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May 28, 2008

Mr. Keith Payne  
USDA-FSIS  
1400 Independence Avenue, SW  
Room 1175 South Building  
Washington, DC 20250  
[Keith.payne@fsis.usda.gov](mailto:Keith.payne@fsis.usda.gov)

Re: Docket No. FSIS-2008-0011 -- Comments on FSIS Federal Register Notice, April 3, 2008 (Volume 73, Number 65) and Public Meeting; "Shiga toxin-producing *E. coli*. Addressing the challenges, moving forward with solutions"

Dear Mr. Payne:

These comments are submitted by Danisco USA Inc., in response to the above meeting and to the request for comments published in the April 3, 2008 Federal Register regarding the meeting and issues relating to the presence of shiga toxin-producing *E. coli* (STEC) in meat and poultry products. Danisco is commenting to support FSIS' stated intent to continue to pursue proactive intervention strategies from "farm to fork" for improving food safety by reducing the risk of STEC and other pathogens in meat and poultry products. Further, in pursuing expanded interventions from the farm to the consumer, we urge that the involved governmental agencies take steps to better coordinate and consolidate their responsibilities, so that regulatory obstacles that delay or make difficult the timely development and adoption of effective intervention technologies are removed.

By way of background, Danisco is a manufacturer of a full array of food ingredients utilized for a number of technical and functional effects in foods, both general foods regulated by FDA, and meat and poultry products regulated by FSIS. Danisco products include antimicrobial agents, binders, enzymes, probiotics, colors, flavors, etc., which are utilized as processing aids, direct and indirect food ingredients, food contact substances, and for other appropriate food functions. Specifically, and consistent with its business intent to develop effective strategies to improve food safety, Danisco and its predecessor companies have been a leader in the research and development of efficacious antimicrobial agents for use in a broad array of meat and poultry products and processing.

First, Danisco would like to commend FSIS for holding the meeting and for soliciting input from industry and the public relating to the causes of foodborne illness, specifically those attributed to

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*E. coli*, including O157:H7 and other serotypes. This action is consistent with previous FSIS initiatives to address foodborne illness attributed to the consumption of meat and poultry products that led to establishing effective intervention systems such as HACCP, SSOPs, poultry on-line reprocessing (initially developed by a Danisco predecessor company), the Listeria rule, and other important regulatory tools in this effort.

Second, we concur with the agency's present focus on STEC in light of last year's recorded increase in STEC-related foodborne illness outbreaks. We do note that the overall number of such incidents is still small and do, therefore, agree with industry concern expressed at the meeting that more years of experience may be needed to determine if the increase is a real trend, or, if it can be attributed to increased sampling, weather, or other variable conditions. Consequently, we believe that collecting such data will be important to the agency's stated consideration of whether an expansion of the adulterated products policy to include primal and other cuts of meat and poultry is warranted.

Third, we do strongly support the agencies continuing interest in, and efforts to, identify and adopt effective intervention strategies to eliminate and control the outgrowth of pathogens in meat and poultry products, especially those efforts that focus on the entire supply chain from the farm to consumer. We believe the adoption of preharvest and postharvest interventions has contributed to a significant reduction in foodborne illness attributed to meat and poultry. Having said that, we know that more can be done.

Much has already been accomplished through the use of antimicrobial agents and other interventions to address the issue postharvest. While additional postharvest interventions still need developing, we agree with the consensus expressed at the meeting that more of the focus and effort needs to turn to preharvest interventions. We, especially, see a need to reduce incoming microbial loads to the slaughterhouse, so that postharvest interventions are not overwhelmed and can be effective as intended. And, while development of new technologies will be a major part of this effort, we believe FSIS should insure, through enhanced consumer education and labeling clarity, that there is follow through and understanding of the food safety process by consumers.

Finally, as industry and the agencies move forward, it is our hope that FSIS, FDA, EPA and any other involved agencies will undertake, as a major part of the effort, identifying and removing regulatory barriers that impede development, testing, approval, and implementation of effective interventions. A consistent, well understood, and seamless regulatory process does not presently exist to effectively address this matter from the farm to the consumer. While we recognize that present statutory requirements and agency responsibilities play a role in this matter, multiple agency involvement, review, and sign off can lead to delays, inhibit industry involvement, and suppress commitment of resources to the issue, which can hamstring making progress in a timely manner.

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In addition to closer cooperation, we would encourage the involved agencies to consider entering into a memorandum of understanding that addresses each agencies responsibilities, that establishes a pathway for interagency coordination, and that provides for a fast track for the approval of needed food safety initiatives and intervention strategies. Such an approach would encourage the further development of food safety solutions by providing greater transparency and clarity to stakeholders and the general public. It should also allow the agencies to better coordinate respective responsibilities, streamline procedures, and complete necessary reviews in a more timely manner to facilitate this process.

In sum, Danisco commends FSIS for its continued commitment to improving food safety. Danisco looks forward to working with FSIS and the meat and poultry industry to develop effective interventions to reduce the incidence of food borne illness.

Sincerely,



Kevin O. Gillies  
Vice President, Regulatory Affairs  
Danisco A/S