Streamlining Food Safety:
Preventive Controls Brings Industry Closer to SQF Certification
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Food safety should not be a competitive issue. Still, companies need to be recognized when they meet certain food safety standards. Customers want assurance that food safety is as great a concern for their suppliers as it is for them. For over 10 years, SQF certification has served as an indication that companies have implemented systems that are intended to achieve and improve food safety. Now, as FDA begins to lay out the expectations of FDA regulated facilities in meeting the preventive controls requirements of the Food Safety Modernization Act (FSMA), it is worthwhile to explore how the forthcoming preventive controls requirements relate to SQF level 2 certification.

A comprehensive, side-by-side comparison of the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (“the proposed preventive control rule”) and SQF level 2 requirements that relate to the preventive controls requirements (specifically Modules 2 and 11) is available at http://www.sqfi.com/wp-content/uploads/SQF-Preventive-Controls-Comparison-FULL-REPORT-April-2013.pdf. Overall, the comparison noted minor differences between the two approaches. This leaves the question: If I’m already certified to SQF level 2, what more will I need to do to be compliant when the final rule is published? And those not yet certified to SQF level 2 might be wondering: If I’m going to need to comply with FDA expectations, how much more will it take to get SQF level 2 certified?

You’re SQF Certified. Does FDA Want More?

The good news is that facilities that are already certified to SQF level 2 need only add a few details to their existing processes and systems to be compliant with forthcoming FDA requirements. It’s important to remember that in 2.4.1, SQF requires that “the food supplied shall comply with the legislation”- so in that regard, SQF has FDA’s preventive controls covered. But to be practical, it is important to examine what an SQF certified facility will need to change in order to ensure compliance with FDA’s proposal.

There are only a few areas where SQF certified facilities will need to double check their systems, processes, and documentation, to ensure that they are satisfying FDA.

Requirements expected in the final preventive controls rule will include development of a food safety plan. SQF also requires a food safety plan. The table below illustrates some of similar and different elements of each. In many ways the SQF food safety plan is more comprehensive. Facilities should consult with their legal counsel to determine if the facility should retain one
food safety plan to meet both needs or if there should be separate, tailored food safety plans for FDA inspectors versus SQF auditors.

<table>
<thead>
<tr>
<th>SQF food safety plan</th>
<th>FDA food safety plan</th>
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</thead>
<tbody>
<tr>
<td>Written or overseen by the “SQF Practitioner” (a full time employee)</td>
<td>Written or overseen by a “qualified individual” (does not have to be an employee)</td>
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<tr>
<td>Contains a hazard evaluation</td>
<td>Contains a hazard evaluation</td>
</tr>
<tr>
<td>Identifies process controls and prerequisite programs</td>
<td>Identifies preventive controls (process, sanitation, allergen)</td>
</tr>
<tr>
<td>Documents validated parameters</td>
<td>Documents validated parameters as applicable</td>
</tr>
<tr>
<td>Identifies monitoring, verification activities, and corrective actions</td>
<td>Identifies monitoring and verification activities, and corrective actions</td>
</tr>
<tr>
<td>Critical food safety limits are re-validated annually</td>
<td>Includes reanalysis (but not revalidation) as needed, at least every 3 years</td>
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The preventive controls rule and SQF require that facilities implement food safety controls. As noted above, both SQF and FDA require that hazard analyses are performed (with FDA including radiological hazards as needing to be considered). Perhaps the biggest difference between SQF and FSMA is the expansion of HACCP philosophy to include “preventive controls” other than process controls. SQF, in accordance with internationally recognized HACCP teachings, consider the importance of “critical control points”. FDA, in accordance with FSMA, recognizes that facilities can use more than just process controls to significantly reduce or minimize the levels of hazards that are reasonably likely to occur associated with food products. In other words, some aspects of sanitation and allergen controls can be elevated to the “CCP” status by their designation as preventive controls. SQF places heavy emphasis on prerequisite programs, which is included only in the updated proposed FDA cGMPs; while SQF does not use the term “preventive controls” the same way as FSMA, SQF and FDA’s proposed preventive controls rules are aligned on using a prevention-based approach to food safety. However, facilities will want to examine if some of their prerequisite programs should be augmented and considered as preventive controls.

Another area for facilities to examine is how they validate process controls. SQF, of course, requires validated processes be used. FDA has proposed more detail in the documentation and nature of the studies that are relied upon to demonstrate that a process has been validated.

FDA is also very specific in what constitutes verification. While SQF 2.5.4 requires that verification be documented, FDA has identified several specific aspects of verification, and for some activities such as records review, has also specified the timeframe within which activities should be conducted. Other aspects of verification, as defined by FDA, include calibration. This is another area where FDA provides more detailed instruction on what is expected.
It is important to note the difference in the level of specificity around corrective actions. Both FDA and SQF require root cause analysis, however, FDA has further expectations around evaluating the safety of products and the methods used to ensure that potentially contaminated product does not enter the market place.

Both SQF and FDA place a great deal of emphasis on records. FDA is specific in requiring that records be kept on site for 6 months and be retained for 2 years, but does not require companies to have a system for document control, the way that SQF does.

**You’ve Prepared for FDA’s Preventive Controls. Is SQF Much More?**

At the point that the proposed preventive control rule is fully implemented, the difference between the “best-in-class” facilities and those who are barely compliant with the regulations will be smaller than the pre-FSMA era. In fact, FSMA is intended to raise the bar for all food facilities, in part by requiring all FDA-regulated facilities (with some exemptions) to do many of the things that SQF-certified facilities have had to do for a long time. Although some FDA-regulated products needed to implement HACCP prior to FSMA, it wasn’t mandatory for most parts of the industry. Conducting a hazard analysis, implementing controls to ensure food safety, and having a written recall plan will now become standard practice, and this positions facilities to go one step further and pursue SQF certification.

Where the path to SQF certification used to be viewed as a lengthy, arduous process, meeting the requirements of the proposed preventive controls rule will bring non-SQF-certified facilities most of the way there. So what more is needed? First, SQF requires a clear, written commitment to food safety. It is important that everyone in a facility, from the President of the organization to the line worker understands and live by the overarching policy. There are a few programmatic areas that are detailed in SQF that are implied, but not expressly called out in FDA’s proposed preventive controls rule. These include:

- Adherence to prerequisite programs (most facilities should have these as part of GMPs)
- Programs to assure the safety of incoming ingredients and other raw materials
- Supplier verification
- Ensuring that product development is done with food safety in mind
- More comprehensive management of allergens
- Environmental monitoring in high risk areas

Additionally, SQF certification requires facilities to train their staff (similar to GMPs), and to implement an internal audit program. Being able to successfully attain SQF level 2 certification requires that these practices and process are well-documented. This is something that some facilities have struggled with in the past. However, documentation is the key to many aspects of
FSMA, including preventive controls. So if a facility needs to conduct a hazard analysis, demonstrate implementation of preventive controls, and be documenting their food safety program, they should consider SQF certification.

With Preventive Controls Required, Why Bother With SQF?
If FDA’s proposed requirements are so close to SQF level 2 requirements, why bother going the extra mile? Attaining SQF certification demonstrates a commitment to food safety that goes beyond meeting the minimum standards of regulatory compliance, and increasingly, SQF demands evidence of management commitment. You comply with regulations because you have to. You pursue SQF certification because you want to, and this requires a “buy-in” at all levels that may not be attained through the regulatory gauntlet. Further, SQF is recognized worldwide, in places where stating compliance with FSMA may not mean much. Last but certainly not least, it is becoming a growing expectation by many customers as a requirement for doing business.

Once finalized and fully implemented, compliance with the FDA Preventive Controls Rule will be expected—but how will compliance be assured? Currently, firms will not need to submit their FDA food safety plans for approval. They say its what you INspect, not what you EXpect. Facilities using the SQF logo have undergone an intense audit—every year—to verify adherence to the SQF code. While audits are always a snapshot in time, there is no corresponding FDA “check” in place, given that FDA inspections more frequent than every few years will only be “for cause”, and by that time, it’s too late.

As the regulatory landscape changes, both in the United States and elsewhere, we remain committed to ensuring that SQF maintains the appropriate level of rigor to protect consumers worldwide from foodborne illness. We will continue to reevaluate the standards to promote and encourage the implementation of robust food safety management systems.

Summary
Whether you’re SQF level 2 certified and wondering “what else” is needed to comply with pending FDA requirements, or you’re preparing for FSMA and wondering “what more” is needed to achieve SQF certification, know that the differences are such that preparing for one lays a good foundation for the other. The Preventive Controls Rule will eventually become final, and much of the food industry will need to ensure compliance. SQF sets out a pathway for implementation that can help firms achieve regulatory compliance.