



THE Society for Food Science & Technology

July 31, 2008

Dear Commissioner von Eschenbach;

Founded in 1939, the Institute of Food Technologists (IFT) is a nonprofit scientific society with 22,000 members worldwide working in food science, food technology, and related professions in industry, academia, and government.

IFT commends the Food and Drug Administration (FDA) for developing a Food Protection Plan and is in general agreement with its core elements of Prevention, Intervention, and Response. We are pleased to have this opportunity to offer comments (Docket No. FDA-2008-N-0188), which we believe will help the Agency strengthen the Plan.

As detailed in the subsequent pages of our comments, IFT recommends that the Agency:

- Seek to achieve the overarching goal of safety of all foods for all people.
- Reinforce requirement for corporate food safety management responsibility.
- Verify that each food manufacturer has used Hazard Analysis and Critical Control Point (HACCP) criteria in conducting and documenting a hazard analysis of its operations and establishing critical control points (CCP) as necessary to control significant identified hazards. When CCPs cannot be established, e.g. in commodity or ingredient handling operations, appropriate preventive controls should be applied within the available HACCP prerequisite programs (e.g., good agricultural practices and good manufacturing practices).
- Conduct outreach and education to promote and enable across-the-board implementation of food safety management systems.
- Enhance collaborative efforts within and among other agencies, including those at the state and local level, and with academia and industry, facilitating use of all pertinent data to inform policy decisions.
- Enhance availability to the food industry of information on food safety programs by country, including their food exports and any particular concerns in dealing with our food imports.
- Promote consistent application and enforcement of scientifically-based third party audits of domestic and international manufacturers of food ingredients and products.
- Support further development of international food safety programs.
- Maintain momentum in food defense along with food safety, as integral and integrated components of food protection.

IFT would be pleased to work with the Agency to elaborate upon any of the comments contained herein.

Sincerely,

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President, 2007-2008

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**Institute of Food Technologists
Comment on
The Health and Human Services/Food and Drug Administration's Food Protection
Plan: An Integrated Strategy for Protecting the Nation's Food Supply**

**Docket No. FDA-2008-0188; Food Protection Plan; Outreach Activities;
Opportunity for Public Comment**

Founded in 1939, the Institute of Food Technologists (IFT) is a nonprofit scientific society with 22,000 members worldwide working in food science, food technology, and related professions in industry, academia, and government. IFT's long-range vision is a safe and abundant food supply contributing to healthier people everywhere. A critical part of our mission is advancing food science and technology, in which we share a common commitment with the Food and Drug Administration in promoting food protection.

IFT commends the FDA for developing a Food Protection Plan and is in general agreement with its core elements of Prevention, Intervention, and Response. We are pleased to have this opportunity to offer comments, which we believe will help the Agency strengthen the Plan. Our comments were drafted by a select group representing the diverse scientific expertise of IFT members: Frank Busta, Ph.D. (University of Minnesota and National Center for Food Protection and Defense), Catherine Cutter, Ph.D. (Pennsylvania State University), Michael Doyle, Ph.D. (University of Georgia), Gale Prince (Kroger Co., retired), Arthur Miller, Ph.D. (Exponent), and William Sperber, Ph.D. (Cargill, Inc.).

There are some fundamental aspects that must serve as a foundation to the core elements of the Plan. Foremost, IFT believes that a key overarching goal is safety of all foods for all people. To reach this goal, the science component, including staffing, of FDA must be strengthened. Current laboratory facilities and IT systems need to be modernized and the scientific expertise of the agency can be enhanced. The scientific component of the FDA must be maintained at a level that permits the Agency to effectively exercise its responsibilities.

Core Element #1: Prevention

IFT agrees with FDA's statement that prevention of adulteration, intentional or unintentional contamination, is fundamental to food protection. It is important that prevention continues as the cornerstone of the Food Protection Plan. We believe today's food industry must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. Prevention requires that food safety be

designed into products from the beginning via close interaction with suppliers, growers, manufacturers, distributors, service providers, and importers.

- **Corporate responsibility: Food safety management systems.** IFT recommends that the food industry, regardless of size, respond to the Plan with establishment- and product-specific food safety management systems that incorporate management's understanding of its corporate responsibility for ensuring food safety. Food safety depends upon top management commitment, employee training, and effective regulations.

The Food Protection Plan recommends that food safety be built in "from the start." Designing food safety into food products and controlling the processes by which they are produced is in fact a long-held consensus in the food industry and the essence of the Hazard Analysis and Critical Control Point (HACCP) concept, a term that is notably omitted from the Plan. Thus, IFT heartily supports this vital component of prevention.

Ideally, in each establishment a food safety management system would describe corporate philosophy of food safety management, best practices for preventing contamination and foodborne illness, proactive attention to hazard analysis and other HACCP principles as applicable, HACCP prerequisites (e.g., good agricultural practices [GAPs] and good manufacturing practices [GMPs]), and specific responsibilities of key personnel in the system in ensuring compliance. In such food safety management systems, a key responsibility of the Agency is verification that industry is fulfilling its responsibility.

- **Global food supply chain.** It is important that FDA clarify in its Plan the need to assure food safety throughout the global food supply chain. The food supply chain is now a complex mesh of raw materials and finished products in channels involving hundreds of countries. Foods manufactured and/or imported in the United States often contain raw materials (e.g., packaging and ingredients) originating in a number of countries. IFT commends the Agency's intent to highlight the expectation that Importers of Record will be held to the same safety standards as those domestically produced. In addition all imported raw materials and products must be held to the same safety and regulatory requirements as those produced domestically. It is the responsibility of the Importer of Record to require and verify that such suppliers have appropriate food safety management systems in place at each of the facilities providing products.
- **HACCP.** Combined with prerequisite programs, HACCP is an internationally recognized proven, scientific, risk-based preventive food safety management system that when properly implemented provides the highest level of safety assurance. We strongly advocate the use of HACCP principles.

The successes of the Pasteurized Milk Ordinance (PMO) and the low acid canned foods regulations, first published in 1923 and 1973, respectively, and the HACCP system, as described by the National Advisory Committee on Microbiological Criteria for Food (1997) and Codex Alimentarius Commission (2003), for designing food safety into

products are notable. IFT believes manufacturers must be expected to implement HACCP prerequisites, conduct hazard analyses, and implement other internationally recognized applicable HACCP principles.

We believe FDA must establish regulations for the safe production, harvesting, and packaging of those types of fruits and vegetables for which FDA has determined that such regulations are needed to minimize the risk of serious adverse health consequences or death. The regulations must provide for coordination by state, local, and foreign governments and must address development and adoption of GAPs for produce. Additionally, we believe that the Agency must complete its work on modernizing existing GMP regulations.

IFT recognizes the challenges faced in attempting to apply HACCP from farm to table, particularly at steps or nodes in the food chain lacking critical control points (CCPs), for example. Still, however, IFT believes that the food industry must be required to design food safety into food production processes through application of HACCP principles and its prerequisites (e.g., GAPs and GMPs) to adequately address and control hazards.

IFT strongly encourages increased federal efforts and support of activities to educate food industry and other personnel having food safety responsibility throughout the food system on the need for food safety management systems and train them in effective implementation. This should be a joint effort involving regulatory and food industry leaders in reaching out to the entire food sector and the regulatory community in the enhancement of food safety programs at all levels.

- Hazard control. Although there is merit in a risk-based approach to focusing and allocating limited resources, emphasis on high-risk foods and additional modeling to identify such foods have substantial limitations. Additional modeling capabilities, for example, would not be expected to anticipate food safety issues caused by accidental or intentional contamination. Recent outbreaks associated with Salmonellae in peanut butter and veggie chips, botulinum toxin in canned food, and melamine in pet food, occurring because of management failures and deliberate economic adulteration, would not likely have been anticipated through risk ranking. IFT recommends that the Agency thoughtfully consider how to balance a need to focus on high-risk foods and causative agents with the critical need to maintain a focus on the many well known hazards that do not require additional modeling, in order for industry implementation of across-the-board effective food safety management systems to control hazards.

Toward this end, data and information available within FDA or other agencies would be helpful to the food industry in implementing or enhancing food safety management systems. Specific information, such as that comprising the Agency's algorithms or State Department, Central Intelligence Agency or Department of Defense resources about countries, regions, and food safety programs of concern could be very useful to the food industry's efforts to enhance food safety and food defense. More specifically, an inventory of food safety programs by country, including main food exports and any

particular concerns, would benefit food manufacturers and the Agency in better directing its resources. Additionally, data in such an inventory of food safety programs by country could aid risk and vulnerability assessments and modeling efforts for both industry and the agency.

- **Food defense.** It is imperative that FDA maintain momentum in food defense along with food safety, as integral and integrated components of food protection. Except for our comment on modeling, each of the above statements is applicable to food defense, with appropriate modification for the unique attributes required by addressing intentional contamination. Continued efforts in modeling are needed in food defense to understand the effects of compromising the system by intentionally contaminating the food supply to permit ordering of actions in protection, response, and recovery. IFT encourages continued research on threat agent responses to food environments and food processes and handling throughout the entire food supply chain. This research is urgently needed to develop critical information and methods for detection, control, and decontamination.

- **Collaboration.** IFT is strongly in favor of FDA collaborating with other agencies, such as the Centers for Disease Control and Prevention and U.S. Department of Agriculture. IFT believes that food attribution studies in particular will shed much light on hazardous products and will not unduly tax scarce FDA resources. Individual state and local agencies can be useful allies to the Agency by providing data on product contamination and foodborne illnesses. IFT understands the challenges in assessing and validating surveillance data collected by individual states. Still, FDA should attempt to better use these data to inform policy decisions. Similarly, IFT also recommends that FDA consider closer collaborations with academia, an important scientific foundation component in determining food policy. Increased collaborative efforts with universities could be helpful in filling in scientific data gaps, and increased funding for universities would enhance the needed outcomes of basic and applied research. Collaborating closely with the private sector also has many benefits, as the food industry has extensive information and experience in food safety and defense that could assist in meeting the nation's food protection goals.

Core Element #2: Intervention

- **Responsibility and enforcement.** IFT agrees that the food industry should continue to take more responsibility for the mitigation of hazards and assuring ingredient and food safety at all points of origination. However, IFT encourages FDA to increase enforcement activities using the full range of legal tools currently available including imposition of penalties for failure and non-compliance. Many existing regulations, guidelines, and procedures that promote the safety of our global food supply are available; these must be fully understood and their use expected.

- **Auditing.** IFT applauds the recent release of *Draft Guidance of Voluntary Third-Party Certification Programs for Foods and Feeds*. We support FDA's interest in the use of third party audits that are scientifically based and consistently applied and enforced as

an additional tool to further strengthen food safety management systems. To date, there is not a firm consensus on third party certification programs including criteria and procedures. FDA should encourage and support global food industry efforts to develop practical, effective audits and/or inspections to verify compliance with food safety management systems. However, these must not be replacements for existing facility and/or corporate based components. All parties—industry, governments and consumers—will benefit from the development of equivalent audits and/or inspections applied to domestic and international manufacturers and their food ingredients and products based on internationally recognized standards such as Codex and ISO. An oversight program of third party audits should be considered to achieve uniformity and to ensure accuracy in achieving credibility.

- **Inspection.** IFT recognizes the public pressure to increase inspection and testing of imported and domestic food ingredients and products. It is well recognized that it is not possible to test all products or inspect every shipment. IFT encourages smarter, risk-based approaches to sampling, testing, and inspection and the use of food safety intelligence information. The use of third-party laboratory data and inspection information deserves consideration. IFT encourages FDA to update and minimize its inspection and testing schemes. Although product testing is a costly use of resources, we recognize its value as a critical verification component. IFT believes that availability of relevant prevention-focused guidance documents are more important, practical, and effective for food safety assurance than increased inspections and product testing. While risk-based inspection and testing are not likely to identify unexpected issues, either intentional or unintentional, it can provide directional information on areas deserving additional focus.

- **Food defense.** Again, it is imperative that FDA maintain momentum in food defense along with food safety as integral and integrated components of food protection. Each of the above statements is applicable to food defense, with appropriate modification for the unique attribute required by addressing intentional contamination. Continued research on threat agent responses to food environments and food processes and handling throughout the entire food supply chain is urgently needed to develop critical information and methods for general intervention, inspection, audits, and food defense assurance.

- **Global intergovernmental cooperation.** IFT recognizes that FDA has strong, valuable alliances and that it actively engages key organizations within the international regulatory, food standards, and food safety communities. We encourage FDA to continue to support international food safety activities, particularly with the World Health Organization and Food and Agriculture Organization in achieving uniformity in a global marketplace.

Because the food supply chain is global, food safety regulatory capabilities among countries vary, and responsibilities and resources of existing intergovernmental organizations are limited, IFT believes that establishment of an intergovernmental food safety agency, such as a “World Organization for Food Protection,” would be valuable

for leading the coordination and education that is needed for implementation and verification of food safety management systems worldwide.

Core Element #3: Response

- **Food defense.** Although food protection is defined as including food safety and food defense, the distinction between food safety and defense is ill-defined in the Plan. The authorities requested and measures noted in the Plan apply almost exclusively to traditional, unintentional food safety issues. IFT found the Plan lacking in measures that will increase food defense.

Increasing food safety requirements may also increase food defense protection. A strong food defense system needs a foundation of solid food safety practices; however, there are issues unique to food defense that cannot be addressed by food safety practices alone. These include continuing efforts in food defense awareness programs to alert food manufacturers to the vulnerabilities within the food and agriculture sector, items that are not mentioned in the Plan. Taking advantage of opportunities to reinforce this awareness in government agencies also would be valuable.

Although the likelihood of a traditional food safety event, as well as the possible outcomes, can be modeled, doing so for food defense is more difficult than for food safety. CARVER + Shock should be encouraged as a tool to help companies assess the potential impact of an intentional contamination event; the likelihood of such an event, however, cannot be estimated.

- **Return on investment.** Industry needs guidance, training, and tools to assess the relative “return on investment” of allocating resources toward food safety and food defense measures. Professional and trade associations are well equipped to provide this type of assistance.

- **Food safety vs. food defense.** It is also important for the industry to understand how FDA balances the needs of food defense and safety over time. It appears that current events drive some programs in a reactive mode and that the Agency’s emphasis and priorities may swing between food safety and defense. Food safety threats are vastly different from food defense threats and neither should be subordinate to the other.

- **Mandatory vs. voluntary recalls and records access.** IFT would support mandatory recall authority under certain conditions. However, FDA must provide the responsible party the opportunity to cease distribution and recall any of the product that has entered into commerce. If the responsible party refuses to take appropriate action, the Secretary would be authorized to order the responsible party to do so. Mandatory recall authority should only apply if a company refuses to voluntarily recall a product “for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.”

There are lapses within the food supply chain regarding ability to conduct one step forward and one step back track and trace back requirements. This is an area of particular interest to IFT. Simply providing additional access to records is insufficient; rather, investigating tracking lapses in food commodity supply chains is what is needed. IFT recommends that FDA strengthen policy to require better traceability at all nodes in the food chain, and, concurrently, develop research and development incentives for the development of improved technologies that will facilitate quicker, more efficient, trace and tracking data systems. There is a need to develop a platform to allow for product information to be gathered electronically as products move through the food distribution systems. Such records would facilitate rapid trace back during a time of a food safety concern. Various federal agencies should work with the industry in developing such a platform to integrate record needs with current business systems. Such a system could be an extension or parallel of the current Uniform Product Code (bar code) for consumer packages.

Summary of Principal Recommendations

IFT recommends that the Agency:

- Seek to achieve the overarching goal of safety of all foods for all people.
- Expect corporate responsibility for food safety management.
- Verify that food manufacturers effectively implement food safety management systems that encompass ingredients and products from their origin and apply HACCP principles and HACCP prerequisites where possible.
- Conduct outreach and education to promote and enable across-the-board implementation of food safety management systems.
- Enhance collaborative efforts with other agencies, including those at the state and local level, academia, and industry, using all pertinent data to inform policy decisions and focus limited resources on known hazards.
- Further enhance content in existing inventories of food safety programs by country, including food exports and any particular concerns.
- Promote usage and consistent application of scientifically-based third party certification for domestic and international manufacturers of food ingredients and products based on internationally recognized criteria.
- Support further development and capacity building of international food safety programs.

- Maintain momentum in food defense along with food safety, as integral and integrated components of food protection. Include specific food defense measures and modeling, research, and information needs in the Food Protection Plan.

Conclusion

IFT appreciates consideration of these comments. We hope that FDA finds these comments useful and we extend an invitation to FDA to further discuss any of these points. Additionally, IFT feels well-positioned as a scientific and professional association to assist the Agency in developing educational and training materials to advance food protection practices. We commend FDA on developing the Food Protection Plan and look forward to working together to improve the safety of all foods for all people.

**Institute of Food Technologists
Working Group on DHHS/FDA Food Protection Plan**

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