



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS



WORLD
HEALTH
ORGANIZATION

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Agenda Item 1.4

Conference Room Document 74

SECOND FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS
Bangkok, Thailand, 12-14 October 2004

**How Official Services Foster and Enforce the Implementation
of HACCP by Industry and Trade**

(Prepared by the United States of America)

Background

Federal regulations in the United States require that seafood (December, 1995), meat and poultry (July, 1996), and juice (January, 2001) sold in the United States be processed under Hazard Analysis Critical Control Point (HACCP) systems. Because this was a major shift in government regulation of these foods, the rulemaking process in each case went beyond the written notice and comment required and included public meetings and discussions in many areas, especially implementation. Before each regulation was published, the regulatory agencies developed a comprehensive outreach plan and guidance materials, such as guidelines for hazard identification and control, lethality and stabilization performance standards, and model HACCP plans for common processes and products. The U.S. agencies with jurisdiction—the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA) for meat and poultry and the Food and Drug Administration (FDA), Department of Health and Human Services (HHS) for seafood and juice—allowed ample time before the effective dates of their implementation of new regulations for training and education of those affected. This included phasing in the regulations over several years, giving the smallest firms a longer period to comply. Implementation of HACCP has been an evolutionary process. Many issues have been identified since implementation, requiring frequent revision of outreach plans and guidance materials.

Discussion

The principles underlying the HACCP regulations strongly influence the guidance provided during and since implementation. These include:

1. The inspected establishments are responsible for developing and implementing their own HACCP plans, using a person trained in HACCP, covering each process.
2. Traditional sanitation requirements are not replaced by HACCP, but rather are an essential pre-requisite and must be part of a company's standard operating procedures.
3. Government inspection, which previously focused on assessing the status of individual products, is refocused on (1) ensuring appropriate HACCP plans are in place and being followed to control processes, and (2) verifying the effectiveness of those HACCP systems in producing only unadulterated product.
4. Non-compliance may result in severe sanctions, including closing of the business.

Upon issuing final regulations, the agencies conducted extensive outreach activities, including publication of hazard guides, model HACCP plans, and question-and-answer guides. These materials were distributed (1) by agency personnel using a variety of media, (2) through agency-

supported workshops and educational programs conducted by partnering non-profit associations and academic institutions, and (3) by industry trade associations.

FSIS focused much of its efforts on the smallest establishments needing the most help. HACCP coordinators were designated in each state to provide local, one-on-one access to expert advice. The two agencies formed partnerships with consortia of universities and state regulators to provide ongoing, free or low cost training programs for state regulators as well as industry, and jointly support the HACCP Training and Resource Materials Database at the USDA's National Agricultural Library.

FSIS and HHS/FDA guidance materials have been refined and supplemented many times since publication of the final HACCP regulations. A full listing of current guidance materials and other information on FSIS and HHS/FDA HACCP implementation is available on their web sites (www.foodsafety.gov).

Beyond mandatory HACCP, FSIS and HHS/FDA have assisted with the voluntary application of HACCP principles in allied food industries producing other manufactured foods; dairy products; and shellfish; and in the retail, food service, and food transportation sectors. HHS/FDA is considering developing regulations that would establish HACCP as the food safety standard throughout other areas of the food industry, including both domestic and imported food products. To help determine the degree to which such regulations would be feasible, the agency is conducting pilot HACCP programs with volunteer food companies. The programs have involved cheese, frozen dough, breakfast cereals, salad dressing, bread, flour, and other products. Increasingly, large companies are demanding that suppliers provide products produced under HACCP, applying marketplace incentives for the adoption of HACCP and making HACCP-based production controls increasingly common throughout the food industry.

Conclusion

Implementing HACCP as part of a regulatory mandate to ensure safe food is a complex undertaking, especially in the context of mandatory inspection laws for meat and poultry. HACCP regulations have been successfully implemented by FSIS and HHS/FDA through frequent and open dialogue among government, industry, and other stakeholders, and through expansive programs for inspector training and outreach to industry. Industry outreach has included agency-developed training and guidance materials and collaborative efforts with trade associations, universities, and others, all continuously refined as issues emerge and modifications are made to the regulatory programs, which mandate HACCP.