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## **FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakech, Morocco, 28 – 30 January 2002*

### **INTEGRATED APPROACHES TO THE MANAGEMENT OF FOOD SAFETY THROUGHOUT THE CHAIN**

#### **COUNTRY PAPER PROPOSED BY THE USA**

#### **SUMMARY**

The existing US scheme of food safety responsibilities, involving the Food and Drug Administration, US Department of Agriculture, Environmental Protection Agency and other government agencies, is based on laws and regulations that place responsibility for safety on those that produce, process, transport and store the food.

In 1997, a new initiative to revamp the regulatory approach extended its scope throughout the food chain, "From Farm to Table." The initiative was needed to address significant outbreaks of foodborne illness and increasing international trade, and was based on extensive consultation with all stakeholders. Actions that were taken to prevent and respond to foodborne illness involved improved recognition of foodborne illnesses and outbreaks, establishment of an outbreak response team, research on new technologies, development of good agricultural practices, food safety education, and increased federal-state partnerships. As a result, food safety is now seen as a shared responsibility between consumers, industry, and government at all levels with better-understood roles for each. Increased transparency and visibility have brought more resources, higher priority and incentives to implement the initiative.

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## **INTRODUCTION**

In 1997, the United States launched a national initiative aimed at revamping its regulatory approach to food safety. The program was aptly named "Food Safety from Farm to Table: A National Food Safety Initiative" as its scope extends throughout the entire food chain. This paper describes this program, the reasons behind it, and the U.S. experience in implementing it.

## **BACKGROUND**

Like many countries, the United States traditionally focused its food safety regulatory programs primarily on chemical contaminants and filth in food and unsanitary conditions in food processing plants. National government regulatory efforts were directed at finding such problems during inspections or in examining or analyzing the food products themselves.<sup>1</sup>

This general scheme of food safety responsibilities had served the United States well for almost a century. It was based on a system of laws established over time by the U.S. Congress that authorized the U.S. government agencies to write and enforce regulations pertaining to the safety of foods produced and imported into the United States. These laws and regulations clearly place the responsibility for food safety in the hands of those that produce, process, transport, and store the food.

## **FOODBORNE ILLNESS AND GLOBAL TRADE**

Several significant outbreaks of foodborne illness occurred in the United States in the early 1990s. Some of these caused serious illness and deaths. Some involved pathogens that were unusual or "emerging". Some involved fresh fruits and vegetables, which had previously been thought to be low-risk foods with regard to human pathogens. The outbreaks were caused both by imported and U.S.-grown products. All of these situations presented many questions about how the risks could have been prevented, contained once found, or mitigated. Further, federal and state agencies, food industries, and the public recognized that such situations were going to recur unless there was an integrated approach to determining the causes and managing the risks. The recognition that foodborne microorganisms were being transported undetected from country to country clarified the need for bilateral and global approaches.

## **WHAT WE DID NOT KNOW**

Foodborne pathogens are invisible to the naked eye and thus escape detection unless food samples are analyzed. We had few rapid detection methods that could be useful in the face of the rapid farm to table commerce of today. Further, we were uncertain as to the extent of risks from foodborne pathogens in the United States. Our surveillance for foodborne illness generally was passive, insensitive, and slow. The system depended on a doctor recognizing that an illness related to a food borne pathogen, confirming this with a culture, and reporting to a state health department and the Centers for Disease Control and Prevention. Our national foodborne illness and death statistics based on available data did not provide good estimates of the incidence and severity of illness. We had similarly weak data on the

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<sup>1</sup> In the United States the Department of Agriculture (USDA) is responsible for the regulation and inspection of meat, poultry, and egg products. The Food and Drug Administration (FDA), under the Department of Health and Human Services, regulates other foods. The Environmental Protection Agency (EPA) approves pesticides for use in crops and sets limits for their residues that are enforced by FDA and USDA. The Centers for Disease Control and Prevention (CDC) collects data on food borne disease. State governments focus their efforts on food processing operations and retail establishments, such as restaurants and retail food stores. The federal government and the states have a history of coordinating efforts and partnering on many programs, especially in the areas of shellfish and dairy programs. The Pasteurized Milk Ordinance (PMO), developed by FDA in cooperation with states, is an example of this partnership. The PMO is a guide for safe practices at dairy farms, plants and testing laboratories, which is adopted by States into their food legislation to give this guidance the force of law. A second example is the Food Code, applicable to retail establishments, developed by FDA in cooperation with USDA agencies and the States, and adopted by many states.

frequency of contamination of foods by the most common causes of the foodborne illnesses. Additionally, microbial risk assessment techniques were still underdeveloped, and more and better risk assessments were needed to guide appropriate risk management measures.

It was clear from the outbreaks that occurred in the early 90's that federal and state agencies, food industries and consumers each had responsibilities in preventing the occurrence of food borne illness. Yet, each sector did not know what the others were doing to mitigate risk and how best to manage the residual risk.

## **CONSULTATION AND ACTION**

The U.S. food safety initiative was born through an intensive and constructive consultative process with consumers; food producers, packers, processors, importers, transporters, warehousemen; academics; federal agencies responsible for regulation and research related to food safety; exporting countries (generally through their U.S. embassies); food safety educators; and state and local agencies. USDA, FDA, EPA and CDC joined together in holding many public meetings which produced much information and a better understanding among all who participated of their respective roles in preventing foodborne disease. These meetings enabled the national food safety agencies to develop a plan of attack on foodborne illness that encompassed all components of the food chain, from farm to table.

### **The "Farm to Table" Approach**

Under the "farm to table" approach, each link in the chain from production to consumers has a critical role. Significant efforts have been expended to assure that the roles are understood and supported. Of note is that the existing delineation of responsibilities between industry and regulatory agencies has been reaffirmed. Industry has primary responsibility for the safety of the food it produces and distributes. Government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action when necessary.

### **Understanding the risks**

Because our understanding of many pathogens -- how they contaminate foods, how much must be present in food for there to be a risk of illness, how often illness occurs, and how to prevent illness -- was limited, several actions were needed.

First, we needed a national system to actively track and gather data on the character, types, and incidence of foodborne illness. This system, called FoodNet, has been operating for five years. Its nine sentinel sites are able to capture data on almost 13% of the U.S. population. Through FoodNet and other surveillance efforts, we now have solid data on the nature and types of foodborne illness in the United States. These data have changed our concept of many foodborne illnesses -- from the species of organisms most commonly causing disease (such as *Salmonella enterica*) to the frequency of occurrence (17.4 cases per 100,000 population for *Salmonella enteritidis* and 2.01 cases per 100,000 for *E. coli* O157.)<sup>2</sup> There are an estimated 76 million cases of foodborne illness in the United States each year.

Second, we needed to develop an early warning system to electronically link epidemiologists, food safety authorities, and state public health laboratories. The linkage permits rapid sharing of DNA fingerprinting information on microbes involved in foodborne illness incidents. It would also enable rapid determination of whether outbreaks in different states come from the same source. This system is called PulseNet, and has been very effective in linking outbreaks to a single source of food. At the same time, it has been able to indicate situations in which an increase in the number of cases of a foodborne illness is not related to a single source.

Third, we needed to conduct research to develop rapid and low-cost methods to detect pathogens in foods. This research is ongoing and will be long term.

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<sup>2</sup> Data are from the 1999 FoodNet annual report

Fourth, we needed to improve food pathogen risk assessment methods. The plan included efforts to develop appropriate expertise to establish better databases and modeling techniques. The federal agencies established a Risk Assessment Consortium to provide better guidance on research on risk assessment techniques. We have now conducted several full-scale risk assessments on several pathogens, including *Listeria monocytogenes* in ready-to-eat foods and *Salmonella* Enteritidis in eggs. We are learning how these assessments can be useful, despite many data gaps. The data gaps point the way for further research.

Fifth, we decided to increase surveillance of both domestic and imported foods for pathogens by using available detection methods. The existing methods do not always allow for sufficiently rapid detection so as not to impede the flow of commerce. However, the data gathered has identified types of foods and problem areas for further study. The United States and some of its trading partners are working closely to resolve both food safety and trade issues that have been revealed through this surveillance.

### **Taking Action to Prevent and Respond to Foodborne Illness**

We needed to learn a great deal about the character of foodborne pathogens and their associated illnesses. However, we had enough information to take immediate actions to decrease the occurrence of foodborne illness. The public meetings assisted us to identify these actions.

**IMPROVE RECOGNITION OF FOODBORNE DISEASE AND RESPONSE:** Sufficient information was available to enable doctors and State Health Departments to increase their recognition and appropriate treatment of foodborne illness. We have prepared and distributed a practical guide on the most common and serious foodborne organisms.

**ESTABLISH AN OUTBREAK RESPONSE TEAM:** In the past, epidemiological follow-up to a suspected/known foodborne disease outbreak did not always involve participation of food regulatory agencies. We developed a standard multiagency approach to learn how the outbreak occurred and translate the knowledge into risk management and risk communication actions. This approach required the involvement of national, state, and local food safety agencies as well as public health departments. The approach has been effective in investigating outbreaks both within the United States and in working with exporting countries.

**RESEARCH ON NEW TECHNOLOGIES:** We needed to revise research priorities to focus on prevention and control of pathogens, especially for known high-risk foods. Specifically, we focused on developing mechanisms for decontamination and prevention of pathogen occurrence in animal derived foods (such as meat, poultry, seafood, eggs, and prepared deli foods) as well as fresh fruits and vegetables.

**GOOD AGRICULTURAL PRACTICES:** The U.S. government had never attempted to compile guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for the production and processing of fresh fruits and vegetables. The development of this guidance was considered a high priority under the food safety initiative due to several outbreaks of foodborne disease associated with fresh fruits and vegetables. A high proportion of fruits and vegetables are consumed fresh from the field or prepared without further decontamination steps such as cooking. We collaborated with all segments of the produce and food processing industry, foreign governments and foreign industry, and farmers and consumers from around the world to develop the guidance. The Fresh Produce GAPs/GMPs have been translated into many languages and are now used globally as the best general guidance for production of safe fruits and vegetables.

**FOOD SAFETY EDUCATION:** Two factors are associated with much of the food borne illness that occurs in the United States. First, food preparers are not adequately informed as to how to prevent illness and second, they do not use safe food handling practices. Therefore, the food safety initiative needed to reach the general public, including children. A public-private partnership for food safety education was established. The partnership provided the funds, expertise and infrastructure to launch the Fight Bac!!™ campaign. This campaign has reached adults and children on TV, in schools, in

popular magazines. It has been adopted by a number of other countries for communicating simple food safety lessons to the public.

**INCREASE STATE-FEDERAL PARTNERSHIPS:** The national government does not have the resources to effectively control food from where it is grown, produced, or caught to where it is consumed. If the goals of the food safety initiative to reduce the incidence of foodborne illness were to be successful, all components of the food chain need to work together. The food safety initiative was established to institute dramatic changes in the way food is regulated in the United States, and the state governments and other stakeholders have had an integral role in making these changes.

## **LESSONS LEARNED**

The food safety initiative has led to significant changes in how we view food safety and how food safety is regulated in the United States. The safety of the food supply is now seen as a shared responsibility. The roles of industry, regulators and consumers are much better understood. The food safety initiative also brought greater transparency and visibility to food safety problems and issues. Greater visibility brought more resources, higher priority, and incentives to implement the initiative's objectives and achieve some permanent successes. This phenomenon has occurred in all the involved sectors and contributed to getting the job done, and should become a transboundary effort. Information on the food safety initiative is available through the website: [www.foodsafety.gov](http://www.foodsafety.gov).