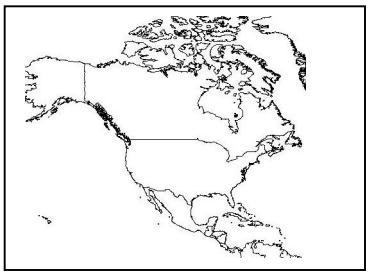
7. NORTH AMERICAN REGION



Although the North American Region is considered to have one of the most advanced food safety programs, the region faces significant challenges. Numerous factors affect food safety, including new technologies, more sophisticated distribution systems, increased concentration in production and manufacturing systems, the rise of monoculture in crop and livestock production, and increased access to imported foods. New foodborne pathogens and the increased susceptibility of certain segments of the population to foodborne infections pose additional challenges. Improving food safety in the North American Region will require its three countries to establish greater links, in part, through an integrated surveillance program.

The North American Region contains the following countries:

Canada, Mexico, and the United States of America.

7.1 Foodborne diseases in the North American Region

Public health departments and agencies in the three North American countries have estimated the prevalence of foodborne diseases. In Mexico, for example, there were 6.8 million reported cases of foodborne illnesses among its 100 million inhabitants in 1999.[1] Mortality from diarrheal diseases in children under five years of age was estimated to be 25 per 100,000, and many of those deaths were linked to contaminated food and water.[2]

Canada, with a population of 32 million, has approximately 10,000 reported cases of foodborne diseases each year and an estimated two million actual cases.[3]

In the United States, the Centers for Disease Control and Prevention (U.S. CDC) estimates that foodborne diseases cause approximately 76 million illnesses annually among the country's 294 million residents, as well as 325,000 hospitalizations and 5,000 deaths per year. Known pathogens account for about 18 percent of the illnesses and 36 percent of the deaths, while unknown agents account for the rest. Three pathogens in particular, *Salmonella, Listeria*, and *Toxoplasma*, are estimated to cause 1,500 deaths each year.[4]

Since 1996, the U.S. CDC has been tracking well-known foodborne diseases through its FoodNet program and has reported a decline in major bacterial foodborne illnesses including *Yersinia, Campylobacter, Escherichia coli*

O157:H7, and *Salmonella*.[5] While the FoodNet data has many strengths, one weakness is that illnesses cannot be attributed to specific food categories.

Foodborne illness outbreaks in the United States are primarily investigated by state and local health departments. However, the states are not required by law to report foodborne illness outbreaks to the U.S. CDC, which means that many - and perhaps most - outbreaks never enter the reporting system maintained by the U.S. CDC. (See Box.[6])

Outbreak Alert!

The Center for Science in the Public Interest (CSPI) maintains a unique listing of foodborne illness outbreaks, categorized by food. CSPI's database, *Outbreak Alert!*, is compiled from various sources, including the U.S. CDC, state health departments, and scientific journal articles. The database contains only those outbreaks with known or suspected etiology and an identified food source. *Outbreak Alert!* highlights the food vehicles most often linked to outbreaks, and provides an important source of information on food-pathogen combinations. According to *Outbreak Alert!*, the most common foods linked to foodborne illness outbreaks are seafood, produce, poultry, beef, and eggs.

U.S. economists have estimated that foodborne illnesses cost billions of dollars each year in medical costs and lost productivity. In 2000, the costs associated with five major pathogens[7] amounted to at least $7 billion annually.[8] In 2003, the annual cost of salmonellosis alone was $3 billion.[9]

7.2 Food safety concerns in the North American Region

7.2.1 Foodborne illness

Despite having many programs and resources devoted to fighting foodborne disease in this region, the incidence of foodborne illnesses in North America is still quite high. In the United States, for example, one in four consumers gets ill from food annually, according to the U.S. CDC estimates.[10] Outbreak data demonstrate that food once considered low-risk, such as fruits and vegetables, cause a surprising number of outbreaks. Imported produce has been implicated in a number of large outbreaks and has introduced unique pathogens. For example, *Cyclospora* on Guatemalan raspberries shipped widely throughout the United States and Canada caused thousands of illnesses in the 1990s.[11]

Recent improvements, such as the introduction of Hazard Analysis and Critical Control Point (HACCP) systems in seafood, meat and poultry plants and greatly expanded food testing programs, have reduced the disease burden from some products. Intensified surveillance reported a reduced incidence of foodborne disease in most areas of the U.S.[12] Systems for highly sensitive pathogen subtyping have been adopted in the U.S. and Canada, and Mexico is

partnering with Central and South American countries to establish such a system.[13]

7.2.2 Antibiotic resistance

Farmers frequently use antibiotics at low non-therapeutic levels to compensate for crowded conditions on factory farms and promote faster growth among their food animals. That use increases the likelihood that bacteria will become resistant to antibiotics and lead to harder-to-treat human infections. To address that public health risk, WHO recommends that medically important antibiotics should not be used for non-therapeutic purposes. However, antibiotics continue to be widely used for those purposes in the North American Region.

In the United States, over half of all antibiotics produced domestically are used in livestock production. Much of that use is routine and includes prolonged "non-therapeutic" dosing of animals. The U.S. Food and Drug Administration (U.S. FDA) estimates that 5,000 people per year have had illnesses prolonged due to the use of a medically important antibiotic (fluoroquinolone) in flocks of poultry.[14]

In Mexico, antibiotic resistance is of great concern due to the absence of strict regulation over the distribution of many types of antibiotics.[15] As a consequence:

- fruit growers spray their crops with antibiotics to fight diseases[16]
- the use of antibiotics in poultry has quadrupled in the late 1990s[17]

In Canada, antibiotics are prescribed and used therapeutically for the treatment of diseases in animals, as well as non-therapeutically. As part of the approval process for veterinary drugs used in food animals, Health Canada has set Maximum Residue Limits (MRLs) – the level of drug residues in the tissue or food product that poses no adverse health effects. A similar approval system is used in the United States. However, those limits do not lessen the threat of antibiotic resistance, which is the consequence of use on the farms.

In recent years, each country of the North American Region has established a national system to monitor trends in antibiotic resistance. Canada has developed a surveillance program called CIPARS. One of its key objectives is to monitor trends in the development of antimicrobial resistance (AMR) in the food chain.[18]

In the United States, the U.S. CDC established the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) in 1996, and in 2001 a Task Force of 11 government agencies issued a Public Health Action Plan to Combat Antimicrobial Resistance.[19]

Mexico is working with the U.S. FDA's Center for Veterinary Medicine (CVM), using NARMS as a template, to develop a cooperative project known as *ResistVet.* This program will monitor trends in antimicrobial resistance in human infections, bacterial populations in animals, and bacterial pathogens in retail foods at four sites in Mexico. To further support antimicrobial resistance monitoring in Mexico, the U.S. FDA collaborated with WHO to conduct a training course in 2001 on the surveillance of *Salmonella* and antimicrobial resistance in foodborne pathogens.[20]

7.2.3 Contaminants in food

Animals and fish in particular are vulnerable to contamination by toxic industrial and agricultural pollutants, such as pesticides, mercury, polychlorinated biphenyls (PCBs), dioxins, flame retardants, and other lipophilic chemicals. Those pollutants can accumulate in fish that are then consumed by people.

In the United States, scientists at the U.S. Environmental Protection Agency (U.S. EPA) have estimated that as many as 630,000 children are born each year having been exposed to unsafe levels of mercury in the womb. Many adverse birth outcomes have been linked to prenatal exposure to excessive amounts of mercury. Even small amounts are predicted to cause delayed motor development, delayed speech, and other adverse effects among exposed children.[21] As a result, in March 2004, the U.S. government issued a warning for women who are or might become pregnant, nursing mothers, and young children: (i) not to eat shark, swordfish, king mackerel, or tilefish because they contain high levels of mercury; (ii) eat no more than two average meals a week of a variety of fish and shellfish that are lower in mercury and; (iii) check local advisories about the safety of fish caught by family and friends in local lakes, rivers, and coastal areas.[22]

In the 1970s, the commercial marketing of PCBs as insulation in electrical transformers was banned by the U.S. EPA because of concerns over their extreme persistence in the environment. It categorized PCBs as a probable

human carcinogen and warned that those poisons also compromise the immune system and can cause low birth weight and learning disabilities in children. PCBs are fat-soluble, accumulating in the marine food chain and reaching high levels in predator fish. More than 90 percent of Americans' exposure results from diet, mostly from fish. Children also can be exposed through breast milk. Human fetuses also are exposed in the womb, as PCBs are able to cross the placenta and concentrate in the fatty tissue of the brain.

According to the U.S. EPA, PCBs remain in human fat cells for 25 to 75 years. High levels of PCBs have been documented in the sediments of the Hudson River, the Great Lakes, and other bodies of water in this region.[23]

7.2.4 Bioterrorism

According to the WHO, "food is…vulnerable to intentional contamination by debilitating or lethal agents. The diversity of sources of foods, including the global market, makes prevention difficult, if not impossible."[24] Sporadic threats of tampering and several incidents of intentional contamination of food products already have occurred in the North American Region. For example, in 2003, an employee deliberately contaminated 200 pounds of ground beef at a grocery store in Michigan with a nicotine-based pesticide, resulting in almost 100 illnesses.[25]

Since the terrorist attacks of September 11, 2001, which served as a wake-up call in the region, bioterrorism has become an issue of great concern in North America.

In Canada, the "Centre for Emergency Preparedness and Response**"** (CEPR) was created in July 2000 to serve as the country's single coordinating point for public health security. Regarding food safety, the Centre for Emergency Preparedness and Response is supported by the Canadian Food Inspection Agency (CFIA), which is specifically responsible for preparing emergency plans[26] and developing effective response capabilities for food safety emergencies.[27] The Canadian government also is establishing a nationwide network of local, provincial, and federal laboratories that will be able to quickly test foods and identify unknown agents. Moreover, in 2002, Canada promulgated a new statute, the *Public Safety Act*, which provides new power to various Ministers, including the Minister of Health, to issue an emergency interim order (for example, to prohibit the sale of a food) if the Minister believes that immediate action is required to deal with a significant risk - direct or indirect - to human life, health, and safety.[28]

Canada has also worked with WHO to develop and implement the Global Public Health Intelligence Network, a database that uses the Internet to provide preliminary intelligence on global public health issues, such as disease outbreaks, infectious diseases, contaminated food and water, and bioterrorism.[29]

In 2002, the United States Congress approved the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act). The Act gives the U.S. FDA several important new tools to protect the food supply, including provisions for the registration of food facilities, prior notice of imports, recordkeeping to trace foods, and administrative detention of suspect foods.

Nevertheless, the primary U.S. food safety agencies, U.S. FDA and the U.S. Department of Agriculture (USDA), lack essential powers such as mandatory recall authority which would assist in removing tainted products if terrorists attacked the food supply. In addition, the U.S. FDA lacks authority to certify that countries exporting food to the United States have systems in place to deter intentional contamination.

7.2.5 BSE

Several cases of BSE have been found in the North American Region. However, the incidence of BSE has been minimal and the risk of contracting the human form of "mad cow disease," called variant Creutzfeldt-Jakob Disease (vCJD), is virtually nil.

The first case of BSE in an indigenous cow was detected in May 2003. Until then, cattle crossed borders freely in the region. Canada implemented measures to enhance food safety controls regarding BSE, working closely with provincial and territorial authorities, the cattle industry, and U.S. representatives to ensure their implementation, and where appropriate, harmonization with U.S. measures.[30] Specifically, Canada has excluded bovine specified risk materials (SRM) from human food, and enhanced animal identification and BSE surveillance. Also, it is working to extend the ban on SRM to all animal feed.[31] Nevertheless, in January 2005, two other cases of mad cow disease were confirmed in Canada,[32] presumably due to infected feed consumed by cattle prior to the tightened regulations.

No cases of BSE have been detected in Mexico**,** but the government has nevertheless agreed to enhance efforts to increase harmonization of BSE regulations within the North American Region.[33]

In December 2003 in the United States, the USDA announced the first diagnosis of BSE in an adult Holstein cow from Washington State. An ear-tag identification number indicated that the BSE-infected cow was imported into the United States from Canada in August 2001. The first case of BSE in the United States led USDA and the U.S. FDA to announce a number of policy changes, including expanded surveillance for BSE[34] and additional safeguards for human and animal food.[35] Despite government assurances, however, enforcement of those new rules is largely dependent on government testing, and an animal identification system is lacking.

Early in 2004, the agriculture ministers of Canada, Mexico, and the United States agreed to enhance ongoing efforts to resume the North American trade in beef.[36] Some limited trading in beef products continues in the North American Region, but the findings of BSE in Canada have dramatically curtailed trading in beef products among those three nations, as well as with many other countries.

In addition to the animal health concerns, two human illnesses were also reported in this region. In April 2002, a case of vCJD (the human form of BSE) was reported in Canada, in a patient who was a resident of the United Kingdom in the late 1980s during the early years of the BSE outbreak. Only one case of the variant Creutzfeldt-Jakob Disease (vCJD) has been discovered so far in the United States. The case was a Florida woman who probably became infected while growing up in England during the height of the mad cow epidemic there.

7.2.6 Genetically engineered (GE) foods

Genetic engineering (GE) allows specific genes isolated from any organism (such as a bacterium) to be incorporated into the genetic material of a different organism (such as a corn plant). That differs from traditional plant and animal breeding in which the genes of only closely-related organisms (such as a corn plant and its wild relatives) can be exchanged. Thus, GE plants and animals can carry unique traits that could not have occurred by natural reproduction.

While highly controversial, that unique technique for manipulating hereditary traits can provide significant benefits. Genetic engineering has the potential to decrease adverse environmental effects of conventional agriculture, increase yields for farmers, improve the nutritional quality and taste of crops, and contribute to sustainable agriculture. Concerns about GE crops in the North American Region include the introduction of an allergen; the transfer of the

engineered gene to wild species; the emergence of pests resistant to pesticides; and the potential for adverse effects on small farmers or developing nations.

In Canada, the Novel Foods Regulation requires companies to notify the Health Products and Food Branch (HPFB) prior to marketing or advertising a GE food. Pre-market notification permits Health Canada to conduct a thorough safety assessment of all biotechnology-derived foods to demonstrate that they are safe and nutritious before they are marketed.

In Mexico, the "Comisión Intersecretarial de Bioseguridad y Organismos Genéticamente Modificados" (CIBIOGEM) coordinates the Mexican government's policies on the production, import, propagation, and consumption of GE products and byproducts. Specific legislation about GE foods also has been approved to protect Mexican consumers.

Moreover, unlike the United States and Canada, Mexico has ratified the Cartagena Protocol on Biosafety[37] which seeks to address the potential risks that may be posed by "living modified organisms" (LMOs)[38] resulting from modern biotechnology on biological diversity.

Although Mexico imposed a ban on planting GE corn in 1998, scientists detected GE corn growing in Oaxaca province in 2001. The researchers' report suggests that the GE corn got into fields when farmers planted corn imported from the United States intended for consumption.[39]

In the United States, in 2003, approximately 40 percent of all field corn (mostly used for animal feed), 80 percent of all soybeans (also used primarily for animal feed), and 73 percent of all cotton grown was genetically engineered. U.S. farmers also grew small amounts of GE papayas, summer squash, and insect-resistant sweet corn.[40]

Three government agencies share oversight of GE plants: the U.S. FDA, the USDA, and the U.S. EPA.

Although the U.S. FDA is responsible for ensuring that plant-based foods are safe to eat, it lacks the legal authority to approve GE crops before they are commercialized. The U.S. FDA regulates GE crops through a voluntary notification process rather than a mandatory pre-market approval process.

USDA regulates GE plants to ensure they do not pose any risk to plant health. Unlike the U.S. FDA, USDA has established a mandatory notification and permitting process that developers must comply with before planting any GE

crop on open fields. However, developers can petition USDA to deregulate the GE plant, allowing crops to be grown commercially without any regulatory requirements. Over 9,000 field trials have gone through the USDA's regulatory procedures and over 75 crops have been deregulated.

The U.S. EPA is responsible for the safety of pesticides, including GE plants, such as *Bacillus thuringiensis* (Bt) corn or Bt cotton, that have been engineered to produce a natural toxin that acts as a pesticide. In its regulatory process, the U.S. EPA determines the benefits and risks from the crop and imposes any conditions it believes will minimize or eliminate any potential harmful effects on the environment. The U.S. EPA's formal approval process also assesses the safety to humans and animals if they consume the pesticide and establishes a safe tolerance level below which the pesticide is considered harmless.

In approving Bt crops for commercial use, the U.S. EPA has imposed planting restrictions to inhibit the development of resistance to the crop by pests and ensure long-term benefits from those crops. Nevertheless, a 2003 report by CSPI found that approximately 20 percent of Midwest corn farmers did not comply with government planting restrictions for Bt corn.[41] Therefore, to better protect the environment, the U.S. EPA and USDA should pursue rigorous post-approval oversight of GE crops.

Concerns also have arisen over the use of engineering food crops as factories to produce pharmaceuticals or industrial chemicals. Such activities appear to be experimental but commercialization is being considered.

Genetically engineered animals, for which commercial approval is also being sought, raise new safety and ethical questions. The U.S. government does not have an adequate program in place to monitor and control these animals.

7.2.7 Irradiation

Food irradiation is a process in which food is treated with a controlled amount of ionizing radiation to kill or control bacteria, parasites, insects, and fungi. Irradiation is also used to reduce spoilage and slow down ripening and sprouting of produce.[42]

There has been controversy in the North American Region over the risks and benefits of irradiation. In certain situations, irradiation may be useful to reduce the risk of microbial foodborne illness. Some consumer groups believe that irradiation may cause other problems. Among their concerns are

inadequate testing and approval processes, dangers to workers and the environment, toxic byproducts, and the potential for cellular or genetic damage.[43] Scientific and medical groups, industry, and government contend that irradiation is safe and a useful way to reduce the risk posed by harmful bacteria in the food supply.


Radura logo

Canada established a list of foods that may be irradiated, the maximum doses allowed, and other appropriate requirements. All irradiated foods must be labeled. In addition to a written description, such as "irradiated," a distinctive logo - the "radura" - must be on the package to identify the product. Owing to the division between standard setting and enforcement that is relatively unique to Canada, Health Canada is responsible for establishing those regulations. It is, however, the responsibility of the Canadian Food Inspection Agency (CFIA) to enforce them.

Mexico has some irradiation facilities and has given clearance to irradiate more than 60 categories of food.

A variety of foods have been approved for irradiation in the United States, for several different purposes. For meats, separate approval is required both from the U.S. FDA and USDA.[44] The radura logo also is required on food packaging if the product has been irradiated, though not for minor ingredients such as spices or when the irradiated food is part of a multi-ingredient food. According to polls, U.S. consumers strongly support labeling of irradiated foods.

7.2.8 Consumer Education

To reduce the risk of foodborne illness, consumer education is considered a critical element of food safety.

In the United States, numerous programs and campaigns are designed to improve consumer education about food safety.[45] One of the main educational tools is the "*Fight*BAC!™" campaign, which is supported by a partnership among the food industry, government, and consumer organizations.[46] Moreover, electronic information networks have been launched by the U.S. FDA to provide up-to-date information regarding food safety.[47]

In Canada, a partnership led by the food industry and federal and provincial government agencies, with participation from health, environmental, and consumer organizations, resulted in the formation of the Canadian Partnership

for Consumer Food Safety Education. In 1998, it launched a "*Fight*BAC!™" campaign based on the U.S. program.[48] (See Box.[49])

In Mexico, the National Service for Agriculture and Food Hygiene, Safety and Quality has established a General Office for Consumers' Communication to inform the general public - especially users of the office's services - about relevant legislation and regulations in force.

Food safety mistakes caught on tape

University research suggests that consumer education programs have had only limited effectiveness.

A 2000 FDA-funded study conducted by Utah State University, researchers placed video cameras in the kitchens of 100 families and observed them preparing salad ingredients and following one of three recipes. Among those families who tended to be confident in their food safety habits, cooks were "caught on tape" undercooking meals and making other food handling mistakes during preparation: improper refrigerator storage of raw meat and seafood, and improper or nonexistent hand-washing, countertop cleansing, and fruit and vegetable washing. Such research shows that the effect of limited consumer education on the overall burden of foodborne illness may be negligible.

7.3 Policies and plans of action in the North American Region

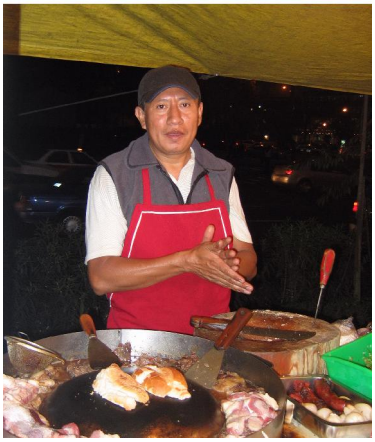
The Canadian food safety system operates in a multi-jurisdictional setting, involving federal, provincial, territorial, and municipal authorities.[50]

Health Canada is responsible for establishing and administering regulatory standards under the Food and Drugs Act - the core federal legislation regulating the safety and nutritional quality of food sold in Canada. The Canadian Food Inspection Agency (CFIA), operating under the auspices of the Minister of Agriculture and Agro-food, is responsible for conducting inspections and enforcement of federal food safety law. The Pest Management Regulatory Agency (PMRA), within the Department of Health, has a mandate to protect human health, safety, and the environment by minimizing risks associated with pesticides, while enabling access to pest management tools - namely, pest control products and pest management strategies.

However, some laws governing food safety are also set and enforced by provincial/territorial and municipal authorities. Those authorities also carry out some enforcement duties in respect of federal laws pursuant to agreements with the federal agencies.

Because of the shared jurisdiction in Canada regarding food safety,[51] protocols have been developed to clarify the roles of all participants, as for example the "Foodborne Illness Outbreak Response Protocol" and the "Canadian Code of Practice - General Principles of Food Hygiene."

Moreover, to foster the collaboration of the non-governmental stakeholders in the Canadian food safety system, partnerships have been established with the public, private, and academic sectors, such as the "Canadian Supply Chain Food Safety Coalition" and the "Royal Society Expert Scientific Panel on the Future of Food Biotechnology."[52]



Mexico has only recently developed an integrated food safety program, and legislation is currently being revised to improve food safety in the country. Since 2001, the National Service of Agro-food Safety and Quality (SENASICA) controls the agro-food sector and the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) unifies and harmonizes the policies of the Mexican government regarding health and food safety. These new measures should, for example, improve oversight of farms and help them reduce microbiological, chemical, and physical risks.

In 2002, a National Forum on Food Safety was held in Mexico with the participation of consumers, industry, farmers, and state governments to discuss strategies for ensuring food safety. Participants agreed that food safety should be a priority for the federal government and that it was necessary to have an agency exclusively devoted to food safety. They also agreed on the need for comprehensive national laws and regulations to oversee food production from the farm to the table. The government subsequently established the National System for Food Safety.[53]

In the United States**,** food is regulated by 12 different federal agencies and 35 different statutes.[54] That highly fragmented system divides regulatory responsibility based on food products. The primary agencies that inspect and regulate food are USDA, which oversees meat, poultry, and processed egg products, and the U.S. FDA, which is responsible for all other foods.

Although U.S. FDA-regulated foods are linked to two-thirds of the outbreaks with known causes, the U.S. FDA's budget is just 31 percent of the total federal budget for food safety inspections.[55] The U.S. FDA, hampered by limited funding, inspects less than two percent of the estimated five million shipments of imported food each year.[56] Although meat-processing plants are inspected by USDA daily, plants processing seafood, eggs, produce, or processed foods containing less than two percent meat are inspected by the U.S. FDA about once every five years.[57]

When foodborne illness outbreaks do occur, neither USDA nor the U.S. FDA has the power to order recalls of contaminated food. They must ask food companies to voluntarily remove foods from the market. That lack of authority can delay recalls and increase the number of illnesses linked to outbreaks. Recent lawsuits brought by meat processors have curbed USDA's ability to close down plants producing contaminated meat.

7.4 Consumer organizations in the North American Region

Consumer organizations in the North American Region work on food labeling, reducing foodborne illness, obesity, alcohol policy, and antibiotic resistance. They also conduct product evaluations that are published in their magazines and the general media. Several consumer organizations are relatively large and well-funded. Two such organizations are almost completely funded though the sale of magazines evaluating food and other consumer products. Government funding of consumer organizations is less common than in other regions, though some organizations have obtained specific project grants from the government. Smaller groups are funded by foundations.

Recommendations for reform of U.S. food laws

The primary food safety laws in the United States were passed in 1906. Many organizations have put forth ideas for modernizing U.S. food law, including the National Academy of Sciences, the U.S. Government Accountability Office, and the Center for Science in the Public Interest (CSPI). These groups recommend that the U.S. Congress and Executive branch should unify all of the federal food safety activities.

Current legislation proposes the formation of a single, independent agency – the Food Safety Administration (FSA). That agency would be responsible for setting food safety and labeling standards, approving new food technologies, conducting food safety inspections, and enforcing the relevant laws. The new statute would build on the strengths of the existing laws, while modernizing the mandates and authorities of the new FSA. The unification of the food safety system would be accomplished over a period of several years, with full participation by many stakeholders, including the food and agriculture industries, scientists, public health experts, and consumer organizations.