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**Defining the Responsibilities and Tasks of Different Stakeholders within the Framework of a
National Strategy**

(Prepared by the United States of America)

Background

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and on industry's legal responsibility to produce safe foods. Until the early 1900's, the regulation of food safety in the United States was primarily the responsibility of State and local officials. The Meat Inspection Act and the Pure Food and Drugs Act were both passed by the U.S. Congress in 1906, establishing the federal framework that has survived to this day. From their inception, these laws focused on different areas of the food supply, and they took different approaches to ensure food safety.

Discussion

Two federal agencies have primary statutory responsibility for assuring the safety of the U.S. food supply – the Food and Drug Administration, within the Department of Health and Human Services (HHS/FDA), and the Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA).

Other key federal agencies with a significant role in food safety include the

- Centers for Disease Control and Prevention (HHS/CDC);
- Environmental Protection Agency (EPA);
- Agricultural Research Service, USDA; and,
- Customs and Border Protection.

HHS/FDA is the federal agency that regulates 80% of the nation's food supply - everything except meat, poultry and certain egg products, which are regulated by FSIS. HHS/FDA and FSIS share responsibilities for egg safety. HHS/FDA has authority for shell eggs, and FSIS has authority for egg products. HHS/FDA is responsible for ensuring that food products under its jurisdiction are safe, sanitary, nutritious, wholesome, and adequately labeled. Its jurisdiction includes much more than food processing plants; it also includes live food animals, animal feed, approval and surveillance for new animal drugs, medicated feed, and all food additives (including coloring agents, preservatives, food packaging, sanitizers and boiler water additives) that can become part of food. HHS/FDA's responsibility also extends to ensuring that human drugs, human biological products, medical devices, and radiological products, as well as veterinary drugs, are safe and effective, and that cosmetics are safe.

HHS/CDC has an important complementary and non-regulatory public health role. As the lead federal agency for conducting disease surveillance, HHS/CDC monitors the occurrence of illness in the United States attributable to the food supply. The disease surveillance systems coordinated by HHS/CDC provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. These systems can be used to indicate new or changing patterns of foodborne illness. HHS/CDC also conducts surveillance for outbreaks of foodborne illness through its network of state and local public health departments and laboratories. Because HHS/CDC detects and assists in the investigation of outbreaks of foodborne illness through its networks, HHS/CDC is able to alert HHS/FDA, FSIS, local, state and other federal officials about implicated food products associated with foodborne illness. HHS/CDC works closely with the states and other federal agencies so they can take protective public health action.

EPA protects our water supply by setting drinking water standards under the Safe Drinking Water Act. It also regulates pesticide products used in the United States and establishes tolerances or maximum legally permissible residue levels for pesticides in all types of food and feed. The same food safety standards apply to pesticide residues in imported and domestically produced food and feed. If the food or feed contains residues for which no EPA tolerance exists (or which exceed an established tolerance), it may not legally be marketed in the United States even if the same pesticide is approved to be used for other types of food or feed. HHS/FDA and FSIS enforce the pesticide residue standards set by EPA for products under their respective jurisdictions.

The U.S. Bureau of Customs and Border Protection, now within the Department of Homeland Security is our nation's primary enforcement agency protecting the U.S. borders. They work closely with all federal partners to help keep unsafe food from entering the United States.

Food safety can only be effective if it has strong underpinnings in scientific research and risk assessment. The federal government has major capabilities to perform both basic and applied research related to food safety problems.

Together these federal agencies promote food safety and food security, and prevent food borne illness and food hazards through inspections, surveillance, enforcement, research and risk assessment, premarket approval of food and color additives, pesticides, and new animal drugs and, through establishing controls for safe processing.

To help achieve our food safety and security goals, we also establish partnerships and work cooperatively with State, local, and foreign governments; health professionals; academia; consumer groups; and the private sector. The federal government has a long history of reaching out to its State and local partners and has worked effectively with them utilizing a variety of mechanisms – cooperative agreements, contracts, grants, memoranda of understanding and partnerships. These partnerships include working extensively with state and local health departments to build their epidemiology, laboratory, and environmental health expertise in foodborne disease surveillance and outbreak response.

HHS/FDA, HHS/CDC, and FSIS has also work jointly with the states and other interested parties on the Food Code to provide a model ordinance to local, state, and Federal governmental bodies and tribal nations to ensure that the food provided by retail food establishments and institutions, such as nursing homes and child care centers, is not a vector of communicable diseases. The Model Food Code is updated every two years. It provides practical, science-based guidance to assist in mitigating risk factors known to cause foodborne illness. In 1999, the United States established an interagency Federal Food Safety Coalition to focus on food protection of high-risk populations. The group's objective is to promote the development of effective public health protection systems for

food safety within federal programs by using the Model Food Code, emphasizing foodborne illness interventions, and seeking to reduce the occurrence of the five leading illness risk factors.

Conclusion

The U.S. food supply is protected and managed by a comprehensive system of agencies at the local, state, and national level. Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The system is guided by the following principles: (1) only safe and wholesome foods may be marketed; (2) regulatory decision-making in food safety is science-based; (3) the government has enforcement responsibility; (4) manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and (5) the regulatory process is transparent and accessible to the public. As a result, the U.S. system has a high level of public confidence.

U.S. food agencies are accountable to the President, to the Congress which has oversight authority, to the courts which review regulations and enforcement actions, and to the public, which regularly exercises its right to participate in the development of statutes and regulations by communicating with legislators, commenting on proposed regulations, and speaking out publicly on food safety issues. Fulfillment of these different responsibilities results in a system that provides consumers the assurance that the food they eat is safe.