated with E. coli O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption.

64 Fed. Reg. 2804. Finally, the FSIS announced that:

> Intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as

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> non-intact cuts since pathogens may be introduced below the surface of these products when they are further processed into non-intact products. Manufacturing trimmings ...are an example of this type of product. Although manufacturing trimmings may be intact, they are generally further processed into non-intact products.
>
> The Agency believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, and E. coli O157:H7 contaminated beef product must not be distributed until it has been processed into a ready-to-eat product – i.e., a food product that may be consumed without any further cooking or other preparation. Otherwise, such products (i.e., non-intact products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption) must be deemed adulterated.

64 Fed. Reg. 2804.

Raw ground beef that is further processed either at USDA establishment further processing facility, or at retail, is presently subject to regulatory action if it is found to be contaminated with E. coli O157:H7. Similarly the USDA-FSIS has recently announced that it intends to issue a final rule that will deem E. coli O157:H7 as a food safety hazard reasonably likely to occur in trimmings intended to be used for raw ground products. The USDA-FSIS also announced its intention to amend FSIS directive 10.010.1 to expand its sampling and testing program to include trimming. This latter move was considered, but not made, by the January 19, 1999 "policy statement." See 64 Fed. Reg. 2804.

Notably these recent moves by the USDA are consistent with the January 19, 1999 "policy statement" except to the extent that it remains unclear whether intact cuts of meat intended for further processing at retail will, for purposes of the FMIA, be deemed adulterated if found to be contaminated with E. coli O157:H7.

It is also unclear whether intact cuts that are sold for further processing at retail are similarly subject to recall if found to be contaminated with E. coli O157:H7. Plainly, such products do not fit within the stated rationale of the "intact product rule" since the pathogens on the meat will inevitably be introduced below the surface prior to distribution for consumption. If the "intact product rule" were to apply to intact cuts that are further processed at retail, there is a clear threat to the public health and safety.

This is also not a theoretical risk. The E. coli O157:H7 outbreak that occurred in 2002 in Milwaukee at two Sizzler restaurants was linked by health authorities to sirloin tri-tips contaminated with E. coli O157:H7. These tri-tips were sold as intact cuts but were specifically intended for further processing at retail. The supplier of these tri-tips successfully argued in State Court that the FMIA did not deem the tri-tips adulterated. In so doing, it relied exclusively on the FSIS's January 19, 1999 policy statement in making this argument. It was also joined by the American Meat Institute (among other industry trade groups) in arguing that the FSIS policy statement was an authoritative and binding

interpretation of the FMIA. The court dismissed the lawsuits, including one by a little girl who had died as a result of consuming adulterated food, holding that the FMIA preempted state law, and that it authorized the company to knowingly sell tri-tips contaminated with E. coli O157:H7.

In its ruling, the court emphasized that it was "the USDA's job to determine when meat is safe, wholesome, and not adulterated." (A copy of the Court's decision is attached for your reference.) The court therefore accepted the meat industry's argument that the USDA's stamp of inspection, once applied, meant that the meat that bears it is "safe, wholesome, and not adulterated" – even when, as a factual matter, it is neither safe nor wholesome. The court therefore concluded that states are powerless to prevent or prohibit the sale of surface-contaminated meat within their borders, and that meat companies can knowingly sell such meat without risk of being subject to a lawsuit filed under state law.

According to the court's ruling, the "policy behind preemption in this area makes sense. [The meat company's] processing plant is an 'official establishment' governed by the Federal Meat Inspection Act. The federal government has acted in this area to provide national standards so that properly handled and cooked meat products are safe for human consumption. These standards protect the meat processors also, so that they know what is expected of them in regards to the products that are distributed among the many states. In an area of such great national concern, it is essential that the rules be uniform. Federal inspectors are in these meat plants, testing the meat and monitoring the processing programs. The federal regulatory scheme is so long-standing and so comprehensive that I conclude it preempts any state laws to the contrary. That includes bringing civil suits against meat processors."

It is in light of the Court's ruling, and the continuing confusion over what is, and is not, deemed adulterated under the FMIA that we ask the FSIS to amend its January 19, 1999 policy statement to expressly exclude from its scope any intact cuts intended for further processing at retail.

Pursuant to 7 C.F.R. 1.28, I ask that my petitioner receive prompt consideration. I would be happy to discuss any of the issues addressed in this petition or to provide additional information if it would be of assistance. Thank you for your attention.

Very truly yours,

Denis W. Stearns

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

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Dear Mr. Stearns,

The Food Safety and Inspection Service (FSIS) has received your petition dated October 3, 2002, requesting that the Agency amend its policy statement issued in the Federal Register on January 19, 1999, regarding beef products contaminated with *Escherichia coli* O157:H7 (*E. coli* O157:H7) (64 FR 2803). In the petition, you request that FSIS amend this policy statement to specifically exclude intact cuts of beef intended for further processing at retail from the beef products that FSIS deems to be adulterated if contaminated with *E. coli* O157:H7. As stated in your petition, this action is needed because the January 19, 1999, policy statement is unclear as to whether FSIS deems intact cuts of beef intended for further processing at retail adulterated for purposes of the Federal Meat Inspection Act (FMIA). Your petition has been referred to the Regulations and Directives Development Staff (RDDS) of the Office of Policy and Program Development (OPPD) where it will be considered as a comment in response to a recent FSIS Federal Register notice on beef products contaminated with *E. coli* O157:H7.

On October 7, 2002, FSIS published a notice in the Federal Register, "*E. coli* O157:H7 Contamination of Beef Products," in which the Agency provides information on its views about the application of the hazard analysis and critical control points (HACCP) regulations to contamination of beef products with *E. coli* O157:H7 (67 FR 62325). In this notice the Agency announced a series of new measures to prevent *E. coli* O157:H7 contamination in ground beef. The new measures are based on recent information indicating that *E. coli* O157:H7 is more prevalent than was previously thought. In the notice, the Agency states that, under the HACCP regulation, if establishments have not already reassessed their HACCP plans for raw beef products in light of the most recent data on the prevalence of *E. coli* O157:H7, they must do so now. The Agency went on to explain that even establishments that produce intact beef product will need to reassess their HACCP plans based on the new *E. coli*. O157:H7 data because much intact beef product may be used to make non-intact product, such as ground beef. FSIS also announced that it intends to gather pertinent information concerning suppliers of beef products from Federal grinding establishments and retail facilities if FSIS confirms that ground product produced by official grinding establishments or at retail is positive for *E. coli* O157:H7.

FSIS invited comments on, among other things, the matters presented in the October 7, 2002, Federal Register notice. FSIS has determined that, because the issues raised in your petition are related to the matters discussed in the October 7, 2002, notice, the Agency will consider your petition in conjunction with the comments received in response to that document. The Agency believes that considering your petition along with other comments received in response to its most recent policy document on *E. coli* O157:H7 offers the opportunity to comprehensively address the issues that have been raised about the Agency's *E. coli* O157:H7 policy. In addition, FSIS believes that this approach makes the most effective use of the Agency's resources.

Sincerely,

Philip S. Derfler
Deputy Administrator
Office of Policy, Program and Employee Development

cc: G. McKee, Adm.
L. Swacina, AA
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