REGO - SINGLE FOOD SAFETY AGENCY

HHS 03: DEVELOP A NATIONAL, UNIFORM, SCIENTIFIC, RISK-BASED INSPECTION SYSTEM TO ENSURE A SAFE FOOD SUPPLY

Background

The Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) estimates that at least 9,000 Americans die from food-borne illness each year; another 6.5 million become sick from eating contaminated foods.[1] Because many of these cases go undiagnosed, the actual figure is probably much higher than the conservative estimate of 6.5 million. An estimate by the Food and Drug Administration (FDA) is in fact much higher, at a minimum of 24 million cases per year.[2]

Most cases of foodborne illness reported in the U.S. today can be traced to meat, poultry, eggs, milk and shellfish.[3] Shellfish alone caused 21 percent of all reported food poisonings arising from meat, fish, or poultry between 1978 and 1987.[4] Foods can be contaminated with harmful microorganisms (such as bacteria, viruses, and fungi); parasites (such as tapeworms, roundworms, and flukes); chemicals (such as pesticides, animal drugs, flavor and color additives, or industrial chemicals); and natural poisons (such as the toxins in some shellfish). Since 1985, the U.S. has witnessed significant and highly publicized outbreaks of foodborne illness caused by highly pathogenic bacteria, including cheese contaminated with Listeria, milk and cantaloupe contaminated with Salmonella, canned mushrooms contaminated with Staphylococcus, and hamburger contaminated with E. coli O157:H7. In addition to these acute outbreaks, chemical contamination of foods with animal drugs and pesticide residues may contribute to unknown increases in cases of cancer and birth defects.

Some increases in foodborne illness may be attributable to improved detection and reporting methodologies. Others seem to be an outgrowth of modern food processing techniques, and changing consumer habits.

Much of what Americans eat today is processed at centralized facilities geared to high-speed mass production, rather than in local shops and in the home. More food is transported across the country and imported from other countries.

In 1993, few consumers stay home and spend hours preparing food, but instead eat

on the run. They buy from carry-outs, eat at fast-food chains, and cook in microwave ovens. Much more of our food is bought pre-prepared and pre-cooked.

Finally, consumers themselves are physiologically different than they were in the early 1900s, when most of our current food safety laws were written. The "baby boomers" are dominating an aging U.S. population. Lowered immunity is a natural part of the aging process, increasing susceptibility to various infectious diseases, including foodborne illness.[5] Due to modern medicine, today's consumers are living longer and are more likely to live with chronic illnesses, such as cancer and Acquired Immunodeficiency Syndrome (AIDS) that also increase susceptibility to foodborne illness. Some foodborne bacteria, including Salmonella, have been associated with chronic diseases such as arthritis.[6] The parasite Toxoplasma gondii has been shown to cause dementia in individuals with compromised immune systems; more than half all cases of dementia occurring in AIDS patients may be of foodborne origin.[7]

The prevention and control of foodborne illness is of great economic importance. Such outbreaks are expensive, not only for those who become ill, but for society at large. An April 1985 *Journal of Food Protection* article estimated that foodborne illnesses cost the U.S. between $1 to $10 billion annually. This figure includes direct medical costs, lost wages and productivity, and industry losses through embargoes, voluntary destruction and recall. The article stated that "Any money spent on research, surveillance and public education would be only a small fraction of the cost otherwise borne by the economy when disease occurs...In most instances food supplier losses in the form of recalls, lost business, legal fees, legal settlements and wages exceeded the medical costs and lost earnings of the victims, thus the indirect cost to the economy may equal or even double the patient-related cost estimates."[8] Several recent studies have reached similar conclusions.

The *New England Journal of Medicine* of August 1978 published a CDC study on the impact of one foodborne disease--salmonellosis. The study showed that "Salmonellosis is much more than an inconvenience--it is responsible for complications, operations and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly." The study also stated that "...the cost of public health programs to detect, control, and prevent salmonellosis must be measured against the unnecessary

medical expenses and loss-of-productivity costs, which may be *more than a billion dollars a year*. [emphasis ours]"[9]

The present food safety and inspection system has not kept up with the changing environment. It is a complex regulatory system consisting of as many as 35 different laws and involving 12 federal agencies. Of these agencies, five have primary responsibility for food safety inspections. The FDA is responsible for the safety of most foods. Within the U.S. Department of Agriculture (USDA), the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety of meat and poultry products; the Agriculture Marketing Service (AMS) for ensuring eggs and egg products; and the Federal Grain Inspection Service (FGIS) for the exported grain products. The Department of Commerce's National Marine Fisheries Service (NMFS) is primarily responsible for grading seafood products, but also provides voluntary food safety inspections at the request of the seafood industries. The FDA and the FSIS are responsible for about 95 percent of all food inspections mandated by law.[10]

However, inconsistencies among these agencies' policies, procedures and enforcement authority weaken the system's effectiveness. Frequently, when a food processing plant is inspected, the actions taken to enforce regulatory standards for safety are determined by the legislation that governs the inspecting agency, *not* the relative risk the products in question pose to public safety. An optimal inspection system is one with different levels of intensity of inspection, reflecting the degree of public health risk at various stages in the processing of foods. It has a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system does not meet these criteria. Different regulatory approaches, jurisdictional conflicts among agencies, and a persistent inability to allocate resources across agencies efficiently all have hampered the federal government's inspection efforts.[11] Viewed in its entirety, the existing regulatory structure is inefficient, cumbersome, and costly.

The U.S. needs a scientific, risk-based system. FSIS inspectors continue to inspect using a method developed in the early 1900s, when the Federal Meat Inspection Act, the Poultry Products Inspection Act, and other food safety statutes were enacted. This method,

called "organoleptic inspection," simply means using the five senses to determine product wholesomeness. Such inspections are a critical step in the elimination of dead, dying, diseased, disabled, visibly contaminated, and otherwise unwholesome meat and poultry products from the food supply. For example, in 1989, organoleptic inspections eliminated about 70 million head of poultry, 140,000 cattle, and 181,000 pigs from the food chain.

However, public health experts now realize that the most serious outbreaks of foodborne illness in this decade are due to pathogenic microorganisms *that may not be detected by the five senses during inspection.* These experts are also concerned with potential risks from chemical residues--again, hazards that cannot be detected by organoleptic inspection alone. Scientific inspections, including chemical and microbiological testing or other appropriate verification steps, must be developed and implemented if regulatory agencies are to be successful in reducing foodborne illness. Rapid, on-site microbiological and chemical diagnostic tests are needed to keep pace with the daily food production volume. Process control must be a priority to prevent product contamination and ensure a safe product.

FDA's enforcement strategy, which is grounded in the Food, Drug, and Cosmetic Act, emphasizes end-product testing. Periodic inspections provide only a snapshot of what is happening in a facility at the time of inspection. There is no way to tell whether the conditions observed at the time represent a norm. Given the agency's current resources and level of sampling, this strategy simply cannot adequately cover the expanding universe of food products and manufacturers. Again, process control must be a priority to ensure a safe product.

Viable models exist for effective process control. In 1971, the National Aeronautics and Space Administration (NASA), the U.S. Army Natrick Laboratories, and the Pillsbury Company developed the Hazard Analysis Critical Control Point (HACCP) approach to process control for the production of food products. The program was intended to ensure that products produced by Pillsbury for use by astronauts were wholesome and essentially pathogen-free. Pillsbury demonstrated that adequate controls in the manufacturing process could produce a high degree of assurance that the end-products would be safe.

In 1985, a National Academy of Sciences Committee on the Scientific Basis of the

Nation's Meat and Poultry Inspection Program and the National Academy of Sciences Subcommittee on Microbiological Criteria of the Committee on Food Protection embraced the HACCP concept as an effective and efficient approach to manufacturing safer food products. FDA has successfully applied HACCP principles in controlling the safety of low-acid canned foods.[12]

HACCP principles are defined differently by different users, making it imperative that a clear and consistent definition be understood by the food industry. If regulatory agencies encourage HACCP implementation by food manufacturers, each manufacturer could develop its own specific HACCP plan for each category of products it produces. HACCP would allow the industry to take responsibility for identifying and controlling public health hazards under their control.

It is not enough, however, to simply implement a system such as HACCP. It is *not* a regulatory program; HACCP only assists the industry in taking responsibility for a safer product.

An *optimal* inspection system provides varying levels of inspection that reflect the degree of public health risk present at each of the various stages in the process. Such a system would include a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system clearly does not meet these criteria; neither does HACCP. HACCP only addresses process control, concentrating on critical control points in the process that pose potential public health risks. It does not provide a reliable monitoring system or an accurate compliance history of food establishments.

The current U.S. food safety inspection system also is inconsistent in its intensity and frequency of inspection for foods posing similar risks. FDA inspectors responsible for inspecting the nation's food supply are also responsible for inspecting firms that produce medical devices, drug manufacturing facilities, and blood banks. Due to limited resources, these medical-support firms usually are assigned a higher priority than food processing plants producing high-risk foods (low-acid canned foods and infant formulas).

Although FDA attempts to assign a risk priority to foods by categorizing them as "high" or "low" risk, the assignment of inspection frequency is inconsistent and is not based

on risk analysis principles. Instead, frequency is usually based on the availability of resources. Availability is often controlled by the existence of a perceived "crisis" in the drug or medical device industry or in the nation's blood supply. Such crises usually demand that FDA concentrate its limited resources on the crisis issue and reduce its inspection of food manufacturing firms.[13] A recent GAO report indicated that, on average, FDA inspects food establishments only once every three to five years.[14]

The Federal Meat Act of 1907 and the Poultry Products Inspection Act of 1957 require the Department of Agriculture to provide continuous inspections at slaughter establishments, examining every carcass. The acts also require that inspectors visit meat and poultry processing plants on a daily basis. These laws are inflexible and do not allow FSIS to vary its frequency of inspections to concentrate its resources on risk and issues significant to the public's health, as recommended in the National Academy of Sciences report of 1985.[15]

GAO Report RCED-92-152 states, "...in fiscal year 1991, FSIS devoted about 9,000 staff years to oversee about 6,100 establishments, while FDA devoted about 255 staff years to oversee an estimated 53,000 food establishments."[16] (This statement referred to the inspection of domestic food establishments and did not include import inspections.) The two agencies also have different approaches for foods posing similar risks. For example, beef broth is inspected daily by FSIS, while plants manufacturing chicken broth may be inspected by FDA once every *three to five years*. Meat and poultry products are inspected daily by FSIS, while shellfish are normally inspected by a small number of state inspectors. These are only a few examples of inconsistencies in the present system.

As already indicated in this paper, most authorities believe that the frequency and intensity of inspection should be based on *risk*. Risk should be determined by a form of risk analysis that takes into account hazards associated with the food product, the process by which it is manufactured, and the compliance history of the establishment producing the product.[17] This could allow federal agencies responsible for food safety inspections to use their resources more efficiently.

The food safety inspection system also suffers from inconsistent enforcement authority. FDA lacks the necessary enforcement power to ensure a safe food supply. FDA

must prove actual or potential product contamination or establish that conditions are unsanitary. Most FDA findings of adulteration or unsanitary conditions or practices are resolved through voluntary compliance. FDA does not have direct authority to detain adulterated food products; its inspectors must take control of suspect products through federal court warrants, often a lengthy process. While an inspector is obtaining the warrant, the product may end up in the marketplace, unless the state uses its authority to seize or detain the product. FDA also lacks the authority to recall adulterated products from market and access company safety and quality-control records.[18]

FDA lacks a mandatory registration requirement. Establishments that are not identified by the agency go uninspected. FSIS, by contrast, requires the industry to prove safety before food products can be marketed. It possesses many authorities that FDA lacks, but cannot seize or prevent the shipment of known infected animals to market for slaughter.

The current food safety inspection system provides little incentive for food establishments to exceed minimum requirements. There should be a system of incentives for companies to regularly *exceed* standards for wholesomeness. These incentives may be positive or negative. A negative incentive would be an increased inspection cost for less than desirable compliance.

Food safety research is also duplicative and driven by the varying missions of some 21 agencies. A January 1993 report by the Committee on Food, Agricultural, and Forestry Research of the Federal Coordinating Council for Science, Engineering, and Technology reports that these agencies spend approximately $200 million on food safety research under about 50 laws that directly or indirectly authorize such research. This research may be basic or applied, laboratory based or social studies research. It may be broadly or specifically focused and carried out in federal laboratories, through contracts, cooperative programs, or grants to academia and the private sector. The areas of research include infectious disease agents and their toxins, drug and pesticide residues, food additives, environmental and industrial contaminants, food product processing, storage and packaging, diet and nutrition, and food production. Each area may address improved methods to identify hazards, prevention and control, mechanisms of action, risk assessment and risk management methods, or consumer behavior studies.[19]

The U.S. needs coordinated efforts for food safety research, driven by a single mission and accountable to a single authority. This would eliminate the duplication of expensive research projects and provide effective communications and information sharing among researchers.

The food safety inspection system also maintains overlapping and duplicative inspections. Inspection efforts are poorly coordinated. Coordination agreements under which agencies are required to notify other responsible agencies of plant problems or deficiencies found during inspection do not always work; a recent GAO report states such notifications do not always take place, and that problems referred to a responsible agency are not always promptly investigated.[20] The use of interagency agreements has been hindered by a lack of resources to follow up on referrals.

Recommendation

Create a single food safety agency responsible for administering a uniform set of scientifically based food safety laws.

The President and Congress should establish a single food-safety agency within FDA responsible for food safety inspections and research. Authority for enforcing all federal food inspection laws and regulations, and all personnel, facilities and equipment currently used by such programs, should be transferred to the new agency. (See Table HHS03-1 for a list of food safety functions that should be transferred to this new agency). The ideal location of the new agency should be such that congressional committees responsible for the appropriation of its funds are unlikely to be those with a special interest in promoting the inspected industries.

Current laws regulating federal food inspection should be reviewed immediately to identify areas in which changes in the laws are needed to base food inspections on sound science. The new agency also should begin a review of current regulations governing federal food inspection for the purpose of producing uniform regulatory requirements, taking into consideration inherent risk in products and production methods, and the unique nature of the foods and the industries that produce them.

An immediate study should be made by the new agency of current staff and

resources and the policies governing their use, and the information obtained is to be used to construct a new organizational structure, a management system, inspection procedures, and research program capable of meeting public health based objectives.

This new food safety agency must serve as a reinvention model. Its primary mission must be consumer protection and food safety. It will be customer-driven, meeting consumer needs within the boundaries of sound science. Consistent prevention of foodborne illness and poor sanitation and manufacturing practices will replace crisis management. There will be in place a management system for continuous improvement, concentrating on the continuous reduction of risks of foodborne illness. This will include continuous evaluation and reduction in the numerical regulatory standards for sanitation, microorganisms, and residues that assist in reducing risks. Empowering the front line food inspector and eliminating cumbersome layering and complicated chain-of-commands will simplify decision making in the field and improve regulatory effectiveness.

The new agency should be given the authority to impose user fees for appropriate services, to aid in the cost of improving inspection processes. User fees should be considered for food establishments that require additional inspections and enforcement efforts due to repeated noncompliance. Laboratory testing conducted to release detained or recalled products in cases of known or potential contamination could be subjected to a user fee, as could other testing outside of normal monitoring or surveillance sampling. User fees also should be considered for overtime, additional shifts requiring inspection oversight, inspection of imported food products, certification of exported food products, agency responses to FOIA (Freedom of Information Act) requests, and other special services as appropriate.

The single food safety agency would eliminate the need for interagency agreements coordinating inspection activities between agencies, as well as duplicative inspections in establishments with similar products under the authority of different agencies.

The food safety agency should meet the following criteria:

(1) ***The new agency should provide a scientifically sound, risk-based inspection system.*** The agency must have an adequate foodborne disease outbreak reporting system. This system will provide the data needed to determine risks associated with different types

of food products. This will be an integral part of the foundation of a scientifically based food safety inspection system.

HACCP or an equivalent system could be another important component of a scientific risk-based inspection system, placing responsibility for safe products on the food industry. Each food processing firm would be encouraged to have a HACCP plan for each category of food products it produces. Appropriate verification testing would be an integral part of each HACCP program.

(2) ***The agency would have an automated reporting system to aid in determining inspection frequencies.*** An automated reporting system can assist in identifying food establishments that are consistently out of compliance with federal regulations. This system could be adjusted to determine inspection frequency for each establishment based on the type of product manufactured, its inherent safety risks and the compliance history of the manufacturer. High-risk food establishments with poor compliance histories could be inspected more often than those that produce low-risk foods and maintain good compliance histories. The automated system could assist in establishing user fees for establishments requiring additional oversight.

(3) ***New food safety laws should provide for uniform regulatory action and give inspectors sufficient enforcement authority. Incentives should be used to encourage companies to consistently exceed minimum requirements.*** The new agency should have authority over *all* food products, including meat, poultry, milk, eggs, fish, shellfish, fruits, vegetables, grain products, bottled water, beverages, and any other item eaten by humans.

Food safety inspectors should be given enforcement authority to seize, detain, or embargo suspected contaminated or adulterated products or food ingredients; order recalls of potentially unsafe products in the market place; and have access to industry quality control, food safety, and shipping records. Authority also should be granted to require the registration of all food establishments.

The law also should give the agency adequate criminal prosecution authority, authority to impose civil penalties, and to terminate operations when appropriate. Authority should be granted to control hazards from the farm (or production environment) to the marketplace. For meat and poultry products in particular, an adequate trace-back system

from the farm to the consumer should be put into place, with full authority to take corrective action at any point in the process. Authority also should be granted to destroy imported products known to be public health hazards.

(4) ***The new agency should administer all food safety research functions.*** All food safety research should be mission-driven and have a "protected budget"—a separate and independent line item. New food safety legislation should allow for in-house research capabilities and contracts with the best available scientists. All data and results should be published and made available to the scientific community on a competitive basis.

Research should strive to improve the scientific validity, applicability, and efficiency of inspection procedures, control measures, and risk assessment methodologies. Studies examining the cost-effectiveness of various hazard control options should be conducted as part of the agency's continuous improvement process.

Implications

The creation of a single food safety agency will provide enforcement of uniform, scientifically based inspection laws, eliminate unnecessary regulations and allow for more efficient use of inspection resources. It will also eliminate a complex bureaucracy that often interferes with effective health-based decision making.

A uniform set of food safety laws could be administered by the present food safety agencies. This option would eliminate the inconsistent treatment of food products posing similar health risks. However, it would *not* address the issue of overlapping and duplicative inspections without requiring additional interagency agreements and the resources necessary to keep these agreements updated and effective.

A single food safety agency would allow inspection resources to be appropriately distributed to areas of highest risk. A uniform set of food safety laws administered by the present agencies would not allow for this efficiency, for it would be impractical to move inspectors from FSIS and place them in FDA, for instance, to meet the requirements of a uniform risk-based inspection system. Moreover, multiple agencies would continue to operate under separate appropriations. Any savings incurred by one agency could not easily be redirected to another agency that needed them. Duplicative administrative

functions and management positions would continue; many cost-cutting opportunities inherent in a single food safety agency would be missed.

Fiscal Impact

All funds appropriated for current food safety activities would be transferred into FDA. Savings associated with this consolidation might include those from consolidating FDA and FSIS field offices and inspection activities, administrative activities such as personnel offices and activities, resource management and duplicative management positions.

Additional costs would arise in creating the new agency and retraining field inspectors who now may perform different food safety tasks. Specific savings or additional costs cannot be determined at this time; this report assumes that the savings and additional costs will balance, with a neutral budget impact.

The present total budget authority for fiscal years 1995 through 1999 for the FDA and the USDA (FSIS and the food safety components of AMS) are shown in the following fiscal impact table:

TABLE HHS03-1
FISCAL IMPACT TABLE
In Millions of Dollars

	1995	1996	1997	1998	1999
Budget Authority -	$817	$824	$840	$849	$853
Outlay -	$0	$0	$0	$0	$0
Revenues	$0	$0	$0	$0	$0
Change in FTEs					

The new agency also may include food safety inspection or research components of agencies not included in this table, such as the NMFS, Department of Commerce, or the food safety residue component of the EPA.

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April 2, 1997

Ms. Elizabeth Drye
Chief of Staff
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222 Old Executive Office Building
Washington, D. C. 20500

Dear Elizabeth:

Enclosed is a reprint of the article I was working on late last year. It is not substantially changed from the draft you saw earlier, but it does explicitly reference the President's food safety initiative and encourages serious participation in the strategic planning process by all constituents of the federal food safety program. I hope it is helpful.

Jerry is keeping me up on your efforts. Sounds like a very good process. I know it is not easy!

With best regards,

Sincerely yours,

Michael R. Taylor

MRT/pw
Enclosure

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RESOURCES
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RFF NEWS

FOR IMMEDIATE RELEASE
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U.S. FOOD SAFETY SYSTEM NEEDS GREATER GOVERNMENT-INDUSTRY COLLABORATION TO MEET CHALLENGES IN THE 21ST CENTURY

WASHINGTON, DC -- The federal government has made substantial progress recently to improve America's food safety system by adopting a new regulatory framework that focuses on prevention and clearly defines the roles industry and government must play. But reform of the system must go further and assign responsibilities more clearly, make better use of scarce resources, and prepare for future challenges, including those posed by persistent foodborne illnesses and the globalization of the food economy, according to an article published in the new *Food and Drug Law Journal.*

The article, titled *"Preparing America's Food Safety System for the 21st Century: Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?"* appears in the Journal's current issue (Volume 52, Issue 1). It is authored by **Michael R. Taylor**, who served from 1994-96 as both the Acting Under Secretary for Food Safety at the United States Department of Agriculture (USDA), and administrator for its Food Safety and Inspection Service (FSIS). He is now a visiting scholar in the Center for Risk Management at Resources for the Future (RFF).

"There really are two food safety systems in the U.S.," says Taylor. "One for meat and poultry, administered by USDA, and one for seafood and all other components of the food supply, administered primarily by the Food and Drug Administration (FDA). Certainly, the current system is not the one anyone would design if starting with a clean state."

In his article, Taylor argues that the organizational and statutory fragmentation of the current system for food safety -- which includes twelve Federal agencies working under thirty-five statutes -- hinders the best use of resources; complicates adoption of consistent, risk-based food safety strategies; and is at odds with the clear assignment of responsiblity and accountability for food safety. Further, food safety research is conducted by 21 Federal agencies. Although more than $200 million is spent annually on research activities, Taylor notes that there is no formal coordinating mechanism and government-wide food safety research strategy.

However, the regulatory changes recently adopted by FDA and USDA are cause for optimism, says Taylor, because they establish a sound conceptual framework for the future. Called the Hazard Analysis and Critical Control Points (HACCP) system, this new approach

- over -

targets significant risks, minimizes costly command-and-control regulation in favor of performance-based standards, and focuses the food industry and government on what each does best. It aims to systematically prevent food safety problems by clearly defining the food's industry's responsibility -- and respecting its capacity -- to produce safe food, and gives government agencies the modern, scientific tools they need to verify the success of the industry's efforts.

In his article, Taylor outlines successes and progress made in food safety in recent years through industry and government collaboration; describes the traditional (and often overlapping) roles and responsibilities for food safety at FDA and USDA; and highlights the differences in day-to-day responsibilities and implementation as well as the strengths and weaknesses of each.

Taylor concludes by identifying some of the key issues that still need to be resolved to meet the food safety-related challenges of the next century. These challenges include: further reducing the risk of foodborne illnesses; successfully managing the introduction of new food technologies; overseeing and facilitating international trade; and maintaining public confidence in the food supply. To meet these challenges, Taylor urges expanded collaboration between industry and government, better coordination within government, and improvement in such areas as epidemiological surveillance of foodborne illness, food safety research, technology development, and food safety education for consumers and commercial food handlers.

Taylor notes that the food safety initiative announced by President Clinton in January 1997 as part of his budget proposal for the next fiscal year is intended to address many of these needs. The initiative, says Taylor, provides a golden opportunity for a national discussion by the food industry, the consumer community and the government about the future of the nation's food safety system.

"The adoption of HACCP is an important step forward in food safety," says Taylor. "But it is only a first step. To satisfy the public's food safety expectations and realize the food industry's full potential in the global food economy, we must work to resolve what we want our food safety system to do for us in the next century, who will be responsible for what, and how we are going to pay for it."

# # #

In addition to his appointment at RFF, Michael Taylor is a partner at the law firm of King & Spalding. Under Taylor's leadership at USDA, the agency adopted the HAACP system for meat and poultry inspection; established the first performance standards for reducing harmful bacteria in raw meat and poultry; began the elimination of outdated, command-and-control regulation; and realigned and streamlined FSIS management structures to carry out the new food safety system. Before joining USDA, Taylor served for three years as deputy commissioner for policy at FDA where he oversaw the agency's policy development activities and the processing of all regulations.

# # #

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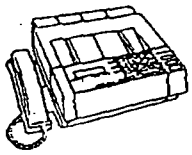

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1) Table on p. 4/6 - basis of #'s

2) Discussion of Archer - p. 44 in footnote.

Foodborne Pathogens: Risks and Consequences

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Council for Agricultural Science and Technology

5 Risk Characterization: Estimated Numbers of Illnesses and Deaths

The estimated number of acute foodborne disease cases occurring in the United States is determined with difficulty, and various estimates exist. Comprehensive estimates of the number of human illnesses caused by many foodborne microorganisms are unavailable; those that are available frequently provoke controversy. This chapter identifies and evaluates selected data sources containing foodborne disease estimates. Plausible estimates from the literature regarding number of U.S. cases of acute illness caused by specific foodborne microorganisms are summarized. The general consensus of the CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually. Chronic disease sequelae as a result of exposure to foodborne pathogens are less well understood, and estimates have been attempted for only a few chronic foodborne disease sequelae.

Sources of Data on Acute Foodborne Illnesses

Data sources include (1) foodborne disease reports collected by the CDC[1] under its various programs, (2) national hospital databases or health surveys in which intestinal diseases are reported, (3) risk models based on infectious doses and on pathogens' prevalence in foods, and (4) experts' extrapolations to estimate number of foodborne disease cases and distribution of disease severities.

[1]The CDC was established in 1973 as an operating health agency within the Public Health Service and is composed of 10 major operating components. It is the federal agency charged with protecting the public health of the nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions and by responding to public health emergencies. In 1993, the name was changed to the Centers for Disease Control and Prevention.

CDC Foodborne Outbreak Data

The CDC outbreak data rely on reports from state and local health departments that have received information from two or more[2] individuals experiencing a similar illness, have conducted an investigation identifying food as the common source, and have notified the CDC (Figure 5.1). A great variety of diseases are reported including some, such as ciguatera and scombroid poisoning, that are diagnosed without laboratory testing (Table 5.1). Because tests for the most common foodborne disease pathogens are the most likely to be ordered, reports contain information primarily on these microorganisms; in theory, however, outbreaks caused by any pathogenic microorganisms should be reported. Reports also are limited by the ability of state and local health departments to follow up leads and to report investigations to the CDC. Typically, budget constraints impede thorough investigation, and outbreaks involving restaurants or institutions are more likely to be recognized than those involving homes or processed foods. This difference exists because of the greater numbers of individuals served by a commercial kitchen at any one mealtime and perhaps also because of the health department's responsibility to protect consumers from commercial sources and processed foods.

Data differ widely by state and reflect, for the most part, the vigilance of health departments and their priorities for food safety (Bartelson, 1987; Chalker and Blaser, 1988). The Council of State and Territorial Epidemiologists pointed out that final decisions regarding foodborne disease surveillance are made by each state and that 12 of the states have no surveillance staff specifically assigned to monitoring food associated or waterborne pathogens; in other words, outbreaks will not be reported routinely from these states (Berkelman et al., 1994). Typically, 400 to 500 foodborne outbreaks are reported annually to the CDC, with an average of about 40 cases per outbreak, for an average of about 18,000 foodborne disease cases

[2]For botulism, toxic fish, mushroom, and certain chemical poisonings, one case constitutes an outbreak.

annually (Table 5.1).

CDC Laboratory-Based Surveillance Data

The CDC laboratory-based surveillance data are reported by state laboratories identifying microorganisms as causes of human illness. The CDC has laboratory-based surveillance systems for a number of foodborne[3] diseases: botulism, campylobacteriosis, cholera, hepatitis A, listeriosis, salmonellosis, shigellosis, trichinosis, and typhoid fever. Around 44,000 nontyphoidal salmonellosis cases[4], 20,000 shigellosis cases, and 10,000 campylobacteriosis cases are reported annually to the CDC (Bean and Griffin, 1990). The

[3]These data do not show the percentage of foodborne cases (except for trichinosis, which always is foodborne). Typhoid fever, nontyphi salmonellosis, cholera, hepatitis A, and shigellosis can be transmitted by water and by person-to-person spread (fecal-oral), as well as by food. Infant botulism may be soil/dustborne. Salmonellosis has been transmitted through the hospital environment. Hence, all such laboratory data cannot be judged as exclusively foodborne.

[4]Some positive laboratory tests, especially those for *Salmonella* serovars and *Shigella* spp., are for carriers of the disease, not for actual cases of illness.

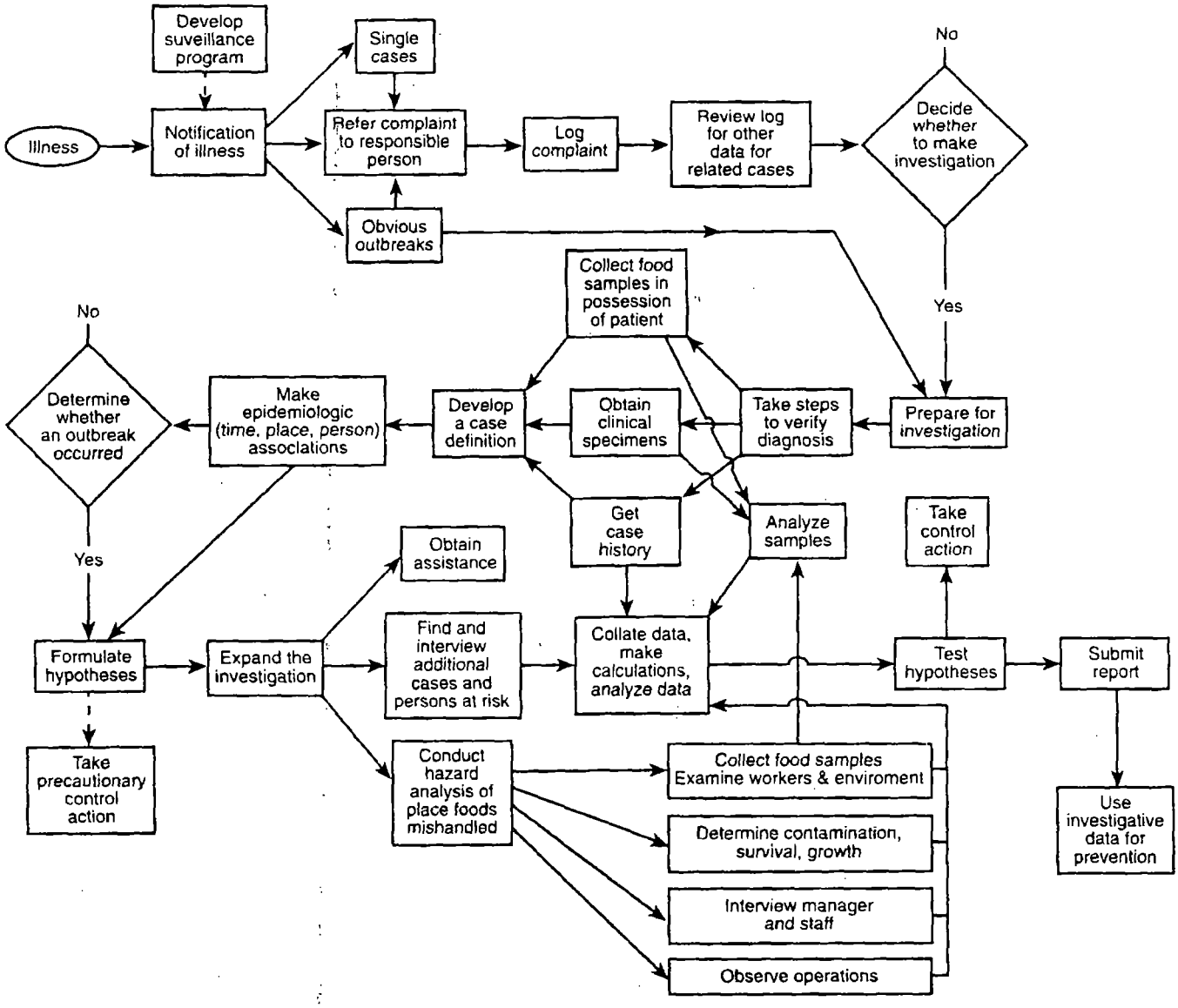

Figure 5.1. Sequential events in investigating a typical outbreak of foodborne illness (Bryan et al., 1987).

Table 5.1. Annual average numbers of foodborne disease outbreaks, cases, and deaths, by etiologic agent reported to CDC[a]

	Outbreaks[b]		Cases		Deaths	
Etiologic agent	Number	%	Number	%	Number	%
Bacterial						
Bacillus cereus	3.2	1.8	52	0.5	0.0	0.0
Brucella	0.4	0.2	8	0.1	0.2	0.7
Campylobacter	5.6	3.1	145	1.3	0.2	0.7
Clostridium botulinum	14.8	8.1	28	0.3	2.0	7.3
Clostridium perfringens	4.8	2.6	549	4.9	0.4	1.5
Escherichia coli	1.4	0.8	128	1.2	0.8	2.9
Salmonella	68.4	37.6	6,249	56.3	7.8	28.5
Shigella	8.8	4.8	1,994	18.0	0.6	2.2
Staphylococcus aureus	9.4	5.2	636	5.7	0.0	0.0
Streptococcus, Group A	1.4	0.8	200	1.8	0.0	0.0
Streptococcus, other	0.4	0.2	17	0.2	0.6	2.2
Vibrio cholerae	0.2	0.1	0	0.0	0.0	0.0
Vibrio parahaemolyticus	0.6	0.3	2	0.0	0.0	0.0
Other bacterial	0.6	0.3	52	0.5	14.0	51.1
Total	120.0	66.0	10,061	90.6	26.4	96.4
Chemical						
Ciguatoxin	17.2	9.5	66	0.6	0.0	0.0
Heavy metals	2.6	1.4	35	0.3	0.0	0.0
Monosodium glutamate	0.4	0.2	1	0.0	0.0	0.0
Mushroom poisoning	2.8	1.5	10	0.1	0.4	1.5
Scombrotoxin	16.6	9.1	61	0.6	0.0	0.0
Paralytic shellfish poisoning	0.4	0.2	1	0.0	0.0	0.0
Other chemical	6.2	3.4	74	0.7	0.2	0.7
Total	46.4	25.5	249	2.2	0.6	2.2
Parasitic						
Giardia lamblia	0.6	0.3	8	0.1	0.0	0.0
Trichinella spiralis	6.6	3.6	32	0.3	0.2	0.7
Total	7.2	4.0	41	0.4	0.2	0.7
Viral						
Hepatitis A virus	5.8	3.2	213	1.9	0.2	0.7
Norwalk virus	2.0	1.1	233	2.1	0.0	0.0
Other viral	0.4	0.2	112	1.0	0.0	0.0
Total	8.2	4.5	558	5.0	0.2	0.7
Confirmed agent	182.0	100.0	11,108	100.0	27.4	100.0
Unknown agent	290.0	NA[c]	7,228	NA	NA	NA
Total	480.0	NA	18,336	NA	27.4	NA

[a]The published numbers that were comprehensive for the 5-year period, 1983–1987, are presented here as one-year averages.
[b]Outbreak is two or more cases except for botulism and chemical cases.
[c]NA = not applicable.
Sources: Bean and Griffin, 1990; Bean et al., 1990a, 1990b.

laboratory-based surveillance data also are likely to be nationally representative of patients ill enough to seek medical attention although the distribution of illness severities will be unknown without additional survey efforts. Some states report more complete results to the CDC than do others. This difference is largely a function of funding provided by states to their health departments.

CDC Sentinel County Studies

Sentinel county studies sometimes are undertaken by the CDC for a specific pathogen. These investigations typically have a specific goal such as identifying the number of foodborne disease cases caused by a pathogen, e.g., *Listeria monocytogenes*, identifying virulence mechanisms, discovering potential food vehicles, or identifying severity distribution across cases. In recent sentinel county studies, data were collected on *Campylobacter*, *Listeria*, *Salmonella*, and *Shigella*. These sentinel county studies are a sample of selected counties, and more data, e.g., information about disease severity, are collected than under the passive foodborne data collection system. The sentinel studies, however, are not conducted annually and have been used for only a few pathogens because they are time consuming and expensive.

In 1979 and 1984, the CDC conducted sentinel county studies of reported salmonellosis cases in a representative sample of counties (Cohen and Tauxe, 1986). In both years, roughly 40,000 salmonellosis cases were confirmed by laboratory tests. Based on the survey, more than 22,000 people consulted a physician but were not hospitalized; 18,000 were hospitalized; and 500 died. But these 40,000 cases represent only a fraction of the total number of salmonellosis illnesses. Cohen and Tauxe (1986) stated that "only 1 to 10% of actual cases are reported," which suggests that between 400,000 and 4,000,000 salmonellosis cases occur annually. Adjusting for the undercounted cases by doubling the number of people in each severity category, Tauxe estimated 1,000 deaths, 36,000 hospitalizations, and 44,000 cases who only saw a physician. The remaining 1,919,000 cases were assumed to be mild (Table 5.2; Roberts, 1988).

Summary of Data Sources

The most comprehensive CDC data, in terms of the causes of foodborne illness, come from outbreak data (Table 5.1), but these include many fewer cases than do laboratory surveillance data. For example, for 1983 to 1987, 6,249 salmonellosis cases per year were reported in the outbreak data compared with 44,000 cases per year in the laboratory surveillance data (Table 5.2). Bennett et al. (1987) estimated that 96% of salmonellosis cases were foodborne.[5]

Medical Data Indicating Infection by Foodborne Microorganisms

Several types of medical data may illuminate either the number of cases of illness or the type of diseases caused by foodborne microorganisms. Autopsy data indicated that 100,000 Americans were exposed to trichinosis annually in the early 1970s (Zimmerman et al., 1973) although the distribution of symptomatic and asymptomatic infection and the relevance to exposure today are unclear. Epidemiologic reports, however, show that there is decreasing incidence of this disease in the United States. Antibod-

[5]Some CAST task force members think this estimate may be a little high because salmonellosis also is spread through contact with reptiles and amphibians and through person-to-person transmission.

Table 5.2. Salmonellosis data from Centers for Disease Control (CDC) sources, number of annual cases

	Outbreak data[a], 1983–1987	Laboratory surveillance data, 1990[b]	Sentinel county studies[c], 1979 and 1984	Extrapolations based on	
				Outbreak data[d]	Special surveillance studies[c, d]
Outbreaks	68	NA[e]	NA	NA	NA
Cases	6,249	44,000	40,000	2,000,000	400,000–4,000,000
Severity					
Deaths	8	ND[f]	500	2,000	1,000
Hospitalization	ND	ND	18,000	34,000	36,000
Physician seen	ND	ND	22,000	101,000	44,000
No medical attention	ND	NA	NA	1,863,000	1,919,000

[a]Bean et al., 1990a, 1990b.
[b]Bean and Griffin, 1990.
[c]Cohen and Tauxe, 1986.
[d]Roberts, 1989.
[e]NA = not applicable.
[f]ND = not done.

ies in blood show that roughly one-half the population is exposed to toxoplasmosis in their lifetimes (Frenkel, 1973), but few develop frank disease. Studies of *Listeria* carriage in feces indicate that at a minimum, 1 to 12% of the population becomes exposed annually (Armstrong, 1985). Whether these data for trichinosis, toxoplasmosis, or *Listeria* carriage indicate foodborne exposure or disease is unclear. Most exposures may be mild enough that the body successfully fights off the microorganisms and the person never is considered ill. Or it may be that a person experiences mild flu like symptoms, or perhaps more severe symptoms, without realizing their foodborne cause.

Studies of groups of ill persons are useful for identifying new pathogens, quantifying the relative prevalence of intestinal pathogens by means of investigating a clearly defined group of persons, or identifying new medical complications. The relative prevalences of salmonellosis, campylobacteriosis, shigellosis, and *Escherichia coli* O157:H7 infection were investigated for a health maintenance organization in the Seattle (King County) area (MacDonald et al., 1988). Smith and Blaser (1985) discovered two deaths of healthy people from campylobacteriosis—previously thought to be a relatively mild foodborne disease unless old age, infancy, or underlying disease impaired the immune system. Obtaining national illness estimates is difficult when generalizing from the limited group of individuals in a study.

One approach useful in calculating total estimates of foodborne disease is the analysis of health surveys.[6] Garthright et al. (1988) estimated that 99 million acute cases of *intestinal infectious disease*, defined as vomiting and/or diarrhea without respiratory symptoms, occur each year in the United States. In half the cases, the illnesses caused more than a day of restricted activity. A physician consultation occurred in only 8.2 million cases. Hospitalization occurred in 250,000. No attempt was made to estimate deaths (see Chapter 6 and Table 6.2 for cost estimates of medical expenses and lost productivity).

Although the fraction of total intestinal infectious disease cases that are foodborne is uncertain, an earlier paper by Garthwright's coauthors, Archer and Kvenberg (1985), suggested that 30 to 35% of these intestinal infectious diseases is foodborne. If the severity of foodborne disease was the same as that of intestinal infections from other sources, then foodborne disease annually would cause 83,000 hospitalizations, 2.6 million illnesses for which only a physician was consulted, 15 million cases involving no physician consultation but restricted activity for more than a day, and 15 million cases involving restricted activity for less than a full day.

The National Hospital Discharge Survey lists diagnoses for patients discharged from nonfederal, short-stay hospitals. Infectious and parasitic diseases are listed by the *International Classification of Diseases* (9th revision) (ICD-9) codes, which are specific to pathogens. For example, there are 15,408 cases for *Salmonella* (Code 003) (Table 5.3). Most cases of foodborne disease, however, are listed under the general codes of 008, 009, and 558.9 rather than under the causative microorganism.[7] Smith and Blaser (1985) found that in Colorado all diarrhea associated deaths are coded as noninfective diarrhea (Code 558) unless the word *infective* is mentioned on the death certificate. Further analysis of these data is required before definitive statements about hospitalizations for foodborne disease can be made.

Expert Opinion

Food scientists and epidemiologists, recognizing that reported data are just the tip of the iceberg, have made several attempts to determine the extent of foodborne disease incidence. Hauschild and Bryan (1980) estimated incidence of foodborne disease on the basis of about 50 thoroughly investigated foodborne outbreaks published in the scientific literature. The

[6]Studies include the Cleveland study, the Tecumseh study, the National Medical Care Utilization and Expenditure Survey, the National Health Interview Survey, and the National Hospital Discharge Survey (Garthright et al., 1988).

[7]Hospitalizations in the miscellaneous categories likely associated with food (008, 009, and 558.9) total 701,503 cases annually (Table 5.3). There may be two methods for estimating which percentage of these hospitalized cases is attributable to foodborne pathogens. Archer and Kvenberg (1985) analyze the National Ambulatory Medical Care Survey for 1977–1978 and suggest that 30 to 35% of physician visits is for intestinal infections with a foodborne cause. If this also were a good approximation for patients hospitalized in these three miscellaneous categories, then 210,000 to 245,510 hospitalizations/yr should be added to the list of hospitalizations with a foodborne cause. An alternative is to use Bennett et al.'s (1987) estimate that 95% of miscellaneous enteric disease is foodborne in origin for the high end of the range. Using this 30 to 95% range for miscellaneous foodborne hospitalizations yields an estimated range of 210,000 to 666,380 hospitalizations with a foodborne cause annually. To this can be added the 51,000 hospitalizations in Table 5.3 that are attributable to specific pathogens known to be associated with food. Resulting is an estimated 260,000 to 710,000 hospitalizations annually that may be due to foodborne pathogens.

Table 5.3. Patients discharged from hospitals, by category of disease likely to have been foodborne[a] by days of care, average length of stay, and average annual hospital costs, United States, 1987 through 1990 (adapted from Steahr and Roberts, 1993)

Diagnostic category and ICD–9–CM code	Yearly average	Average length of stay in hospital (days)	Average[b] annual hospital costs ($1,000)
Cholera 001	84	6.2	358
Typhoid 002	1,195	7.3	5,993
Salmonella 003	15,408	7.5	79,390
Shigellosis 004	5,344	4.6	16,888
Other food poisoning 005	5,958	3.3	13,507
Amebiasis 006	1,726	8.3	9,842
Other protozoal intestinal disease 007	6,125	8.1	34,084
Intestinal infections due to other organisms 008	139,382	7.5	718,166
Ill-defined intestinal infection 009	31,432	6.6	142,519
Listeriosis 027	1,089	13.9	10,399
Viral hepatitis A 070	12,404	8.9	75,842
Cysticercosis 123.1	1,133	8.0	6,227
Trichinosis 124	131	6.3	567
Unspecified gastroenteritis and colitis 558.9	530,689	5.4	1,968,750
Noxious substance eaten as food 988.9	698	3.2	1,534
All conditions above	752,798	6.0	3,084,066

[a]Includes patients with mention of disease on lines 1–7 of the hospital discharge certificate.
[b]Based on 1990 national average cost per day of $687 (U.S. Department of Commerce, 1992).

extrapolations for the United States ranged from 1.4 to 3.4 million cases per year.

Chalker and Blaser (1988) searched the literature and evaluated the likelihood of a salmonellosis case's being reported at each stage of the surveillance process (Table 5.4). Infections can go unreported because the infected person does not become ill, a sick person chooses not to see a physician, the physician does not obtain a specimen, the laboratory does not identify the microorganism from the specimen, the laboratory fails to report its test results to the health department, or the health department fails to report the laboratory test results to the CDC. Chalker and Blaser (1988) estimated the median reporting ratio for each step and obtained the total reporting ratio by successive multiplication of the ratio from each surveillance step. The total reporting ratio of 39 means that for each case of salmonellosis reported under the CDC's surveillance system, 39 human cases of salmonellosis are missed. Chalker and Blaser's estimates also contain the range of estimates reported in the literature for the number of illnesses not reported for each one that is. The range of ratios appearing in the literature also is shown. The actual underreporting ratio lies somewhere between 3.8:1 and 7,326:1.

Similarly, the basic technique to compensate for

Table 5.4. Summary of sequential artifacts in *Salmonella* surveillance (adapted from Chalker and Blaser, 1988)

Surveillance step	Estimated cases divided by reported cases	Range of estimates in the literature
Patient infected	1.0	
Patient ill	2.2	1.3 – 17.0
Patient consults a doctor	2.2	1.3 – 12.0
Doctor obtains a specimen	2.4	1.2 – 4.3
Laboratory identifies the organism	1.4	1.2 – 2.9
Laboratory reports to health department	2.0	1.3 – 2.4
Health department reports to Centers for Disease Control and Prevention	1.2	1.2[a]
Multiplier	39.0	3.8 – 7,326

[a]Only one study in the literature.

Note: Estimates of the degree of underreporting differed greatly for the first two steps—whether the infected person actually becomes ill and whether the ill person actually consults a physician. The variability in the reporting at each stage may be partly a function of the severity of illness due to variability in the number of *Salmonella* organisms ingested, the virulence of *Salmonella* serotype (Madden et al., 1986b), or host resistance/susceptibility as discussed in Chapter 3. *Salmonella* surveillance reporting ratio = 39.0; range = 3.8 to 7,326. The total multiplier of 39.0 is obtained by successive multipication of ratios from each surveillance step.

underreporting is to apply a multiplication factor to existing data. The recent publications of Bennett et al. (1987) and Todd (1989a, 1989b) estimated most known foodborne disease cases and are selected for discussion here. These publications contain estimates that are not at the high or low ends of the ranges and generally are considered by CAST task force members to be estimates based on defensible assumptions. Researchers at the CDC estimated morbidity and mortality for all infectious and parasitic diseases (Bennett et al., 1987), of which 17 were identified as foodborne diseases in whole or in part (Table 5.5). They used CDC surveillance and outbreak data, published reports, and expert opinion to estimate over-

Table 5.5. Best estimates of the annual cases and deaths for specific foodborne diseases in the United States

Foodborne disease or agent	Cases (No.)		Deaths (No.)	
	Bennett[a]	Todd[b]	Bennett[a]	Todd[b]
Bacterial				
Bacillius cereus	5,000	84,000	0	0
Botulism, including infant	180	270	7.2	3.9
Brucellosis	20	1,000	0.1	0.1
Campylobacteriosis	2,100,000	170,000	2,100[c]	1
Cholera	25	13,000	0.3	1.7
Clostridium perfringens	10,000	652,000	10	7.6
Escherichia coli O157:H7	ND[d]	25,000	ND	5.6
Escherichia coli (enteric)	50,000	44,000	100	0.6
Listeriosis	ND	25,000	ND	67.9
Miscellaneous enteric bacteria	190,000	107,000	1,900	11
Salmonellosis, nontyphi	1,920,000[e]	2,960,000	1,920	31.9
Shigella spp.	90,000	163,000	180	2.6
Staphylococcus aureus, excl. toxic shock syndrome (TSS)	1,513,000	1,155,000	1,210	5.9
Streptococcus Group A	500,000	52,000	150	0.2
Typhoid	480	240	28.8	0.1
Vibrio, infectious, excl. cholera	9,000	29,360	360	30
Yersiniosis, excl. plague	3,250	20,000	1.6	0.1
Total bacteria	6,380,955	5,500,870	7,968	170.2
Viral				
Hepatitis A	4,800	35,000	14	1.6
Norwalk-like agent/other 27 nm particles	ND	181,000	ND	0
Total viruses	?	216,000	?	1.6
Parasites				
Trichinosis[f]	100,000[f]	40,000	1,000[f]	3.8
Other parasites	ND	1,446,500[g]	ND	310.0
Seafood toxins	ND	58,260	ND	2.4
Plant poisons	ND	7,000	ND	5.9
Chemicals	ND	96,000	ND	5.4
Unknown agents	ND	5,217,000	ND	23.4
Total	6,485,755	12,581,630	8,982	522.7

[a]Bennett et al. (1987) omit food as the vehicle for some illnesses with partial foodborne etiology: listeriosis, toxoplasmosis, cysticercosis. *Escherichia coli* O157:H7 infection, Norwalk virus infections, rotavirus, and giardiasis.

[b]Todd's classification (1989b) differs from Bennett et al.'s (1987) in minor ways which include/exclude other species in the genus or associated disease syndromes. Todd's differing categories are *Streptococcus* spp. including Group A, *Vibrio cholerae/parahaemolyticus*, *Vibrio vulnificus*, and *Yersinia enterocolitica*.

[c]The latest Centers for Disease Control and Prevention estimates are 120–360 deaths from *Campylobacter* (Tauxe, 1992).

[d]ND = not done.

[e]Although some of the CAST task force contributors feel strongly that this estimate is too high, we do not have a verifiable lower estimate to offer.

[f]For trichinosis the cases and deaths originally reported are now considered excessive by both CDC parasitologists and some CAST task force members, but we were unable to agree on other estimates.

[g]Primarily *Toxoplasma gondii*.

all incidence and case-fatality ratio for each pathogen. The proportion spread by food was estimated for illnesses caused by each pathogen, and that estimate was used to allot cases and deaths to foodborne vehicles. The incidence of symptomatic illness from foodborne microorganisms was estimated at 6.5 million cases annually in the United States, with about 9,000 deaths.

Todd (1989a, 1989b) compared the estimates of Bennett et al. (1987) with estimates for the United States that were based on Canadian surveillance (this approach assumes that the underlying foodborne disease incidence is the same in both countries but that the different reporting systems cause different estimates). Four methods of extrapolating from outbreak data were used, each applying the same multiplication factor for all pathogens (with the exception of botulism and PSP). The methods included the following: (1) the CDC outbreak data multiplied by 350; (2) the Bennett et al. (1987) estimate used directly; (3) the CDC outbreak data multiplied by the estimated rate of salmonelloses underreporting, or 1,733; and (4) the Canadian estimates extrapolated to the U.S. based on population differences. The median of the estimates from these four methods was calculated and used. Todd (1989a, 1989b) used the same standard multiplication factor for all diseases, whereas Bennett et al. (1987) used a different multiplication factor for each pathogen. The greatest difference between the two sets of data is the number of deaths (Table 5.5).

Risk Models

As discussed in Chapter 3, risk assessment models may be used to evaluate potential health impacts of foods contaminated with pathogens. In addition to using the correct probability model, pathogen level must be determined accurately. Application of modeling to foodborne disease is in its infancy and is hindered for the following reasons.

1. Most methods recover only a fraction of the microorganisms present in foods; exposure, therefore, would be underestimated accordingly.
2. Surveys determining past contamination may not be useful in predicting future contamination.
3. Pathogen levels in meals served in homes and restaurants are not as well known as in commercial food and generally are rough estimates.
4. Risk models used to estimate the occurrence of foodborne disease generally are very uncertain although in the future such techniques may have sufficient precision to provide valuable estimates.
5. Complexity of cooking practices complicates risk modeling.
6. The impact of nonpathogenic bacteria, including spoilage organisms, in food or pathogens is unclear and may vary with the type of food and storage conditions.

If new studies sample foods for microbiological characteristics at the point of consumption and if we gain understanding of what an infective dose is, the modeling will become easier. Some studies have sampled raw and processed foods sold in supermarkets and other stores. Storage and preparation practices may increase or decrease the pathogen load on foods. Data on per capita consumption (including consumption patterns by age and by sex) of various foods exist and eventually could be used to estimate exposure to the risk of foodborne disease by specific pathogens in specific foods.

Limitations of Data Sources

None of the databases is designed to answer the questions (1) how many cases of foodborne disease are there or (2) what is the distribution of severity associated with each disease (Table 5.6). The limitations of current databases for foodborne disease estimation include the following:

1. The CDC outbreak data, which are designed to identify large foodborne disease problems threatening public health, require that two or more people have confirmed cases investigated by local or state authorities, a requirement that eliminates reporting of sporadic cases.
2. The CDC surveillance data usually are passive. The CDC sentinel surveys are limited to a few studies. Even for salmonellosis cases, survey sample size is small.
3. Expert opinion to arrive at "best estimates" of the extent of foodborne disease is based on extrapolations from outbreak and surveillance data.
4. Although medical case report data may identify new diseases and signal the kinds of disease outcomes caused by various pathogens, the data cannot be used to make reliable population estimates.
5. Medical data based on illnesses, hospitalizations, and deaths are incomplete. The Intestinal Infectious Disease Data do not identify causative pathogens that can be linked to foodborne sources. The National Hospital Discharge Survey lists most foodborne diseases under the miscellaneous

Table 5.6. Advantages of data sets for acute foodborne illnesses

Data set	Advantage	Cost
Outbreak data	Identify common-source outbreaks that typically are large or serious enough to justify an investigation and identify some foodborne cases	Medium
Laboratory surveillance	Identifies foodborne pathogens causing moderate to high to severe symptoms and is useful for quantitative risk assessment	High
Review of medical cases in the literature	May discover new diseases, pathologies, and severities, but is quite general	Low
Monitoring data from hospitals and public surveys	Identifies illnesses and deaths but often not specific foodborne pathogens	Medium
Sentinel county data and special epidemiology surveys	Identify case numbers, severity distributions, deaths, and may identify food vehicles. Useful for quantitative risk assessment	High

ICD-9 foodborne disease codes rather than under the specific codes for foodborne pathogens.

6. Modeling is a new approach that has been applied to specific examples and has not yet been used to generate comprehensive estimates of foodborne disease cases and deaths.

Data on Chronic Foodborne Illnesses

Data on long-term complications are not collected systematically.[8] Complications of foodborne illness may include arthritis, kidney damage, blood poisoning, heart disease, pancreatic infection, pneumonia, and neurological damage (Table 2.2). The range of possible effects is broad for most microorganisms. Archer and Kvenberg (1985) estimate that chronic illnesses are likely to occur in 2 to 3% of cases of foodborne infection. But identifying the specific chronic illness that a foodborne infection likely will cause is difficult. The long-term consequences of the chronic illness may be more serious than the acute illness (Archer and Young, 1988) (Table 5.7). Because symptoms may be neither unique nor linked temporally to a foodborne illness incident, chronic illnesses are especially difficult to relate to a specific pathogen or food vehicle.

Four examples of chronic illnesses that have been linked to foodborne disease are provided below to illustrate the magnitude of chronic illnesses and the potential to apply risk assessment procedures to understand these complications.

[8]Chronic complications sometimes are a function of infection, not illness, and can occur even if the immune system successfully fights off the illness. In such cases, activation of the immune system facilitates the chronic condition.

Chronic Sequelae of Toxoplasmosis

Congenital impairments associated with a maternal toxoplasmosis infection passed on to the fetus, range from mental retardation to blindness to hearing loss (Table 5.7). Roberts and Frenkel's (1990) review of the literature found most of the impairments were not immediately detectable. Table 5.7 shows the percentage detected in the first year, second year, and from the third through seventeenth years. What is striking is the high percentage of impairments. Only 20% of the children are without impairment after

Table 5.7. Impairments caused by congenital toxoplasmosis in prospective studies (adapted by Roberts and Frenkel, 1990)

	Couvreur et al. (1984)		Wilson et al. (1980)	
Impairment	1st yr (%)	Addl. in 2nd yr (%)	3 to 17 yr (%)	Total affected (%)
Deaths	2	0	0	2
Severe illness	11	0	0	11
Severe retardation	11	+2	+20	33
Moderate retardation	5	+3	+9	17
Slight retardation	5	+6	+12	23
Blindness (bilateral)	6	0	+2	8
Moderate visual impairment	16	+17	+20	53
Strabismus[a]	5	+2	+13	20
Deafness[b]	2	0	0	2
Hearing loss (moderate unilateral)	0	+0	+10	10
Normal	55	36	20[c]	—

[a]Cross-eyed vision.
[b]Deafness varied widely, from 0 to 13%.
[c]After 20 yr.

reaching 20 years of age. While moderate visual impairment affects over half the cases, severe mental retardation sufficient to keep a child from working occurs in 33%. Moderate retardation, which is associated with reduced income and frequent unemployment, affects 17%. The majority of those with mild retardation are able to work at a wage only slightly below average.

The epidemiological information on the incidence of congenital toxoplasmosis is uncertain. Roberts and Frenkel (1990) suggested that cases range from 407 to 9,500 annually (1990). Roberts and Murrell use a "best estimate" of 4,179 cases annually (1993). The percentage attributable to food also is uncertain (Smith, 1993b). By looking at the age of exposed persons, Frenkel and Ruiz (1981) concluded that consumption of, and/or contact with, contaminated meat is a more important cause of toxoplasmosis in the United States than is contact with cats.

Another chronic syndrome associated with *Toxoplasma gondii* is toxoplasmic encephalitis, which can occur if an individual's immune system is impaired. AIDS and the side effects of certain cancer treatments weaken an individual's immune system, and old infections in muscles can be reactivated and cause severe complications or death. "Toxoplasmic encephalitis, marked by dementia and seizures, has become the most commonly recognized cause of central nervous system opportunistic infection in AIDS patients" (Schantz and McCauley, 1991). Steahr found 1,360 hospitalizations annually for toxoplasmic encephalitis (ICD-9 code 130.0) recorded in the National Hospital Discharge Survey from 1987 to 1990 (Roberts and Murrell, 1993).

Arthritis as a Sequela from Foodborne Pathogens

Diarrheic infections due to foodborne pathogens such as *Campylobacter jejuni*, *Salmonella typhimurium*, *S. enteritidis*, *Shigella dysenteriae*, *S. flexneri*, *S. sonnei*, or *Yersinia enterocolitica* may act as triggers of one of the reactive arthritides in susceptible individuals. There is strong familial association, i.e., individuals with the HLA-B27 antigen encoded by the major histocompatibility complex are more susceptible to arthritis induced by foodborne pathogens. Approximately 2% of a population exposed to a triggering infection will succumb; however, approximately 20% of exposed HLA-B27$^+$ individuals will develop arthritis. If there are 5 to 10 million cases annually of foodborne disease from these pathogens, there will be 100,000 to 200,000 cases of reactive arthritides annually (Edmonds, 1984; Smith et al., 1993).

The reactive arthritides are sterile, i.e., the triggering microorganisms cannot be isolated from the affected joints. The sterile reactive arthritides include reactive arthritis, Reiter's syndrome, and ankylosing spondylitis and are characterized by disease of the sacroiliac joint, peripheral inflammatory arthritis, and *absence* of rheumatoid factor. Other pathological effects may develop in the entheses (sites of ligamentous insertion into bone), eye, aortic valve, lung parenchyma, and/or genitals (Edmonds, 1984; Smith et al., 1993).

While only a fraction of the population is affected by arthritis after a case of food poisoning, the afflicted individuals undergo economic hardships. The protracted nature of the illness may prevent full-time productive employment and may involve medical expenses such as medicine, visits to physicians, and hospital stays. Thus, illness from foodborne pathogens is not always a simple one- or two-day inconvenience.

Hemolytic Uremic Syndrome as a Result of *Escherichia coli* O157:H7 Infection

Hemolytic uremic syndrome (HUS) has been known to be associated with food since 1982 and became well known as a result of enteric infections from the 1993 hamburger outbreaks in Washington, California, Nevada, and Idaho (U.S. Department of Health and Human Services, 1994). Various studies have estimated the incidence of *E. coli* O157:H7 disease to be 3 to 8/100,000 population annually, or 7,668 to 20,448 U.S. cases annually (Griffin and Tauxe, 1991; Marks and Roberts, 1993). Most of the cases are young children, although the elderly are the second most likely age group to be affected. Twenty percent of persons hospitalized for *E. coli* O157:H7 are estimated to develop HUS, a severe disease characterized by kidney failure and perhaps neurological impairment. Some individuals with HUS recover fully, some die, and a few develop chronic kidney failure—requiring lifelong dialysis or a kidney transplant (Figure 5-2).

Patients diagnosed with chronic kidney failure (approximately 24 to 63 cases annually) continue hemodialysis at the hospital on an outpatient basis, are able to perform peritoneal dialysis outside the hospital, or receive a transplant. Statistics for HUS pediatric patients show that by the end of the first year of treatment, 24% were undergoing hemodialysis in an office, clinic, or hospital; 29% were undergoing peritoneal dialysis; and 47% received a kidney

transplant. Over an average lifespan of 77 years, 17 to 42 chronic HUS patients are estimated to die from complications of either kidney dialysis or transplants. Many of these deaths occur before the age of 16.

Guillain-Barré Syndrome Preceded by *Campylobacter* Infections[9]

Campylobacter is the most common precipitating factor for Guillain-Barré syndrome (GBS), the leading cause of acute neuromuscular paralysis in the United States now that poliomyelitis has been virtually eliminated by vaccination programs (Mishu et al., 1993; Parry, 1993). Kennedy et al. (1978) estimate that the annual incidence of GBS is 1.7 cases in 100,000 people, or 4,250 new GBS cases in the United States annually. The GBS is considered to be an autoimmune disease with several antecedent triggering factors. Fifty to 75% of all GBS cases are preceded 1 to 3 weeks by an acute infectious illness of the gastrointestinal or respiratory tract (Mishu and Blaser, 1993). Although respiratory symptoms are reported most frequently, gastrointestinal symptoms precede GBS in 10 to 30% of cases. Mishu and Blaser (1993) estimate that 10 to 30% of all GBS cases are precipitated by *C. jejuni* infections, or *C. jejuni* accounts for 425 to 1,275 new GBS cases annually in the United States.

The GBS, as with other autoimmune diseases, can strike otherwise healthy individuals in their youth and early adulthood. Several studies found bimodal age distributions in GBS patients (Halls et al., 1988; Moore and James, 1981; Storey et al., 1989). In general, these studies showed an initial peak of GBS incidence for people in their twenties, a lower incidence for people in their thirties and forties, and the largest peak for people older than fifty. A similar age distribution was found for *Campylobacter jejuni* infections (Nolan and Harris, 1984).

Ropper et al. (1991) state that GBS "is usually a monophasic illness, with a rapid initial onset, progressive weakness over 1 to 4 weeks, and recovery over subsequent months." Although most GBS patients recover after several weeks or months, others are bedridden permanently or have fatal complications. Some patients have relapses. Hughes (1990) states that the prognosis of GBS varies and "up to 13% die and a further 20% are left significantly disabled" and unable to work after a year. Parry (1993) found that 85% of GBS patients he studied achieved a "complete functional recovery." Ropper et al. (1991) found that 75% of GBS patients recovered enough to return to normal life in 6 to 12 months and in one study, less than 15% had "absolutely no residual symptoms."

All documented GBS patients are hospitalized. Steahr (pers. com., 1994) analyzed hospital discharge data and found GBS (ICD-9 code 357.0) as the primary cause of 3,000 to 9,000 hospitalizations annually in 1987 to 1990. A review of nine articles on GBS revealed that 6 to 45% of all GBS patients were put

[9]This discussion is based on preliminary work by Jean Buzby, University of Kentucky and the USDA's Economic Research Service, and by Ban Mishu and Martin Blaser, Vanderbilt University, who are collaborating on research to estimate the incidence, severity, and costs of GBS associated with *C. jejuni*. Technically, *Campylobacter* enteritis is caused by two similar species: *C. jejuni* and *C. coli*. However, *C. jejuni* is the more prevalent species and often is used to discuss both species (Skirrow and Blaser, 1992). Guillain-Barré syndrome was once called acute postinfectious polyneuritis.

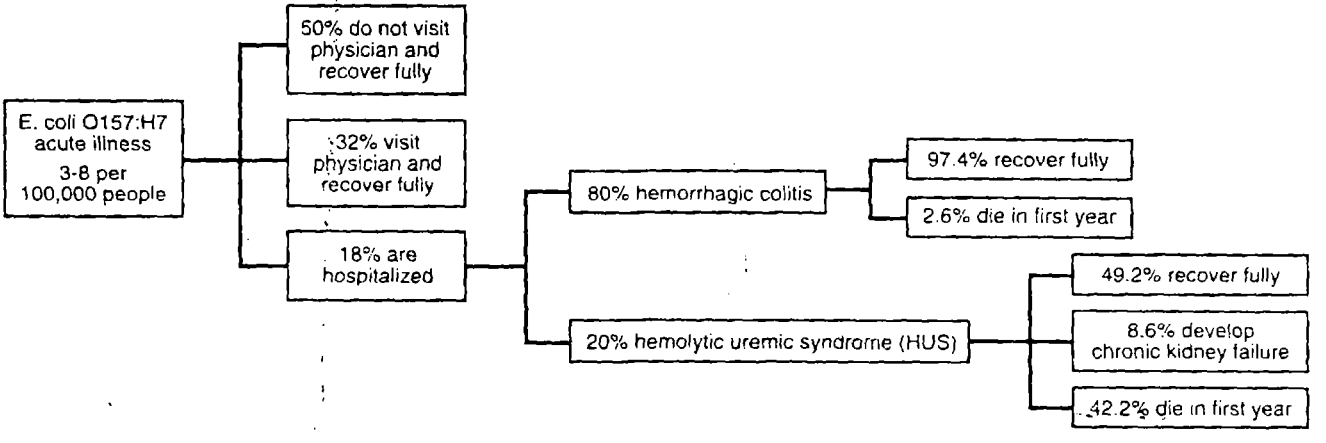

Figure 5.2. Estimated cases and severity outcomes for *Escherichia coli* O157:H7 infections (Marks and Roberts, 1993).

on ventilators to assist their breathing during some portion of their hospital stay. Sunderrajan and Davenport (1985) found that the mean hospital stay was 98.5 days for ventilated patients and 19.1 days for nonventilated patients.

Up to 65% of GBS patients report neurological pain (Beghi et al., 1985). One patient's pain persisted for more than one year (Andersson and Sidén, 1982). As with other illnesses involving lengthy hospitalizations, pain, and paralysis, GBS patients can face difficult psychological problems. Patients may worry about when the pain will cease, the extent that they may have a permanent disability or lingering minor deficits, and if they face a premature and impending death. Also, given the widespread occurrence of underinsured people and the high cost of ventilator treatment in a hospital, financial concerns may add to the mental burden of GBS patients and their families.

Discussion and Conclusions

All CAST task force members agreed that the outbreak cases reported to the CDC constitute a small fraction of the actual numbers. Although the literature provides estimated ranges of 1.4 million to 81 million cases annually (Archer and Kvenberg, 1985; Bennett et al., 1987; Hauschild and Bryan, 1980; Garthright et al., 1988; Todd, 1989b), realistically the range is more likely to be 6.5 million to 33 million cases annually. There are several factors to consider during evaluation of whether a foodborne disease likely will be identified:

1. The more serious the disease, the more likely it is to come to the attention of the medical community and the more likely it is to be reported.
2. The more distinctive the disease symptoms, the more clearly identifiable the causative microorganism.
3. The more quickly the disease follows the ingestion of the contaminated food (see incubation periods, Table 2.1), the more likely the foodborne association can be made.
4. The availability of rapid, inexpensive tests increases the likelihood of identification and reporting (viral causes of foodborne disease are exceptionally underreported).
5. "Name recognition" affects testing, e.g., physicians know that *Salmonella* causes food poisoning, which increases the likelihood that the stool sample will be tested for this bacterium.
6. When a great number of people become ill at the same time, the chances of a food being identified as the vehicle increase.

The importance of these factors and the degree of underreporting differ considerably by disease. "At the current level of disease surveillance (in the United States), it may take thousands of cases for an outbreak causing diarrheal illness randomly in a large urban area to be detected by public health authorities." (Berkelman et al., 1994)

In the future, we may be able to describe more fully the likely severity of disease caused by various pathogens and to calculate a probability distribution for disease severity by pathogen. For example, *Salmonella* has the full range of severity outcomes with much greater numbers of mild cases than deaths, *Listeria* may have a bimodal distribution with either mild or severe cases, and *Bacillus cereus* may cause only mild to moderate cases.

Estimates of deaths differ considerably, e.g., from hundreds to thousands. The CDC's estimates of 1,000 to 2,000 salmonellosis deaths (Table 5.2) were unacceptable to some CAST task force members because of the small sample size for the CDC's salmonellosis sentinel county survey. The National Research Council's (NRC) Institute of Medicine (1989) reported that 100 salmonellosis deaths are listed annually in the National Death Index (NDI) published by the National Center for Health Statistics (U.S. Department of Health and Human Services, 1984). For an additional 100 deaths annually, salmonellosis is listed as a contributing factor (U.S. Department of Health and Human Services, 1984). "The NDI data may underestimate the number of deaths from salmonellosis for several reasons: (1) a death certificate may be filled out by a physician or other authorized person who is not familiar with the illness of the deceased and may not recognize the contribution of the infection to 'cardiac arrest' or some similar noninfectious process; (2) a *Salmonella* infection may be recognized and reported as septicemia, meningitis, or other infection without identification of the causative microorganism; or (3) failure to take a bacterial culture from a patient with salmonellosis as a complication of a terminal illness might lead to failure to identify the organism."

The NDI is a compilation of death certificate information from the states' vital statistics offices. The death certificate is not intended as an epidemiological tool; hence, the epidemiological information on the certificate can be both limited and inaccurate as to actual cause of death (Hopkins et al., 1989; Israel et al., 1986; Rosenberg, 1989).

While recognizing that there is great uncertainty

associated with estimates of annual foodborne deaths, the majority of CAST task force members was willing to accept the Bennett et al. (1987) "best estimate" of around 9,000 deaths annually from foodborne microbes (Table 5.5). Some thought that the Bennett et al. (1987) estimates for deaths were excessively high and were more comfortable with Todd's estimate of 200 to 500 foodborne deaths annually (Table 5.5).

Another issue is the underlying health of individuals dying from foodborne pathogens. In the western states in early 1993, the *Escherichia coli* O157:H7 associated with undercooked hamburger infected healthy children primarily, a few of whom died (Centers for Disease Control and Prevention, 1993b). Additional outbreaks and deaths of children from *E. coli* O157:H7 were reported in Texas in November 1993 (Steele, pers. com., 1993). Other pathogens, e.g., *Listeria monocytogenes*, mainly cause severe illness and death in persons with immature (fetal) or compromised immune systems (adults with cancer, diabetes, renal disease, heart disease, or AIDS) (Schwartz et al., 1988). For other pathogens, the severity of illness may depend largely on number of microorganisms ingested as well as on individual susceptibility factors (Table 3.2). Until better data are available, the likelihood of a healthy versus an infirm individual's dying from exposure to foodborne pathogens cannot be determined.

As data from new epidemiological studies and increased microbial testing become available, estimates of foodborne disease number and case severity will continue to improve for both acute and chronic illnesses. New foodborne pathogens also will be discovered for human illnesses previously thought unassociated with food. And as the *Escherichia coli* O157:H7 case indicates, mutations and evolving econiches will create new concerns.

There is much uncertainty in the estimates of case number, foodborne association, and disease severity. Deaths, because of their small number and great importance, were flagged in data collection efforts. Given current information, the majority of the CAST task force believes that foodborne disease may range from 6.5 million to 33 million cases annually and that foodborne deaths may be as high as 9,000 annually. Five hundred deaths annually due to foodborne pathogens is a conservative low estimate.

DRAFT

Preparing America's Food System for the 21st Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?

by

Michael R. Taylor[1]

I. Introduction

Nothing is more vital to the success of a society than the success of its food system. Food is essential to survival, important to good health and, in many societies, food production, processing, distribution and marketing is the dominant economic activity.

The American food system is the most successful in the world. It provides a safe, abundant, and economical supply of food and almost unlimited food choices to American consumers. It contributes over $500 billion to the domestic economy, employs over 10 million Americans, and exports an estimated $60 billion in food commodities and products.[2]

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[2]In 1993, American consumers spent $617.1 billion on food, $ 511 billion of which was spent on foods originating on U. S. farms. USDA, Agriculture Fact Book 1996 at 7-9. The employment estimate includes people employed on farms, in food processing, and at retail. Id. at 23; U.S. Department of Commerce, Statistical Abstract of the United States 1996 at 762, 862-63. The export figure is USDA's widely reported estimate for 1996, which is up sharply from the

The future of the American food system is full of promise and opportunity. Consumer demand for value-added food products is growing all over the world, and the United States' advantages in natural resources and technology will enable it to compete well in the expanding global market for food. But, for all of its strengths and past successes, the American food system must meet important challenges to achieve its full potential in the 21st century. Many of these fall under the heading of food safety.

Microbial contamination of a wide variety of food products remains a real food safety concern.[3] Controversies about the safety of new food technologies continue to capture public attention, potentially affecting the public's acceptance of them.[4] Food safety controversies can occasionally disrupt the rapidly growing international trade in food.[5] And public confidence in the food supply can be fragile: unanswered questions concerning the safety of British beef resulted in the virtual collapse last year of public confidence in that important product of the United Kingdom.

1994 figure of $45.7 billion. Id. at 673.

[3]This is evidenced by the continuing problems of Salmonella enteriditis in eggs, Vibrio vulnificus in raw oysters, and Salmonella and Campylobacter contamination of meat and poultry; the recent outbreaks of illness associated with cyclospora on imported strawberries and Cryptosporidium in drinking water; and the continued emergence around the world of E. Coli 0157:H7 and related strains toxin-producing bacteria as dangerous foodborne pathogens.

[4] Recent examples include food irradiation to kill harmful bacteria, the non-caloric fat substitute Olestra, and genetic modification of food crops.

[5] This has been illustrated recently by the obstacles raised in Europe to American exports of genetically modified soybeans and beef from cows treated with hormones.

While the American food supply is fundamentally sound, the importance of proper food safety regulation to protect public health and maintain public confidence in the food supply is widely accepted. Market mechanisms work reasonably well to satisfy consumer demands for economy, convenience, and choice in the food supply, but they fail to satisfy fully the very high consumer expectations for food safety.[6] Thus, since the enactment in 1906 of the first comprehensive food safety laws at the Federal level, the public interest in food safety has been pursued through a combination of government and industry efforts, including Federal regulation of food safety.

Substantial progress has been made in recent years in identifying and adopting effective food safety standards and procedures. The system of process control to prevent food safety problems known as Hazard Analysis and Critical Control Points(HACCP) has become the framework for both government and industry efforts to improve food safety. The adoption of HACCP procedures was mandated in 1995 by the Food and Drug Administration(FDA) for seafood processors[7] and in 1996 by the Food Safety and Inspection Service in the Department of Agriculture(USDA) for meat and poultry processors, including slaughterhouses.[8] Many companies in other segments of the food

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[6] The information consumers would need to make safety-based purchase decisions is often not available, and post-hoc remedies through the private liability system are generally insufficient, due in part to the complex and difficult-to-prove chain of causation commonly associated with cases of foodborne illness. See generally...[AEI study].

[7] 60 Fed. Reg. 65096(December 18, 1995).

[8] 61 Fed. Reg. 38806(July 25, 1996).

industry have adopted HACCP on their own, and HACCP is increasingly recognized in other countries and by international organizations as the state of the art in science-based process control for food safety.[9]

An important feature of HACCP is that it provides the basis for clearly defining and modernizing the roles industry and government must play in ensuring the safety of food. Government does not produce food; government cannot make it safe. At the point of production and processing, only food companies have the capability and responsibility to make food safe. Government's core role should be to verify that companies are meeting their responsibility by defining in law the companies' basic food safety obligation, establishing food safety performance standards, and providing accountability for meeting those standards through appropriate oversight and enforcement.

In the food safety system, as with any other human social activity, a clear delineation of responsibilities is essential to success. It provides people working in the system -- in government and industry alike -- the basis for knowing what they are supposed to do and what they will be held accountable for achieving. A clear delineation of responsibilities is especially important in a food safety system that involves multiple

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[9] The Codex Alimentarius Commission of the United Nations, whose food safety standards are deemed by the Sanitary and Phytosanitary Agreement within the General Agreement on Tariffs and Trade (GATT) (Uruguay Round) to be presumptively valid for purposes of complying with the S&P Agreement, has endorsed HACCP. The European Union has adopted HACCP for seafood and is considering HACCP for meat and poultry.

agencies at all levels of government, as in the United States, and extensive public-private interaction.

The thesis of this article is that the Federal government's adoption of HACCP for seafood, meat and poultry is an important step toward a better definition and allocation of roles and responsibilities for food safety, but it is only the first step. Meeting the four major food safety-related challenges that will be important to the food system's success in the future -- reducing foodborne illness, managing the introduction of new food technologies, overseeing and facilitating international trade, and maintaining public confidence in the food supply -- will require a new level of cooperation and coordination among the many government agencies involved in food safety and a new understanding of the appropriate interaction between government and the food industry.

In short, full achievement of the public's food safety goals and the food industry's economic potential will require a clearer understanding among all participants in the food system of who is responsible for what when it comes to food safety.

The next section of this article will briefly characterize the allocation of roles and responsibilities in the Federal food safety system prior to the movement toward HACCP. Section III will describe the HACCP paradigm and its implications for modernizing the delineation of roles and responsibilities for food safety. The concluding section will identify some of the important issues that must still be resolved to make HACCP fully

successful and to meet the food safety challenges -- and achieve the full potential of America's food system -- in the coming century.

II. Where the Food Safety System Has Been

When it comes to allocating roles and responsibilities for food safety, there really are two food safety systems in the United States -- one for meat and poultry, administered by USDA, and one for all other components of the food supply, administered primarily by FDA. The systems have common features -- statutory origins in the same year(1906), similar legal definitions of safety-related "adulteration," and shared safety standards for food additives and chemical contaminants -- but they could not be more different in their day-to-day implementation and their practical allocation of responsibility between government and industry.

A. The FDA Food Safety Paradigm[10]

In the FDA system, food companies have a legal duty to produce foods that are not "adulterated" as that term is defined in the Federal Food, Drug, and Cosmetic Act.

[10] For a more detailed description of FDA's approach to food safety regulation, see Taylor, "Food Safety Regulation," a chapter in Food and Drug Law(Food and Drug Law Institute, 1991).

Through its implementing regulations and policy statements, FDA has spelled out what adulteration means in certain circumstances. For example, FDA establishes quantitative limits on various chemical contaminants in food, considers certain microbial pathogens to adulterate various foods, issues regulations defining the conditions under which food additives may be safely used, and provides general guidance concerning the "good manufacturing practices" that FDA considers necessary to prevent insanitary conditions and product adulteration.

FDA enforces these adulteration provisions when violations are encountered as a result of illness outbreaks, consumer or industry complaints, or observations made during periodic FDA inspections. FDA has jurisdiction over 53,000 establishments that produce, process or store food. Its 250 food inspectors conduct about 5,000 establishment inspections annually. The typical FDA enforcement action involves removal of the adulterated food from commerce through a voluntary recall by the responsible company or FDA-initiated court action.[11]

Due to the infrequency of FDA inspection for any firm -- years can pass between inspections -- the FDA system relies heavily on the commitment and competence of food companies to produce safe products, and most companies take their food safety responsibility very seriously. The strength of the FDA system is that it has spelled out in

[11] FDA can also seek court injunctions to prevent future adulteration violations or criminally prosecute those responsible for adulterating food, but the agency rarely resorts to these remedies.

a number of circumstances what it considers an appropriate standard of safety -- in regulatory parlance, food safety performance standards -- and creates through its enforcement activity an added incentive for companies to meet those standards. This interaction between private responsibility for food safety and FDA standard setting and enforcement has yielded generally good food safety results.

The principle weakness of the FDA system has been that, with respect to emerging food safety problems or dealing with companies that are unable or unwilling to meet their food safety responsibilities, the system has been largely reactive. It has responded well to problems after they occur, by investigating illness outbreaks, supervising recalls, and taking enforcement action, but the system has lacked strategies and mechanisms to systematically anticipate and prevent the most significant food safety problems, such as ones mentioned in the Introduction.

B. The USDA Food Safety Paradigm[12]

In the USDA system, meat and poultry companies also have a legal duty to produce food that is not adulterated within the meaning of the Federal Meat Inspection Act and the Poultry Products Inspection Act, but the practical allocation of responsibility

[12] The preamble to USDA's proposed rules on HACCP provides an overview and history of the USDA food safety program. 60 Fed. Reg. 6774 et seq. (February 3, 1995).

for achieving this result is very different from the FDA system. By law, USDA carries out "continuous inspection" of meat and poultry plants, which means that USDA inspectors physically examine every carcass passing through slaughterhouses[13] and carry out daily inspections of plants that process meat and poultry products(ranging from cut up fresh chicken parts to pepperoni pizza and chicken noodle soup). Carcasses and processed products cannot be shipped into commerce without the USDA mark of inspection indicating that the product has been "inspected and passed" by the U. S. Department of Agriculture and found by USDA not to be adulterated. USDA employes 7,500 fulltime inspectors to conduct these inspections in about 6,000 plants.

The design of the USDA system reflects its historical origins at the beginning of this century, when the primary public concerns were extreme insanitation in meatpacking houses and the use of diseased animals or visibly contaminated carcasses for human food. The USDA system has worked well to address these problems, but it has done so by assuming a large share of responsibility for the operation of the plants it inspects and for the quality and safety of products leaving those plants. For example, USDA inspectors bear the primary responsibility for sorting diseased carcasses from wholesome ones; USDA approves facility blueprints, processing equipment and product labels prior to their use; and USDA inspectors, rather than the plant's managers, have traditionally made the

[13] In 1994, USDA inspectors individually examined approximately 130 million head of livestock(mostly cattle and swine) and 7.5 billion chickens, turkeys and other poultry. USDA, Meat and Poultry Inspection -- 1994 Report of the Secretary of Agriculture to the U.S. Congress(1995) at 39-40.

daily decision whether a slaughter plant has been adequately cleaned and is ready to commence operations.

The strength of the USDA system is that it puts government inspectors in a position to promptly detect and correct visibly observable food safety and sanitation problems. It also provides the assurance many consumers say they want that an objective government inspector has overseen the production of the product.

The primary weakness of the traditional USDA approach from a food safety perspective is that it has not clearly defined the responsibility of the slaughterhouse for preventing and minimizing contamination of carcasses with microbial pathogens -- such as Salmonella and E. coli 0157H:7 -- which are the most significant form of contamination in food safety terms and a form of contamination that is not visually observable by government inspectors. Indeed, prior to October 1994, USDA did not consider any microbial pathogens on raw meat and poultry products to be adulterants under the law.[14]

More broadly, the traditional USDA system has severely blurred the line between government and industry responsibility for food safety, which has, in some respects, stood in the way of progress on food safety. For some companies, the extensive system of

[14] This policy was changed in October 1994 with the determination by USDA that the presence of any amount of E. coli 0157:H7 in raw ground beef legally adulterates that product. The policy change was upheld in court. Texas Food Industry Association v. Espy, 870 F. Supp. 143(W.D. Tex. 1994).

command and control regulation associated with continuous USDA inspection has discouraged or delayed the introduction of new food safety technologies. For other companies, the USDA mark of inspection has been a crutch that plant operators have depended on in lieu of taking full responsibilty themselves for food safety and sanitation -- if the product passes inspection, everything must be okay, even though no amount of inspection can by itself make food safe or keep a plant clean.

The traditional USDA inspection system powerfully illustrates the importance of clearly delineating food safety roles and responsibilities. Despite all the good it has done in overseeing meat and poultry production, by failing to assign clear responsibility and accountability for reducing harmful bacteria on raw product, the USDA system has not succeeded in reducing adequately the burden of foodborne illness associated with these products.[15] And when the tragic outbreak of illness associated with E. coli 0157:H7 and hamburgers occurred in the Northwest in 1993, USDA investigated and determined that the inspection system had worked as it was designed to work. It just had not been designed to address that problem; it had not assigned clear responsibility for minimizing contamination with that deadly organism.

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[15] In connection with its HACCP rulemaking, USDA estimated that the four microbial pathogens most commonly occuring in meat and poultry plants could contribute annually to as many as 5,000 deaths and 4,000,000 cases of foodborne illness. 61 Fed. Reg. at 38964-95. Through a combination of steps, including the prevention and removal of contamination, effective cooling during transportation and storage, and proper cooking, these deaths and illnesses are largely preventable.

C. The Fragmented Federal Food Safety System

The task -- and challenge -- of assigning clear responsibility for food safety goes beyond the core food safety oversight activities of FDA and USDA and the allocation of responsibility between food companies and the government. Responsibility for food safety is widely dispersed among Federal agencies and agencies at the state and local levels of government, and the roles of these agencies vary widely depending on their statutory authority and resources. This fragmentation and diversity, which is embedded in the statutes adopted over the years by the Congress, undercuts both the government's ability to have the most effective food safety program and the government's accountability for food safety.

Just a few examples make the point. As already discussed, FDA regulates seafood, while USDA regulates red meat and poultry -- unless "game" species are involved, like buffalo, ostrich, and game hens.[16] Game species are under FDA's food safety regulatory jurisdiction but are commonly subject to "voluntary" inspection by USDA.

Shell eggs are under FDA's jurisdiction, while processed egg products are under USDA's jurisdiction, except certain processed egg products, which FDA regulates.[17] USDA's Food Safety and Inspection Service inspects processed egg product plants on a

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[16] [statutory cites]

[17] [statutory cites]

daily basis, but the only daily presence of government inspectors in shell egg packing houses is not the FDA inspector, with jurisdiction over the safety of those eggs. It's the inspectors from USDA's Agricultural Marketing Service, who grade the eggs for quality.

FDA has jurisdiction over plants producing cheese pizza, but rarely inspects such plants. USDA has jurisdiction over plants producing pepperoni pizza and inspects such plants on a daily basis, after having already inspected the animal from which the pepperoni was made at the time of slaughter and the processing of the meat into pepperoni.

The Environmental Protection Agency(EPA) regulates pesticides and makes food safety decisions concerning the amount of a pesticide residue that can be present on food as a result of the pesticide's application to crops. As EPA implements the pesticide reform law passed by Congress last year,[18] it will be making hundreds of important food safety decisions about chemicals in food, many more than FDA will make, despite the fact that FDA is considered the Federal government's lead food safety agency. FDA's responsibility for agricultural pesticides is to enforce EPA's tolerances for residues of the pesticides on foods other than meat and poultry. Pesticide tolerances for meat and poultry are enforced by USDA. However, when agricultural pesticides contaminate food as a result of having persisted in the environment rather than being applied directly to a food crop, the safety standards are set by FDA rather than EPA.

[18] Food Quality Protection Act of 1996, P.L. 104-170, 110 Stat. 1489(1996).

The Centers for Disease Control and Prevention(CDC) has primary responsibility at the Federal level for epidemiological monitoring of foodborne illness and conducts investigations of specific outbreaks of illness when invited to do so by the health department in the state in which the outbreak occurred. FDA and USDA also investigate illness outbreaks to determine whether regulatory action is needed, such as seizure or recall of the responsible food product, and they require up-to-date information on rates and causes of foodborne illness to plan their regulatory strategies and evaluate the effectiveness of their programs.

Food safety research -- which includes understanding the characteristics of emerging microbial pathogens, testing the safety of particular chemicals, and developing and evaluating new food safety technologies -- is essential to progress on food safety and to the success of the food safety regulatory agencies. Food safety research is currently conducted by some 21 Federal agencies.[19] Some of the agencies coordinate on an ad hoc basis but there is no formal coordinating mechanism and no government-wide research strategy.

State and local agencies have their own food safety programs and play a critical role in the nation's food safety system. In addition to having primary jurisdiction to

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[19] FDA, the National Institutes of Health, and USDA's Agricultural Research Service have the largest research budgets. See generally Federal Coordinating Council for Science, Engineering, and Technology, An Overview of Federal Food Safety Research -- Including Research Needs for the Future(Washington, D.C.,1993). USDA's food safety agency, FSIS, is precluded by Congress from conducting food safety research.[cite report language]

investigate illness outbreaks within their boundaries, they conduct most food safety inspections at the retail level -- grocery stores and restaurants -- and they play the primary oversight role for certain product categories, such as milk products and shellfish.

These examples provide only a snapshot of the fragmentation and wide dispersal of responsibility that characterizes the nation's food safety system. The National Performance Review(NPR) Food Safety Working Group found in 1993 that 12 Federal agencies, working under 35 statutes, are involved in food safety regulation. The Working Group found the system "cumbersome, inefficient, and ineffective," and Vice President Gore's first NPR report recommended the consolidation of Federal responsibility for food safety into a single agency.

Such fundamental structural reform may be in order. Certainly, the current system is not the one anyone would design if starting from scratch. It does not make the best possible use of available resources; it complicates greatly the design and implementation of coherent, consistent food safety strategies; and it is at war with clear assignment of responsibility and accountability within the Federal government for specific food safety problems and for food safety in general. But fundamental structural reform in the Federal government, however desirable it may be, is so difficult to achieve politically that agency managers rightfully tend to focus on how progress can be made within the existing structure. And that is what the Federal food safety agencies are doing, with HACCP as the conceptual framework for their reform efforts.

III. The HACCP Paradigm

HACCP was developed in the 1960's by food industry experts as a process control system for safe food production. The concept is simple. It calls for the operator of a food production process to have a plan for producing safe food. The HACCP plan identifies the potential hazards in the process -- such as the possibility of harmful contamination with bacteria or chemicals -- and specifies process controls -- such as proper cooling of perishable raw materials or adequate cooking temperatures -- that have been validated as effective in preventing or minimizing the hazards. The HACCP plan also establishes recordkeeping and monitoring procedures that enable the operator to verify on a continuing basis that the controls are working and to detect and promptly correct processing errors.

As originally conceived, HACCP was a process control system for use by food companies to ensure the safety of their products. It was not considered a regulatory tool. Its strength was its systematic, scientific approach to identifying and preventing food safety hazards and its recognition that process control plans developed by each plant operator, tailored to each plant, and validated and monitored by plant managers would work best to ensure food safety. HACCP has gained wide acceptance in the scientific and technical community and has been adopted by many food companies.

In a landmark 1985 report on USDA's meat and poultry inspection system, the National Academy of Sciences recommended that USDA adopt HACCP as a regulatory framework for meat and poultry.[20] The NAS report documented the failure of the traditional inspection program to focus sufficiently on the most significant hazards, especially those posed by microbial pathogens, and to deal with them preventively. USDA's HACCP regulations largely implement the NAS recommendations.

By the early 1990's, the safety of seafood also had become the subject of public attention and concern, and FDA began developing its own HACCP-based food safety strategy for seafood, which culminated in FDA's regulations mandating HACCP for seafood processors.

For FDA and USDA, HACCP has certainly become a regulatory tool: it is the approach operators of meat, poultry and seafood plants must take to establishing and implementing the controls needed to produce safe food. But HACCP means more than that to FDA and USDA. HACCP represents nothing less than a new conceptual framework -- a new paradigm -- for their food safety programs. It is a paradigm based on focused and systematic prevention of food safety problems, clearer delineation of responsibility for food safety, and better use of the Federal resources available for food safety oversight. The HACCP paradigm provides the framework for bringing greater

[20] National Research Council/National Academy of Sciences, Meat and Poultry Inspection -- The Scientific Basis of the Nation's Program(National Academy Press, Washington, D.C., 1985).

conceptual consistency to the FDA and FSIS programs and addressing some of the other structural weaknesses in the Federal food safety program outlined above.

Prevention should be a fundamental tenet of any public health program. A food safety system based on systematic, science-based prevention of hazards is obviously preferable to a system based largely on after-the-fact enforcement and correction of problems after they occur, and HACCP provides the framework for systematically preventing food safety problems. This is especially important to FDA's program, with its very limited inspection capacity.

HACCP also clarifies the allocation of food safety responsibilities between industry and government and strengthens the capacity of both to meet their responsibility. While the nation's food safety laws in the past have implicitly made the food company responsible for preventing food safety hazards and producing safe food, HACCP makes this responsibility explicit and establishes a general standard of process control companies must achieve to satisfy their food safety responsibility. Under HACCP as adopted by USDA, the slaughter plant's responsibility to target and reduce contamination with harmful bacteria is now crystal clear.

HACCP also clarifies the government's role and responsibility in a way that will have a profound effect, particularly on USDA's program. No longer will USDA attempt to control -- and, in effect, take responsibility for -- so many of the details of a plant's

operations.[21] USDA will instead focus on verifying through its inspection activity that the company-designed HACCP plan is appropriate for the plant and working properly and that the company is meeting relevant food safety performance standards, such as the new standards for reducing Salmonella contamination in slaughter plants.[22]

This new delineation of responsibility has enormous potential to improve the food safety system because it focuses both industry and government on what they do best. Food companies know how to run their operations, and they have the capability to make the food safe; but food companies are not in a position to set and enforce food safety standards that the public can have confidence are appropriate to protect public health.

Likewise, government agencies can never know enough or have the resources to successfully direct the operations of the thousands of facilities producing or processing food in this country and establish the food safety controls that will work best in each plant. Agencies can, however, determine on behalf of the public what constitutes an acceptable food safety outcome or level of performance; and they can set and enforce standards that the public can trust are appropriate to protect public health.

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[21]As part of its regulatory reform strategy to support HACCP and improve the allocation of responsibilites between FSIS and the industry, FSIS has published rulemaking proposals to eliminate its prior approval systems for facility blueprints and equipment. [FR cites] USDA also intends to rely more heavily on plant managers to decide when a plant has been properly cleaned in accordance with the plant's own sanitation standard operating procedure(SOP) and is ready to commence daily operations. 61 Fed. Reg. at 38829-35.

[22] 61 Fed. Reg. at 38835-54.

It is by focusing government and industry on what each does best and enhancing their responsibility and accountability for doing it that the HACCP paradigm will improve food safety.

Finally, HACCP provides an opportunity for FDA and USDA to make better use of their resources. For FDA, which is able to inspect each facility only infrequently, it is important to enhance the value of each inspection and gain insight concerning plant conditions and whether food safety controls are being operated successfully between inspections. HACCP does this by generating records that continuously document the successful operation of the plant's food safety controls, including how processing problems have been detected and corrected in accordance with the HACCP plan. HACCP-based inspection of seafood processing plants will thus provide FDA with more than a snapshot of plant conditions as they exist at the time of inspection, as under the current system; future inspections will provide a window on the plant's operations over time and a much better basis for confidence in the plant's future operations.

HACCP also provides USDA a framework for making better use of its resources, though for USDA the resource challenge is very different. The statutory mandates for carcass-by-carcass inspection in slaughter plants and "continuous" or daily inspection in processing plants are the legal anchors for a large inspection workforce, but they also severely constrain the allocation of USDA's inspection resources. A large share of USDA's workforce is committed to the very labor-intensive mode of inspection currently

practiced in slaughter plants and to meeting the statutory mandate for continous inspection. USDA's discretion to allocate this resource in accordance with risk is limited. This results in the deployment of USDA inspectors within plants -- including the specific tasks they are assigned to perform -- being less than optimal from a food safety standpoint;[23] and USDA has been unable to provide meaningful inspection oversight outside of the plants themselves, even though many food safety problems arise from the manner in which meat and poultry products are handled during transportation, storage, and retail sale.

HACCP creates both the opportunity and necessity to improve the deployment of USDA inspectors. HACCP will assist USDA in focusing its inspectors on the most important food safety concerns in the plant and enhancing the productivity of each inspector, thus freeing up inspector time for tasks not currently being performed. Much of this time will go to necessary oversight of HACCP, but USDA also recognizes that redeployment of some inspectors outside the plants is necessary to address food safety concerns.

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[23] The current mode of slaughter inspection is labor-intensive, consuming approximately half of USDA's inspection resources, and devotes substantial attention to carcass conditions that do not relate to food safety. See generally National Research Council/National Academy of Sciences, Poultry Inspection -- The Basis for a Risk-Assessment Approach(National Academy Press, Washington, D.C., 1987). USDA plans to develop and test alternative inspection models that would make better use of the agency's resources to improve food safety and implement HACCP[cite].

The new HACCP paradigm currently applies as a regulatory matter only in plants producing meat, poultry and seafood. It remains to be seen whether the agencies will consider regulatory adoption of HACCP necessary or appropriate for other segments of the food supply. But the core concepts -- prevention, a clearer delineation of responsibilities, and better use of resources -- provide the conceptual framework for the future of the Federal food safety program.

These concepts are at the heart of what USDA has characterized as its farm-to-table food safety strategy.[24] USDA is working with agricultural producers, meat and poultry companies, distributers, retailers and consumers to devise prevention strategies -- and a clearer understanding of who is responsible for what -- at each stage of the food system, from the farm to the table. In some cases, the answer may be embodied in new regulatory standards, such as the new standards USDA and FDA are considering for the proper cooling of raw meat and poultry and other perishable foods to help prevent food safety hazards during transportation and storage.[25] In other cases, the answer may lie in new forms of voluntary collaboration, such as the coordination of food safety research with animal producers or expanded cooperation with industry and other groups on food safety education for consumers and retail food handlers.

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[24] 61 Fed. Reg. At 38810-11.

[25] [FR cite to transportation notice]

IV. Beyond HACCP: Assigning Responsibilities in the System of the Future

Without doubt, the food safety paradigm is changing at FDA and USDA. HACCP is here to stay as a regulatory tool for at least some segments of the food industry, and the core concepts discussed in the preceding section have been embraced by the agencies as the conceptual framework for the future of their programs. These concepts -- prevention, responsibility, and better use of resources -- provide the foundation for a food safety system capable of meeting any challenge, but there are many additional questions involving who will be responsible for what in the system of the future that are yet to be resolved.

A. Reducing the Risk of Foodborne Illness

The goal all participants in the food system share -- government, industry, and consumers alike -- is to reduce the risk of foodborne illness to the maximum extent reasonably possible. USDA announced this as its goal when it adopted its HACCP rules for meat and poultry,[26] and the Department of Health and Human Services(DHHS) includes reduction of foodborne illness rates associated with microbial pathogens among its goals for the nation in its Healthy People 2000 report.[27]

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[26] 61 Fed. Reg. at 38807.

[27] DHHS, Healthy People 2000 -- National Health Promotion and Disease Prevention Objectives(U.S. Government Printing Office, Washington, D.C., 1990).

But who is really responsible for reducing foodborne illness in the United States? At one level, the answer is that the responsibility is shared by everyone involved in the food system and by all of us as consumers -- the safety of food and the potential for illness really can be affected at every step from production to consumption, and illness typically results from the cumulative effect of multiple missteps along the way. That is why FDA and USDA are pursuing farm-to-table food safety strategies, including consumer and commercial food handler education.

At the level of public policy, however, the question of responsibility for reducing foodborne illness has more to do with the proper roles of food companies and government agencies. For food companies, the answer is relatively straightforward. A food company makes its core contribution to reducing the risk of foodborne illness by ensuring that it has done everything reasonably possible to make the food safe when it leaves the company's control. HACCP or some similar system of process control for food safety is a tool for doing that.

For government, the question is more difficult. As outlined in this paper, government has a regulatory role to play. Government can require, where appropriate, that HACCP or comparable approaches to hazard prevention be adopted by food companies, and it can establish and enforce food safety performance standards, as it does now for the control of pesticides and some harmful bacteria. But further reducing the risk of foodborne illness requires scientific, technical and behavioral advancements that are not

achievable through regulation and thus the possible roles for government go beyond regulation. They include leadership and investment in areas such as food safety research, technology development, epidemiological surveillance, and food safety education. The Federal government is active in all these areas, but its roles in relation to the food industry and the respective responsibilities of the various agencies are not well defined

For example, the potential of HACCP to improve food safety is clear, but HACCP can only be as good as the science and technology available to identify hazards and devise effective preventive controls. HACCP places a share of the hazard identification burden on individual food companies, certainly to the extent of knowing which of the recognized food safety hazards potentially affect their products. But many of the most troubling food safety problems of recent years have involved new or emerging hazards that no single food company can reasonably be expected to anticipate, study and prevent. Indeed, fully understanding an emerging problem, such as that posed by E. coli 0157:H7 in ground beef, apple juice or other foods, can require extensive scientific research, beyond the means of any individual company and arguably the responsibility of government.

Similarly, the development of control measures is an element of a company's responsibility under HACCP, and some companies have invested resources to develop or adapt food safety technologies for their operations. But technology development can require investment beyond the means of some companies, and, when effective new control

measures are devised, the public interest lies in having them reasonably available to all companies.

What is the proper allocation of responsibility between government and industry for food safety research and technology development? Can and should public policy foster private investment in these areas? By what mechanisms?

Some 21 Federal agencies are spending about $200 million annually on food safety research, but there is no formal process for establishing a government-wide research agenda, setting priorities, or coordinating research activities. What should be the government's role and responsibility for food safety research and technology development? Is the government investment in food safety research at the right level? Is it properly targeted to address the most important research questions? Is it conducted efficiently to avoid duplication and overlap? Who within the Federal government is really responsible as a practical matter -- and who can be held accountable -- for ensuring that the overall Federal effort in food safety research and technology development is on target and achieving what it should achieve? The answer today is that no one is clearly responsible.

Similar questions could be asked about government's role in epidemiological surveillance and investigations to understand the frequency and causes of foodborne illness. This knowledge is essential to the development of effective strategies to reduce

illness, but the data available today on foodborne illness are notoriously soft -- estimates of total cases range from 6 million to 80 million[28] -- and many states lack the facilities, equipment and personnel to collect better data. How should Federal and state agencies work together in this area? How can the efforts of CDC, FDA, and USDA be better coordinated and enhanced to ensure that the data needed to support the Federal food safety program are generated? Who is in charge and who is really responsible for the success of this effort?

Improving the food safety practices of consumers and commercial food handlers with regard to such basic matters as handwashing and proper food storage and cooking would go a very long way toward reducing the risk of foodborne illness. Food safety education is not a panacea and cannot substitute for other food safety measures, but it should be a major component of society's public health program to reduce foodborne illness.

Who is responsible for food safety education in the United States? FDA, USDA, and CDC all have staffs working in this area; USDA requires safe handling labels on raw meat and poultry products; and some industry groups have conducted or are planning food safety education campaigns. But food safety practices among Americans leave a lot to be desired. Who is responsible for devising and implementing a comprehensive strategy to improve food safety education and food safety practices? We know what constitutes safe

[28] [cite]

food handling practices, but who is responsible for conducting the research needed to devise education strategies that will actually work to improve consumer behavior?

Reducing foodborne illness is an important social goal that will require the efforts of many to achieve. The process of achieving it cannot be neat and tidy. But, without a clearer understanding of who is responsible for what, progress will not be as rapid as we want it to be -- and we won't know exactly why.

B. Managing the Introduction of New Food Technologies

New food technologies have been essential to building the safety, abundance, convenience, and economy of the American food supply. Many of these -- including food additives, food packaging, animal drugs, pesticides, and genetically modified food crops -- are closely regulated by government to ensure their safety and may require some form of government approval before they can be lawfully introduced.

When a government safety approval is required, the basic allocation of responsibility for the approval decision is clear. The sponsor gathers and presents data demonstrating safety, and the government agency -- most often FDA but also EPA and USDA, depending on the product -- evaluates the data and makes the decision to approve or reject the new product.

This approval system has generally worked well to assure the safety of new food technologies, but, as currently designed and administered, the system is essentially neutral with regard to fostering the introduction of technologies that can improve food safety or otherwise enhance the food supply. The governing statutes preclude consideration of a new technology's benefits at the time of approval, and the responsible agencies take pains to avoid favoring or promoting any particular new technology for fear the credibility of their safety decisions will be undermined.

The value of new food technologies is instead generally tested and revealed in the marketplace. Agricultural producers buy and use products that increase their productivity and lower their costs. Food processors use technologies that give products value consumers will pay for. But public and market acceptance of new food technologies is not determined solely by economic considerations. Public understanding of the technology and confidence in its safety can also have a profound effect, as evidenced perhaps most starkly by the failure of food irradiation to take hold despite its food safety benefits.

When Congress passed the law creating the pre-market approval system for food additives in 1958, it explicitly found without great debate that new food technologies convey important benefits.[29] One objective of the new system was to ensure that the safety of food additives, including new ingredients, food packaging, and food irradiation, had been adequately assured so they would be accepted by the public. The effective

[29] [cite FAA]

functioning of that system -- with respect both to the pace and scientific rigor of its safety decisions -- probably remains the greatest contribution government can make to the encouragement of new food technologies.

But should the government do more to foster the introduction of new food technologies? Is it the government's responsibility to help the public understand the technologies and build confidence in their safety? Who in the government could credibly play this role? Today, the Federal food safety agencies generally limit themselves for reasons noted above to the role of neutral defender of past safety decisions. For those agencies or others in government to step forward and play a more active role will require public discussion and a new undersatanding of government's role and responsibility in this arena.

C. Overseeing and Facilitating International Trade

The expanding international trade in food confers great benefits. Imports expand consumer choice and contribute to maintaining a competitive -- and thus efficient and low cost -- market for food. Food exports are good for the American economy. But this trade also poses challenges and unresolved issues for the U. S. food safety system.

On the import side, the issues involve both maintaining America's high food safety standards in the new era of international harmonization and ensuring those standards are

met by those who seek to export food to the United States. American food safety standards and regulatory systems are among the strongest in the world. This is good for consumer protection in the United States, and it is a source of strength for U.S. exporters of food products. In the new trade policy environment created by the Uruguay Round of GATT, maintaining these high standards will require careful attention and a clear understanding of roles and responsibilities within the Federal government.

The GATT agreement on sanitary and phytosanitary standards(the S&P agreement) strikes an important balance. It encourages international harmonization of food safety standards and forbids the disguised use of safety standards as discriminatory non-tariff barriers to trade, but it also respects the right of countries to maintain their own levels of consumer protection. In the United States, the trade agencies, including the Office of the United States Trade Representative(USTR) and the Foreign Agricultural Service at USDA, understandably tend to focus on the international harmonization and non-tariff trade barrier aspects of the S&P agreement, while the food safety agencies tend to focus on ensuring that international harmonization does not weaken U.S. food safety standards.

Both sides of the S&P balance are important, but they can conflict. For example, promoting international acceptance of pesticide residue limits adopted by the Codex Alimentarius Commission of the United Nations would facilitate U. S. exports of agricultural products and pesticides, but, since some of the Codex limits are less strict than

EPA's, this could jeopardize U.S. safety standards. The lines of responsibility within the U.S. government for ensuring that the United States strikes the proper balance in its implementation of the S&P agreement are not clear. In addition to USTR and USDA, the Department of Commerce, the State Department, FDA, and EPA all play a role and have major interests at stake. Coordination and the resolution of disagreements among these agencies is largely ad hoc.

The ability to hold food imports to the high U.S. safety standards is also affected by the nature and intensity of the FDA and USDA import inspection programs. FDA inspects no more than one or two percent of import shipments and is able to conduct only a handful of food plant inspections overseas. USDA has a more elaborate system for ensuring that foreign inspection programs for meat and poultry destined for the United States are equivalent to USDA's system, and USDA inspects 5 to 10% of import shipments.

The FDA and USDA import inspection programs have both been criticized from time to time by the U.S. food industry and consumers as not thorough or strict enough to guarantee that all imported food meets U. S. standards.[30] To what standard of effectiveness should the two programs be held? Are the differences in the programs justified? Do the agencies have the legal tools and the resources to do what is expected of them in policing imports?

[30] [cite GAO reports]

Fostering exports presents a different set of questions. As already noted, the various trade agencies of the Federal government actively pursue this agenda through various means, but what is the role of the U.S. food safety agencies in facilitating food exports? FDA and USDA already play a technical role by issuing export certificates verifying that particular shipments have been produced under conditions that satisfy U.S. food law and, in some cases, verifying that certain specific requirements of foreign regulatory bodies have been met. What should be the role of the food safety agencies beyond this?

Should they actively promote foreign acceptance of food products produced under U.S. safety standards? What role should they play in resolving particular disputes, such as those underway concerning the exportation to Europe of genetically modified soybeans and beef produced with the use of FDA-approved growth promotants? What role should they play in Codex and other international standard-setting bodies? The food safety agencies have traditionally limited themselves to a largely scientific and technical role in these settings, generally avoiding overt advocacy on behalf of U.S. exports. But, since food exports are clearly in the public interest and trade disputes are increasingly likely under the new GATT agreement to involve safety and other consumer protection issues, should the proper role of the food safety agencies be revisited? If regulatory agencies are not the appropriate government source for strong advocacy concerning the safety of U.S. exports, what is the appropriate source?

D. Maintaining Public Confidence in the Food Supply

Maintaining public confidence in the safety of the food supply is one of the most often cited yet most ephemeral challenges facing the food system. Everyone is for it, but what does "public confidence" really mean? It is perhaps best understood not in positive terms -- most people don't spend time or want to spend time thinking about the safety of the food supply -- but rather as the absence of concern about food safety. In operational terms, public confidence could be defined as the state of mind that enables people to make their food choices free of unwarranted anxiety about the safety consequences of their choice.

Why is public confidence in food safety important? Part of the answer, of course, is that no one wants to be anxious about the food they purchase and provide for themselves and their families. Another part of the answer is that doubts about food safety can skew food choices in ways that are detrimental to public health. A person who avoids consumption of fruits and vegetables out of a general concern about the safety of pesticide residues is making a food choice that is bad for their health.

Public confidence is also important because it can affect the public's acceptance of new products and technologies, whether it is a new ingredient(such as a new sweetener or fat substitute), a new processing technology(like irradiation to kill bacteria), or a new production technology(like genetic modification of food crops). Moreover, when a safety

cloud hovers over any particular product or product category already on the market, demand for those foods can plummet -- witness the drop in apple consumption when the public was concerned about the safety of the fungicide Alar[31] and the devastation of the market for British beef in the wake of public pronouncements concerning the possible transmissibility of bovine spongiform encephalopathy(BSE) from beef cattle to humans.[32]

Most Americans have a relatively high degree of confidence in the safety of the food supply,[33] based presumably on a combination of experience -- most people rarely experience what they can identify as a food safety "problem" -- and on the assumption and belief that there is a system in place for ensuring that food is safe -- "they" wouldn't let the food be sold if it weren't okay. People react strongly, however, when a food safety problem strikes home or when the system itself seems in some manner to have failed. Such real or perceived failures in the food safety system certainly are what capture media attention, which in turn heavily influences public opinion and reaction.

Outbreaks of foodborne illness or other food safety problems will never be totally eliminated. The food system is too large, too complex , and too human to expect that.

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[31] [cite]

[32] [cite news reports]

[33] [cite surveys]

Most consumers are smart enough to recognize and accept this reality. But what should the food system do to maintain public confidence? And who is responsible for doing it?

Part of the answer no doubt lies in the realm of communication and education. If people understand food safety issues better and understand how they can protect themselves from the most common food safety hazards by the way they handle and prepare foods, their confidence in the safety of what they eat can be enhanced. As discussed in section III, this kind of education is a shared responsibility of government and industry.

But public confidence in the safety of food is not just a matter of public relations. When real food safety problems arise or when anxiety is raised by reports of new information or concerns about food safety, there is no substitute for having in place a system of food safety protection that meets public expectations by credibly addressing and working to prevent food safety hazards. This is true at the level of the individual food company; and it is true at the level of the government's food safety system. Public confidence is in greatest jeopardy if, when problems or questions arise, the efforts of the government or the involved company are found wanting.

The fundamental elements of a sound food safety system are in place with the strong commitment most food companies make to food safety, the Federal government's traditional regulatory role, and the HACCP initiative, but the future success and credibility

of the system -- and the public's confidence in the safety of the food supply -- require more. They require a sustained effort to ensure that government and industry have clearly defined and are successfully fulfilling the roles each can best perform to ensure the safety of food. As discussed in the preceding sections of this paper, there are issues still to be resolved.

V. A Concluding Note on the Problem of Resources

The questions that may control the future of the Nation's food safety system involve money. How much are we willing to spend? What should we spend it on? Where will the money come from? These are questions food companies ask every day as they plan and conduct their operations, including their activities related to food safety. They are also questions the Federal food safety agencies are asking themselves with increasing urgency.

The bi-partisan commitment in Washington to balance the Federal budget by 2002, while cutting taxes and not seriously cutting Defense, Social Security, Medicare or Medicaid, is creating a budget crisis for the remaining agencies on the "discretionary" side of the Federal budget. This includes the food safety, environmental, and other health and safety agencies of the government. None of these agencies will be immune from the

scarcity of public resources. All must critically re-examine their missions, their roles, and how they use the resources they have.

But the agencies cannot do this successfully on their own. People and organizations throughout our society who care about what the agencies do and who have a stake in their success must engage in the re-examination. In the food safety arena, the questions are particularly pressing. The FDA food safety program has suffered serious erosion of its resource base to the point that its capacity both to manage routine business and develop strategies to deal with new food safety concerns is in jeopardy; and the credibility of FDA's inspection program is in decline.[34] What resources and capabilities should FDA have to inspect domestic food establishments, inspect imports, implement HACCP, and evaluate new food technologies?

USDA has a substantially larger resource base, but USDA recognizes that the current inspection model does not make the best use of that resource and has begun a public process to consider redeployment of its inspection resources. What approach do we want our government to take to the inspection of meat and poultry?

And how are we going to pay for what we want the government to do? If history is our teacher, the President understandably will continue to propose greater reliance on industry-paid use fees; the industry understandably will continue to resist fees; and, for the

[34] [cite CFSAN budget trends]

next couple years, the agencies will muddle through as is, with static budgets or budgets that continue to decline gradually. The food safety agencies will survive -- they are too important not to.

But this budget scenario is not a recipe for success. It will not equip the agencies to do what is expected of them; it will undercut the food industry's efforts to adopt new technologies and expand trade; and it will disappoint a consuming public that has shown its capacity to react harshly when it believes the nation's food safety system is falling short of what can reasonably be achieved in protecting people from the risk of foodborne illness. To maintain America's world leadership on food safety, it will be necessary by the turn of the century to have resolved comprehensively what kind of food safety system we want to have and how we are going to pay for it.

Goals –

Food Code 1993 – State adoption
- What is it? Published in 1993
- Expect widespread adoption 1995-2000

Goal 70% of states adopt by year 2000.

- Food Handling - Restaurants / Food Code
- Concern about targets (reduction).
- Coordinated Education – what message will work
- Current system is not EWS.
- Cataloging current system for surveillance
- layer hens - post-post
- Norwalk virus - seafood the minority

Inspections

January 14, 1997
Redlined

More explicit recitation of resource question - it was in ReGo - we spend $1B not remotely related to risk could go in strategic planning, inspection, HACCP risk assessment.

FOOD SAFETY FROM FARM TO TABLE: A NEW STRATEGY FOR THE 21ST CENTURY

3pm.

INTRODUCTION

Protecting the food supply in the 21st Century will mean having in place effective, coordinated means for government and industry to prevent outbreaks of foodborne illness. We have managed until now to provide one of the safest food sources in the world by responding to outbreaks when they occur and correcting problems after the fact. That is no longer good enough, as millions of illness and thousands of deaths occur each year from contaminated food. To effectively carry out our public health mission, we must prevent illness before it occurs, and that in turn means putting into place the kinds of programs that:

where are risks
↓
allocate resources to risks where great est good can come.
↓
HACCP impl will occur where risk is.

- o Identify illnesses when they occur and rush in to track them down, control their spread and prevent their recurrence;
- o Ensure that food processors and handlers use state-of-the-art methods of protecting food and monitored for adherence to those standards;
- o Can assess the risk of various threats to food and make sound regulatory decisions that fix the problem at the least cost to taxpayers and lowest burden on industry; and
- o Empower our citizens to improve their health by educating them in proven, effective methods for avoiding food-related disease.

~~it~~ it is doubt finding the right balance between Congress?

All of this can happen only if the Federal agencies charged with ensuring food safety work together in a concerted effort to fight the many hazards that threaten our food. The threats to food go as far back in our past as humankind itself. But we now have the technology, scientific skill and practical know-how to relegate so much of it to just that--the past. As we move toward the year 2000, we must look to the future and to ways of making this vision come true. If we do this right, in the short term we can prevent up to 9 million cases of foodborne illness, and save almost 3,000 lives, each year.

EXECUTIVE SUMMARY

Ensuring the safety of the food supply is one of government's most enduring and important functions. It is a responsibility shared by government and the private sector. In responding to new technologies that enable food producers to grow, process, and market a growing variety of food products, the private sector and federal, state and local governments fact many

challenges to maintaining and improving the safety of the nation's food supply. Disease-causing micro-organisms (pathogens) continue to threaten public health as new organisms emerge as food-borne threats, and well-known organisms acquire greater potency.

This report outlines innovative ways of doing things, to get the diverse talents and resources in the Federal government pulling together--in partnership with State and local health officials, the food industry, academic scientists, non-governmental organizations and consumer groups--to identify and act against threats to the safety of the food supply. In this report, specific steps are proposed that would begin to reduce food-related disease and death over the near term, and build the foundation for improved food safety for years to come.

Every day, thousands of Americans are stricken by illness caused by the food they consume, and up to 9,000 a year--mostly the very young and the elderly--die as a result. The threats to food are numerous and varied, ranging from *Escherichia coli (E. coli)* O157:H7 in meat and apple juice, to *Salmonella* in eggs, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water. Our understanding of many of these pathogens (disease-causing organisms) is limited; for some, we do not even know how much must be present in food for there to be a risk of illness. The public health-care system in this country has limited means to identify and track the causes of foodborne illness; and Federal, State, and local food safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Meat and poultry plants are inspected every minute they're operated, yet years can go by before other food plants receive a Federal inspection. Increasing quantities of imported foods flow into this country daily with little scrutiny by FDA inspectors. Some food processors, restauranteurs, supermarket managers, and consumers are often ignorant of the threat of foodborne contaminants and how to protect food from them.

The United States continues to have one of the safest food supplies in the world. More can be done, however, to make our food supply safer. There is enormous medical and scientific talent in the public agencies responsible for food safety. Working with the food industry, we have devised a quality assurance system for the harvesting, processing, transportation, handling, and storage of food. That system, which relies upon preventing the contamination of food, must be put into place at every step of the food delivery process--from the farm to the consumer's dinner table. Known as "HACCP," it represents a new paradigm that allocates responsibility between government and the private sector. The Federal government's responsibility is in setting standards, research and development, risk assessment, technical assistance, inspection to hold industry accountable, and education. The private sector is responsible for producing safe food through the adaptation of preventive measures of their own design.

More specifically, we can make enormous strides toward helping our citizens lead longer, healthier lives by implementing the following recommendations:

1) **"Early Warning System"/Surveillance:** Prevent occurrence or mitigate extent and

severity of foodborne illness outbreaks. The current Federal and State infrastructure for foodborne disease surveillance has long had inadequate resources to determine the incidence of foodborne illness and trends, and to assure prompt recognition and response to disease outbreaks. In the past two years CDC, with assistance from FDA and USDA, established five food sentinel sites to actively identify and investigate the occurrence of foodborne disease and determine trends. However, to function as part of an effective early warning system, the capacity of these sites to detect and investigate outbreaks must be enhanced and the number of sites expanded. The enhancement of capacity includes increasing the number of "disease detectives" available to follow up on outbreaks, and updating available laboratory, communications, and computing technologies. In addition, because outbreaks can occur anywhere, resources must be provided to States outside the sentinel network to upgrade the surveillance and response capacity of the nation--assuring that all States have flexible epidemiologic and laboratory capacity to promptly identify foodborne disease outbreaks, and appropriate expertise to investigate and control food safety problems; and providing improved training programs to State and local health departments. This requires increased epidemiologic, microbiological, and communications resources at CDC, FDA, and USDA to provide needed coordination of the Federal response during foodborne disease outbreaks.

2) **Coordination**: Improve overall efficiency and emergency response coordination for outbreaks. Since no food protection system will prevent all outbreaks, we must be prepared to move rapidly and effectively when they occur. The considerable expertise of Federal, State, and local health authorities must be brought together to better manage such outbreaks.

3) **Bioscience Research:** Expand bioscience research to develop new methods for identifying and controlling foodborne pathogens. The expertise of the U.S. Department of Agriculture's (USDA) Agricultural Research Service, ~~Research, Education, and Economics agencies and Food Safety and Inspection Service (FSIS),~~ the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) would be coordinated and combined with new funding to find new ways of detecting disease-causing organisms in food, water, animal feeds, and animals used for food, to develop new methods for preventing, combating, or destroying such organisms, and to improve our knowledge about the best techniques for handling and storing foods.

4) **Risk Assessment:** Improve risk assessment tools and interagency coordination in risk assessment. Finding a contaminant in food tells us little if we do not know what, if any, danger it poses to human health. We need to determine, for example, how much of a given contaminant must be present in food to make consumers ill, how often various contaminated foods are consumed, and where in the chain from farm to table our food is most vulnerable. The efforts of the various public health agencies must be

coordinated for maximum consistency and efficiency in conducting risk assessments, via a "consortium" of agencies whose scientists would work closely together to develop the best information about the nature, causes, and prevention of risk. With that information in hand, along with sound economic analyses, regulators can understand the costs and benefits of alternative regulatory interventions and thus make informed, cost-effective decisions about how to reduce the risks to the food supply.

5) **Inspections**: Implement HACCP and enhance and better coordinate FDA inspections with other agencies. ~~Increase FDA inspection frequency and coordinate with other inspecting agencies.~~ We cannot know if the food industry is properly implementing adequate food safety procedures unless they are regularly inspected. USDA does so daily for meat and poultry plants, but FDA's average inspection frequency has eroded to once every ten years. FDA must be given new resources to inspect more frequently, at least once per year for the highest risk foods, such as seafood; and new partnerships must be developed with the States to maximize Federal resources.

6) **Education**: Expand and improve food safety education for food processors, retailers, restauranteurs, food service workers, and consumers. An essential element in improving the safety of our food supply would be informing food processors, retailers, restauranteurs, food service workers, and consumers about the latest safe food processing, preparation, and handling procedures. This will encourage behavior change and thus enhance prevention. Because the messages of the various agencies are basically the same, redundancies should be replaced with a consistent, coordinated education campaign that can effectively modify behavior. This campaign would include new school curricula, a national clearinghouse of food safety information, town meetings, and numerous other mechanisms for getting information out. Informing consumers of specific high-risk behaviors and educating physicians and clinical microbiologists on methods for diagnosing foodborne diseases and identifying foodborne pathogens are important elements of preventing foodborne diseases.

7) **Strategic planning**: Develop a strategic plan and a shared long-term agenda for an improved food safety system. The initiative outlined above is targeted to reduce the hazards that present the most immediate risks, microbial pathogens. Stakeholders would be consulted in design of its implementation. A further process is proposed in which stakeholders would participate in setting a longer term agenda for food safety reform. The major purposes of this strategic planning exercise are to develop the knowledge base necessary to reduce foodborne diseases, and to identify systemic change (including organizational, procedural, and structural changes) that would lead to lasting improvements.

Making the necessary improvements in the food safety system will not be easy. Because many lines of authority must be crossed, many new working relationships established, and fundamental changes in infrastructure made, the current system must be "reinvented." But for

the most part, the statutory authority, scientific expertise, and dedication to the public good already exist. The benefits from these improvements can be enormous. Based on a recent model developed to assess the impact of foodborne illness, the improvements recommended in this report will reduce the occurrence of foodborne illness by up to 1.8 million cases, save almost 3,000 lives annually, and save society many millions of dollars in health care costs. They can also be expected to blunt the rise in foodborne illness that is predicted for the next five years, and to enhance confidence in foods prepared for a rapidly growing export market.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven by the high expectations of American consumers for the foods they purchase for their families.

Foodborne illness, however, still occurs in the United States, and steps have already been taken to tackle the problem. Over the last four years the Clinton Administration has sponsored the development and implementation of major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.

- FSIS and FDA issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.

- Beginning in 1994, CDC embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.

- The Food Quality Protection Act of 1996 streamlined regulation of pesticides by FDA and the Environmental Protection Agency (EPA) and put important new public-health protections in place, especially for children.

- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help States and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they are not enough. New pathogens, new food products, huge increases in imported foods, and increasing antimicrobial resistance present new challenges to the nation's food safety programs. Continued food safety and consumer challenges demonstrate that the food safety system is in need of reform, especially to build on the preventive principles embodied in HACCP.

HISTORY OF FOOD SAFETY

Since the Federal Food and Drugs Act and Meat Inspection Act were enacted in 1906, advances in securing a safer food supply in the United States have been both steady and increasingly certain. Scientific understanding of food contamination and human nutritional needs resulting in tighter food safety standards have been a major factor in increasing the length and quality of Americans' lives.

In the late 19th Century, when it was first demonstrated that Louis Pasteur's scientific principles had practical application to the food industry, food spoilage was a major economic loss to both the food industries and to retailers, dietary deficiency diseases were common throughout the country, and food poisoning was a major public health threat, particularly to young children and to the elderly. Especially in urban centers, where contaminated meat and milk were common, the weaning of a child was a perilous process and infant mortality rates were high. Once it was established that bacteria caused canned foods to spoil, that heat killed bacteria and refrigeration retarded their growth, it became possible to make foods safer. Thus, highly perishable foods such as milk and eggs, and seasonal fruits and vegetables, became widely available.

After World War II, new packaging and new food forms, especially frozen foods, as well as new functional food ingredients--emulsifiers, antioxidants, flavorings, and preservatives--created new concerns about the safety of the food supply. Concerns about carcinogens led to a ban of the use of diethylstilbestrol (DES) as a growth promoter in cattle, and prompted a re-evaluation of many pesticides and food and color additives in light of their cancer-causing potential. Some questionable ~~products~~ food components (either added or naturally present) such as aminotriazole (in cranberries), alar (in apples), coumarin (in flavoring), and several colors, including Red #2 were banned from the food supply. As regulators have begun to make progress in assessing both the theoretical and actual cancer risks posed by food ingredients, however, concern has steadily shifted away from ingredients added to foods back to food contamination and food sanitation. The discovery of new hazards, some of them naturally occurring, such as paralytic toxins in shellfish, have led to new methods of detection and new regulatory efforts. Outbreaks of foodborne illness due to *E. coli* in hamburger, apple juice, and other fresh produce, parasites in raspberries, and others, have led to a new focus on the need for preventive controls from the farm to the table.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over $3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between $6 billion and $9 billion. Total costs for all food poisonings are likely to be much higher. These estimates do not take into account the burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens. Nor do they account for the costs of the often "silent" consequences of exposure to foodborne chemical contaminants such as PCBs, or heavy metals such as lead.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella* enters eggs directly from the hen. It is not unusual or abnormal for raw fruits and vegetables in the field to have bacteria (occasionally pathogenic) on their surfaces. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Misuse of pesticides, herbicides, and other chemicals may result in unacceptably high levels of these chemicals in various foods. Seafood may become contaminated from agricultural and other chemical runoff, sewage, and accidental spills of hazardous substances, as well as from microorganisms and toxins that naturally occur in marine environments. Milk, eggs, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, disposal of solid waste on land, or toxic emissions to air. Foods may also become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; chemical spills during transportation; and improper storage. Foods may become contaminated in retail facilities and in the home through poor food safety practices.

Major Food Safety Hazards and the Diseases They Cause[1]

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. They are: *Campylobacter jejuni/coli*, *Salmonella* species, *E. coli* O157:H7 and other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting are the most common initial symptoms of "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome, the most common cause of acute paralysis in adults and children, and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children.

Salmonella

Salmonella bacteria cause diarrhea and blood-stream infection, which can be fatal in particularly susceptible persons, such as the very young and the elderly. An estimated 800,000 to 2 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Between 128,000 and 640,000 of these infections are associated ~~Infections~~ with *Salmonella enteritidis* (SE) ~~associated with~~ in eggs. ~~have increased five-fold over the past 20 years.~~ Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate meat, dairy products, eggs, etc. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. Although outbreaks are rare, these infections

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1 Although food is threatened by both microbiologic and chemical contaminants, this initiative focuses on microbiologic hazards. However, improvements in our food safety system will generally provide improved protection from such chemical contaminants as lead and mercury. Furthermore, the initiative's strategic planning process should focus on approaches to reduce food hazards associated with chemical, heavy metal, and other non-microbial threats.

are even more common than those of *Salmonella*. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are ~~is~~ commonly foodborne, and ~~is~~ are the infectious agents most frequently described in association with Guillain-Barré syndrome. The major source of *C. jejuni /coli* infections is raw or undercooked chicken; ~~outbreaks~~ incidents of foodborne illness have also been associated with unpasteurized milk.

Escherichia coli

Several strains of the bacterium *E. coli* cause disease in humans and animals. *E. coli* O157:H7 is a type commonly associated with human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools. Life-threatening kidney failure can result, especially in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. *E. coli* O157:H7 outbreaks have recently occurred in ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996, was associated with unpasteurized apple juice, and sickened dozens of people and killed one child, in several western States.

Toxoplasma gondii

Toxoplasma gondii is a parasitic protozoan. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* and contact with cats that shed cysts in their feces during acute infection. The consumption of unwashed fruits and vegetables is also a major factor contributing to infection.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. *Cryptosporidium* is found in feces of infected mammals, and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of many cases of digestive system disease, both scattered cases and outbreaks that can involve overwhelming, dehydrating diarrhea.

Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among Federal, State, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- On the farm, food is regulated by State agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, and by the FDA, which oversees use of drugs and feed in milk- and food-producing animals. Federal responsibility also extends to assuring that the food industry manages production and harvesting activities that discharge of wastewater to surface and ground waters; to use of excessive amounts of solid waste on land or toxic emissions to air, all of which could contaminate growing and process waters or grazing land.

- Food processing for foods other than meat and poultry is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. Meat and poultry are regulated by the Food Safety and Inspection Service, whose inspectors monitor the slaughter and processing of animal products daily in about 6,000 plants. States and local governments also inspect food processors, with varying frequencies and under varying standards.

- Food being transported in interstate commerce is subject to Federal and State regulation, although that area has received little attention in the past.

- The importation of food from foreign countries is overseen by FDA for all foods other than meat products, and by FSIS for meat products. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.

- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by States and local health authorities, and FDA has a "food code" which consists of model requirements for safeguarding public health when food is offered to the consumer .

- National standards for drinking water are set by EPA, and enforced generally by local

public water authorities; FDA establishes complementary standards for bottled water.

- Surveillance of foodborne illness is primarily the responsibility of State and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.

- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness.

- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA research agencies, FDA, CDC, EPA, the National Institutes of Health, other Federal components, and the States. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The Federal government also supports related research in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify and track and prevent food-related illness and prevent future cases from occurring. State and Federal resources are not closely coordinated, and duplication of effort is not uncommon. FDA inspected food firms in 1981 every 2-3 years, but can now visit those plants on average only once every 10 years, while FSIS inspectors are in meat and poultry plants every minute that the plant is in operation. Our understanding of some disease causing organisms is so limited that our ability to protect the public health is seriously constrained. And food processors, restauranteurs, supermarket managers, and consumers are often woefully ignorant of the threat of foodborne pathogens and the methods available to protect food from them.

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

The Clinton Administration's interagency food safety initiative is based on the public health principles that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks. This means preventing and reducing food contamination to a degree that substantially reduces and minimizes the risk of foodborne illness. Achieving this goal would require joint commitment to the principles of preventive control, and long-term commitment and action from government agencies and from industry and academia to incorporation of these principles into all components of the food safety system.

The actions to be undertaken through this food safety initiative beginning in Fiscal Year 1998 are designed to achieve near-term reductions in foodborne illness and disease associated with specific high-risk contaminants. However, the larger problems with the food safety system, such as the need for fundamental infrastructure changes in Federal agencies, coordination with State and local governments, and the need for a long-range research agenda, require more deliberation and in-depth discussion with all stakeholders in food safety.

A STRATEGIC PLAN FOR A NEW FOOD SAFETY PARADIGM

A significant activity proposed as part of this food safety initiative would be to create a process by which all stakeholders in the nation's food safety system can participate in setting an agenda for and discussion of the issues raised by consideration of fundamental change for the food safety system. These stakeholders include Federal, State, and local public health, agricultural, and regulatory officials, food producers and manufacturers, academic scientists, consumers, representatives from the food-service sector, including retail, restaurant, and institutional food-service settings, and veterinary professionals.

A contract would be established with an independent organization to bring together all major stakeholders for discussion of fundamental changes to the present food safety paradigm. A major purpose of this strategic planning exercise would be to identify changes that should be made to the present organizational and procedural structure that would bring about permanent improvements in efficiency and coordination. Dialogue groups would be established to develop a strategic plan. Opportunities for input would include symposia held in geographically dispersed sites to encourage stakeholder participation. Documents developed from the deliberations and recommendations of these symposia could be the focus of further discussion during a series of open round-table meetings. The product of this series of dialogues, symposia, and hearings could form a report, which would provide the outline necessary for targeting needed structural changes in the Federal-State food safety system.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

This initiative would focus on the hazards and foods that present the greatest risks to public health, would emphasize development and implementation of preventive controls of those risks, and would seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry. This prevention-control concept is Hazard Analysis Critical Control Points (HACCP), which is a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being

implemented by FDA and FSIS in collaboration with the meat, poultry, and seafood industries. The extension of such preventive controls across the food supply will be the cornerstone for a new way of protecting food in the years to come.

Under a HACCP-based approach, the Federal government, in concert with State and local governments, will conduct research and risk assessments to determine how foodborne illnesses occur and can be controlled and prevented, surveillance and investigative efforts to locate and monitor illnesses caused by food, inspections of food processors to ensure compliance with the best manufacturing practices, and education of all those involved in food production and use in the implementation of safe practices. These activities are described below.

HEALTH AND ECONOMIC BENEFITS OF IMPROVED FOOD SAFETY

The public health impacts of the interagency food safety initiative described in this report would be significant. The model used to estimate these benefits uses the Council for Agricultural Science and Technology (CAST) report for the current annual incidence of foodborne disease. Numerous factors such as the growth in susceptible populations, emerging pathogens, growth in imports, growth in antibiotic resistance, and other factors are used to extrapolate to the likely annual number of cases and deaths 5 years from now. Illnesses may grow between 10 to 16% in that time period and deaths as much as 37%. The model examines each of the components of the initiative to determine the likely number of reduced cases (illnesses and deaths) the initiative will accomplish.

- Increased **inspection** activity is likely to reduce cases by 20%, with a 23% reduction from the entire initiative. Inspections are likely to increase compliance with food safety laws, particularly HACCP, through better detection of contaminated food at plants and on the docks and, perhaps more importantly, through providing more of a compliance incentive than that provided by the current low rates of sampling and plant inspections.

- Increased **surveillance** is likely to reduce the average number of cases per outbreak through quicker detection.

- **Education** of both consumers and food handlers workers has the potential for large gains, given the decline in food safety education in secondary schools and the projected increase in labor force participation rates for women (forcing more men to prepare food with an inadequate understanding of food safety). Poor food handling practices in restaurants has been traced to numerous foodborne disease outbreaks.

- **Coordination** and **research** contribute to greater efficiencies in surveillance and inspection.

- **Risk assessment** will reduce the costs of regulations by producing more targeted

regulatory approaches.

For the pathogens targeted by the initiative's proposed activities, this report estimates that the number of cases will be reduced by between 940,000 and 1.8 million cases and the number of deaths will be reduced by 300 to 1,500 annually. For all pathogens (including those not specifically targeted in this report), the number of illnesses can be reduced by 1.6 million to 8.8 million and the number of deaths can be reduced by between 550 to 2,600 annually. These numbers are not be considered precise, but rather representative of the kinds of public health benefits that a relatively small investment might obtain.

A NEW "EARLY WARNING SYSTEM" FOR PUBLIC HEALTH SURVEILLANCE

Background

The primary goal of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a ~~more~~ effective early warning system that can catch outbreaks early, preventing illness and death. This system will also advance our understanding of foodborne illness and further our prevention efforts.

The Problem

Surveillance and investigation of foodborne disease is a powerful way to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among States. Enhancing the capacity of States to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to enhance this is to increase the capacity of the existing Active Foodborne Disease Surveillance Network to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many States to address new foodborne challenges. These enhancements will help us catch outbreaks and other foodborne disease challenges early, and prevent illness and deaths.

Recommendations and expected benefits

The Federal government in cooperation with State and local health departments would take the following steps to establish a new early warning system for, and enhanced surveillance of, foodborne disease. These changes will result in an improved system for detecting and reporting foodborne illnesses and outbreaks that will enable public health agencies to rapidly

put into place measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

1) **Enhance and expand the Active Foodborne Disease Surveillance Program**

CDC, FDA, and USDA currently support five food sentinel sites at State health departments to track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and the number of "enhanced" sites should be increased to 7 in FY 97, and up to 10 in the following year. The sites and Federal food safety agencies should be electronically linked together to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional States will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

2) **Enhance early detection of foodborne disease nationwide**

In addition to establishing enhanced food sentinel sites, an early warning system would require improved early detection of foodborne disease in 5 to 10 additional States in FY 98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among bacteria, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools would be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies, and new education tools to provide training to State and local health department staff concerning foodborne disease surveillance, investigation and prevention. CDC also should provide additional resources to States to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

3) **Modernize public health laboratories**

CDC should provide resources and training to upgrade public health laboratory capabilities in the Active Surveillance sites and in other States so that they can rapidly identify a broad range of foodborne infections including new parasitic and viral pathogens, and can use new techniques of DNA "fingerprinting". CDC would work with States to develop, standardize, and transfer those methods. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

4) **Create a national electronic network for "fingerprint" comparison**

CDC, FDA and USDA will fund a new computer network and database system that would capture bacterial "fingerprints" in a national database, linking States that have this new capacity as well as the Federal laboratories into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington was contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, surveillance of contamination levels in foods, in animals used for food, and in their feed is important to control and prevent foodborne diseases, and to monitor the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities are required.

5) **Increase national surveillance for antimicrobial resistance of foodborne pathogens**

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for bacterial samples from food-producing animals and food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increase in resistance, or other "red flag events" such as the discovery of an important new resistant bacterium.

6) **Increase the monitoring of layer hens and bulk liquid egg products for *Salmonella* contamination before pasteurization ~~Monitor laying hens and bulk liquid egg products before pasteurization for *Salmonella*~~** also post-pasteurization.

USDA should sample specific egg-laying poultry populations and in liquid eggs ~~before they are pasteurized~~ for the frequency of *Salmonella* contamination, particularly for *Salmonella enteritidis*. This is critical to monitoring the success of measures to reduce the frequency of this pathogen in the nation's egg supply.

7) **Enhance surveillance for the impact of drugs and other therapies in food animal populations and pathogens in animal feed and feedstuffs ~~foodborne pathogens in food animals and feed~~**

USDA should expand the periodic surveys of pathogens in live food-producing animals to include human disease causing organisms. FDA should monitor animal feed

production facilities, emphasizing risk-based preventive controls. USDA should support *Salmonella* serotyping by the National Veterinary Services Laboratory.

8) **Enhanced foodborne pathogen testing ~~in the HACCP program~~**

USDA/FSIS proposes to improve their *E. coli* O157:H7 testing by joining the national electronic laboratory network for comparison of *E. coli* isolates and to acquire capability to serotype *Salmonella* bacteria, also linked to the electronic surveillance network.

COORDINATION

Background

At the Federal level, there are four agencies charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA, CDC, USDA, and EPA. While CDC's primary responsibility is to work with State and local health departments to identify and investigate sporadic cases and outbreaks of illness, FDA, USDA, and EPA have the additional responsibility of taking regulatory action against the suspect products, or those who contaminate the air, land, or waters used to produce the food product. Which regulatory agency gets involved depends on the type of food involved, with USDA having jurisdiction over meat and poultry, FDA over all other foods, and EPA over water and pesticides. While each agency has clearly defined areas of responsibility, most outbreaks of foodborne illness involve more than one agency.

In addition, investigations of foodborne illness usually begin at the community or State level. These illnesses may cross jurisdictional boundaries and may be linked to foods or food ingredients that were processed or produced in another State or by international trading partners, necessitating the involvement of Federal agencies. Federal involvement is also necessary when contaminated foods from the same sources may be in grocery stores, restaurants, and homes in other parts of the country. Companies responsible for the affected product also have a critical role to play, as many product recalls are voluntary. In most outbreaks of foodborne illness, the role of Federal agencies is to work with State and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and State authorities or is determined to be necessary. For large or multi-State outbreaks, Federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

The Problem

Although significant coordination already occurs among the Federal and State agencies, the mere fact that more than one agency is involved in any one outbreak of foodborne illness can cause some confusion. Many times a joint effort is hindered by a lack of communication and a misunderstanding of each agency's role in a particular situation.

Recommendations and expected benefits

Improved coordination among the Federal agencies, between Federal and State agencies, and among the various State agencies would enhance the level of public health protection, make the best use of interagency collaboration, and avoid duplication of effort.

1) **The Federal agencies should improve their coordination in the management of response to foodborne illness.**

Outbreak response ORCG

An ~~Interagency~~ Coordinating Group (ICG) made up of representatives of the Federal and State agencies charged with responding to outbreaks of foodborne illness should be created to coordinate the investigation and response to significant outbreaks of foodborne illness. The overall goal of the ICG should be to ensure that a coordinated and professional response, with all governmental resources pulling together, is undertaken to effectively investigate and respond to foodborne illness. The ICG should determine jointly which agency would take the lead during the various phases of outbreak investigations, and who would play the role of spokesperson for each phase or component of an outbreak. In addition, the ICG should coordinate communications and make decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks. The ORCG should also meet several times a year to review the response to outbreaks.

Each participating agency should fund and enhance programs that provide opportunities to exchange employees, on a temporary basis, among Federal agencies and between Federal and State agencies. Such an exchange would facilitate coordination by sharing expertise and providing an opportunity to better understand the various roles each agency plays in an investigation of a foodborne illness.

2) **The Federal and State agencies should improve their coordination in the management ~~of~~ and response to foodborne illness.**

Better coordination between Federal and State officials and among the various State officials would speed the identification and subsequent control of foodborne illness and the removal of the contaminated foods from the distribution chain.

In order to improve coordination, the Federal agencies should sponsor a national meeting of State and local health officials to develop recommendations on how to better coordinate the overall government response to foodborne illness.

One specific problem that should be addressed is *Salmonella enteritidis* in shell eggs. The Federal agencies should also work to establish a Federal/State cooperative program to solve this problem.

3) **The basic infrastructure for foodborne illness surveillance and coordination at State health departments should be enhanced.** Should first be cataloged.

The epidemiology offices and laboratories within State health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other State officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments and other sources. Yet, the resources available in many States for the surveillance and investigation of foodborne diseases are limited and decreasing,

thereby limiting the States' effectiveness. As a result, outbreaks may go undetected or are never investigated.

→ assessing & cataloging existing state resources

This problem should be rectified by providing Federal support for foodborne disease surveillance programs and assistance for the States to better investigate outbreaks of foodborne illness.

Need specific mechanism for coordination.

BIOSCIENCE RESEARCH

Background

The most critical needs in food safety research are for tools to more rapidly and accurately identify and characterize foodborne hazards and assess the risk they pose to human health. FDA, CDC, EPA, and the USDA's Research, Education, and Economics agencies (the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service, and the Economic Research Service) all conduct research generally focussed on pathogenic micro-organisms and other contaminants that threaten the safety of food.

The Problem

New disease-causing organisms, many of them foodborne, have emerged over the last 10 years. Many of these organisms can't be easily detected, or detected at all. Others, previously innocuous, have evolved into dangerous forms. Just because organisms are present at levels that can't easily be detected, however, does not mean that the organisms are not dangerous. New organisms and newly virulent strains of common organisms that are capable of "flying under the radar" are causing serious disease outbreaks. Foodborne pathogens are increasingly overcoming time-tested controls, such as heating and freezing, and are developing new virulence and new ways to evade our immune defenses.

Recommendations and expected benefits

Effective control of foodborne disease-causing organisms requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution. These interventions ideally are guided by risk assessment, for which all too often we have insufficient data. The initiative's research agenda would support HACCP implementation, would enable verification that HACCP critical control points are working, and would target the data gaps that hamper risk evaluation.

1) **Improved detection methods**

FDA and USDA should develop, validate, and implement methods for rapid testing of very low levels of *Campylobacter*, *Salmonella*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, and naturally occurring toxins in food animals, in agricultural and aquaculture products, animal feeds, and processed food products. This would be coordinated with EPA's efforts to develop better test methods and assessments of health effects from *Cryptosporidium* and other contaminants in drinking water. CDC should develop improved methods for identifying foodborne pathogens, including emerging pathogens, in clinical specimens and to subtype known foodborne pathogens.

2) **Fighting antimicrobial resistance**

Microorganisms can become resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens and are often not sufficient to prevent breakthrough of newly emerging pathogens. USDA and FDA will conduct research to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. This research will lead to the identification of food production and processing practices that are likely to be at risk from pathogens and provide guidance in the modification of traditional or development of new techniques to control their growth.

3) **Fighting antibiotic ~~and antimicrobial~~ resistance**

Pathogens in food-producing animals become resistant to drugs partially due to over-use of the drugs in those animals. FDA and USDA suspect that drug-resistant pathogens may lose resistance during the required period of drug withdrawal prior to slaughter. FDA and USDA should conduct studies to explore possible changes to "withdrawal time" requirements that could reduce transfer of resistant pathogens with minimal disruption to industry production practices. In addition, USDA should determine the basis for the ability of micro-organisms to rapidly adapt to changing environments, and should develop food handling and treatment mechanisms to minimize this adaptive ability.

4) **Prevention techniques: Pathogen control, reduction, and elimination**

Contaminants are introduced into the food supply at numerous points along the way from farm to store. Food animals may carry disease-causing organisms, but remain healthy themselves, complicating controls at the point of slaughter. Animal feed and drinking water can be "hidden" but significant sources of contamination. Recommendations to address these problems for *Salmonella*, *Campylobacter*, *Toxoplasma, Vibrio*, *E. coli* O157:H7, *Cyclospora*, and *Cryptosporidium* in all food products are the following (to be carried out in conjunction with the private sector):

FDA and USDA should work to develop drugs and other therapies to prevent initial infection.

FDA and USDA should develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.

FDA and USDA should develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.

FDA and USDA should develop new methods of surface decontamination of fresh fruits and vegetables.

~~FDA and USDA should develop methods to deactivate organisms such as *Salmonella* and transmissible spongiform encephalopathies (or TSEs, such as the agent that causes "mad cow disease") in animal feeds.~~

FDA and USDA should develop heat-based and other disinfection methods for meat, eggs, and produce, and animal feeds.

4) **Food handling, distribution, and storage**

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that makes animals and plants more susceptible to infection, and cross-contamination from the vehicle itself.

FDA and USDA should investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.

FDA and USDA should develop techniques such as on-line ~~biosensors~~ and scanning systems for detecting contamination and monitoring package integrity at all points along the production, transportation, storage, and distribution chain.

performance standards?

FDA and USDA should develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

5) **Long-term research agenda**

The Federal government needs to develop a long-term research agenda to truly address research needs to support a fundamentally improved food safety system. Strategies for developing a long-term research agenda would be developed through the strategic planning process discussed above.

What can we stop doing? How are priorities set now? Can we be more frank?

RISK ASSESSMENT

Background

It is a basic public health tenet that public resources should be devoted to reducing risks in at least rough proportion to the toll they take on human health. Risk assessment is the tool best suited to set priorities among public health risks. Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are required by law for all major Federal regulations. Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness. Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to World Trade Organization treaty negotiations, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

The Problem

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require a substantial amount of specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk, and mathematical "models" of chemical action or of the way that the body deals with a chemical.

Risk assessment is far less developed for foodborne pathogens such as bacteria. Intensive commitment would be necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Recommendations and expected benefits

This initiative's risk assessment activities would focus on developing better use of data and better models to inform surveillance plans, HACCP-based prevention strategies for smarter inspections, and research programs to fill critical food safety information gaps.

1) **Establish a Risk Assessment Consortium**

The FDA, in conjunction with USDA, CDC, EPA, and possibly other Federal agencies with similar risk management responsibilities, should establish a new forum at which Federal agencies can set collective priorities for risk assessment research.

The Risk Assessment Consortium should be established at the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and the University of Maryland.

The consortium should focus Federal research on developing data for risk assessments ~~risk-relevant data~~ focussed and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.

Research supported and conducted through this initiative should cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

2) Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply

Risk assessment of foodborne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative will address the numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research will be conducted in: incidence and prevalence of microbial pathogens and chemical contaminants; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; and intake data regarding food consumption patterns of the general population and sensitive subpopulations. Research using biomarkers will be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain.

3) Develop dose-response models for use in risk assessment

Dose-response models describe the consequences of exposure to the hazard. The dose-response model is an essential component of risk assessment, but one that is lacking for most foodborne bacteria, viruses, and natural toxins. Toxicokinetic data enable risk assessors to estimate with much greater accuracy the actual amount of a hazardous substance that reaches the target organ.

~~2) **Ensure the generation of high-priority and high-quality biological data, and develop and validate exposure data and models**~~

~~For example, the food safety initiative should fund a study to test whether levels of an indicator bacterium present in seafood at the point of sale can be modeled to back-estimate initial contamination levels of the bacterium in seafood at harvest or at a specific processing step. Another example is the development of measures of the frequency and amounts of~~

consumption of contaminated foods by susceptible populations.

3) **Develop dose-response models**

Dose-response models describe the consequences of exposure to the hazard. The dose-response model is an essential component of risk assessment, but one that is lacking for most foodborne bacteria, viruses, natural toxins.

4) **Initiate research on the use of "biomarkers" of exposure and effect**

Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain. Biomarkers include changes to DNA indicating that aflatoxin exposure has occurred (aflatoxin is a natural fungal toxin that occurs in nuts and grains). A biomarker of effect might be a change in certain immune cells indicating immune system damage.

5) **Initiate research on target-dose toxicokinetics**

Toxicokinetic data enable risk assessors to estimate with much greater accuracy the actual amount of a hazardous substance that reaches the target organ. Such data are needed for assessing risk associated with domoic acid, a natural shellfish toxin that damages nerves, and urethane, a carcinogenic byproduct naturally present in fermented foods and beverages.

INSPECTIONS

Industry pushes for resources to keep up w production

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by Federal, State and local authorities, with State and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the Federal level, FSIS has inspectors in meat and poultry plants while they are operating--about 8,000 inspectors for 6,000 plants. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all imported foods.

Meat and poultry 8,000 for 6000 plants ✓
700 for 53,000 plants ✓

The Problem

Because meat and poultry inspections are conducted under a legal requirement for continuous inspection, resources for that program at USDA have not been an issue. At FDA, however, the number of inspections have decreased steadily since 1981, when 21,000 inspections were done, so that today resources exist to carry out only about 5,000 inspections per year. The result is that the average non-meat plant gets inspected by FDA only once every 10 years, as opposed to the daily inspection by FSIS of meat facilities. FDA also relies upon the States to conduct some inspections, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. It is widely believed that FDA's inability to inspect food processors and imports regularly contributes to the rise in recent years in food borne illnesses. Certainly FDA is finding greater problems, e.g., ~~it is recalling~~ the number of products recalled ~~almost 5 times the number of products~~ for life-threatening microbial contamination has increased almost 5-fold since ~~than it recalled in~~ 1988 and inspectors are finding more hazardous conditions in the plants they inspect.

over last 15 yrs 21,000 inspections for 5,000

Recommendations and expected benefits

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; and FDA plans to extend HACCP to other segments of the food industry. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, ~~provide the necessary inspectional coverage of the non-meat food industries,~~ the following recommendations are being made.

1) **Enhance development of HACCP procedures**

FDA should ensure comprehensive implementation of HACCP throughout the non-meat food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. FDA should conduct inspections to ensure that HACCP is being properly implemented and provide necessary training and outreach activities.

2) **Upgrade FDA's food inspection program**

If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art quality control procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the Federal inspection role, the Administration should integrate the current National Marine Fisheries seafood inspection program (190 inspectors and support staff) with FDA's seafood inspection program. To maximize the joint Federal-State role in inspections, new partnerships must be developed with the States that focus on coordinating the inspection coverage and preventing duplication of effort.

FSIS and FDA should develop joint procedures for overseeing the safety of food in transportation, such as trucks shipping food long distances. This would provide for coverage of an area of how food is handled that has been largely ignored, yet is known to be a contributing source of food contamination.

FSIS and FDA should develop Memoranda of Understanding under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are in these plants anyway; their presence should be utilized to lessen the resources burden on FDA. Thus if a pizza plant is producing both cheese and pepperoni pizza, one inspector would cover that plant.

3) **Inspectional coverage should be enhanced through Federal-State partnerships and use of third-parties**

Federal-State partnerships should be created that ensure coordination between FDA and State regulators, that provide FDA training of State inspectors in Federal safety standards, and that permit FDA to provide the States with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This would make the inspection process far more efficient and would maximize the Federal resources considerably.

FDA should establish a process for certifying private laboratories who would be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable Federal standards while at the same time relieving the taxpayer of this responsibility.

4) **Greater inspectional coverage of imported food should be attained, to address the problem of rising imports and FDA's inability to provide adequate inspections of them.**

Imported Foods

FDA should develop Mutual Recognition Agreements with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA should focus its import inspections on foods coming from countries with the least reliable safety standards.

- Study which messages will work

- Give industry & consumers credit for what they have done.

EDUCATION

Background

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Educational efforts have already been made at the Federal level. For example, FDA has a website which offers information on many food safety issues, has established a 24-hour seafood hotline, and has published brochures on such topics as food safety advice for persons with AIDS and posters on such topics as listeria in soft cheese. USDA, through its Cooperative Extension Network and other means, has taken similar steps with its meat and poultry hotline and safe handling instructions for meat and poultry products.

The Problem

Despite these efforts, foodborne illness still occurs from a lack of knowledge of the risks involved at all stages of food preparation. For instance, choices consumers make about how they handle food prepared at home and whether they eat food that increases the risk of foodborne illness can have a significant impact on the incidence of foodborne illness. Studies show, for example, that 53% of the public eat food with raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Foodborne illnesses have also been traced to commercial food establishments. For example, many food establishments do not know that the pooling and undercooking of eggs can increase the risk of *Salmonella enteritidis*. ~~Moreover, the risk of foodborne illness is magnified for high risk populations in hospitals, nursing homes, assisted living facilities, child day care, and senior day care. During 1985 to 1995, for example, nursing homes accounted for approximately 6% of the nation's *Salmonella enteritidis* infections but 72% of the deaths.~~ Currently, a much higher percentage of those who receive their food in an institutional environment are victimized by the more serious consequences of foodborne illness. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *S. enteritidis*. *S. enteritidis* also resulted in more deaths than any other pathogen with 85% of these deaths occurring among residents of nursing homes.

Producers of animals used in human food production and veterinarians treating such animals also need education in food safety practice. Drugs used to treat these animals are not always used appropriately, and can be purchased over the counter by non-veterinarians and mis-used, resulting in harmful residues in meat and milk, decreased effectiveness of these drugs, and increased antimicrobial resistance.

Finally, those responsible for the transportation of food are often unaware of their unsafe practices that result in the contamination and mishandling of food during shipment.

Recommendations and expected benefits

Understanding and practicing proper food handling procedures from farm to table would significantly reduce foodborne illness.

1) Improve consumer education

An overarching food safety awareness campaign for consumers should be developed, highly focused on messages and tactics targeted to special populations such as high-risk consumers. The campaign should be centered around an easily recognized symbol or catch phrase and should include a national print and broadcast media campaign and incorporating food safety messages into school curricula. An emphasis should be placed on multilingual activities to ensure the widest coverage.

Innovative methods for sharing information related to food handling behaviors should be developed in order to reach larger audiences. As part of this effort, a National Food Safety Education Alliance of industry, consumer, trade, State and local food protection agencies, and academic organizations focused on changing unsafe food handling practices should be convened. A national clearinghouse should be established to provide consumers with food safety information and to serve as a central contact point for reporting food problems.

2) Improve retail, food service, and institutional education

A highly focused campaign should be developed to change food workers ' unsafe food preparation behaviors. A multilingual approach will be developed. An alliance of Federal, State, and local health agencies, as well as private parties, should be formed to develop education efforts of food safety issues. Activities of the alliance should include educating retail food service workers about the safe handling perishable food product provisions in the 1997 Food Code.

In addition, guidelines should be developed by USDA and the States for retail and food service operations which process meat and poultry products to train State level inspectors to identify hazards at the retail level. Efforts should also be undertaken to educate the retail, food service and institutional industries in order to increase the use of HACCP principles.

3) Improve veterinary and producer education

A program should be developed and implemented to educate producers of animals for human food consumption, veterinarians, State and local regulators about proper drug use and the incorporation of HACCP principles into industry quality assurance programs. The program should entail regularly scheduled training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials should also be developed and disseminated through a national

clearinghouse to food producers and the veterinary medical community.

4) **Improve industry education in the transportation area**

Government agencies should form an alliance to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. Training and education for State and local health and transportation authorities should also be conducted so they can apply this information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

5) **Improve education and training of epidemiologists, microbiologists, and physicians**

CDC, State, territorial, and local public health agencies would collaborate to develop education and training materials and programs for public health professionals and others who are critical to diagnosis, surveillance, intervention, and policy development. This effort should also establish a foodborne disease prevention network to provide telecommunications and teleconferencing ability. The delivery of the educational materials should take advantage of and enhance existing distance learning capabilities at CDC, and the National Laboratory Training Network at CDC.

salmonella enteritidis in egg shell - problem? jurisdiction?
control?
Fed/state coop prog?
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Surveillance
Research $200 million annually - no coord. role vis a vis industry not well defined
Risk Assessment
Inspection
Education FDA/USDA/CDC - private?

USDA - redeployment of inspectors under discussion publically - WH engage? FDA's ability to execute mission under increasing pressure; user fees - Industry wants value added