Kraft Foods

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USDA/FSIS Hearing Clerk
300 12Th Street, SW
Room 102 Cotton Annex
Washington, DC 20250-3700

Re: Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection, 65 Fed. Reg. 30956 (May 15,2000) Docket No. 00-014N

Dear Sir or Madam:

Kraft Foods, Inc. is the leading food manufacturer in the U.S., producing over 8 billion individual packages of food a year, with annual sales of over $17.5 billion in 1999. Kraft products are sold under well-known brand names--such as Oscar Mayer, Tombstone, Kraft, Maxwell House and Post--that are found in almost every American home. The safety of our products and of our brands, whether regulated by the Food Safety and Inspection Service (FSIS) or the Food and Drug Administration (FDA), is of paramount importance to Kraft. Accordingly, Kraft has a very substantial interest in the implementation of effective Hazard Analysis and Critical Control Point (HACCP) programs that will assure the continued safety of all food products.

While Kraft applauds the agency's efforts to modernize how it inspects meat and poultry products, we are concerned that current FSIS interpretations of the existing regulations foster the "command and control" enforcement patterns of the past, rather than the scientific food safety systems needed for the future. Kraft produced approximately 1.1 billion pounds of ready-to-eat meat and poultry products in 1999, all under a food safety program built upon the scientific HACCP principles adopted in 1997 by the National Advisory Committee on Microbiological Criteria for Food (NACMCF) (3), our Sanitation Standard Operating Procedures (SSOP's), and the Good Manufacturing Practices (GMP's) in our prerequisite programs. We have long supported HACCP as a valuable tool in the effort to deliver safe, wholesome foods to the public, because we know from experience that science-based HACCP works, when built upon a strong foundation of SSOP's and other prerequisite programs.

Kraft urges FSIS to recognize, directly and explicitly, that all prerequisite programs are designed to reduce the presence of food safety risks. To the extent that these programs effectively reduce the prevalence of food safety hazards, the reduction should be considered in the development of HACCP plans. In particular, if a potentially hazardous condition is not reasonably likely to occur and to result in unsafe food, due to a company's effective prerequisite programs, there is no need to apply resource-intensive critical control point procedures (CCP's). Industry can make substantially more progress toward the ultimate food safety goal by focusing resources on hazards that do need to be addressed through CCP's. Accordingly, Kraft supports the ideas advocated by the trade associations in the industry petition.

## GENERAL COMMENTS

Based on our world-wide manufacturing experience, Kraft appreciates the importance of building successful HACCP programs upon a common sense approach to food safety management that relies on, and indeed presumes, the use of SSOP's and the GMP's in prerequisite programs. The manufacture of safe food products requires the use of a HACCP system built on a solid foundation of prerequisite programs. As stated in the NACMCF principles, "Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food (3)". The same conclusion is reached in the Codex Alimentarius General Principles of Food Hygiene.

At the moment, HACCP is being viewed, first and foremost, as a regulatory mechanism. The agency's current perspective has even been termed "regulatory HACCP". The fundamental problem with this view is that prerequisite programs are not sufficiently recognized by FSIS when the agency reviews a plant's hazard analysis and HACCP plan. As a result, regulatory CCP's, those CCP's which do not meet the scientific criteria established by NACMCF, are made mandatory in practice through enforcement actions.

To be effective, CCP's must be selected solely on the need to manage a "biological, physical, or chemical agent that is reasonably likely to cause illness or injury in the absence of its control"(3). It is the manufacture's responsibility to conduct a hazard analysis using all available information to determine the severity of a hazard, the likelihood of occurrence, and the most effective means to control the hazard. The agency's role is not to second guess the manufacturer's plan, but instead is to double-check the results the plan produces when applied by the manufacturer.

The key to the success of the HACCP system is the focus it brings to truly critical food safety activities. This essential focus fades quickly among regulatory CCP's that do not enhance consumer protection, but meet arbitrarily imposed regulatory requirements. Moreover, the paperwork that necessarily proliferates, when regulatory CCP's are imposed, diverts precious resources from activities that could make a substantive improvement in food safety.

The petitioner's recommendations to make the key terms in section 417.1, the definition section of the regulation, consistent with the recommendations of the NACMCF are sound. In particular, Kraft supports the following clarifications that would return the rule to its scientific origin:

> Delete the term food safety hazard and substitute the following definition of a hazard: "A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control."
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> Define hazard analysis as: "The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan."
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> Define the severity of a hazard as: "The seriousness of the effects(s) of a hazard."
>
> Define shipped product as. "A product has been shipped if it has been sold to a third party and is not under the direct or effective control of the inspected establishment. Products have not been shipped in circumstances such as when the product is still owned by the inspected establishment, whether stored at the inspected establishment or at another storage locations, as well as when the product is moving from one facility to another that is owned by the same person or company."
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> Modify Section 417.2 (a)(1) to include the amendment: "Every official establishment shall conduct, or have conducted for it, a hazard analysis to develop a list of hazards that are of such severity and significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to cause injury of illness do not require further consideration within a HACCP plan. The hazard analysis shall consider the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer."
>
> Clarify section 417.3 regarding when product produced under a HACCP plan has been shipped. Amend section 317.3(b)(3) by eliminating the term "enters commerce" and substituting in lieu thereof "is shipped."
>
> Amend section 417.6(e) to provide that a HACCP system may be found inadequate when adulterated product has been shipped. The section should be amended to by striking "produced or."

The sooner these clarifications are agreed upon, the more effective the FSIS rule will be in enhancing food safety.

Kraft Foods offers the following comments in response to the agency's request for input on specific questions about the petition:

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?**

Yes, there is abundant information that supports taking the actions in the petition. The NACMCF committee is appropriately qualified and the guidelines adopted by the committee are well supported by scientific data. Additionally, Kraft will cite just a few of the many examples that support the need for FSIS to act favorably upon the petition.

HACCP is most successful when managed with an integrated approach to food safety management using science to select CCP's and supported by SSOP's and GMP's as prerequisite programs (4). Effective HACCP systems keep employees focused upon the most important, scientifically based food safety activities. By mandating CCP's for activities properly considered prerequisite programs, "regulatory HACCP" diverts attention from critical activities and undermines the very core of the HACCP concept: focus on true CCP's. True CCP's must deal with potential acute health hazards and must be monitored and controlled using techniques based upon objective measurements and sound science.

The importance of focusing on true CCP's has been recognized by The Canadian Food Inspection Agency (1) and the Food and Drug Administration (2). Prerequisite programs are included in the Canadian Food Safety Enhancement Program and the new HACCP regulations for seafood processing in the United States. By focusing on true CCP's these agencies have maintained their management as a key food safety tool. Kraft cannot allow the focused attention our employees pay to food safety activities to be diluted or diverted by well-intentioned, but misguided regulatory CCP's.

Additionally, the USDA generic HACCP model for Fully Cooked, Not shelf stable products, page 26, recognizes the use of prerequisite programs and references the ability to use "production and process controls to reduce a potential hazard".

The resource requirements and costs of monitoring a single CCP may require 4 to 6 hours a day since the efforts of several production and management personnel are required to monitor and verify the activities associated with a single CCP. The arbitrary requirement for regulatory CCP's places unjustifiable costs on a manufacturer, interrupts customer service, and dilutes efforts to focus employee activities on true food safety controls.

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 and the Poultry Products Inspections Act?**

   Yes. Indeed, the requested changes would actually enhance food safety programs. Clarifying what process steps are true CCP's would enable industry to focus properly and enable the agency to allocate its limited inspector resources more effectively by concentrating on those process steps critical to public health.

3. **Should FSIS consider regulatory modification that would acknowledge the prerequisite program concept of NACMCF?**

   Yes, without doubt. Recognition of the role prerequisite programs play in food safety management is critical to the success of HACCP. The NACMCF acknowledged the role of prerequisite programs when the HACCP guidelines first where adopted, long before anyone

was talking about "regulatory HACCP." These programs support the efforts of manufacturers to manage hazards effectively by focusing their resources on actual CCP's, those points in the production process that must be monitored to keep measurable parameters, like temperature, within critical, scientifically supported limits. Mandating CCP's for risks that are not likely to occur is counterproductive to the efforts required to manage an effective food safety program.

Perhaps the Agency should review the FDA position on GMP's as a solution for assuring that Industry develops and maintains the appropriate level of prerequisite program management. GMP's require companies to have appropriate foundation programs in place, but allow flexibility in the means used to accomplish the stated goals. FDA has general GMP regulations for food manufacturers 21 CFR part 110 and a specific GMP regulation requiring internal audits for medical device manufacturers, 21CFR 820.22; 43 FR 31508; July 21, 1978.

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?**

Yes. Current FDA regulations outlined in 21 CFR 110 clearly support the concept of prerequisite programs as recommended by the NACMCF. By recognizing the role these programs play in HACCP management, FSIS will stop the unproductive debate about the need for unscientific, "regulatory CCP's." The GMP approach is the approach upon which scientific HACCP always has been based; there simply is no inconsistency with the HACCP concept. Indeed, the approach would strengthen the very foundation upon which HACCP rests.

To make the prerequisite requirements clear, FSIS should adopt GMP regulations, using the FDA regulations as a starting model. Meanwhile, FSIS should interpret the existing HACCP regulation reasonably, in a manner consistent with scientific HACCP, as most stakeholders thought FSIS intended to do when the regulation was adopted, before FSIS introduced the concept of "regulatory HACCP."

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

The FSIS and FDA HACCP regulatory programs are dissimilar today, due to the unexpected and unduly restrictive manner in which FSIS has interpreted its HACCP regulation. Essentially, FSIS, but not FDA, has taken the position that the agency must apply HACCP as if none of the basic programs and controls everyone agrees must be in place as the foundation for HACCP exists. The differences between the agencies would be reduced, not increased, if FSIS accepted the petitioner's recommendations.

Continued regulation of the food industry with dissimilar HACCP standards places considerable resource constraints on companies regulated by both agencies, especially in the same facility. Harmonizing approaches to HACCP between both agencies will simplify

and will enhance the industry's efforts to manage food safety risks without imposing different management criteria.

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?**

Yes. These changes will only improve the safety of foods regulated by the FSIS. Codex recognizes the usefulness of the HACCP principles and supports the concept of an integrated food safety management system.

## SUMMARY AND CONCLUSIONS

Kraft advocates the implementation of a HACCP system that is science based following the guidelines of the NACMCF. A sound HACCP system is founded on the use of prerequisite programs and GMP's to establish the basic conditions under which CCP management through HACCP can be effective. CCP's are identified through hazard analysis. Only those biological, physical, or chemical agents that are reasonably likely to cause illness or injury in the absence of control are managed as CCP's. Mandating regulatory CCP's, treating a HACCP plan as a failure if adulterated product is produced even though it was identified and controlled by the HACCP system, or failing to recognize the contribution of plant programs such as SSOP's and GMP's in managing food safety, diminishes the effectiveness of HACCP.

In conclusion, Kraft is fully committed to food safety and we recognize the need to modernize the Agency's inspection system. Kraft supports the application of HACCP to assist in accomplishing this goal, but with the modifications discussed in this comment and requested in the Petition to Amend the HACCP Rule filed by the various trade associations. We also urge FSIS to accept the role GMP's play in food safety management and adopt regulations paralleling the FDA regulations in 21 CFR Part 110. Harmonizing the FSIS HACCP rule with the FDA rule will improve the manufacturer's ability to train employees correctly with proper focus on true food safety activities, rather than on peripheral paperwork dictated by regulatory politics.

Respectfully submitted,

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References:


1. Canadian Food Inspection Agency (CFIA). 1998. Food Safety Enhancement Program. Volume 4, Operational Guidelines, 2nd edition, Appendix II CFIA, Ottawa, Canada.

2. Food and Drug Administration. 1995. Procedures for the safe and sanitary processing and importing of fish and fishery products; final rule. Fed. Regist. 60:65096-65202 (December 18).

3. National Advisory Committee on Microbiological Criteria for Foods. 1997. Hazard analysis and critical control point principles and application guidelines. Adopted August 14, 1997, FSIS, Washington, D.C.

4. Sperber, W. H., K. E. Stevenson, D. T. Bernard, K. E. Deibel, L. J. Moberg, L. R. Hontz, and V. N. Scott, 1998. The role of prerequisite programs in managing a HACCP system. Dairy, Food and Environ. Sanitation, 18:418-423.