

Food Safety and the Consumer Perspective

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Before addressing national food safety issues and the consumer's perspective, I'd like to explain who S.T.O.P. - Safe Tables Our Priority is and the focus of our concern. S.T.O.P. was formed in the summer of 1993 by victims of foodborne illness. Most of our founders were parents of children maimed or killed by *E. coli* O157:H7 in meat. The organization's membership has grown to include adult survivors of debilitating foodborne illnesses, and victims of a variety of foodborne pathogens from a variety of sources. S.T.O.P. provides victim support, consumer education, and advocates improved food safety policies. Our purpose is to reduce illnesses and deaths caused by foodborne illness.

The Problems

Foodborne illness is a serious and growing problem. The Council for Agricultural Science and Technology (CAST) estimates there are between 6.5 and 81 million illnesses and 9,000 deaths attributed to foodborne illness each year in the U.S. The USDA's Economic Research Service (ERS) estimates that the top seven foodborne pathogens cost the U.S. between \$5.6 and \$9.4 billion annually in lost productivity and medical expenses.

While the majority of illnesses are limited to belly aches or the "24 hour stomach flu," some illnesses are quite severe. Our members have suffered brain damage, strokes, heart attacks, kidney failure, liver failure, and blindness due to foodborne illness. Some of our members have spent between \$300,000 and \$500,000 to treat single cases of Hemolytic Uremic Syndrome (HUS) induced by *E. coli* O157:H7 infection.

Of FDA regulated food products, contaminated fruits and vegetables are S.T.O.P.'s primary concern. Produce contamination is a major problem because these products are often intended to be eaten raw, and there is very little consumers can do to reduce or eliminate contamination. While rinsing produce with water helps to reduce contamination, it will not make tainted products safe.

Produce linked foodborne illnesses are increasing. Representatives of the CDC characterize the increase of produce linked illness as "real," rather than a reflection of better reporting of illness. Between 1973 and 1987 approximately 2% of foodborne illnesses were linked to produce, but this number jumped to approximately 5-8% between 1988 and 1991. According to recent information

released by the Minnesota Department of Health, 27% of MN foodborne illness outbreaks between 1990 and 1996 were linked to produce.

The forecast for food safety is not optimistic. Unfortunately, the risk and incidence of foodborne illness is expected to rise. There are several factors contributing to this anticipated increase. First, the population is becoming more susceptible to foodborne illness. Approximately 20% of the U.S. population is composed of children, senior citizens, immune compromised individuals, and pregnant women. Population experts predict that this vulnerable sub-population will significantly increase in the near future.

Second, the pathogens are changing: new pathogens are emerging and presently recognized organisms are acquiring new traits. For an example of an old pathogen that has acquired new traits, one could examine *Salmonella*. This pathogen has been recognized since the 1880s. In the 1980's new strains such as *enteritidis* and the more virulent *enteritidis* phage type 4 developed.

Salmonella has a fairly high infectious dose of 100-1,000 organisms. *Salmonella enteritidis*, on the other hand, causes illness with as few as 10-100 cells, and can therefore be transferred person to person. In the 1980s, it was discovered that *Salmonella enteritidis* had migrated into hen ovaries and that the pathogen was incorporated into the interior of eggs. *Salmonella* on egg shells could be addressed with washing, but *Salmonella* inside of eggs can only be addressed with thorough cooking.

E. coli O157:H7, on the other hand, is a good example of a newly emerging pathogen. This virulent organism was first recognized in 1982. Since its discovery, it has become increasingly acid resistant. Traditional food preparation and preserving techniques are no longer adequate to address this organism. Therefore, the standard pH level required to kill pathogens has been lowered from 4.5 to below 4.0. This is why *E. coli* O157:H7 survives in unpasteurized apple cider and cured salami.

Recent USDA Agricultural Research Service research indicate that *E. coli* O157:H7 can also develop heat resistance. Pre-heated *E. coli* O157:H7 survives one and a half times as long as organisms not heat treated. Organisms subject to sub-lethal heat become resistant by synthesizing heat shock proteins. This resistance lasts for at least 48 hours. When dealing with *E. coli* O157:H7, minor cooking or handling errors can lead to illness and death.

Third, our food supply is increasingly concentrated and produced in high volume. Food made in large quantities that is widely distributed has a greater likelihood of causing harm if it is contaminated. For example, the widely publicized Hudson recall of 25 million pounds of ground beef represented approximately 15 weeks of production at a medium sized processing facility. This quantity of product could be used to make 100 million quarter pound hamburgers -- enough burgers to feed nearly half of the U.S. population!

Fourth, the U.S. is importing more food, particularly fruits and vegetables. Trade provides an opportunity for pathogens from other parts of the world to be introduced to the U.S. This was the case with *Cyclospora* in imported Guatemalan raspberries, which caused illness in 1996 and 1997.

U.S. consumers vacationing in countries exporting fruits and vegetables to the U.S. usually take special precautions when eating these products in the country from which they originate, but they often eat these products at home without peeling or washing these items with special solutions.

Fifth, the nation's food inspection programs weren't designed to address human pathogens. The U.S. food inspection programs were established to prevent sick animals from becoming human food, to find and eliminate economic adulteration, and to remove adulterated products from the market place. Given the emphasis of our inspection programs, it isn't surprising that pathogens which cause human illness but not animal illness were selected for survival.

In fact, there is little, if any, government regulation at the farm level and scant research on the correlation between foodborne pathogens and animal husbandry practices. Of the five pathogens targeted by the President's food safety initiative, at least four are zoonotic or animal origin organisms: *Campylobacter*, *Salmonella*, *Cyclospora*, and *E. coli* O157:H7. Pathogens are riding animals into the human food chain and there is little done on the farm to prevent these pathogens from hitching rides to our tables.

This is an important point because prevention is often the only way to address a pathogenic threat. As was mentioned earlier, some produce, such as lettuce, is intended to be eaten raw. If there few safeguards on the farm, little oversight of farming practices contributing to food contamination, and no means by which consumers can remove pathogens from produce; the only way consumers can prevent illness is by cooking all foods or avoiding certain foods that are intended to be eaten raw.

The U.S. has a fragmented and inconsistent inspection system. Not only do several different agencies execute jurisdiction over a variety of foods, the laws governing the inspection agencies differ substantially. FSIS is charged with assuring that all meat and poultry entering the market place is inspected and approved. An inspector must be present for slaughter and processing to take place. Product that meets USDA standards is stamped with a seal of approval. Product cannot be sold in interstate commerce unless it bears that seal.

FDA on the other hand, occasionally inspects food plants. An inspector is not necessary to the functioning of FDA inspected food establishments. In fact, FDA inspected food establishments are not even required to register with the federal government. FDA does not certify product safety with a seal. The agency generally discovers adulterated product after it reaches the market. While FSIS prevents bad products from reaching the market, FDA deals with adulterated products once they are in commerce.

Animal feed is under FDA jurisdiction, but enforcement of feed regulations is generally left to state governments. Animal drugs are also under FDA jurisdiction, and FDA regularly tests animals to assure that those used for human food will not contain drug residues. Animal manure is under FDA's jurisdiction. Human manure is under EPA's jurisdiction, and is heavily regulated. The chemical composition of animal manure is monitored for environmental reasons, but pathogen content of this manure -- an immediate public health threat -- is virtually ignored. Enforcement of existing manure regulations is also left largely to the states.

The gaps in the present food safety system are apparent. Recent foodborne illnesses linked to FDA regulated products include:

- *E. coli* O157:H7 contaminated cole slaw served at an IN Kentucky Friend Chicken
- *Salmonella* contaminated Malt-O-Meal cereal, which sickened at least 188 people in IA, IL, IN, MI, MO, KS, NY, OH, PA, WI and WV
- ETEC *E. coli* contaminated potato salad served at an IL deli, which sickened an estimated 6,500 people
- *Vibrio parahaemolyticus* tainted oysters, which caused 306 illnesses in CA, FL, GA, OK, TN, and TX
- *E. coli* O157:H7 and *Salmonella* contaminated sprouts caused several illnesses in CA

New Food Safety Initiative

Fortunately, the Administration has recognized the growing food safety problem and proposed some useful recommendations to address it. The President's food safety initiative encouraged FDA to develop regulatory options to increase fruit and vegetable juice safety, to improve the safety of egg products, to develop a review of produce production, to evaluate whether HACCP can be applied to other foods, to improve the implementation of seafood HACCP, and to identify instances where FSIS inspectors can enforce FDA regulations. While the initiative doesn't completely address all gaps in the FDA food safety net, it is a significant step in the right direction.

Of the FDA goals outlined by the initiative, S.T.O.P. prioritizes the following:

- development and implementation of HACCP regulations for fruit and vegetable juices
- development and implementation of on-farm regulations to address pathogenic contamination of produce
- development and implementation of animal manure control regulations
- development and placement of warning labels on foods that have been identified as causing multiple outbreaks or that have been associated with diseases that result in chronic illnesses
- development of a list of food types that represent a strong potential for public endangerment. This list should serve as a notice of impending government scrutiny for identified risky food industries.
- improved public notification of emerging foodborne pathogens, instances of illness associated with FDA regulated foods and FDA regulated foods recalls
- pathogen research
- food handler education

HACCP

S.T.O.P. strongly supports mandatory HACCP for produce from farm-to-fork. Mandatory HACCP results in cleaner and safer foods by ensuring that potential for contamination is addressed at all critical control points. We recommend that CFSAN set minimum HACCP certification standards among produce growers.

According to the recently released produce guidance document, it will take years for FDA and CFSAN to appropriately address food safety in produce. In the meantime, growers should be encouraged to begin voluntarily implementing HACCP programs of their own. S.T.O.P. recommends developing, in conjunction with the state and local entities, an HACCP education, testing and certification program. Under this envisioned program, growers would be required to have staff on site that are certified in understanding HACCP principles and applying them to produce farming and processing.

Animal Manure Control

S.T.O.P. strongly supports prevention of contamination at the source. Since it is frequently impossible to remove pathogens from produce, some produce is intended to be eaten raw, and some pathogens linked to produce cause severe illness or death at very low doses; prevention should be central to a fruit and vegetable safety strategy.

An obvious farming practice that compromises food safety involves the application of manure or composted animal feces as fertilizer to produce that is consumed uncooked or lightly cooked. FDA should take steps to eliminate the use of unsterilized manure and compost as fertilizer on human food crops. Manure must reach 160 degrees F to be safely applied to crops.

Scientific studies have demonstrated that the Organic Foods Production Act's (OFPA) 60 day limitation on application of raw manure is insufficient based on the survival abilities of pathogens in both feces and soil. Yet, this is one of few recommendations that exist for restricting the application of raw manure.

Labeling

Since new pathogens are rapidly emerging and old pathogens are spreading to new food sources and developing resistance to control measures faster than government agencies have been able to address them, S.T.O.P. recommends that FDA give consumers the means to protect themselves until the government can address recognized food safety hazards. The primary means by which FDA could assist consumers is by sharing information about foods that have been recognized as repeated causes of illness. S.T.O.P. supports the warning labels developed for unpasteurized fruit and vegetables juices, and recommends that FDA immediately develop and implement similar warning labels for raw oysters, sprouts and lettuce.

Dissemination of Information

Repeated outbreaks and deaths linked to particular foods are signs that the process of producing and delivering the food results in repeated contamination and at-risk consumers are not sufficiently warned about the hazards of the food. In order to facilitate industry and consumer awareness about food risks, S.T.O.P. recommends that FDA issue a press release about each recall that:

1. identifies the product and producer,
2. lists retail outlets where the recalled food was distributed,
3. gives directions to return the food type to the grocer,

4. details illness symptoms, and
5. advises consumers to seek medical treatment when symptoms occur.

Since press releases usually are not distributed to consumers, S.T.O.P. recommends that FDA promptly post information about all FDA related foodborne pathogen recalls on its website. FDA should also work with CDC to post a list of foodborne illness outbreaks on the website. S.T.O.P. encourages the agency to include in this list ongoing outbreaks which have not had food sources identified and outbreaks that have been epidemiologically linked to CFSAN regulated foods. In addition, we recommend that FDA develop an e-mail list to distribute information about recalls and outbreaks to major news services, consumer groups, retailers, and interested individuals. USDA has a similar system already in place.

Recall and outbreak information should also be posted at the point of purchase site at which any contaminated food was sold. Recall and outbreak information must reach everyone potentially affected in order to best protect the public's health and this information must be specific to facilitate action. If consumers, retailers, processors, and growers are not informed of the extent of our food safety problems, they will not understand the need to take safety precautions. By providing foodborne illness and risk data to the public, the government will give consumers the opportunity to make informed purchasing decisions, the incentive to handle food properly, and the chance to facilitate voluntary adherence to good farming and processing practices.

S.T.O.P. also recommends that FDA disseminate information through liaisons with major medical, patient, and at-risk consumer organizations, such as the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, the American College of Emergency Physicians, the Arthritis Foundation, the American Association of Retired Persons, and the Parent Teacher Association. S.T.O.P. applauds FDA for organizing the district consumer forums, and urges the agency to connect with additional organizations in an effort to incorporate food safety information in materials distributed to organizations, constituents. This outreach initiative would also contribute to the success of focused education campaigns, such as an unpasteurized juice educational campaign that targets parent and child organizations.

Lastly, S.T.O.P. recommends that FDA develop a regular constituent bulletin to inform interested parties of recent FDA rulemaking activities, public meetings, recent enforcement actions, new scientific information, and other relevant news. Many advocacy groups and individuals concerned about food safety have limited access to the Federal Register or the FDA website. A document to notify interested parties of impending meetings or regulations would facilitate greater public participation in government. USDA's "FSIS Constituent Update" is a good model for this initiative.

Research

S.T.O.P. recommends that CFSAN support research that identifies and assesses areas of contamination under realistic scenarios and the extent to which contamination is possible or probable. In this list we include:

1. Microbial testing of produce at retail to develop a microbial baseline.

2. Survival of pathogens in compost to identify the effectiveness of compost and composting methods in eliminating pathogens.
3. Survival of pathogens in manure.
4. Survival of pathogens on food plants.
5. Uptake of pathogens in food plants.
6. Pathogen penetration of fruit and vegetable skins.
7. Survival of pathogens inside produce.
8. Cross contamination rates of produce subjected to various water treatments.
9. Transfer of pathogens by insects.
10. Transfer of pathogens by blown dust.
11. Relation between pathogen contamination and appearance of produce.

Food Handler Education

Consistent with S.T.O.P.'s emphasis on preventing contamination of produce, the organization recommends that CFSAN broaden its food safety education campaign to include food processors and growers. Numerous foodborne outbreaks demonstrate that processors and growers are often unaware of the risks associated with their food products and are ignorant about methods of preventing or decreasing contamination. These links in the food safety chain are just as important to preventing illness as consumers. In the case of some produce contamination, industry education is the only means of avoiding foodborne illness.

In addition, S.T.O.P. recommends that CFSAN evaluate the quality of its present education initiatives. Government agencies should only participate in education initiatives that incorporate sufficient public health, consumer, and patient group input to balance the participation of food industry representatives. Industry biased efforts tend to downplay food safety risks and hazards, and thereby reduce the incentive for consumers to change food preparation behaviors.

Other Elements Influencing the Success of FDA Food Safety Efforts

While recent food safety initiatives at FDA will make significant improvements in the nation's food safety net, there are some aspects of FDA's program that are beyond the agency's or the Administration's control. The inspection statutes and FDA's funding levels are both directed by Congress.

Over the years, Congress has cut FDA's budget while ignoring the nation's food safety crisis. The results of this neglect are apparent at FDA. Due to severe resource strains, inspections are not occurring as frequently as they should. Here are some facts to illustrate FDA's problem:

- The number of FDA inspected imports has doubled over the past five years, yet FDA only inspects 1-2% of imported food shipments
- There are approximately 800 inspectors assigned to an estimated 53,000 U.S. plants
- Under the current structure, a plant is inspected approximately once every 10 years
- In 1981 FDA conducted approximately 21,000 inspections annually, but by 1996 the number of inspections dropped to approximately 5,000 per year.

S.T.O.P. and other consumer organizations are working hard to convince the agriculture appropriations conferees to fully fund the President's food safety initiative in the FY 99 budget. Out of a proposed \$91 million budget, the House approved \$16.8 million and the Senate approved a mere \$2.6 million. The House Ways and Means Committee has declared the intent to invalidate a Senate amendment increasing the appropriation to \$68 million.

With regard to statutory authority, S.T.O.P. recommends that Congress grant FDA the authority to mandate recalls and assess civil penalties and fines. These enforcement tools are needed to provide sufficient compliance incentives. We also recommend that Congress pass legislation providing FDA the authority it needs to conduct imports inspections in a manner consistent with FSIS, imports inspection program.

It is unlikely that Congress will address food safety concerns until committee jurisdictions change, the committee appointment process is reformed, or there is a monumental foodborne illness outbreak. In the meantime, I encourage anyone interested in improving food safety to contact their representatives and urge them to support full food safety initiative funding and the previously mentioned statutory alterations.

I am grateful to FDA for inviting me to address this forum. Thank you for your time and attention.