FOOD SAFETY INSIGHTS | October/November 2018

The Uphill Path to FSMA Compliance

By Bob Ferguson



The fact that the Food Safety Modernization Act (FSMA) has been one of the biggest issues for food processors in decades should not be a surprise for anyone who reads *Food Safety Magazine*. FSMA has been called "the biggest overhaul of the food safety laws in the U.S. in more than 70 years"; we believe that we will not get any arguments if we say that it has lived up to this claim.

We checked in again with processors to find out more about how FSMA compliance has affected their operations, costs, and the biggest issues they say that they still face. We received answers from 280 processors from around the world across a wide variety of processing categories including protein, dairy, fruits and vegetables, baking, processed foods, and confectionary, including 224 processors from the U.S. and Canada, and another 56 from outside North America.

The first question we asked was "Do you consider your facility to be in compliance with FSMA?" For processors in the U.S. and Canada, approximately 70 percent reported that they are confident that they are indeed in compliance with FSMA, with only about 3 percent reporting that they are not, and just under 27 percent said that they are still "working on it." For processors outside the U.S. and Canada, slightly more than 51 percent reported that they are confident that they are in compliance, 15 percent reporting that they are not, and about 34 percent said they are also "working on it."

At first glance, perhaps it is surprising that only 7 in 10 U.S. and Canadian processors and about 50 percent of international companies are reporting that they are in compliance with a regulation that has been coming their way since 2011. In the August/September issue of Food Safety Magazine, where we convened an expert panel on FSMA implementation, John M. Ryan, Ph.D., PCQI, Ryan Systems Inc., made the excellent point that "FSMA regulations attempt to define a complex system-wide set of rules designed to move the food supply chain to improve over the next 50 years. Such changes generally take a generation to effectively implement. Current deadlines for 'full implementation' are unrealistic." With that backdrop, perhaps these are reasonable compliance rates.

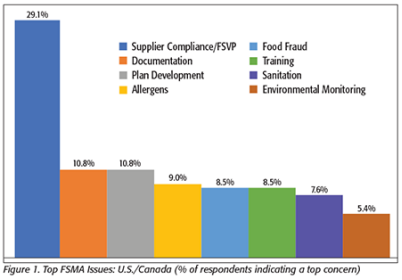


Figure 1. Top FSMA Issues: U.S./Canada (% of respondents indicating a top concern)

Ryan's comments on the complexity of the supply chain were also echoed in our latest survey. In the comments we received, it was clear that the supply chain presents the most pressing issues. This was also reflected in our second question, where more than 20 percent of the respondents in the U.S. and Canada, with almost three times the mentions of the second most frequent answer, reported that issues related to supplier compliance, or more specifically Foreign Supplier

Verification Program (FSVP) compliance, were their area of top concern (Figure 1). Processors frequently offered comments about getting their supply chain in compliance, saying, “We work with facilities all over the world and many are still working to understand their requirements and responsibilities and what they need to do…” and “We are still working with our supply chain partners to get them trained in FSMA.”

With the complexity and globalization of most companies’ supply chains, this task of supply chain control can be overwhelming. This can be especially true for smaller companies with more limited resources but nonetheless with a supply chain that still spans the globe. One comment that we think will sound very familiar to many was “… dealing with the supplier preventive control has been especially difficult given our small QA team and our large numbers of prepared products.”

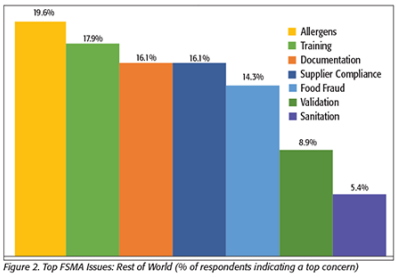


Figure 2. Top FSMA Issues: Rest of World (% of respondents indicating a top concern)

Some of this is also reflected in the answers we received from international processors and suppliers. Although the number one issue that they cited (Figure 2) was allergen control, the next three most frequently cited issues were training, documentation, and supplier compliance. It was clear from the comments that these concerns referred to their compliance as a supplier to FSMA-regulated companies and that the companies meant that program, training, documentation, and similar compliance issues were really their single top concern, and these together outnumbered any other concerns by better than two to one.

We also wanted to know more about the estimated costs of FSMA compliance. Prior to the survey, we had expected that this would be a provocative issue, especially considering the financial impact—in addition to the operational impact—that FSMA must have on most processors. We have to say we were surprised, however, when about 85 percent of the respondents said they did not track their FSMA compliance costs. To be fair, almost everyone who responded cited different investments that they had to make. Many cited one or more employees who were hired solely for FSMA compliance activities, while others cited specific costs paid to training providers or consultants. Few, however, reported that they had a full accounting of their compliance costs. One person, who identified themselves as being in a corporate management function, may have captured some of the reasoning behind these answers best when they added, “…It’s mandatory and not worth tracking costs.”

Of the 15 percent who did report that they tracked costs, roughly 60 percent said their costs were less than $50,000, about 18 percent had costs between $50,000 and $100,000, and the remainder had costs greater than $100,000 (Figure 3). While this

small sample size makes it difficult to draw too many conclusions, a qualitative review of the responses indicates more of a direct correlation between a company's size and its FSMA compliance costs than other factors such as the types of food it produces.

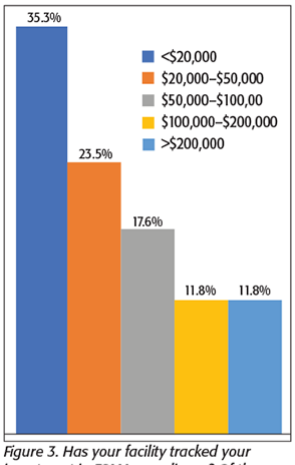


Figure 3. Has your facility tracked your investment in FSMA compliance? Of those responding yes, breakdown by investment in U.S. dollars is shown (% of respondents indicating a top concern).

We mentioned that companies cited allergen control (number four for U.S./Canada and number one for international companies) as one of their key compliance issues. We anticipated this response and, as part of this survey, we also asked detailed questions about how processors are changing their allergen control programs.

We first asked, "Has FSMA changed the way that you test or control for allergens?" Roughly 30 percent reported that FSMA had caused them to implement specific changes. We then asked what these changes were, and the most frequent answer, with more than 40 percent of the responses, was "more testing."

We will expand further on this allergen program data from the survey in our next edition of Food Safety Insights. We will report how much additional testing is being done and the analytical methods being used. Allergen control is, of course, more than just testing, so we will also describe the changes in other program elements such as segregation and labeling. We asked what products or services processors would find most valuable to help them improve their programs. We look forward to bringing those insights to you in the next issue.

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