

February 7, 2001

FSIS Docket Clerk  
Docket No. 00-014R2  
Room 102, Cotton Annex  
300 12th Street, SW  
Washington, DC 20250-3700

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**[Docket No. 00-014R2]      Announcement of and Request for Comment Regarding  
Industry Petition on Hazard Analysis and Critical Control  
Point (HACCP) Petition; 65 *Federal Register* 63229;  
October 23, 2000**

Dear Ms. Moore:

The undersigned trade associations respectfully submit these supplemental comments in regard to the Food Safety and Inspection Service's (FSIS) request for comment on the industry petition on HACCP noted above.

We feel it appropriate to provide additional comments in light of a significant recent development regarding federal implementation of HACCP for food processing plants – publication on January 19 by the Food and Drug Administration (FDA) of a final rule (66 *FR* 6138) mandating HACCP for juice processing plants. In a Federal Register Notice (65 *FR* 30952), published last year, FSIS requested comment on an industry petition seeking modification of certain provisions in the FSIS HACCP rule. One of the specific questions posed by FSIS relative to the petition involved the impact of differences between HACCP regulations prescribed by FDA and by FSIS. In this regard, FSIS asked: **“What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?”**

In our responses, we stated that we did not believe the requested changes would result in any functional dissimilarity. We noted existing differences between the FDA seafood HACCP rule and the FSIS HACCP rule. Importantly, we noted that FDA would publish a final rule on HACCP for juice products.

While there are a number of differences between the new rule for juice HACCP and FDA's existing seafood HACCP rule, FDA made several specific changes that we would like to bring to your attention. In a decision that is directly in line with the reasoning espoused in the industry HACCP petition, FDA has abandoned the definition for a food safety hazard that it utilized for seafood HACCP (which is virtually identical to the FSIS definition), and has adopted instead the definition of a hazard set forth by the National Advisory Committee on Microbiological Criteria for Foods (which is the definition sought in our HACCP petition for FSIS HACCP regulations). The new definition prescribed in the FDA juice HACCP rule at 21 *CFR* 120.3(g) is: "Food hazard means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control."

As explained in preamble discussion (66 *FR* 6150), FDA made this change in response to a comment requesting that it adopt the most recent NACMCF definition of a food hazard to clarify the mechanism by which a hazard analysis is conducted. Several pertinent FDA statements in response to that comment are noted below:

“Adopting the most recent NACMCF recommendations to the extent feasible will allow the HACCP regulation to remain current with the science of HACCP.”

As a second step in conducting a hazard analysis, “..... processors must determine whether the potential hazards identified are ‘reasonably likely to occur’ in their particular process.”

FDA noted that a hazard that has a severe, acute public health impact presents “..... a significant risk even at an extremely low frequency of occurrence and must be appropriately identified as a hazard that is ‘reasonably likely to occur.’ “On the other hand, chronic hazards would need to occur at a higher frequency to be identified as a hazard that is “reasonably likely to occur.”

“Because hazards can be either acute or chronic (*i.e.*, having short-term or long-term effects, respectively) and the purpose of HACCP is to focus on public health hazards that are ‘reasonably likely to occur,’ FDA finds that the NACMCF definition better describes what must be considered in a hazard analysis. Therefore, the agency is modifying § 120.3(g) to state that a ‘food hazard’ means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.”

In another significant and related change from its seafood HACCP rule, FDA has added a new section [21 *CFR* 120.7(a)(2)] requiring that the hazard analysis include a step in which each initially identified hazard is evaluated “.... to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan.” Also included in that section of the final regulation is this statement. “This evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs.”

Finally, in preamble discussion (66 *FR* 6155) FDA’s response to a comment that it should “..... emphasize the NACMCF recommendations, including consideration of both likelihood of occurrence and severity of hazards” was the following: “The agency agrees that the approach outlined by the NACMCF will best assist processors in conducting a hazard analysis.”

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We believe that FDA's incorporation of these provisions into its juice HACCP rule provides clear and convincing support for the statement in the industry petition "The NACMCF definition and interpretation of a 'hazard,' is more precise and consistent with the principles of HACCP because it provides useful guidance for identifying those properties that, when all factors are considered, present a significant risk of illness or injury."

Thus, we encourage FSIS to adopt these same provisions in the course of making needed refinements to its HACCP rule for meat and poultry. Doing so will enhance the effectiveness of the HACCP rule and will bring more, not less, harmony between the requirements of the sister Agencies responsible for the oversight of the US food supply. It will also promote international harmony by bringing consistency with international practice and World Trade Organization (WTO) obligations, which state that scientific determinations of risk are needed to form a sound basis for food safety standards.

We appreciate your consideration of these supplemental comments.

Respectfully submitted,

American Association of Meat Processors  
American Meat Institute  
Eastern Meat Packers Association  
National Chicken Council  
National Food Processors Association  
National Meat Association  
National Turkey Federation  
North American Meat Processors Association  
Southeastern Meat Association  
Southwest Meat Association