2016 FSMA Readiness & Compliance Strategy

Survey Results

Sponsored By:

SafetyChain SOFTWARE

TAG THE ACHESON GROUP

Spring 2016
Introduction
The 2016 FSMA Readiness Survey was conducted to better understand how prepared the food industry is for FSMA and what the impact of FSMA will be on their organizations. Survey questions probed what compliance programs or systems were in place or being considered, as well as each company’s comprehension and confidence in those plans for meeting the FSMA requirements.

Survey Response
Approximately four hundred companies participated in the survey; primarily large, domestic companies involved in the production, manufacture, and movement of human food.

Survey Demographics

**Company Revenue & Number of Employees**
- **Company Revenue**
  - 88% > $1 Mil
  - 12% < $1 Mil
- **# Employees**
  - 72% < 500 Employees
  - 28% > 500 Employees
Which FSMA Rules Apply to Your Company?

Only 85% of the companies were certain if the rules apply to them; 15% were unsure if they applied. Still, for the companies who were fairly certain about what rules applied, they may need to revisit some of their assumptions. For example, many said they must follow Foreign Supplier rules, which were intended for foreign importers, not domestic companies; many also said they needed to follow Sanitary Transport rules, which will not apply to time-temperature-stable products.

<table>
<thead>
<tr>
<th>Rule</th>
<th>Applies</th>
<th>Does Not Apply</th>
<th>Unsure If Applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls for Human Food</td>
<td>85%</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Preventive Controls for Animal Food</td>
<td>30%</td>
<td>63%</td>
<td>7%</td>
</tr>
<tr>
<td>Produce Safety</td>
<td>34%</td>
<td>59%</td>
<td>7%</td>
</tr>
<tr>
<td>Foreign Supplier Verification Programs</td>
<td>54%</td>
<td>33%</td>
<td>13%</td>
</tr>
<tr>
<td>Sanitary Transportation</td>
<td>98%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Accredited Third-Party Certification</td>
<td>95%</td>
<td>19%</td>
<td>16%</td>
</tr>
<tr>
<td>Food Defense</td>
<td>83%</td>
<td>5%</td>
<td>12%</td>
</tr>
</tbody>
</table>

Is Your Company Ready for FSMA Compliance?

Three out of four respondents felt that their companies were not completely ready for FSMA compliance, even though large companies must be ready by mid-September of 2016. To best prepare now, companies should at least form a Compliance Team with a designated Qualified Individual, conduct full hazard analyses, and write an action plan to address those hazards.
Is Your Company Ready for the Challenges of Complying with FSMA?

All companies felt that there would be some difficulty associated with complying with FSMA. For each program, companies will need to evaluate hazards, how to respond to those hazards, how to best manage and document their processes, and how to evaluate and improve those processes.

<table>
<thead>
<tr>
<th></th>
<th>Not Considering</th>
<th>Considering</th>
<th>Implementing</th>
<th>Have in Place Already</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Management</td>
<td>21%</td>
<td>26%</td>
<td>19%</td>
<td>34%</td>
</tr>
<tr>
<td>Audit Management</td>
<td>28%</td>
<td>28%</td>
<td>14%</td>
<td>30%</td>
</tr>
<tr>
<td>Supplier Compliance</td>
<td>22%</td>
<td>29%</td>
<td>22%</td>
<td>27%</td>
</tr>
<tr>
<td>Food Safety Program Management</td>
<td>25%</td>
<td>23%</td>
<td>18%</td>
<td>34%</td>
</tr>
<tr>
<td>LIMS (laboratory info management)</td>
<td>53%</td>
<td>18%</td>
<td>9%</td>
<td>19%</td>
</tr>
<tr>
<td>GFSI Automation System</td>
<td>52%</td>
<td>29%</td>
<td>9%</td>
<td>10%</td>
</tr>
</tbody>
</table>

How is Your Company Preparing for FSMA?

Most large companies are relying on hazard (GAP or GMP) analyses to prepare for FSMA, since understanding the food safety risks inherent in their business is the cornerstone of preparing an effective food safety plan. Most of these companies state they are not using outside resources to conduct their hazard analyses. It is the smaller companies that will need more assistance in reaching compliance with FSMA.

Have You Conducted a FSMA Gap Analysis to Determine Current Plan Deficiencies?

<table>
<thead>
<tr>
<th></th>
<th>Complete Gap Analysis</th>
<th>Gap Analysis in Progress</th>
<th>Plan to Conduct Gap Analysis</th>
<th>Not Planning to Do Gap Analysis</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Gap Analysis</td>
<td>40%</td>
<td>22%</td>
<td>22%</td>
<td>14%</td>
<td>3%</td>
</tr>
<tr>
<td>Gap Analysis in Progress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Is Your Organization Utilizing Outside Resources to Help with a Gap Analysis?

Has Your Company Updated Food Safety Plans?

Only 10% of companies reported their Food Safety Plans are completely updated. Again, larger companies state they are not using outside resources to update Food Safety Plans. Though this low number may indicate a very narrow definition of what an “outside resource” is, since both large and small companies use a variety of educational and technical information from a variety of free and low-cost, as well as contracted, services.

Have You Updated Your Current Food Safety Program(s) to Meet FSMA Requirements?

Survey Sponsored by:

Spring 2016 | Page 4 of 9
Is Your Organization Utilizing Outside Resources to Help Update Program(s)?

- Have or will use outside resources: 27%
- Not be using outside resources: 69%
- N/A - no plans to update programs: 4%

Does the Company’s Record-keeping Meet FSMA Requirements?

Most companies keep both paper and electronic records, and indicate confidence in the accuracy, accessibility, and functionality of those records; they also stated they feel confident they can produce those records within 24 hours for audits. Companies may actually be too dependent on paper for records and a future best practice may be to move toward electronic record-keeping, which may be why only half of the companies felt they would be ready for FSMA audits. This discrepancy may result from an overall confusion regarding how records integrate with FSMA requirements, indicating more guidance is required.

Able to Produce Required FDA Records Within 24 Hours:

- Yes - 76%
- No - 2%
- Unsure - 22%

Are you Keeping Paper or Electronic Records?

- Both - Paper and electronic: 83%
- Electronic: 3%
- Paper: 14%
Will Your Company be Audit Ready on Day One of FSMA Enactment?

What Resource Plan Does Your Company Need to Support FSMA Compliance?

More than half of companies were unsure whether or not they will need more staffing or technology to comply with FSMA, yet three-quarters of the companies stated they will not use outside resources to deal with FSMA. These split statistics may indicate that companies need more guidance about the ramifications of these regulations, including information about what resources are available.

Resource Plans to Support FSMA Compliance:
What Technology is Being Used or Considered for FSMA Compliance?

Approximately 75% of companies indicated they are considering, implementing or are already utilizing technologies to support FSMA compliance. The question did not delineate if FSMA was the primary driver of those considering or implementing said technologies, though the higher percentage of companies adopting technology strategies suggests that the industry is acknowledging the need to update manual-based processes to better meet their growing food safety and quality management complexities.

### Technology Being Used to Help with FSMA Compliance

<table>
<thead>
<tr>
<th>Technology</th>
<th>Not Considering</th>
<th>Considering</th>
<th>Implementing</th>
<th>Have in Place Already</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Management</td>
<td>21%</td>
<td>26%</td>
<td>19%</td>
<td>34%</td>
</tr>
<tr>
<td>Audit Management</td>
<td>28%</td>
<td>28%</td>
<td>14%</td>
<td>30%</td>
</tr>
<tr>
<td>Supplier Compliance</td>
<td>22%</td>
<td>29%</td>
<td>22%</td>
<td>27%</td>
</tr>
<tr>
<td>Food Safety Program Management</td>
<td>25%</td>
<td>23%</td>
<td>18%</td>
<td>34%</td>
</tr>
<tr>
<td>LIMS (laboratory info management)</td>
<td>53%</td>
<td>18%</td>
<td>9%</td>
<td>19%</td>
</tr>
<tr>
<td>GFSI Automation System</td>
<td>52%</td>
<td>29%</td>
<td>9%</td>
<td>10%</td>
</tr>
</tbody>
</table>

What is the Overall Impact of FSMA to Your Company?

Although most companies think FSMA will have a positive impact on food safety, there is slightly less confidence in their comprehension of what FSMA regulations are, and moreover, few believe their upper management understands and supports the need for compliance with FSMA. Senior leadership needs more education about with FSMA, and what complying with its requirements will entail.

### FSMA Impact: Thoughts on FSMA

- Positive Impact: 48%
- Creating financial/resource burdens: 8%
- FDA has enough resources to enforce: 44%
**Conclusion**

Most companies have or are considering programs and systems to deal with upcoming FSMA regulations, but they do not have confidence that those programs and systems will actually meet requirements.

The survey indicated that: (1) more information is needed on how to meet FSMA requirements, (2) companies need to understand how programs and systems meet FSMA requirements, (3) companies need to know what resources are available to meet FSMA, and (4) upper management needs to be more involved in the compliance process.
FSMA Compliance Resources

- Monthly Live FSMA Updates: FSMA Fridays [www.FSMAFridays.com](http://www.FSMAFridays.com)
- FSMA compliance automation systems: [www.safetychain.com](http://www.safetychain.com)

About Survey Sponsors

SafetyChain Software

SafetyChain provides the food industry a comprehensive food safety and quality management solution with the tools, visibility and real time access to data needed to more effectively manage program execution, regulatory and non-regulatory compliance, and ongoing continuous improvement. SafetyChain’s solution suite, complemented by mobile apps, includes Supplier Compliance, Food Safety & Quality Management and Audit Management. [www.SafetyChain.com](http://www.SafetyChain.com)

The Acheson Group (TAG)

The Acheson Group is a consulting firm for food and beverage companies and those providing technical support to the food industry. With a focus on strategic risk management, TAG provides the latest food safety consulting insights in a global environment in providing Operational Risk management, Reputational risk management, and Regulatory Risk services—all with the goal of achieving brand protection. [www.achesongroup.com](http://www.achesongroup.com)