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SQF Level 2– Final Preventive Controls for Human Food Rule Comparison (Modules 2 & 11)

Executive Summary

Overview. The use of global food safety and quality standards, such as SQF, have become a major driver of raising the standards for food safety and moving toward a focused risk based preventive control approach for food industry. The Food Safety Modernization Act is also heaving focused on risk based preventive controls and the FDA's recently published final rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (the "Final Preventive Controls Rule" or "the Final Rule") has a heavy focus on preventing food safety problem. The rule emphasizes the importance of, taking effective corrective actions and maintaining robust documentation, while giving industry adequate flexibility to implement preventive controls appropriate to the food, facility and the organization's food safety program.

Given the obvious parallels between GFSI and the FSMA preventive controls, SQF contracted with The Acheson Group (TAG) to compare the elements of SQF Level 2 (specifically Modules 2 and 11) to the Final Preventive Controls rule requirements, in order to identify similarities, and to enable SQF leadership to address any areas in which they could be in better alignment with this new Preventive Control rule.

Similarities and Differences. Table 1 summarizes the key areas addressed in SQF and/or the FDA Final Rule (preventive controls and/or cGMPs). The main areas addressed by SQF are largely comparable to FDA's expectations. In some areas FDA is more prescriptive, however SQF's approach makes allowances for that and has a requirement to be in compliance with regulations (2.4.1) that may vary slightly by country. This takes into account that SQF is a global program that is not intended to be US or FDA-centric.

In many areas, SQF is more specific than FDA in the requirements. For example, SQF requires environmental monitoring for high-risk processes, whereas FDA requires environmental monitoring for ready-to-eat foods where the RTE product is exposed

to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed, but does not go so far as requiring environmental monitoring for all high-risk processes in the Final Rule.

SQF also has clearer requirements than FDA around ensuring the safety of incoming and raw materials.

TABLE 1

	SQF – Level 2	**FDA Preventive Controls Food Safety Plan**	**FDA GMPs (117 subpart B)**
Overarching policy statement	Yes	No	No
Written Plan	Yes	Yes	No
Experienced individual in charge	Yes	Yes	No
Trained Staff	Yes	Yes*	Yes
Prerequisite programs	Yes	No	Yes
Raw material/ incoming product safety assurance	Yes	No	No
Supplier Verification	Yes	Yes, in specific cases**	No
Allergen Management	Yes	Yes	Yes
Validation of Controls	Yes	Yes	No
Finished product testing	No	Yes, in specific cases**	No
Sanitation Control	Yes	Yes	Yes
Environmental monitoring	Yes	Yes, in specific cases**	No
Corrective Actions	Yes	Yes	No
Traceability	Yes	No[1]	No
Recall	Yes	Yes	No
Record retention	Yes	Yes	No
Food defense	Yes	No[2]	No
Internal Audit	Yes	No[3]	No

[1] FDA has already established traceability requirements under regulation stemming from the 2002 Bioterrorism Act, and traceability is a component of sec 204 FMSA which is separate from the Final Preventive Controls Rule

[2] FSMA addresses food defense in Sec 103. FDA has released a proposed rule pertaining to intentional contamination that will stand separately and finalize in 2016.
[3] Some of the record review requirements accomplish similar objectives to the internal audit
*Denotes a change from the Proposed Rule to the Final Rule
** Denotes a change from the Proposed Rule to the Final Rule *may be a required verification activity in certain circumstances)

Table 1 shows that generally the SQF elements are comparable to the Final Preventive Controls Rule requirements. However, in some cases, the SQF requirement is different in that it is not as prescriptive as the FDA requirement.

There is clearly very close alignment between the Final Preventive Controls Rule and SQF and yet there are still several areas addressed by SQF that have not been addressed in the Final Rule. Some items may be covered by existing regulations unrelated to FSMA or are covered by the other six "pillars" of FSMA and will be addressed in forthcoming FSMA –related regulations; however other items were not contemplated or addressed by the Final Rule or other aspects of FSMA ((e.g. traceability, for which FDA has already established traceability requirements under regulation stemming from the 2002 Bioterrorism Act), and traceability is a component of sec 204 of FMSA which is separate from Preventive Controls. Moreover, the Preventive Controls Rule provides FDA the authority to require additional records for high-risk foods. SQF also requires a process which describes the way in which the responsibility and methods outlining how non-conforming product is received. In the full comparative table each SQF Module 2 and 11 element is listed along with the Preventive Control Rule counterpart (if one exists) and the designations of Exceeds, Comparable or Different are noted.

<u>What Should SQF-Certified Facilities Do Now to Prepare in Light of this Analysis</u>?

SQF-certified facilities that are regulated by FDA will want to ensure that they pay particular attention to the areas where FDA may currently have more prescriptive or specific requirements than SQF (refer to Table 1). While these areas are identified more fully in the comparison table in the full report, of note, facilities should ensure that their FDA food safety plans identify the corrective actions specified by FDA, include monitoring at a frequency that meets FDA's requirements, and ensure that the food safety plan include clear procedures for retaining and reviewing records (with regard to calibration, testing, monitoring, etc.).

As noted being compliant with SQF level 2 will place a facility in a significant positive position for Human Preventive Control Rule compliance. However, it is important to note that FDA will likely still want to see a HARPC focused food safety plan. This will obviously refer heavily to all that is in the SQF material, but planning on how to address a FDA inspector's question "Please show me your food safety plan" is a good idea. So being ready to have some type of overarching

document that pulls together all the various aspects of a food safety plan, referring to all your SQF compliance information, is a good way to prepare.

Conclusion:

As the food industry looks to protect customers and their brand as well as be in compliance with the final new rules, TAG's analysis indicates that being SQF Level 2 certified to today's SQF standards is a very strong approach to FSMA compliance. Companies who already have SQF level 2 will want to stay abreast of, the issuance of guidance documents associated with this Final Preventive Controls Rule for Human Food, as well as new FDA FSMA regulations as the agency continues to implement FSMA to ensure that they are ready to fully implement the final rules while continuing to meet SQF requirements. Further, take a look at some of the prescriptive details in the Final Rule and make sure that you have those covered in your food safety plan which will heavily leverage all that you have in your SQF program.