



November 22, 2013

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2011-N-0920, RIN 0910-AG36, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food”**

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority. The Food and Drug Administration’s (FDA or the agency) proposed rule generally does not directly affect Food Safety and Inspection Service (FSIS) inspected establishments but many federally inspected meat and poultry processing establishments use inputs from FDA regulated facilities and for that reason have a vested interest in the above-referenced proposed rule.

Moreover, a number of FSIS inspected companies operate facilities that are subject to “dual jurisdiction,” *i.e.*, some products from the establishment are processed under FSIS inspection and others are subject to FDA jurisdiction, *e.g.* a facility that produces pepperoni pizzas and cheese pizzas. For that reason, it is imperative that the regulatory “schemes” of the two agencies are coordinated with respect to applicable food safety regulatory requirements.<sup>1</sup>

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<sup>1</sup> In 1998 FDA and FSIS entered into a Memorandum of Understanding (MOU), which states that “each agency’s resources and experience will be used efficiently, and duplication of inspection effort is to be avoided.” As FDA moves forward with this rulemaking it should consider the efficiencies attendant to not requiring duplicative programs. In addition, this rulemaking process affords FDA and FSIS the opportunity to revisit the MOU such that the requirements on dual jurisdiction plants ensure the safety of the food products while not being unduly burdensome under either regulatory system.

Although the Food Safety Modernization Act (FSMA or the law) constitutes a sweeping change in the food safety statutes, it is important in this rulemaking for FDA to learn the lessons offered through FSIS's experience in promulgating its Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) rule in 1996. AMI petitioned for mandatory HACCP believing that the application of HACCP principles would greatly enhance the meat and poultry food safety system. Fifteen years later, thanks to a concerted effort by industry and FSIS working together, meat and poultry products have never been safer. However, FSIS regulations strayed from true HACCP principles creating unnecessary and unwanted challenges for both the regulators and the regulated industry. For that reason, it is important that, in promulgating its regulations, FDA track the statutory concepts and requirements set forth in the law. FSMA was deliberately designed to not be simply HACCP. In that regard, FDA should recognize the contributions that prerequisite programs can make when determining whether a hazard is significant or probable and allow facilities to manage preventive controls according to scientifically based food safety principles without the need for making everything a critical control point (CCP).

The above general observations are intended to assist FDA as it develops a final rule. Recommendations more specific to the proposed rule follow.

### **The Regulation Must not be Prescriptive and Must Look beyond HACCP.**

FSMA, and the proposed rule, affects a broad array of products. For that reason alone, a prescriptive “one-size fits all” regulatory approach will not effectively enhance food safety. Indeed, the law directs FDA to take a risk-based approach and the agency should adhere closely to the statutory purpose as it develops and implements regulations.

To that end, any regulation needs to provide companies with sufficient flexibility to allow them to adapt general requirements to the food safety demands inherent in their products and manufacturing circumstances. Specific recommendations should be provided by issuing guidance, which can more easily be amended, and should not be incorporated into the regulation.

The proposal is misguided in its suggestion that the hazard analysis focus on hazards that are “reasonably likely to occur.” This phrase is not one used in the statute and should not be incorporated into the regulation. FDA has promulgated HACCP regulations for certain products, *e.g.*, juice, and in those regulations the “reasonably likely to occur” phrase references CCPs, which are a sub-set of preventive controls. If Congress had wanted FDA to employ the HACCP standard the agency has used previously it could and would have done so. Congress, however, did not do that. Rather, in enacting FSMA, Congress moved in a somewhat different direction with respect to hazards and provided a different standard, the “known or reasonably foreseeable” approach found in the law, and that is the guide FDA must follow for purposes of this regulation. To that end, facilities should implement a range of preventive controls—beyond just CCPs—and FDA should recognize the broad definition of “preventive controls” under the statute.<sup>2</sup>

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<sup>2</sup> For example, the statutory definition of “preventive controls” includes programs that most HACCP experts would not consider to be control measures, *e.g.*, recall plans. The breadth of the definition does not mean that Congress intended for recall plans to be subject to CCP-like monitoring; rather it

FDA also should allow for gradations in the level of rigor used to manage the range of preventive controls. Management of preventive controls should be commensurate with the nature of the risk and the controls used—i.e., management should be applied as “appropriate and necessary.” Consistent with that approach, when determining the level of management oversight needed for an effective preventive control, the benefits derived from existing prerequisite programs, such as good manufacturing practices (GMPs), must be considered because such programs can affect the probability and severity of a hazard.<sup>3</sup>

### **The Proposed Ingredient Testing Suggestion Must be Reconsidered**

Of particular concern in the proposed rule is the agency’s position regarding verification testing of raw materials and ingredients.<sup>4</sup> Rather than require that facilities perform mandatory periodic or routine pathogen testing on their incoming ingredients, ingredient suppliers should perform the pathogen testing prior to releasing their product into commerce so that lot control can be maintained. The premise behind this recommendation is based on the practice followed by companies with strong food safety systems, whereby a prudent establishment should have all potentially implicated product under its control when pathogen testing is conducted. Indeed, FDA should follow the FSIS approach in which manufacturers of non-intact raw beef test for the presence of *E. coli* O157:H7 or ready-to-eat products are tested for *Listeria monocytogenes* or *Salmonella*, which allows the product to be held and controlled by the manufacturer until results are obtained.

In addition, other effective methods already exist to address the non-testing verification of a vendor's raw materials. For example, companies can conduct an on-site risk assessment (or have one conducted by a third party) at high-risk ingredient manufacturers to ensure they have implemented a robust environmental sampling program and that they have adequate finished product pathogen testing controls in place to monitor the safety of their raw materials. Another option, as FDA acknowledges in the proposed rule, is periodically conducting pathogen testing on a high risk supplier’s incoming ingredients. In this circumstance, however, the manufacturer (ingredient supplier) should be notified in advance of the testing to afford the manufacturer the opportunity to hold all products that could be implicated by a “positive” test result.

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means that Congress provided FDA with authority to oversee how the industry develops and uses recall plans.

<sup>3</sup> Presumably, CCPs need the most rigorous management, but they are only one component of an effective food safety system. Treating all preventive controls as if they are CCPs diverts company resources and attention away from the control measures that must be managed as CCPs and in doing so could lessen the effectiveness of the company’s overall food safety system.

<sup>4</sup> See Appendix I. C., 78 *Fed. Reg.* 3646, 3813 (Jan. 16, 2013).

**Summary**

FSMA is, in essence, a Congressional recognition that FDA needs to accommodate diverse food safety systems and establish programs that do not hinder advances in science, technology, and public health. To that end, any regulation should closely track the statute in several ways. First, facilities should conduct a hazard analysis that identifies “known or reasonably foreseeable hazards” and assesses risk by evaluating the significance of those hazards (*i.e.*, their probability and possible severity). Second, facilities should adopt preventive controls to address the identified hazards and those preventive controls should include both specific controls, such as CCPs, that directly manage significant hazards, and general controls, such as current GMPs, that may decrease the likelihood or severity of a hazard. Finally, the regulation should utilize an “appropriate and necessary” concept for managing preventive controls to allow facilities to select the activities necessary to address their particular food safety needs.

AMI appreciates the opportunity to submit these comments. If you have any questions regarding these comments or anything else regarding this matter, please contact me at (202) 587-4229 or mdopp@meatami.com.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark Dopp', with a long horizontal flourish extending to the right.

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cc: Patrick Boyle  
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