AMERICAN MEAT INSTITUTE

J. Patrick Boyle
President and CEO

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The Honorable Tom Vilsack
Secretary
U.S. Department of Agriculture
Jamie L Whitten Federal Bldg.
Room 200-A
1400 Independence Avenue, SW
Washington, DC 20250

Dear Secretary Vilsack:

The American Meat Institute (AMI) looks forward to working with you and other government regulators in our efforts to continue the substantial progress that has been made in improving the safety of the nation's meat and poultry supply.

Food safety is AMI's top priority. Over the past 20 years, the meat and poultry industry has had significant success in reducing the pathogen risk profile of its products. Our members have instituted a non-competitive policy with respect to openly sharing food safety practices and knowledge, as well as supporting food safety research. The AMI Foundation has provided grants totaling more than $7 million to various institutions for the purpose of developing new food safety technologies that can be adopted by livestock producers, packers, processors and other food handlers.

One issue that is at the fore front of industry concern is the control of shiga-toxin producing *Escherichia coli* (STEC) including *E. coli* O157:H7. Substantial progress has been made in controlling *E. coli* O157:H7 in raw beef products, but AMI is concerned that the designation of non-O157:H7 STECs as adulterants will result in a misdirected regulatory program that will cause more harm than good. To that end, we are providing the following recommendations.

1150 Connecticut Ave., NW, 12th Floor, Washington, DC 20036
Ph: (202) 587-4200 ● Fx: (202) 587-4300 ● www.meatami.com

Focus on Prevention

AMI supports President Obama's Food Safety Working Group recommendation that "food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures designed to prevent problems before they occur." Declaring non-O157:H7 STECs to be adulterants in beef products does not fulfill President Obama's objective. Making a pathogen illegal through a policy change will not prevent this pathogen from occurring. Making non-O157:H7 STECs illegal also will needlessly divert scarce resources away from enhancing food safety prevention efforts when research shows that the intervention technologies we currently have in place are effective against various strains of *E. coli*.

Any new regulatory initiative must focus on developing and implementing effective process control programs to prevent rather than detect pathogens. The FSIS regulation to control *Listeria monocytogenes* in ready-to-eat meat and poultry products is an excellent example of the success that can be achieved by a regulatory approach that encourages implementation of effective preventive process control programs.

Regulatory programs that focus on testing as a way to eradicate pathogens from the food supply have historically been proven ineffective. Scientific experts worldwide know that testing cannot guarantee pathogens do not enter the food supply. That can only be done by using proven preventative measures that keep foodborne hazards from entering the food supply in the first place. Testing is useful to verify that food safety processing controls are working properly, but it is an ineffective tool for keeping hazards from entering the food supply. Safety cannot be tested into the product; safety must be built into the product. Any regulatory scheme that focuses on testing, instead of process control, will not make food safe.

AMI therefore recommends that any regulatory program that FSIS contemplates be addressed within the framework of the existing Hazard Analysis Critical Control Point regulation. USDA should commission a group of qualified experts to review the current science related to the development of a comprehensive farm-to-table preventative process control program for non-O157:H7 STECs in beef products and report their finding to USDA and other stakeholders. Such an examination could provide a practical means to establish quantifiable food safety objectives that can be used by USDA and the industry to improve public health.

Conduct a Comprehensive Public Health Risk Assessment

A better understanding of the public health issues associated with non-O157:H7 STECs is needed. Public health outbreaks associated with non-O157:H7 STECs in various foods have been documented, but no reported outbreak in the U.S. has been confirmed to be directly linked to beef products. [1] All stakeholders realize that such an outbreak could occur due to the endogenous presence of non-O157:H7 STECs in cattle, but many questions remain? In that regard, why have no confirmed outbreaks associated with beef products occurred in the U.S.? Why have non-O157:H7 STEC outbreaks occurred in other foods, but not in beef products? Why have non-O157:H7 STEC outbreaks associated with beef products occurred in other countries, but not in the U.S.? Does the pathogenicity of these microorganisms differ from *E. coli* O157:H7? Does the mere presence of the organism constitute a public health hazard?

AMI respectfully suggests that answers to such questions must be produced within the context of a comprehensive public health risk assessment that is subjected to public review before regulators embark on any regulatory program to control non-O157:H7 STECs in raw beef products.

Validate Analytical Laboratory Test Methods

At the present time, no relevant, validated, FSIS-accepted, rapid analytical test for non-O157:H7 STECs is commercially available. It is important to acknowledge that due to the limited time perishable beef products can be held and the logistics of holding products for several days pending cultural confirmation that non-O157:H7 STECs are present, a viable, rapid screening test is needed to make product dispositions. Therefore, an accurate, validated rapid analytical test must be available to the industry to effectively implement any regulatory program that would make it illegal to enter product containing non-O157:H7 STECs into commerce.

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[1] On August 11, 2010, the Enteric Disease Surveillance Coordinator for the North Dakota Department of Health, Medical Services Section and AMI reviewed the facts surrounding a foodborne disease outbreak that was suspected to be linked to ground beef. Information on the outbreak can be found at http://www.ndhealth.gov/disease/GI/Docs/Foodborne%20Outbreaks%20in%20ND%20updated%202009.pdf (Accessed August 10, 2010). The "suspect" ground beef product was cooked meatballs. The North Dakota Health Department was unable to confirm the suspected food source because no meatballs were available for testing. The meatballs were prepared the day before consumption at a private home wedding reception. No cooking temperatures were documented. The cooked meatballs were cooled at room temperature before transfer to the refrigerator for overnight storage. The temperature of the meatballs during cooling was not taken. The size of the container that was used to store the meatballs in the refrigerator was not determined. On the day of the reception, the meatballs and gravy were placed into a warming appliance, reheated and served. The North Dakota Health Department was able to test the gravy in which the meatballs were served and two macaroni salads. No other foods (*i.e.* side-dishes, salads, fresh produce) were tested. The gravy and the macaroni salads tested negative for shiga-toxin producing *E. coli*. Subsequently, the North Dakota Health Department declared ground beef to be the "suspect" food source because of temperature abuse and improper reheating.

Furthermore, accurate cultural confirmation tests must be available for regulatory purposes. It is our understanding that cultural confirmation tests are available for certain non-O157:H7 STEC serotypes, but not for all the serotypes that have been identified by USDA as a public health concern. Again, it is of paramount importance to have validated, peer-viewed cultural confirmation tests that are accepted by USDA before adopting a policy that beef products containing non-O157:H7 STECs be considered adulterated. Such confirmation tests must have an acceptable false positive and false negative rate for USDA to implement any regulatory program and for USDA to determine if commercially available screening tests are acceptable for use.

AMI strongly recommends that FSIS openly share with the meat and poultry industry, testing laboratories, and test kit manufacturers the sampling and analytical methods that the agency will use to implement any regulatory program and that the analytical methods are peer-reviewed before any regulatory program is initiated.

Conduct a Baseline Survey of Non-O157:H7 STECs on Beef Products

A better understanding of the prevalence of non-O157:H7 STECs related to beef products is needed. A limited amount of research has been conducted to assess the prevalence of non-O157:H7 STECs on beef products, but AMI has no knowledge of any research that has assessed quantitative levels of the pathogen on beef products. Furthermore, much of the prevalence survey work has been conducted by independent, private organizations and the data has not been published in peer-reviewed journals. AMI is not aware of any surveys that provide a validated, statistically balanced representation of the beef products produced in the U.S.

Furthermore, analytical methods to detect and quantify non-O157 STECs have not been standardized because no official USDA reference method is available. This creates a problem that also leads to widely varying interpretation of any prevalence data that has been previously collected and reported.

It is imperative that FSIS conduct a baseline survey of beef products to include beef carcasses, ground beef and the raw materials used to manufacture ground beef in order to assess the impact of any new regulatory program that the agency may be contemplating. The baseline survey design and sampling and analytical methods should be published for public comment to solicit the advice and counsel of scientific and technical experts before proceeding with any such survey.

Measure Progress Based on the Public Health Outcome

Many times food safety progress is erroneously measured by tasks performed, regulations published or other measurements that are not directly tied to a public health outcome. Regulatory or inspection activities that do not improve public health waste scarce resources and divert attention from issues of public health importance.

Food safety progress is most properly assessed by accurately measuring human health outcomes via illnesses, hospitalizations and deaths that are attributed to foodborne disease. For example, the Department of Health and Human Service's Healthy People 2010 goal of a 50 percent reduction in illnesses associated with key foodborne pathogens from 1997 illnesses levels provides an appropriate benchmark for evaluating progress for all food, but it needs to be refined in order to focus on the specific foods that are causing the illnesses.

If FSIS decides to further regulate non-O157:H7 STECs, we must point out that it is ordinarily prudent to evaluate the success or failure of any such initiative by actual illness reductions. In the case of beef, however, this is nearly impossible given that no non-O157:H7 STECs illness outbreaks have been confirmed in the U.S. This lack of documented illnesses is remarkable given that approximately 95 percent of the public health laboratories reported in a recent survey that they are screening for non-O157:H7 STECs. If regulatory efforts to reduce non-O157:H7 STECs in beef products cannot generate measurable, positive public health outcomes, the underlying point of the exercise must be drawn into serious question.

Expedite Approval of New Microbial Interventions

Over the past 15 years, the meat industry has spent millions of dollars researching and developing new technologies to eliminate or reduce STECs on beef products. In fact, the AMI Foundation has provided grants to the USDA's Agricultural Research Service to investigate whether certain microbial interventions currently known to be effective against *E. coli* O157:H7 are also effective antimicrobial treatments for non-O157:H7 STECs.

Many new microbial intervention technologies have been successfully implemented in beef processing facilities. Other highly effective interventions have not been implemented by the meat industry due to a lack of government approval of such technologies. New technologies are generally widely adopted by the industry if they are proven effective.

Specifically, approvals for carcass surface irradiation, bacteriophage use during various phases of production, feed additives such as chlorates, and other innovative technologies have not been approved for various reasons. Those reasons involve disputes over which regulatory agency has jurisdiction, the data that various regulatory agencies

require for approval and a general unwillingness by the federal government to actively assist in the approval process.

AMI recommends that USDA convene a joint task force of all federal agencies that are involved in the approval of new microbial intervention technologies and the affected meat and poultry industry to identify approval roadblocks and to develop a better, expedited approval process that can rapidly move new technology to commercialization. New preventive technologies that are effective against all STECs are needed to control these pathogens before USDA considers making non-O157:H7 an adulterant on beef products.

Determine Impact on International Trade

A policy change to make non-O157:H7 STECs an adulterant on beef products will significantly impact international trade. Such a policy shift will be viewed by our trading partners as erecting a non-tariff trade barrier to prevent entry of beef products into the U.S. The U.S. can expect reciprocal actions by importing countries that will have the effect of curtailing U.S. beef exports.

Any policy change contemplated by USDA must be considered in the context of the global beef market. Imposition of new regulatory mandates can have several unintended consequences that should be carefully considered before any policy changes are implemented.

AMI recommends that USDA, the U.S. Trade Representative, and the Department of State commission a study to determine the impact on international beef trade that would result from declaring non-O157:H7 STECs an adulterant on beef products.

Provide an Open and Transparent Public Policy Process

Any decision to implement new regulatory initiatives to control non-O157:H7 STECs in beef products must be informed through an open and transparent public policy process. Any new regulatory program to control non-O157:H7 STECs will likely impose significant financial and regulatory burdens on the meat industry, particularly if it involves declaring non-O157:H7 STECs to be adulterants. Such a decision will dictate more testing programs, additional operating costs, losing product value if it tests positive, and other inherent costs that must be weighed against any public health benefit.

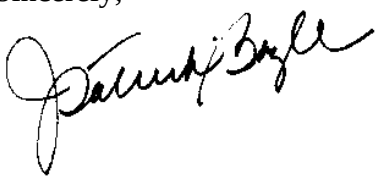
AMI recognizes that additional costs to control non-O157:H7 STECs, not only in beef products but other food products, including those regulated by FDA, may be appropriate if such costs are outweighed by corresponding public health benefits. At present, however, it is not obvious to many leading scientific experts that regulating non-O157:H7 STECs will result in substantial public health benefit, particularly given the available scientific evidence that microbial interventions that are used to control *E. coli* O157:H7 are effective in controlling non-O157:H7 STECs.

Associated legal questions must also be addressed. Prior to publication of the Hazard Analysis and Critical Control Point regulation, FSIS declared that *E. coli* O157:H7 was an adulterant based on an exception to the prevailing regulatory paradigm that raw meat and poultry products containing pathogens are not adulterated. FSIS took such regulatory action as a direct response to unique circumstances where the consumption of undercooked ground beef had resulted in illnesses and deaths caused by the presence of *E. coli* O157:H7. Given the absence of non-O157:H7 STEC illness outbreaks linked to beef, it is not readily apparent that there is an equally compelling reason to declare non-O157:H7 STECs as adulterants under present circumstances.

AMI recognizes that non-O157:H7 STECs in beef products may be a reason for potential public health concern, but the facts do not indicate that they pose a public health emergency. Therefore, AMI strongly recommends that if FSIS decides to further regulate non-O157:H7 STECs in beef products, it should only be done through notice and comment rulemaking. The questions surrounding non-O157:H7 STECs demand a disciplined, open, and transparent regulatory process.

Thank you for considering our views. We believe our recommendations have substantial merit and we would appreciate the opportunity to discuss them with you at your earliest opportunity.

Sincerely,



J. Patrick Boyle

cc: Jerry Mande, Deputy Under Secretary for Food Safety
Al Almanza, Administrator, Food Safety and Inspection Service