



FDA & FSMA Resources

Sorting through the FDA Food Safety Modernization Act (FSMA) Final Rules can be a time consuming and confusing task. We've put together our FSMA Resource page to help you understand the legal and regulatory complexities of FSMA while alleviating some of the pain points our stakeholders are struggling with regarding implementation and execution.

[Note: read the SQF FSMA FAQ's](#)

Preventive Controls for Human Food Rule

Consuming safe food is a basic human right we all have and being in the food safety industry gives us all the opportunity to contribute to the strengthening of food safety requirements. According to the FDA, the "Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years..." We at SQFI realize the importance of this reform and have taken the necessary steps to create additional resources that will assist our stakeholders strengthen their food safety programs and meet the robust requirements of the FSMA PC rule. In response to FSMA, SQFI has developed a voluntary **Preventive Controls audit checklist** and **guidance document** for stakeholders to use as a guide for identifying the necessary steps to bridge any gaps between a company's SQF Program and the PC rule.

[Note: read the SQF Preventive Control Guidance Document](#)

[Note: read the SQF Preventive Control Audit Checklist](#)

It is important to note, however, that using these documents does not guarantee compliance – nor does it absolve the supplier from ensuring that they meet all aspects of the FSMA Preventive Controls Rule for Human Food. While this checklist is voluntary and will not be scored, it is a valuable tool to help suppliers identify and understand any differences between the SQF Program and the PC rule.

In addition to the PC checklist, SQFI contracted The Acheson Group (TAG) to **compare the elements of SQF Level 2 Certification (specifically Modules 2 and 11) to the FDA FSMA Final Rule** requirements. The analysis examined the two major aspects of the Final Rule: the new preventive controls requirements that industry must comply with in order to implement the requirements of Section 103

of FSMA, and the updated current Good Manufacturing Practices (cGMPs) (current 21 C.F.R. Part 110 now re-designated as Part 117).

As the food industry looks to protect consumers, customers, and their brand as well as successfully be in compliant with the final new rules, TAG's analysis indicates that being SQF Level 2 certified is a very robust, strong advantage to fulfilling FSMA requirements.

[Note: read the Executive-Summary-FSMA-October-2015](#)

[Note: read the entire Analysys-SQF-Final-Preventive-Controls-for-Humans-comparison-mod-2-11](#)

Produce Safety Rule

SQF has led the way in keeping pace with the changing regulatory requirements of the US Food Safety Modernization Act and how it compares with its SQF Level 2 standards, which focuses on food safety. Recognizing the suspected parallels between GFSI and the Produce Safety Rule, questions related to the comparability of these requirements and the practices and processes already in place on farms and packing houses certified to a GFSI benchmarked scheme have understandably arisen. As a result, SQF contracted with The Acheson Group, LLC (TAG) to compare the elements of SQF Level 2 (specifically Module 7) to the FDA Final Produce Safety Rule. Further SQF understands that produce growers and packinghouses have historically followed Good Agricultural Practices guidance to control food safety risks on the farm. As such, our analysis examined two major requirements as they relate to the produce industry: the Produce Safety Rule that industry must comply with in order to implement the requirements of Section 105 of FSMA. [Read the SQF Module 7-Produce-safety-rule-comparison and learn more.](#)

In response to FSMA, SQFI has developed a voluntary **Produce Safety Rule audit checklist** and **guidance document** for stakeholders to use as a guide for identifying the necessary steps to bridge any gaps between a company's SQF Program and the Produce rule.

[Note: read the SQF Produce Safety Rule Guidance Document](#)

[Note: read the SQF Produce Safety Rule Addendum Audit Checklist](#)