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JULY 14, 2000

FSIS Docket Clerk, DOCKET #00-014N
U.S. Department of Agriculture
Food Safety and Inspection Service, Room 102
Cotton Annex Building
300 12th Street, S.W.
Washington, D.C. 20250-3700

RECEIVED
FSIS
00 JUL 14 PM 4:22

RE: Docket No. 00-014N Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) notice regarding the industry petition on Hazard Analysis and Critical Control Point (HACCP) inspection.

As you know, AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. AFFI represents almost all processors of frozen further processed meat and poultry products produced in the United States.

AFFI members support the recommendations within the industry petition. Specifically, AFFI believes that making the proposed changes would enhance further the safety of the world's safest food supply.

FSIS has asked the industry to answer specific questions about the petition. The following are AFFI's responses to those questions as they relate to manufacturers of frozen food products:

1) The industry petition relies mainly on the NACMCF document and does not provide any data or examples to support its request. Is there any information that would support taking any of the actions requested in the petition?

AFFI members support the changes recommended within the industry petition regarding Hazard Analysis and Critical Control Point (HACCP) inspection. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) guidelines are consistent with and rely on more than 30 years of experience with HACCP that began with Dr. Bauman's original introduction of the systems' principles in the 1960's.

The agency repeatedly states its desire to base regulatory policy on science. The NACMCF was established to provide scientific advice and recommendations on the development of microbiological criteria for foods for those topics requested by the sponsoring agencies. The Secretary of Agriculture appoints NACMCF members based on their scientific qualifications. To ignore the latest NACMCF guidelines would be to ignore the most current scientific advice on the true science-based application of HACCP from a committee co-sponsored by the agency.

FSIS's rule deviates from established HACCP principles and is based on the agency's perception of HACCP rather than established practices effectively used by industry. It is incumbent on FSIS to embrace concepts accepted by scientists, risk assessors, industry, and governments worldwide in order to maintain the integrity of the HACCP system.

HACCP has been most successful when it has been presented and implemented in the form envisioned by its founder; that is, one which focuses on the critical steps needed to protect public health during the manufacturing process. HACCP was formulated and is intended to be part of an integrated approach to food safety that includes numerous facets. FSIS should embrace "scientific" HACCP as an important tool in the "arsenal of tools" available to enhance food safety. Importantly, the agency must recognize that "regulatory" HACCP as envisioned by the agency creates the potential to incorporate "control points" into a HACCP program. There has never been, nor can there ever be, a HACCP system that operates effectively if it encompasses both control and critical control points as the FSIS program and its proponents require.

The important question for FSIS is not what data and examples support the petitioners' request. Rather, the agency should focus on the principles, experience and technology that support FSIS's deviation from established HACCP principles. AFFI believes scientific HACCP should be the model for industry and that any deviation from "scientific" HACCP to "regulatory" HACCP would be a mistake.

2) Would amending 9 CFR 417.2 (a) in the manner suggested in the petition result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA)?

Amendments made to 9 CFR 417.2 (a) consistent with the recommendations made within the petition not only would meet the requirements set forth in the FMIA and PPIA, but also would enhance food safety. In fact, HACCP as currently implemented by FSIS, because of its regulatory bias rather than scientific principle, is not as effective as it could be. The proposed changes in the petition will strengthen FMIA and PPIA because they will focus on real potential public health hazards.

3) Should FSIS consider regulatory modifications that would acknowledge the prerequisite programs concept of NACMCF?

AFFI members believe FSIS should consider acknowledging prerequisite programs such as those mentioned by NACMCF. The use of prerequisite programs such as Good Manufacturing Practices (GMPs) and Standard Sanitation Operating Procedures (SSOPs) are critical to managing the manufacturing process.

HACCP programs must be built on a solid foundation of prerequisite programs such as GMPs in order to enhance the production of safe foods. Agency recognition of prerequisite programs as part of a total food safety program would provide a more accurate depiction of whether a hazard would be classified as “reasonably likely to occur,” and would offer incentives to meat and poultry processors to incorporate these valuable programs into their operations. Altering the definition of a hazard to “a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control” would draw attention to actual critical control points (CCPs) that inspectors should monitor. Therefore, the agency’s limited resources could be spent in areas that are critical to public health.

Importantly, FSIS should consider that a public health hazard is only reasonably likely to occur during processing if other controls before and after processing, including GMPs and related programs, are not operating effectively.

4) Do FDA regulations, such as the GMP regulations, offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept? How would FSIS implement such an approach?

GMPs constitute valuable tools for the food industry that should be considered more carefully by FSIS. GMPs represent the foundation of an effective corporate food safety management program. GMPs establish a basic model for food plant operations, including personnel cleanliness, building and operation design, sanitation, equipment, utensils, and process controls. GMPs provide recommendations that provide guidance to individual facilities in the development of food safety procedures while providing the flexibility necessary to fit the needs of each individual operation. Thus, AFFI believes GMPs fit within a HACCP framework.

5) What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?

The hazard analysis approach used by FDA currently differs from that used by USDA. This leads to considerable confusion and difficulty in achieving effective HACCP implementation in facilities that produce products subject to regulation by both agencies. Although product standards and program monitoring may vary between FSIS's and FDA's regulation of food products, the underlying concept of HACCP, a preventive system of hazard control, should remain the same in both agencies. The changes suggested by the petition, which would result in making FSIS and FDA requirements more not less similar, can not only remove this confusion but also can enhance understanding of the important food safety controls that exist in manufacturing.

For example, in one processing facility, FDA expects a record of **all** hazards considered while developing the hazard analysis documentation. All potential hazards are listed and a rationale is required as to whether to control the potential hazard via a CCP. This approach assures that all potential hazards are properly considered, thus preventing the possibility of overlooking a potential hazard, and clearly documents how effective control is achieved. It is very useful for communicating the thought process used in determining CCPs.

In the same facility, the current USDA implementation approach severely limits this useful documentation because listing of **any** "hazard" in the hazard analysis requires control by a CCP in a HACCP plan. As a result, only those items requiring control via a CCP are listed in the hazard analysis for USDA products. Other potential hazards that were considered in the process are not listed, and the useful historical record of why they were not considered to require control via a CCP is lost.

The FDA approach is much more powerful in promoting food safety. It reduces second-guessing and repetitive work, and is more aligned with internationally recognized HACCP principles. In addition, the existence of two different approaches to HACCP presents training and implementation difficulties. A harmonized approach is needed for a clear and consistent food safety message.

6) Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

Changes recommended within the petition should be reviewed keeping the Codex concept of HACCP in mind. However, the views of other countries and Codex should only be considered so long as they are science-based.

Conclusion

AFFI appreciates the opportunity to provide comments on the industry petition regarding HACCP inspection. AFFI believes the changes proposed in the petition could make HACCP even more successful than it is today. Publication and acceptance of the petitioners' proposal will address some of AFFI's concerns.

Furthermore, the petitioners' modest request will align the agency's initiative with concepts consistent with those of a nationally integrated and "seamless" food safety system. AFFI looks forward to the opportunity to work with FSIS in the development of Phase II of HACCP by cooperatively focusing on ways to improve the HACCP inspection program.

Sincerely,



Leslie G. Sarasin, CAE
President and
Chief Executive Officer