New Federal Policies and Programs for Food Safety

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The United States excels at producing an abundant supply of safe, nourishing, and affordable food. However, some recent well-publicized incidents, such as the contamination of hamburgers and apple juice with the *E. coli* O157:H7 bacterium and contamination of frozen, sugared strawberries with the hepatitis A virus, have led to increased public concern about the possibility of illnesses caused by foods.

The Government at all levels and the private sector share this concern. Currently, at the Federal level, regulatory authority over food safety is divided among several agencies. The Department of Agriculture's Food Safety and Inspection Service (FSIS) is responsible for inspecting domestic and imported livestock and poultry products, and egg products (such as pasteurized eggs). The Department of Health and Human Services' Food and Drug Administration (FDA) is responsible for other fresh and processed foods, including eggs, fresh produce, and imported foods other than meat and poultry. On a fee-for-service basis, the Department of Commerce's National Marine Fisheries Service (NMFS) may, at industry's request, conduct inspections of seafood harvesters and producers for quality; however, FDA has responsibility for seafood inspection. The Environmental Protection Agency (EPA) is responsible for regulating agricultural chemicals used in farm production and establishing tolerances for pesticides. FDA enforces those tolerances. FDA regulates drugs and feed additives used in food producing animals.

A New System for Inspecting Meat and Poultry

New rules governing meat and poultry inspection in the United States were published in 1996. The Pathogen Reduction/HACCP rule was implemented initially on January 26, 1998, in plants with more than 500 employees, which slaughter 75 percent of U.S. meat. Plants with 10 to 500 employees were to have HACCP plans in place by January 25, 1999. Very small establishments, with fewer than 10 employees or annual sales of less than $2.5 million, have until January 25, 2000.

Four essential elements define this new food safety system:

- All State and Federally inspected meat and poultry slaughter and processing plants must have a Hazard Analysis and Critical Control Points (HACCP) plan.
- Federally inspected meat and poultry plants must develop written sanitation standard operating procedures to show how they will meet daily sanitation requirements.
- FSIS will test for *Salmonella* on raw meat and poultry products to verify that pathogen-reduction standards for *Salmonella* are being met.
- Slaughter plants will test for generic *E. coli* (all types of *E. coli*) on carcasses to verify that the process prevents and removes fecal contamination.

HACCP Plans Identify and Reduce Hazards

USDA now requires that all meat and poultry plants develop HACCP plans to monitor and control production operations. Plants must first identify food safety hazards and

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critical control points in their particular production, processing, and marketing activities. In addition to biological hazards, such as disease-causing microorganisms (pathogens), food safety hazards include chemical and physical hazards, such as chemical residues and metal fragments that may cause a food to be unsafe for human consumption. A critical control point is a point, step, or procedure where controls can be used to prevent, reduce to an acceptable level, or eliminate food safety hazards.

As part of the HACCP plan, these plants then establish critical limits, or maximum or minimum levels, for each critical control point. For example, the plant may determine that water or steam used for cleaning carcasses must be maintained at a minimum temperature of 180 degrees Farenheit or higher. The plant monitors the critical control point to ensure that the critical limits are met. Each plant must list its procedures for monitoring the critical control points and the frequency of its monitoring activities. HACCP also includes steps for recordkeeping and verification, including some microbial testing of meat and poultry products to ensure that the system is meeting the target level of safety. Plants have responsibility to ensure the effectiveness of the HACCP system, although FSIS will perform verification activities.

Plants Must Write Sanitation Procedures and Test for Pathogens

The Pathogen Reduction/HACCP rule required all federally inspected meat and poultry plants to have developed written sanitation standard operating procedures (SOP's) by January 27, 1997, which state how they meet daily sanitation requirements. Sanitation SOP's are important in reducing pathogens on meat and poultry because unsanitary practices increase the likelihood of product contamination. Plants must document and maintain daily records of completed sanitation SOP's and any corrective and preventive actions taken. Plant managers must make these records available for USDA inspectors to review and verify.

FSIS testing for *Salmonella* on raw meat and poultry products verifies that plants are controlling pathogen levels. All plants that slaughter and grind meat and poultry must achieve at least the current baseline minimum level of *Salmonella* control for each type of product produced. One reason that *Salmonella* was selected to be tested as an indicator of all pathogens was because it was the most prominent cause of U.S. foodborne illnesses associated with livestock and poultry at the time the regulations were developed. New data indicate that infections caused by *Campylobacter* may now be more prevalent. Plants must meet the *Salmonella* standard on the same timetables as they meet the HACCP requirement.

Slaughter plants are required to test for generic *E. coli* on carcasses to verify that they are preventing and removing fecal contamination. Generic *E. coli* was selected because of the scientific consensus that it is an excellent indicator of fecal contamination, because the analysis is relatively easy and inexpensive to perform, and because levels of *E. coli* contamination can be quantified. Plants were required to begin *E. coli* testing on January 27, 1997, regardless of plant size. Plants were given an additional 6 months to gain experience in conducting these tests before FSIS personnel began reviewing the test results as part of their inspection routine.

E. coli contamination is not directly correlated with *Salmonella* contamination, which is affected by factors other than fecal contamination, including the health and condition of incoming animals. Therefore, *Salmonella* and *E. coli* testing complement one another and will help slaughter plants and FSIS inspectors ensure that plants are preventing and reducing fecal contamination of meat and poultry products.

Enforcement Strategies

If FSIS program employees find violations of the new Pathogen Reduction/HACCP rule, enforcement action will vary, depending on the seriousness of the problem. USDA's first concern will continue to be preventing potentially unsafe or adulterated product from reaching consumers, which could mean detaining a product at the plant or requesting that the company recall the product.

Minor violations of an establishment's HACCP plan and sanitation SOP's will be noted by FSIS program employees. A pattern of minor violations may result in intensified inspection to ensure that there is no systematic problem of noncompliance or underlying food safety concern.

For more serious violations involving adulterated or contaminated products, FSIS program employees can stop production lines until failures in HACCP and sanitation SOP's are corrected. Program employees can also identify specific equipment, production lines, or facilities that are causing the violations and remove them from use until sanitation or other problems are corrected.

Repeated or flagrant violations will result in other administrative, civil, or criminal sanctions, after due process. For example, improper maintenance or falsified records would have potentially serious

implications because accurate recordkeeping is essential to the proper functioning of sanitation and HACCP systems and to the production of safe foods. USDA will continually monitor and adjust its enforcement approach during the program transition to ensure that enforcement activities are effective, fair, and consistent.

Other Federal Food Safety Programs

In December 1995, the FDA announced a rule requiring seafood processors to adopt HACCP systems. Under the FDA rule, seafood processors are required to identify hazards that, without preventive controls, are reasonably likely to affect the safety of seafood products. If at least one such hazard can be identified, the firm is required to adopt and implement an appropriate HACCP plan. In addition to helping ensure that the food is free of contaminants, this process also helps manufacturers who subsequently have problems with their food determine how and when those problems could have occurred. Seafood processors using the HACCP system continue to be monitored under FDA surveillance and inspection programs. This rule was implemented in stages, with complete implementation effective in late 1997.

On January 25, 1997, President Clinton announced the National Food Safety Initiative, a multiagency effort to strengthen and improve food safety in the United States. The initiative included several new programs to promote food safety, including improved inspection systems and preventive measures, new tests to detect pathogens, a national education campaign for safer food handling in homes and retail outlets, and increased funding for food safety research and risk assessment activities.

The early-warning surveillance system called FoodNet was expanded in 1997 under the Food Safety Initiative to detect outbreaks of foodborne illnesses and to gather data necessary to prevent outbreaks. FoodNet is administered by the U.S. Centers for Disease Control and Prevention (CDC) (see "*Salmonella* Cost Estimate Updated Using FoodNet Data" elsewhere in this issue).

In 1998, FDA proposed new regulations requiring warning labels on all fruit juices not treated to eliminate illness-causing microorganisms. The agency also proposed that that producers of juices adopt HACCP systems to prevent microbial, chemical, and physical contamination (see "New Juice Regulations Underway" elsewhere in this issue).

The initiative calls for increased funding for FDA inspections, proposes implementation of food safety preventive systems such as HACCP, and establishes a national educational campaign to improve the use of safe food practices in homes and retail outlets. This education effort augments efforts at the farm and processing level to reduce risk of foodborne hazards; consumers and retailers are responsible for preparing and handling foods properly to prevent contamination.

The initiative also calls for research to develop new prevention techniques and tests to detect foodborne pathogens, to assess risks to the food supply, to improve response to foodborne illness outbreaks, and to improve coordination among the Federal agencies responsible for food safety.

Produce and Imported Foods Scrutinized

In the past few years, there have been some highly publicized cases of foodborne disease outbreaks linked to fruits and vegetables, in some cases linked to imported foods. Frozen, sugared strawberries contaminated with the hepatitis A virus were served in school lunches in several States. The source of contamination was never determined. Raspberries contaminated with the *Cyclospora* parasite thought to originate from Guatemala caused many illnesses in the eastern United States and Canada.

In response, the Administration announced the Produce and Imported Food Safety Initiative on October 2, 1997. This initiative aims to upgrade domestic food safety standards and to ensure foods, including fresh fruits and vegetables, coming from overseas are as safe as those produced in the United States. Key features of this initiative include:

- Enhanced FDA oversight for imported foods. Proposed legislation requires FDA to establish procedures to assure that foreign food systems meet the same level of protection as in the United States. Increased funding would expand FDA inspection and surveillance activities at home and abroad.
- Improved inspection activities abroad. In addition to committing more resources to FDA's international food inspection force, the initiative calls for increased efforts to assess agricultural and manufacturing processes abroad, identify gaps, and provide foreign countries with technical assistance to improve these practices when necessary.
- Guidance on good agricultural and manufacturing practices. FDA and USDA jointly developed recommendations for growers and producers on how to minimize the risk of microbial

contamination of fresh fruits and vegetables. This document is for guidance only and does not have the legal force of a regulation. The final version of this guidance document was published in late 1998 in the *Federal Register* for public comment. *Good Agricultural Practices Guidance* is available in several languages (English, Spanish, French, and Portuguese).

The steps the Federal Government is taking will help protect public health by improving the safety of the Nation's food supply. Ultimately, though, food safety is everyone's responsibility. Farmers, processors, and consumers must all do their part to ensure that our food supply is safe.

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