AMERICAN MEAT INSTITUTE

November 27, 2002

FSIS Docket Clerk
United States Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

00-022N
00-022N-2
Robert A Seward II

Re: Draft Notice (Docket No. 00-022N): *E. coli* O157:H7 Contamination of Beef Products

Dear Ms. Riley:

Thank you for the opportunity to comment on the Food Safety and Inspection Service (FSIS or the agency) draft notice, "*E. coli* O157:H7 Contamination of Beef Products." These comments are submitted on behalf of the American Meat Institute (AMI). AMI appreciates the opportunity to provide feedback on the draft notice.

E. coli O157:H7 as a hazard reasonably likely to occur

Section 417.2(a)(1) suggests that at any level whatsoever, *E. coli* O157:H7 is a hazard reasonably likely to occur. According to the document, the agency provides an opportunity for an establishment to take a contrary view. With this opportunity, does the agency have a position and rationale for establishing a "limit" for reasonably likely to occur? Is there a difference between a prevalence of 0.05, 0.1, 1.0, 2.0 and 5.0% relative to the definition of a hazard reasonably likely to occur? Without providing the rationale or the limit, the FSIS suggestion that an establishment may take the approach of excluding the hazard from a HACCP plan does not appear to be sound or achievable by an establishment.

The agency should specify the level (prevalence, concentration) of regulatory concern and the methods used to define the level. It is important for the agency to define how *E. coli* O157:H7 at any level (e.g., 1 cell per 2000 pound combo of trimmings) is unacceptable, particularly when there is no opportunity for the very low level of contamination to increase because of temperature control, and because the raw beef will be cooked before serving.

AMI and its members submit that when:

- the prevalence of *E. coli* O157:H7 is measured routinely and is shown to be present only as common cause variation (e.g., found at prevalence levels of less than 0.5% during low prevalence months as demonstrated by historical data generated by an establishment, and at levels of less than 2.5% during the months of higher prevalence based on historical data generated by an establishment; this is in contrast to elevated levels resulting from an assignable cause), and
- is controlled by validated and verified critical control points in an establishment producing raw beef trimmings or ground beef,

the hazard should not be considered as reasonably likely to occur at a level requiring regulatory control and action.

The notice states that the preliminary risk assessment concludes that nearly 90% of grinder loads had at least one *E. coli* O157:H7 organism. If this is realistic and a basis for regulatory action, then it must be concluded that this organism could be detected if enough samples were taken and tested. If FSIS considers *E. coli* O157:H7 unacceptable without a defined level, and thus, a hazard reasonably likely to occur, then does FSIS translate this assessment conclusion into consideration that 90% of all grinder loads are adulterated and should be excluded from manufacturing? If yes, FSIS essentially shuts down the ground beef industry and supply, because no interventions exist to remove 100% of the microbial hazard. If no, what is the rationale for accepting this level of risk under a zero-tolerance regulatory position, and in the absence of a defined level of confidence?

How does this risk assessment conclusion factor into the rationale that *E. coli* O157:H7 is a hazard that is reasonably likely to occur? FSIS has suggested that *E. coli* O157:H7 must be reduced to an "undetectable" level; but the parameters surrounding "undetectable" are not given. FSIS should specify these parameters and could use these parameters to define what is meant by a "hazard reasonably likely to occur" for this pathogen. AMI has suggested a rationale above in this section.

Anecdotal information from inspection personnel and IDVs

The FSIS document states that anecdotal information from inspection program personnel and IDVs has led FSIS to various conclusions. If these conclusions have been used to create new regulatory initiatives on *E. coli* O157:H7, then it would be helpful if FSIS would share this anecdotal information and IDV data with industry and others in order for industry to understand the basis for the FSIS proposals. While it is not clear if the data are from CSOs or other inspection personnel, it has been stated by the agency that, with few exceptions, CSOs are those inspection personnel trained in assessing the design and content of HACCP plans. It would be important to clarify how representative the data were of all establishments, how many establishments were included in these data and observations, and what were the specific questions or observations that led FSIS to its various conclusions.

FSIS states that, based on data from inspection program personnel and IDVs, that establishments have not validated their CCPs. What are these data or information? Will the agency share these data and information from which they have drawn this conclusion? FSIS should share these data, with specific details on the CCPs assessed, and the details surrounding why the CCP was not validated. Knowing the size classification of the plant would help to focus industry education efforts, as well as inspection efforts to raise all plants to a common basis.

Use of a CCP to reduce *E. coli* O157:H7 below detectable levels

The confidence level for this expectation, *i.e.*, below detectable levels, is not given, but along with the expected prevalence, greatly influences the probability of detecting *E. coli* O157:H7 in contaminated product or raw materials.

If the establishment validates and verifies its CCP as providing a 1.5 to 2-log reduction (e.g., the maximum reduction provided by interventions such as thermal carcass treatments), does FSIS recognize that this qualifies as a CCP that reduces the hazard below detectable levels?

It has been well established in the published literature that no interventions (except cooking and perhaps irradiation at high levels of irradiation) will eliminate all potential pathogens on raw agricultural products including beef. If one were to test enough product or raw materials, one would likely be able to detect the hazard, despite the use of all interventions in use today. Thus, how do such CCPs and their limitations, mesh with the document and expectations as written? Does FSIS know of any slaughter or fabrication CCPs that will reduce the hazard to levels that are "undetectable" if very rigorous sampling and testing schemes are used? As far as industry knows, such CCPs do not exist; thus, clarification on the acceptability of existing CCPs in relation to "reduction below detectable levels" is necessary for such regulations to have any meaning in practical terms.

FSIS states that a plan is not validated until an establishment demonstrates that the CCP achieves the anticipated effect under actual in-plant conditions. A logical assumption, based on all testing data today from establishments taking advantage of all proven technologies, is that the hazard will be detectable, if sampling and testing are sufficiently extensive. According to the FSIS document (that does not define a confidence level for pathogen reduction or control), the CCP would not be validated whenever a positive result is found. In fact, if the measurement of validation for any CCP is that the microbial hazard is not detectable, there are no interventions capable of achieving this level of control. While perhaps not detectable when sampling 3, 5 or even 60 samples per lot, the hazard may well be found in the next single sample taken. FSIS needs to clarify under what conditions (pertaining to application of validated interventions) an establishment would be prohibited from operation; this is important because of the ambiguity of the confidence level required by a validated CCP.

The FSIS document suggests that technological limitations, that are defined for interventions, always put an establishment at risk of being told that the HACCP plan and its CCPs, are inadequate based on a single test result. FSIS appears to state that any establishment that has ever had a positive result for the hazard, when all CCPs were operating normally and as prescribed in scientific validation studies, has a CCP that is not validated because the hazard was detectable in spite of having the HACCP plan operating optimally, as defined by the validation study. FSIS should clearly state its interpretations and actions in those instances where an establishment concludes that there are no CCPs that can result in undetectable levels of *E. coli* O157:H7 100% of the time, even when implemented interventions are being implemented fully as part of validated and verified HACCP systems.

AMI would support the position that, as long as the validated CCP is verified as operationally successful, the HACCP plan is working as written, and that any positive found downstream of the CCP would not require reassessment of the HACCP plan, or be characterized as unacceptable by any other regulation.

FSIS states that there are published scientific studies that demonstrate decontamination. FSIS should make clear the extent to which these decontamination steps will reduce the hazard to undetectable levels, and whether these scientific studies represent actual field trials or laboratory or pilot plant investigations. What is the rationale for FSIS to suggest that these literature reports translate into CCPs, or even can translate into CCPs, in establishment operations? Furthermore, FSIS requests that establishments must validate their in-plant CCPs with in-plant data. What is FSIS planning to do if it is found that these literature interventions do not deliver the expected level of control during actual in-plant operations?

FSIS states that their guidance document includes examples "of published studies of decontamination methods that can be used as critical control points addressing *E. coli* O157:H7." FSIS needs to specifically identify the particular guidance documents since in reviewing the guidance documents, it appears that the interventions do not result in a reduction of the pathogen to "undetectable" levels. Furthermore, the guidance documents do not provide results for in-plant studies to support the implied level of control, *i.e.*, reduction to "undetectable" levels. If FSIS is convinced that the scientific data in these reports establishes, without question, that these decontamination methods will reduce the level of contamination to undetectable levels, even if 100% testing of raw materials was done, then FSIS needs to provide their rationale for this conclusion. If not, how does FSIS justify the statement in the document reporting that these are effective CCPs?

FSIS provides an example in the guidance document for a beef slaughter operation with three potential CCPs: final wash (antimicrobial), proper chilling of product, and proper maintenance of finished product temperature during cold storage. FSIS proposes that these three CCPs are representative of many possibilities that an establishment may choose to use; however, FSIS fails to provide guidance on how an establishment would validate these CCPs given the fact that the published literature clearly demonstrates that these interventions do not reduce *E. coli* O157:H7 to undetectable levels after inoculation at levels that could potentially be encountered in a slaughter operation. Does FSIS believe that these interventions would somehow be more effective in an in-plant setting than in a controlled experimental setting? FSIS does not provide guidance on the regulatory response and, how an establishment is to respond, when a positive test is found on carcasses, trimmings or finished ground beef, after proper implementation of the interventions provided as examples.

Use of purchase specifications by grinders as CCPs, or as control measures in SSOPs or prerequisite programs

FSIS states that grinders can incorporate purchase specifications to prevent *E. coli* O157:H7 from entering their establishments in raw materials. AMI requests that FSIS share their data to support this conclusion. Even with optimized technologies for slaughter and fabrication, the historical data suggest that trimmings cannot be produced, despite specifications and sampling and testing, which are 100% free of the microbial hazard. FSIS needs to provide their rationale for their conclusion that purchasing specifications can accomplish this objective.

It is suggested that specifications can be included in the HACCP plan as a CCP. Is there a publication defining specifications as a CCP? Is a specification recognized as a CCP by any scientific body, such as the NACMCF, NAS, ILSI or IFT? Under the scenario described by the draft notice, if grinders use a specification as a CCP, and a positive result is detected downstream in their ground product, does this indicate that their HACCP plan has failed? Furthermore, FSIS needs to explain how a written specification is validated scientifically.

FSIS states that grinders can "effectively include purchasing specifications addressing *E. coli* O157:H7 in SSOPs and other prerequisite programs." FSIS needs to share their data to support this conclusion and position. If FSIS recognizes that grinders may use SSOPs and prerequisites to control *E. coli* O157:H7, why does FSIS not provide the same opportunity for slaughter and fabrication operations to use the controls placed in SSOPs and prerequisite programs? What is the FSIS rationale for differentiating grinders from these preceding operations? The document treats positive results differently under SSOP and prerequisite programs than under HACCP. What is the FSIS rationale for different interpretations of a positive finding, *i.e.*, from a regulatory perspective, a public health perspective, a sanitation perspective, or a prerequisite perspective?

E. coli O157:H7 is more prevalent than was previously thought

Because FSIS states at numerous times throughout this document that *E. coli* O157:H7 is more prevalent than was previously thought, FSIS must provide the background rationale for this conclusion and the requirement for reassessment, beyond simply citing a single reference paper. These data need to be included, explained and interpreted in the document for reference. It is important that the comparison of earlier data to recent data be reasonable and legitimate. The statement, "*E. coli* O157:H7 is more prevalent than previously thought," is arbitrary unless FSIS clearly states what data are being compared to the Elder et al. (2000) and Smith et al. (2001) data. Is this phenomena simply a function of previous poor scientific understanding of the prevalence, or does FSIS believe that prevalence has truly increased? FSIS needs to specifically provide the quantitative data comparison with confidence intervals surrounding the two data sets. Were the two data sets generated for the purpose of determining prevalence? Were the data sets representative of all regions and seasons? Were the FSIS data referenced in the document collected according to a statistically designed sampling plan to determine regional and seasonal variations, as well as prevalence? These data should be clearly expressed in terms of sampling and testing plan, as well as methodologies to ensure that these data truly represent prevalence over time.

Are the data related and linked to human health risks in any way? The NACMCF recently provided expert advice to FSIS on the limitations of existing data sets to define *Salmonella* prevalence and AMI believes that the same limitations are associated with the data used to make the FSIS conclusion regarding prevalence of *E. coli* O157:H7. AMI recommends that FSIS submit their data, on which the prevalence increase was based, to the NACMCF for technical review as was done for *Salmonella* data.

It appears as though FSIS recognizes the role of sampling and testing methodologies in detecting *E. coli* O157:H7 and attributes previous lower rates with these factors. FSIS should state whether this is the rationale for the conclusion that *E. coli* O157:H7 is more prevalent than was previously thought. The methodologies to assess prevalence have changed to become more sensitive over time and could contribute to a perception that there has been an increase in prevalence. To what extent has FSIS considered these biases into their interpretation?

Prevalence of _E. coli_ O157:H7 on live animals

The document makes clear that a relatively high percentage of live animals are contaminated with *E. coli* O157:H7. What steps are being taken by FSIS to encourage producers to share in the responsibility for reducing incoming levels of microbial hazards? Although numerous reports beginning with the Blue Ribbon Task Force report, *Solving the E. coli O157:H7 Problem* (NLSMB, 1994), have stated that on-farm control of the pathogen is critical to downstream control, USDA appears to have done little to implement mandatory controls to reduce pathogens on-farm.

Grinding operations

FSIS recommends that grinders avoid mixing raw materials from more than one supplier. FSIS should partner with industry to determine how feasible this is for industry considering that formulations made to customer specifications usually require blending of various raw materials provided by different suppliers to produce the products specified by customers. FSIS states that mixing of several combos disperses the hazard and results in lower concentrations, but higher prevalence. FSIS needs to provide data and the interpretation to support this conclusion. These data need to be made available to all parties if these claims, and the resulting recommendation, are made. What are the quantitative data available to support this FSIS conclusion? What methods were used to determine prevalence and to quantify the microbial hazard to reach this conclusion?

The document states that interventions "are becoming available" to grinders. FSIS should provide the policy information as to when these will become available, what, if any regulatory and labeling issues are associated with these interventions, and the data demonstrating that the interventions will be effective at delivering the required level of control, while maintaining the traditional product characteristics of ground beef, such as flavor, odor, and color.

FSIS states that to control the microbial hazard in non-intact product, "full bactericidal treatment, such as irradiation or cooking," can be used. AMI believes it is important for FSIS to clarify this statement based on the fact that there is no minimum dose requirement for irradiation, and that lower levels of irradiation may not be fully bactericidal, depending on factors such as initial concentration of the pathogen. We believe it is important to establish a minimum dose or a minimum reduction standard to ensure that irradiated beef does not lead to illnesses when customers believe that irradiated beef is essentially sterile.

FSIS needs to share their thoughts on the science-based justification for lot separation? Are non-homogeneous distribution of contamination and product cleaning of equipment justification in the view of FSIS? What data will satisfy the agency of lot separation? AMI recommends lot separation by sampling and testing plans, or by cleanup and sanitation schedules. Either one should be designated as acceptable by FSIS.

Blade tenderized products

FSIS states that the risk assessment concluded that the risk of illness associated with *E. coli* O157:H7 from broiled tenderized and broiled non-tenderized steaks cooked to 140 °F is "miniscule, regardless of the initial contamination level, or susceptibility of the consumer." How does FSIS rationalize this temperature when the requirement for ground beef is 160 °F, or 155 °F for 15 seconds, particularly in instances where the contamination is present at low levels (e.g., <100 CFU/g) in ground beef? Does FSIS have data to show that there is a difference between the heat lethality of *E. coli* O157:H7

in steaks as compared to ground beef when the concentration of contamination is low?

FSIS states that the incidence of *E. coli* O157:H7 on sub-primals is very low. It would be helpful to the industry if FSIS would share these data, and the methods used in collecting these data, including whether the method assessed the quantitative levels of microbial hazards or simply presence/absence.

The American Meat Institute appreciates this opportunity to comment on the notice. If you have any questions or would like to discuss these comments or anything else regarding this matter, please contact me,

Sincerely,

Robert (Skip) A. Seward II
Vice President – Regulatory Affairs
American Meat Institute

pc: Dr. Dan Engeljohn