NATIONAL CATTLEMEN'S BEEF ASSOCIATION
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FSIS Docket Clerk
Docket No. 00-022N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex Building
300 12th Street SW
Washington, DC 20250-3700

Re: Docket No. 00-022N "*E. coli* O157:H7 Contamination of Beef Products"

To Whom It May Concern:

On behalf of the National Cattlemen's Beef Association (NCBA) I want to express our appreciation for the opportunity to comment on the Food Safety and Inspection Service (FSIS) Docket No. 00-022N "*E. coli* O157:H7 Contamination of Beef Products." Producer-directed and consumer-focused, the National Cattlemen's Beef Association 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.

Beef safety is a top priority for NCBA and the beef industry. We are committed to working with the entire beef chain and the state and federal governments to further decrease the incidence of this pathogen. Multiple interventions at all points in the process will be critical as we work toward further control and reduction of the pathogen. No one sector can do this alone. All sectors of the industry must work together with government and consumers. There must be a unified approach, utilizing the best available science, to control and reduce the incidence of *E. coli* O157:H7.

Since 1993, NCBA has spent ($12 million) in checkoff dollars on research into new interventions at pre and post-harvest to further reduce the presence of *E. coli* O157:H7. Significant progress has been made due to all the available research, not just that funded by the checkoff. As research identifies new technologies, fast approvals by the Food and Drug Administration (FDA) and FSIS are needed in order to test these interventions in the plant and then implement them across the industry.

In this Notice, FSIS states that there is now evidence to demonstrate an increase in the prevalence of *E. coli* O157:H7. This change in available information would require plants producing raw beef products to reassess their HACCP plans and implement the necessary

Critical Control Point (CCP) to adequately address the pathogen. FSIS has taken this step to continue to improve our food safety system. NCBA wishes to work with USDA and FSIS as they take these steps to be a partner in order to achieve a vision of meaningful solutions that work. In this regard, we have provided comments on the Notice below for the agency to consider as they continue to improve the system.

Risk of *E. coli* O157:H7 Contamination

FSIS has made many statements regarding the increased prevalence of *E. coli* O157:H7as the need for the policy change. FSIS specifically cites two studies as the major reason for determining an increase in prevalence, Elder et al. (2000) and Smith et al. (2001). However, FSIS does not make it clear what they are comparing the Elder and Smith studies with to show the increase. Providing all the data clearly will help the industry conduct the necessary analysis and make the agency's reasoning for the decision transparent.

USDA and FSIS made statements during the release of this policy change that the Center for Disease Control and Prevention (CDC) has increased its estimates of illnesses related to *E. coli* O157:H7. These statements are misleading, as CDC has not changed their estimates since 1999. FSIS states that this data has been included in the draft risk assessment. The agency needs to be more careful when making such statements, so that they do not cause unnecessary fear mongering.

FSIS has also stated that methodologies used for testing are up to four times more sensitive than when testing first began for *E. coli* O157:H7. Was this factor taken into consideration when calculations of an increase in prevalence were determined?

NCBA has previously submitted comments on the FSIS draft risk assessment for *E. coli* O157:H7 in ground beef. We urge for the full consideration of those comments as FSIS reevaluates the draft risk assessment.

Relevant Data Requiring Reassessment

FSIS clearly states in the Notice that they are using "anecdotal information from inspection personnel and in-depth verification (IDV) reviews" to make conclusions on industry practices. These conclusions could lead to or already be the basis for regulatory decision making. FSIS should share this data if it was used to make regulatory decisions. Sharing such data will clarify the reasoning behind the proposal. FSIS has made it clear that before considering data from industry, that data must be peer reviewed and published. What review system does FSIS have in place to evaluate anecdotal information from inspection personnel and IDVs before it is considered?

Critical Control Points and Sanitation SOPs and Other Prerequisite Programs

FSIS identifies the acceptable level of *E. coli* O157:H7 reduction as "a level that would not be detectable using the FSIS testing method or a method with sensitivity at least equivalent to FSIS' method." However, FSIS does not identify parameters that define "undetectable." FSIS is now defining *E. coli* O157:H7 as a hazard reasonably likely to occur, making any amount of the pathogen a hazard. Yet, here FSIS states that reduction of the pathogen should be "below detectable levels." FSIS should identify parameters and limits to these terms to clarify the intention of the action.

FSIS states that establishments must validate CCPs to ensure the anticipated effect of prevention, elimination, or reduction of *E. coli* O157:H7 is met under their in-plant operating conditions. If this is not met, then the CCP is theoretical and the HACCP plan is not validated. Currently, only cooking and irradiation provide elimination of the pathogen; yet to be validated, the CCP must take the pathogen below detectable levels. Current interventions alone cannot reach this level.

There is the need for continuing research into new technologies that can further reduce this pathogen. FSIS needs to have a clear, systematic approach to allow for testing of these new technologies under normal operating conditions in the plant. FSIS needs a streamlined review process with the FDA to get these technologies approved, validated, and implemented.

Guidance

NCBA appreciates FSIS publishing these guidance documents of current technologies that can be used or where research is showing potential new technologies to the various sectors of the industry. How will FSIS revise these guidance documents as more information becomes available of new technologies? As an example, the guidance provided by FSIS on risk reduction during animal production is already outdated and in need of revision.

Research is being conducted to identify potential interventions that can be used in the pre-harvest area. Any intervention that is used must fit within current production systems, and be efficient and affordable. NCBA sees these new interventions and all new technologies as one more hurdle that can be used across the process to further reduce the pathogen load at each intervention. A multiple intervention approach is what is needed to make progress to reduce this pathogen.

NCBA appreciates the opportunity to provide comments on this important issue. The beef industry is committed to providing a high quality and safe product to our consumers. The entire beef industry chain must work together with the government to further improve our food safety system. We look forward to continuing to work on the issue and to reach solutions that will benefit public health.

Sincerely,

Leah Wilkinson

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