The Quarterly Quality Report

June 2007

The ASQ Quarterly Quality Report provides a detailed look at a variety of quality-related topics and issues. The report is developed by the American Society for Quality in keeping with its role as the steward of the quality profession—to promote the use of quality as a global priority, an organizational imperative and a personal ethic, and to promote quality concepts, technology and tools to make the world a better place.

Food Safety – A Quality Management Systems Approach

Public attention has been focused as perhaps never before on the safety of the food supply as a result of recent high-profile outbreaks of illness linked to various foods.

According to the United States Centers for Disease Control and Prevention (CDC), a rare strain of *Salmonella* in peanut butter produced at a plant in Georgia between August 2006 and January 2007 sickened 628 people in 47 states. California fresh spinach contaminated with a pathogenic form of the bacterium *E. coli* killed three people and sickened more than 200 people in 26 states in late summer 2006. There were two multi-state outbreaks of pathogenic *E. coli* associated with lettuce used in fast-food restaurants and two multi-state salmonella infections associated with tomatoes in 2006. And while the glare of widespread media attention was focused on these human food incidents, at least 16 pets died from the effects of tainted wheat gluten processed in China and blended into pet foods that were sold in the United States, Canada, and Mexico under more than 100 brand names.

The resultant calls by the media, the public, consumer groups and legislators for more oversight of the food supply almost invariably include a clamoring for more inspectors and more inspection.

“The problem is, the science of quality has told us that more inspection is not going to inspect the defect out of the product,” says Steve Wilson, chief quality officer for the U.S. Commerce Department’s Seafood Inspection Program. “Asking, ‘Do we need more inspectors?’ is a loaded question, because usually you do need more inspectors—but only because of the way the current system is designed,” states Wilson, who is also on the board of directors of the American Society for Quality (ASQ).

There is evidence that food safety in the United States is getting better, not worse.

The CDC's FoodNet surveillance program, which tracks diseases caused by pathogens transmitted commonly through food, found that in 2006 the incidence of infections caused by four of the most common food pathogens—*Campylobacter, Listeria, Shigella*, and *Yersinia*—declined significantly since the baseline period 1996-98. Infections caused by two other pathogens—Shiga toxin-producing *Escherichia coli* O157 (STEC O157) and *Salmonella*—declined but not by a statistically significant amount. Infections caused by *Vibrio* (most often associated with consumption of raw seafood) increased over this period. Incidence of STEC O157 infections declined substantially in 2003 and 2004, but then rose in 2005 and 2006. The decline in 2003-04 was associated with concerted efforts by the USDA Food Safety and Inspection Service and the beef-processing industry to combat *E. coli* contamination in ground beef. Reasons for the STEC O157 increases in 2005 and 2006 are not known.

CDC says that more than half of the reported foodborne outbreaks cannot be attributed to any specific pathogen by current diagnostic methods. In addition, identification is hampered by the increase in new pathogens appearing on the scene and drug-resistant variants of existing known pathogens, as well as well-known pathogens appearing in new types of foods. If we do not yet know how to identify many of these pathogens, as the agency surmises, then more inspection is not going to help in this case.

The enormity of the food production and distribution system, with more than 350,000 retail food outlets in the United States and food imports alone in the billions of pounds, also exposes the foolhardiness of reliance on inspection-based systems to give the public the level of assurance they seek.

The logical extension of an inspection-based system to guarantee food safety would be for every household to have its own inspectors—like the food tasters who protected medieval nobles. Such a vast army of modern-day food tasters would also be required to be trained microbiologists and chemists with access to highly sophisticated laboratories. This is clearly an absurd and outrageously costly option.

If not inspection, what?

Alternatives to a reactive, inspection-based food safety system stress preventive approaches and take into account current trends in food production, processing and distribution.

John Surak, a food safety consultant and member of the ASQ Food, Drug and Cosmetic Division, points to three trends that are reshaping thinking on approaches to assuring food safety. "We've had tremendous consolidation in the food processing industry; our eating patterns, habits and preferences have changed in recent years; and the industry is developing more robust food safety management systems," he says.

Whether it's grains, vegetables, dairy, or meats and poultry, the number of food processing plants has declined and the output of those plants has increased.

"If you're going to have a glitch, the problem is major and can affect a large number of individuals," Surak says. "When we had more locally produced food processed in

smaller, more localized plants, a glitch may not have appeared on the national media radar screen because not very many people got sick," he adds.

Today's health-conscious consumers want fresh fruits and vegetables all year round. They also demand foods that are essentially ready to eat. The fresh-cut sector is the fastest-growing segment of the produce industry. For example, fresh spinach consumption per capita has increased 180 percent since 1992. When these fresh, ready-to-eat foods do become contaminated, the likelihood they will produce a foodborne illness is quite high, since unlike meat and poultry they are not cooked prior to being consumed. Fresh produce has now surpassed beef as the leading source of illness caused by pathogenic *E. coli* in the United States.

This consumer demand has created new opportunities in the way we grow, harvest, and process fresh fruits and vegetables. From a food safety perspective, it has allowed the development of Good Agricultural Practices—a set of food safety principles that can be applied in the farm field, such as controlling animal wastes that originate in feedlots. They are designed to prevent contamination from microorganisms that are naturally present in the agricultural environment. Complementing the Good Agricultural Practices are Good Manufacturing Practices (GMP) which prevent further contamination of fresh fruits and vegetables after harvest.

Elements of a preventive approach to food safety

Some of the elements of a prevention-based approach to food safety are already well established within industry and within the regulatory framework, while other elements are in various stages of development or have been proposed in the past but not implemented. These include:

Going back to the basics

"One of the things I emphasize day in and day out when I work with industry is that you have to do the basics well, and you repeat it time and time again," states Surak. "I see problems in companies where they tend to forget about doing the basics."

An FDA report on causes of food recalls occurring between 1999 and 2003 revealed that 83 percent of the two most serious classes of recalls could be attributed to failure to control GMP issues or to breakdowns in prerequisite programs—in other words, failing to do the basics correctly.

Some of these basics include strictly following good manufacturing practices at the plant level and good agriculture practices at the producer or farm level. These GMPs and GAPs are some of the prerequisites that are the foundation for implementing HACCP.

HACCP (hazard analysis and critical control point) is a quality management system for effectively and efficiently ensuring farm-to-table food safety by controlling microbial, chemical, and physical hazards associated with food production. A prevention-based system, it takes a proactive approach by identifying the principal hazards and the control points where contamination can be prevented, limited, or eliminated across the whole food production process –

rather than trying to identify and control contamination after it has occurred. HACCP principles are being applied to an increasing range of food products.

"In the dairy industry we've voluntarily applied HACCP because it makes sense," states Janet Raddatz, vice president of quality and food safety systems at Sargento Foods Inc. "FDA isn't requiring anyone to do it—we're policing ourselves," she says. Raddatz is an ASQ Fellow and an ASQ Certified Manager of Quality/Organizational Excellence.

HACCP and its risk assessments and prerequisite programs—the food safety basics—form the foundation of the food safety system at Sargento. "We utilize HACCP in all our plants on all our lines for all our products," Raddatz says.

The basics also include having an effective and strong supplier quality program so that food producers and processors can be certain about the quality and wholesomeness of components and ingredients they purchase from their suppliers.

Application of resources and attention to areas of greatest risk

In the absence of limitless resources it makes sense to apply the greatest attention to those aspects of the food supply chain where the greatest safety risks lie. Existing quality and food safety tools, applied within state-of-the-art food quality management systems, can be quite effective at reducing the risk of foodborne illness. There are many food producers and distributors that have a track record of operating in accordance with these proven quality management systems. Applying risk-based criteria to regulatory and inspection efforts means that fewer resources can be directed at these producers, freeing up more resources to be directed at higher risk targets.

Design and implementation of better systems

A fairly recent development—the introduction of the ISO 22000:2005 international standard—provides a common basis for food producers anywhere in the world to design and implement fundamentally sound and robust food safety management systems.

ISO 22000:2005 represents the latest step in the evolution of food safety systems beyond HACCP. It combines the five preliminary steps and seven principles of HACCP into a food safety management system that goes beyond regulatory compliance. The standard is auditable, and it harmonizes national food safety standards, to ensure confidence to customers and consumers throughout the food chain anywhere in the world. It marries accepted state-of-the-art quality management principles with state-of-the-art food safety practice.

"Good quality and food safety management principles will have us take a look at the data and design a system around the data, and do what the data tell us versus what our gut is telling us to do—what the perception is telling us to do," says Wilson. "And then you work on the process versus the product, and you work on the system versus the process. If you do it that way you have a better chance of having stronger product than if you're simply inspecting the product."

For that reason, Wilson, Surak, and others who have studied ISO 22000:2005 say it is a very strong standard that deserves to be widely implemented. Both Surak and Wilson served on the committee that developed the standard.

"So far, those who have implemented it seem to think it's working quite well," Wilson states. "Inspectors and plants who really look at it like the standard."

As of February 2007, more than 250 companies had sites registered to the ISO 22000:2005 standard. The bulk of these, about 75 percent, are in Europe.

Raddatz says her company is investigating ISO 22000:2005. "We're doing a gap analysis right now, comparing what we have under our HACCP based system with what ISO 22000 is asking for. If we're missing anything, can we close the gap? So, if there becomes a competitive advantage—if our customers start to say, 'We will not do business with you unless you become 22000 registered'—then we're poised for that."

What can be done now

Food safety in the United States is better today than ever. Still, there remains huge opportunity for improvement in preventing illness from known food pathogens and in responding to new and emerging foodborne illnesses and threats.

Here are some steps that can be taken now that would have high impact, are do-able, and are consistent with established quality practices.

- **No let-up on the basics.** In the food processing environment, constant reinforcement on the food safety basics is necessary. These basics include such procedures as personnel hygiene practices and training programs, cleaning, sanitation, and maintenance procedures, effective product recall programs, provisions for safe water supply, and procedures for handling product throughout the entire manufacturing and distribution processes.

- **Continuing consumer education.** Once food leaves the processor, there is also a role for consumers and others to play in maintaining basic food safety precautions. Improper food handling in the home and at retail food establishments accounts for more reported cases of foodborne illness than does failure at the food processing level.

- **Greater use of risk-based criteria and greater flexibility in directing regulatory resources quickly and efficiently to high-risk areas.** Massive restructuring of the nation's food regulatory agencies may not be politically or economically feasible, at least in the short term. However, attention can and should be focused on strengthening regulatory agency capabilities in areas where greatest risks lie. In today's world of heightened terrorist awareness, where deliberate contamination of food supplies is a very real threat, additional attention and resources will be directed at this problem. But that

effort can complement existing food safety approaches in many ways. Many of the systems and tools that will strengthen protections against accidental contamination will also help protect against deliberate contamination of the food supply.

- **Expanded partnerships.** The public's perception is that the government will protect them 100 percent when it comes to eating their food. The reality is that government has to work in partnership with industry and in partnership with consumers themselves in guaranteeing safer food.

- **More sharing of information and less duplication of effort.** The advent of international food safety management system standards is opening up new avenues for cooperation and sharing of data among food safety regulatory agencies, the food industry, and the network of private-sector organizations that are springing up to audit the food industry to these new standards. Multiple audits and inspections of individual facilities can be reduced. These opportunities need to be exploited.

- **Greater use of economic incentives.** Economic incentives are demonstrably more effective than regulatory pressure. An example is the USDA Agricultural Marketing Service's use of economic incentives and performance standards linked to statistical process control and continuous improvement to ensure that ground beef purchased for school lunch programs is safe and meets purchasing requirements. In the four years that this program has been in effect there has been a continual improvement in the microbiological quality of the ground beef. If purveyors want to sell ground beef to the school lunch program, they must have systems that are shown to be in process control. If a supplier's process deteriorates, that supplier will be removed from approved status and placed on conditional status. During this time the supplier must take appropriate corrective and preventive actions to bring the process back into compliance with specification. If the supplier fails to do so it will be placed on ineligible status. The recent recalls illustrate the magnitude of the economic incentive for the food industry. ConAgra estimated the cost of its 2006 peanut butter recall at $50 million to $60 million, not including costs for loss of brand loyalty and customer trust. The impact of last year's recalls on fresh spinach farmers and processors has been estimated at between $25 million and $50 million in lost revenue, and the industry has still not recovered fully from the drop-off in sales.

- **Expanded diligence by food companies on supplier quality performance.** The recent sickening of pets from toxic ingredients blended into pet foods was more a failure of corporate supplier quality programs than a failure of the regulatory establishment.

- **Globally applicable tools for a global food chain.** Sourcing of food and food ingredients is now a global business, so it makes sense to tackle food safety issues with internationally accepted and globally applicable tools such as the ISO 22000:2005 standard.

- **More effective inspection—not more inspection.** Federal and combined federal-state inspection resources are limited and workload is growing, so these resources need to be targeted where they are needed most. Food producers and processors—domestic or foreign—that do not show evidence of compliance with HACCP and/or ISO 22000:2005 and those dealing in higher-risk foodstuff should be subject to closer surveillance.

About the American Society for Quality

The American Society for Quality is the world's leading authority on quality. With more than 93,000 individual and organizational members, the professional association advances learning, quality improvement, and knowledge exchange to improve business results and to create better workplaces and communities worldwide. As champion of the quality movement, ASQ offers technologies, concepts, tools, and training to quality professionals, quality practitioners, and everyday consumers, encouraging all to Make Good Great®. ASQ has been the sole administrator of the prestigious Malcolm Baldrige National Quality Award since 1991. Headquartered in Milwaukee, WI, the 61-year-old organization is a founding partner of the American Customer Satisfaction Index (ACSI), a prominent quarterly economic indicator.