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NATIONAL AND TRANSBOUNDARY FOOD SAFETY EMERGENCIES

CONFERENCE ROOM DOCUMENT PROPOSED BY THE USA

INTRODUCTION

Any food may be exposed to contamination during production, harvesting, processing, packaging, transportation, preparation, storage, and service. Processing or preparation conditions may lead to survival of pathogens or toxins, and time-temperature abuse can allow proliferation of pathogenic bacteria and molds.

Rapid detection of outbreaks and identification of the implicated food source protects the public health. Removal of contaminated foods from distribution limits the number of cases and stops the outbreak.

Identification of critical control points in the food process enables prevention of future outbreaks.

MULTISTATE OUTBREAKS OF FOODBORNE DISEASE IN THE UNITED STATES

In 1993, a large outbreak of foodborne illness caused by the bacterium E. coli O157:H7 occurred in the western United States. Less than a week from the first reported illness, the state of Washington issued a public announcement implicating hamburgers from a chain of fast food restaurants as the source of the outbreak. Food isolates were not yet available, but the epidemiologic studies strongly supported the public health action. Weeks later it was determined that the strain of E. coli O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties. Illnesses in three other states were linked to the same source, and the investigation identified two production dates at a single grinder.

A significant outcome of this outbreak is an increased emphasis on food safety and technological tool development to support investigations. This watershed event or catalyst led to regulatory actions extending beyond the immediate recall to include the declaration of E. coli O157:H7 as an adulterant in raw ground beef, labeling requirements, HACCP implementation, and monitoring programs for the pathogen. FDA increased the recommended cooking temperature for ground beef patties when undercooking was found to have contributed to the outbreak. Increased awareness in the public health community led to improved surveillance and diagnosis.

Implementation of the Listeria PFGE protocol occurred as a large multistate outbreak was identified and investigated in late 1998. Four states noticed an increase in the number of patients diagnosed with Listeria in the same week. As the number of ill people grew, the states agreed to a collaborative investigation and submitted isolates to standardized subtyping protocols for comparison. Multiple case control studies were needed to implicate a specific food type and brand names of product were compiled to identify a common source. PFGE patterns were pivotal in determining the food source before isolates were recovered by separating patients with the outbreak pattern from other Listeria patterns that were occurring at the same time. Without this separation, the "noise" of the other patient histories would have delayed the investigation. Confirmation was accomplished later when isolates from the implicated product were found to match the outbreak strain.

The U.S. also initiated the Foodborne Disease Active Surveillance Network (FoodNet). FoodNet is now a collaborative project of CDC, FDA, USDA and several states (representing more than 10% of the U.S. population) to collect more precise information on foodborne illnesses and to conduct related epidemiologic investigations to help public health officials better understand the epidemiology of foodborne disease in the U. S. FoodNet provides a strong network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the source of specific foodborne diseases - all with a view toward developing and implementing effective prevention and control measures.

FOOD SAFETY PROBLEMS WITH AN INTERNATIONAL SCOPE

The above-mentioned outbreaks involved bacterial pathogens and the use of standardized PulseNet PFGE protocols to address food safety issues that spanned multiple states within the United States. The following example pertains to Cyclospora cayetanesis, an emerging pathogenic parasite that created a food safety problem that spanned multiple international boundaries. Before 1996, most of the documented cases of cyclosporiasis in North America were in returning overseas travelers. Beginning in 1996, epidemiologic investigations began to trace cases and outbreaks of cyclosporiasis to the consumption of raspberries from Guatemala. We discuss below the follow up to the raspberry/Cyclospora outbreaks to illustrate the handling of a transboundary food safety emergency.

One of the difficulties in investigating the Cyclospora outbreaks and the source of contamination is that the biology of C. cayetanensis was not completely understood. Although we now know more, we still do not know how raspberries are becoming contaminated. There are several factors that led investigators to assume that the contamination of raspberries must be occurring during the growing, harvesting, or shipment of product.

It is believed that humans are the primary reservoir for Cyclospora oocysts. The oocysts are noninfectious in freshly excreted stools. The oocysts are thought to require from days to weeks outside the host, under favorable environmental conditions, to sporulate and thus become infectious. Direct person-to-person transmission through fecal exposure is unlikely to occur with Cyclospora, and food or water contaminated with freshly excreted oocysts shortly before consumption should not cause cyclosporiasis.

The FDA undertook a number of activities in conjunction with growers, the Guatemalan government researchers, and other stakeholders to address this problem from a number of angles. One important aspect was to take control measures to try to eliminate contamination of raspberries with Cyclospora.

General measures were instituted immediately, in cooperation with growers' organizations and government agencies. Meanwhile, research efforts were underway to identify better analytical and control techniques. Public consultations were held to obtain the best available information about Cyclospora and to further refine research needs. Educational efforts were also important to improve inspection and control techniques during growing and shipping.

CONTROL MEASURES: A TIME-LINE

Following identification of the outbreaks, FDA investigators and scientists traveled to Guatemala twice in 1996, in late summer and early fall, to gain a better understanding of the growth, harvest, and shipment of raspberries and to meet with the Guatemalan Berry Commission (GBC). The GBC is a grower organization composed of owners of raspberry, blackberry, and strawberry farms. Following these visits, representatives of FDA and the GBC remained in contact through frequent conference calls. The GBC also began developing a control plan for all of the raspberry exporters, which was implemented for the spring 1997 growing season. This plan included a farm classification system of low, medium, or high risk based on four factors: water quality, infrastructure (the use of drip irrigation, for example); use of a Hazard Analysis Critical Control Point (HACCP) system, Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and Sanitation Standard Operation Procedures (SSOPs); and maintenance of records. High-risk farms were not allowed to export product to the U.S. Medium-risk farms could export anytime except the spring season. Low-risk farms were allowed to export anytime during the year.

During the spring 1997 growing season, FDA scientists and investigators traveled to Guatemala to observe raspberry operations and perform analytical assessments for Cyclospora to determine possible sources of contamination. CDC and FDA also jointly funded a contract with a Guatemalan food technologist/agronomist to gather local data.

There were additional outbreaks in the spring of 1997, and Guatemala voluntarily halted the shipment of fresh raspberries to the U.S. for the remainder of the year. The reason for the additional outbreaks was not clear. Given the limited knowledge of Cyclospora, it is possible that the new practices did not address the true source of contamination, were ineffective, or were incompletely implemented.

In February of 1998, the GBC and the Guatemalan government presented a Model Plan of Excellence for the exportation of raspberries. The plan encompassed the growing, harvesting, and transport of raspberries as well as employee hygiene and worker health issues. The FDA, Health Canada, Canada Food Inspection Agency, and the Food Marketing Institute provided comments for revision of the plan. FDA did not allow the importation of Guatemalan raspberries from March 15 to August 15, 1998.

This decision was based on three factors:

1) discussions between FDA and CDC on the time-frame of the occurrence of the outbreaks in 1996 and 1997;
2) inability to determine the source of Cyclospora contamination and implement the appropriate corrective action; and
3) public health protection.

In the spring of 1999, FDA allowed the importation of raspberries only from farms participating in the Model Plan of Excellence. There were no outbreaks of cyclosporiasis attributed to the consumption of Guatemalan raspberries in 1999.

In the spring of 2000, FDA visited the farms and one exporter participating in the Model Plan of Excellence. FDA also audited the effectiveness of the Agricultural and Environmental Protection Program (PIPAA) in their oversight activities to assure that raspberry farms and exporters are operating in compliance with the Model Plan of Excellence. PIPAA monitors and certifies MPE program participants for the Guatemalan government to provide proof that the program satisfies food safety requirements. FDA allowed the exportation of Guatemalan raspberries from select farms to the U.S. from March 15 to August 15, 2000.

In the spring of 2001, FDA hired a contractor to evaluate the farms and exporters participating in the Model Plan of Excellence as well as audit the effectiveness of PIPAA. FDA allowed the exportation of Guatemalan raspberries from select farms to the U.S. from March 15 to August 15, 2001.

Research and consultation FDA sponsored a workshop in August 1996 to bring together researchers from U.S. and Canadian government agencies, select state health and agriculture departments and one university to discuss Cyclospora issues. A collaborative study was initiated with participants from FDA, CDC and the State of Florida to develop better analytical techniques for the detection of Cyclospora cayetanensis.

FDA held a public meeting on July 23, 1997 in Washington, DC to discuss the science of Cyclospora. Members of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) served on a panel to comment on
the following items: (1) the life cycle of the Cyclospora organism; (2) its prevalence in the environment: (3) treatment strategies and/or treatment combinations; (4) other prevention strategies; (5) detection methodologies; and (6) research priorities. The NACMCF stated that the scientific knowledge associated with C. cayetanensis was meager. There were many unanswered questions regarding its survival, persistence in the environment, secondary hosts, and seasonality. Research was needed in the following areas: survival studies, soil sampling and the role of insects and other invertebrates as possible vectors. Irradiation appeared to be the most effective intervention strategy at that time. Ozonation might offer some promise but a substantial amount of research needed to be done. Similarly, more data are required for freezing guidelines and useful time/temperature combinations. The committee also recommended the use of Good Agricultural Practices. The NACMCF also stated that water source and filtration were thought to be extremely important. General guidance to minimize the amount of fecal material entering into water supply would be prudent, e.g., the source of water for irrigating and spraying produce should not be downstream from sewage outlets; limit introduction of feral animals into the catchment area-- birds, insects; use irrigation technologies that do not spray water onto the food but go directly into the ground; and stress employee hygiene.

EDUCATION

Numerous visits were made by FDA investigators and scientists in order to understand the growing, harvesting, and shipment of raspberries. FDA scientists traveled to Guatemala to work with their scientists in order to train them in the analytical techniques necessary for the identification of Cyclospora. In 1998, the FDA published the "Guide to Minimize Microbial Contamination of Fresh Fruits and Vegetables." The guide is available in Spanish. This document was shared and discussed with the GBC and aspects of the document were incorporated into the MPE. Also in 1998, FDA provided training in water systems, sanitation and GMPs to PIPAA inspectors to support implementation of the MPE.

LESSONS LEARNED

The interaction of government, industry and academia is important to address emerging public health issues. Even in the presence of large uncertainties, collaboration among government agencies, industry, and academic experts can protect the public's health on an interim basis while targeted research begins to answer the most important questions. As new information becomes available, the collaborative framework facilitates the rapid integration of the new information into the evolving control effort.

INTENTIONAL CONTAMINATION OF FOODS

Response to food safety emergencies requires the ability to recognize unusual health events, to identify the cause with sufficient specificity to permit categorizing the agent, to investigate the possible sources of exposure sufficiently well to determine if food is a likely source of the agent, to refine the food exposure data sufficiently well to permit a reasonable reaction, and to effectively and quickly segregate potentially contaminated food to prevent its consumption. For food safety emergencies that involve well-recognized foodborne hazards in characteristic food vehicles (e.g., Salmonella in eggs, Campylobacter in poultry meat, Vibrio in seafood) a rapid effective response generally requires enhancing the public health and regulatory infrastructure and improving interagency interactions and government-industry-consumer cooperation and communications.

The same systems used for addressing unintentional foodborne disease will be used to identify and address intentional contamination of foods. However, when pathogens are used to intentionally contaminate foods, the necessary interagency coordination and cooperation will include police and other physical security agencies. The possibility of food bioterrorism adds complexity to the situation. Our ability to deter and respond of such threats will increase as we refine and adapt our food safety systems to address this new threat.

CONCLUSION

Effectively and efficiently assuring food safety in a global economy requires a high degree of communication, coordination, and cooperation within and between countries and reliance on existing food safety systems.