Richard F. Stier
Sonoma, CA, U.S.A.

So, What Will the Food Safety Modernization Act Mean?

The end of 2010 witnessed the passage of the Food Safety Modernization Act of 2010. President Obama signed the bill into law on January 4, 2011. There were a number of incidents that pushed the U.S. Congress toward passage of this law, but perhaps the greatest was a perceived loss of confidence in the food supply and the agencies responsible for regulating the food supply. One significant reason for this loss of confidence was the large number of high-profile food recalls prompted by products causing a significant number of foodborne illnesses. Below is a list of recent major food recalls (numbers in parentheses indicate number of cases of foodborne illness reported):

- *Salmonella*, breakfast cereal – 1998 and 2008
- *E. coli*, packaged spinach – August 2006 (206)
- *Salmonella*, peanut butter – February 2007
- *Listeria*, chicken – February 2007
- *E. coli*, ground beef – June 2007
- *Clostridium botulinum*, canned meat – July 2007
- *E. coli*, ground beef – October 2007
- *Salmonella*, frozen pot pies – October 2007
- Animal handling violations, processed beef– February 2008
- *Salmonella*, peppers – June and July 2008
- *Salmonella*, processed peanuts – January 2009 (691)
- *Salmonella*, eggs – August 2010 (>1,500)

So, did the U.S. Congress respond correctly in enacting this law? Is there really something wrong with the U.S. food supply and the food, beverage, and ingredient manufacturers who supply food products? Is the law too much, or is it on target?

First off, we must all understand that this is a law enacted by the U.S. Congress. For a law to become reality, it is up to the administering agency, in this case the U.S. Food and Drug Administration (FDA), to enact regulations to define how the law will be enforced. It will take months and maybe even years before these regulations are drafted, reviewed, and finalized, so as an industry, we have some time before it becomes reality. Even though there are people such as Michael Jacobsen of CSPI who make preposterous statements like the following, "Soon parents should be able to shop without worrying that the spinach, tomatoes, peanut butter or eggs in their cart are going to cause illness and misery," there are many who believe that the U.S. food supply is the most diverse and safest in the world. This was, in fact, the opinion of former Surgeon General C. Everett Koop.

So, what is in the law? Before we discuss that, bear in mind that many, if not all, of the provisions that will affect processors on the technical side are not new but are exactly what the food industry considers to be good quality and safety practices. If you lay the basic requirements of the six audit schemes approved by the Global Food Safety Initiative (GFSI) next to the Food Safety Modernization Act of 2010, you will see that they have a great deal in common. Below is a list of the kinds of programs or documents that all processors, large and small, should have:

1) Organizational Chart
2) Quality Manual: Mission and Quality Policies
3) Stakeholders List
4) Communication Guidelines—Internal/External
5) Food Safety Committee/HACCP Team
6) Master Cleaning Schedules
7) Documented Cleaning Procedures
8) Ingredient Shipping and Receiving Procedures and Records
9) Specification Manual: Ingredients, Packaging, and Finished Goods
10) Letters of Continuing Guarantee/COAs
11) HACCP Program
12) Plant Policies: GMPs, Training
13) Allergen Program
14) Consumer Complaint Program
15) Recall and Traceability Program
16) Nonconforming Products Procedures
17) Regulatory Inspection Program
18) Processing SOPs and Record Keeping
19) Change Control Procedure
20) Process Deviation Procedures and Log
21) Internal Audit/Inspection
22) Product Testing
23) Vendor Approval Program
24) Glass and Brittle Plastic Program
25) Preventive Maintenance Program: Including Emergency Repairs
26) Pest Control Program: Manual and Records
27) Sampling Procedures
28) Sifter/Screen Logs
29) Metal Detection Program
30) Foreign Material Detection Logs
31) Distribution Records
32) Programs for Receipt of Perishable Materials
33) Calibration Procedures and Logs
34) Retain Samples Program
35) Water Quality Program
36) Procedures for CIP Cleanup Evaluation
37) Food Defense: Security Assessment and Plan
38) CAPA Log
39) Legal Requirements: File of Laws and Regulations

This list pretty much covers the food safety, quality, and sanitation requirements in the new regulation. The new issues are related to fees, accreditation, third-party audits, and a few other things.

doi:10.1094/CFW-56-3-0128

So, what is included in the Food Safety Modernization Act of 2010? During AACC International's recent U.S. Regulatory Summit held in February 2011, David Acheson of Leavitt Partners highlighted the key provisions of 2010 Modernization Act, including mandatory inspection frequency, expanded records access, mandatory recall authority, and import certification authority. A recent webinar conducted by the Institute of Food Technologists talked about the regulation and its implications. What the panelists in the webinar agreed on was that they were unsure how the law will eventually shake out when regulations are finally drafted. Let's take a look at some of the technical elements of the 2010 Modernization Act and discuss how they might be enforced.

HACCP/Food Safety – All processors will be required to conduct a hazard analysis, determine hazards that are reasonably likely to occur, and develop programs to control those hazards. The juice HACCP regulation found in 21 CFR, Part 120 and the seafood HACCP regulation found in 21 CFR, Part 123 (4–6) provide guidance as to how this part of the 2010 Modernization Act might be regulated and enforced. Hopefully, the agency will not adopt the U.S. Department of Agriculture model in which in-plant agents have forced meat and poultry processors to change plans. This is one element that has been driven by the economic realities of the food processing industry—have a HACCP plan or you don't sell to me.

Supply Chain Management – There is no regulatory model on which to base potential enforcement. There are industry models, however. These usually include a program for supplier approval that utilizes third-party audits (using in-house personnel or qualified third parties), maintenance of specifications, use of certificates of analysis from competent laboratories, and verification of COAs that are deemed essential for food safety.

Records Maintenance – Processors will be required to maintain records of their hazard analysis and food safety management programs. Again, what has been established for the juice and seafood industries could serve very well for establishing how these records should be maintained and the agency's access to said records. The regulations will probably allow access to records documenting the prerequisite programs deemed essential to ensure safety. This is another element that has been driven by economics. In addition, the ISO 22000 standard, Food Safety Management Systems—Requirements for Any Organization in the Food Chain, emphasizes the necessity of records documenting these areas (1).

Intentionally Introduced Hazards – This is one of the food defense/bioterrorism elements of the 2010 Modernization Act. Processors may well be required to conduct a food defense assessment and clearly identify places where someone could introduce a food safety hazard. This is another of the issues that is part of almost all third-party audits. Processors are already encouraged to conduct a food defense assessment. Both the USDA and FDA have such assessments, which are easily accessible on their websites.

Recalls and Traceability – This is another element that is simply good business. If processors do not know where their products are shipped and where ingredients are coming from, they could be in for a very unpleasant surprise. The low-acid canned food regulation found in 21 CFR, Part 113 mandated this years ago (2,3). In addition, the Bioterrorism Act not only mandated plant registration, but also made traceability mandatory. The spinach recall cited earlier brought this subject to the forefront. One of the reasons that this incident received so much adverse publicity was that the processors were unable to quickly identify the source of the contaminated spinach.

Thanks to pressure from the small business community, some provisions of the 2010 Modernization Act will be waived for very small businesses and farmers. This, however, will depend on who these businesses are marketing their products to. If a customer or potential customer says, "Sorry, we won't buy from you unless you establish a food safety management program or follow Good Agricultural Practices," they will probably do so to maintain their business. As mentioned earlier, business requirements have driven food safety in nonregulated businesses.

The 2010 Modernization Act also includes provisions for greater enforcement powers for the FDA. These will probably include more inspections by the agency, the ability to suspend a processor's registration, and enhanced authority to detain products. However, the greatest new power will be mandatory recall. Currently, the agency can only recommend that a company initiate a recall. There will also be some kind of fee structure, which has yet to be determined. There will probably be fees for recalls, inspections, and even exports.

The food processing industry has some time before the regulations and policies that will allow enforcement of the Food Safety Modernization Act of 2010 to be finalized. However, the technical issues related to food processing are things that every food processor, both large and small, should be doing—programs that are mandated not by the government but by their customers.

One of the issues that needs to be resolved before the 2010 Modernization Act can be enforced is a budget. The act does not provide funding for the agency.

References

1. International Organisation for Standardization. ISO 22000: Food safety management systems—Requirements for any organization in the food chain. ISO, Geneva, Switzerland, 2005.
2. U.S. Food and Drug Administration. 21 CFR, Part 113: Thermally processed low-acid foods packaged in hermetically sealed containers. *Code of Federal Regulations*. U.S. Government Printing Office, Washington, DC, 1989.
3. U.S. Food and Drug Administration. 21 CFR, Part 114: Acidified foods. *Code of Federal Regulations*. U.S. Government Printing Office, Washington, DC, 1989.
4. U.S. Food and Drug Administration. 21 CFR, Part 123: Fish and fishery products. *Code of Federal Regulations*. U.S. Government Printing Office, Washington, DC, 1995.
5. U.S. Food and Drug Administration. 21 CFR, Part 1240: Control of communicable diseases. *Code of Federal Regulations*. U.S. Government Printing Office, Washington, DC, 1995.
6. U.S. Food and Drug Administration. Hazard analysis critical control point: The safe and sanitary processing and importing of juice. Fed. Reg. 66:6137, 2001.

Richard Stier is a consulting food scientist with international experience in food safety (HACCP), food plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology. Stier is an AACC Intl. member and can be reached at Rickstier4@aol.com.