



## Written Statement for the Record

Submitted August 2007 by the American Society for Quality to the  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives

Subsequent to the Subcommittee's hearings entitled "***Diminished Capacity:  
Can the FDA Assure the Safety and Security of the Nation's Food  
Supply?***"

The American Society for Quality thanks the Chairman of the Subcommittee for the opportunity to submit a written statement which we hope will be included in the record of the series of food safety hearings titled, "*Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?*"

We have been following these hearings with a great deal of interest, and our purpose in this commentary is to offer perspectives on the topic from the quality assurance professions that we believe will be useful to the Subcommittee, to the FDA, and to the food processing industry.

The principal advice we could offer to the Subcommittee is to be wary of the drumbeat calling for more inspection as the way to address current food safety problems, as this represents a simplistic solution to a complex situation and an expensive approach that cannot work. The rationale behind this position is explained in more detail in the ASQ Quarterly Quality Report titled "*Food Safety: A Quality Management Systems Approach,*" which is attached to this filing as Appendix A.

The Quarterly Quality Report raises several main points that are relevant to the questions currently before your Subcommittee:

- More inspection is not the answer to improving food safety; however, more effective inspection and assessment pinpointed to high-risk areas can go a long way toward plugging gaps in the current food-safety framework.
- More widespread adoption of HACCP practices and the ISO 22000 food safety management international standard are needed to raise performance worldwide to best practice levels and prevent occurrences of foodborne illness.

In addition, we believe the Subcommittee should focus on several other areas in its

assessment of the FDA's ability to ensure safe food, such as:

**System and process focus.** Today's food safety challenges demand less focus on end-item testing and more push onto the process and as far back into the supply chain as possible.

**Supply Chain Management.** Much of the inspection effort has been concentrated at particular points close to the ends of the food chain, specifically at import and processors. However, what is needed is more focus on the links of the food supply chain. Supporting the "one-up-one-down" mechanism of the members of the chain by finding innovative methods of evaluating the passing of the product between the links may yield better results.

**Joint Agency Activities.** As these Subcommittee hearings have pointed out, Federal food safety oversight is a fragmented undertaking, with multiple agencies playing a role. These agencies are not necessarily working together to meet common food safety or public health goals, as a number of GAO studies have emphasized.<sup>1</sup> Joint agency activities carried out in overlapping and complementary fields could obviate some of the need for additional inspectors and permit more thorough oversight with existing personnel resources. In addition, FDA has a long history of collaboration with state departments of agriculture for inspection of food processing plants using uniform FDA guidelines and procedures—a practice which could be expanded. Rather than continuing to feed the old inspection-based process that was designed for century-old conditions, FDA and Congress should devote energies to re-engineering the process and only then determining what personnel resources are required.

**Government/Industry Partnerships.** There will never be enough inspectors no matter what the design ends up being. What is also necessary is for the agencies to focus on the weak areas. This requires more reliance upon activities that strengthen the food chain, such as the involvement of industry trade groups who are attempting to police their members. Supporting such activities permits the agency to spend time and resources where needed most—on the participants who are not complying.

**International Data System for Traceability.** Food safety professionals are talking more and more about the extreme need to share data internationally in order to have true traceability. This means we must all use common data entry means such as common IUU codes to better trace the transfer of the product throughout the supply chain. This is especially important for highly traded commodities such as seafood where over 80% of the seafood consumed in the US is imported. Countries such as Australia and the EU are very interested in implementing these more sophisticated data systems, even though the percentage of imported seafood is lower there than it is in the United States.

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Footnotes

- 1.) See the following GAO reports: GAO 01-204: *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* and GAO 04-246 *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*

## APPENDIX A



### **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).

“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

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

- **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.

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***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.*