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Executive Summary

Overview. The use of global food safety and quality standards, such as SQF, have become a major driver of the implementation of preventive controls in the food industry. FDA's proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (the "Preventive Controls Rule" or "the Proposed Rule") also has a heavy focus on preventing food safety problems, taking effective corrective actions and maintaining robust documentation. Given the obvious parallels between GFSI and the FSMA preventive controls, SQF contracted with Leavitt Partners Global Food Safety Solutions (LP GFSS) to compare the elements of SQF Level 2 (specifically Modules 2 and 11) to the proposed 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 these new rules.

Similarities and Differences. Table 1 summarizes the key areas addressed in SQF and/or the FDA Proposed 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 requirement to be in compliance with regulations (2.4.1) addresses the fact that requirements may vary slightly by country, and 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 consideration of environmental pathogens for ready-to-eat foods but does not go so far as requiring environmental monitoring in the proposed 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	No	Yes
Prerequisite programs	Yes	No	Yes
Raw material/ incoming product safety assurance	Yes	No	No
Supplier Verification	Yes	No	No
Allergen Management	Yes	Yes	Yes
Validation of Controls	Yes	Yes	No
Finished product testing	No	No	No
Sanitation Control	Yes	Yes	Yes
Environmental monitoring	Yes	No	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 Preventive Controls

[2] Although FSMA addresses food defense in sec 103 FDA has stated that regulations pertaining to intentional contamination will be issued separately

[3] Some of the record review requirements accomplish similar objectives to the internal audit

Table 1 shows that generally the SQF elements are comparable to the proposed Preventive Controls Rule requirements. However, in some cases, the SQF requirement is different in that it is not as prescriptive as the FDA requirement. Impressively, there are several areas addressed by SQF that have not been addressed in the proposed rule. Some items may be covered by existing regulations or are covered by FSMA and will be addressed in other forthcoming regulations (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. In other areas, SQF contains elements that were not included in the proposed rule (such as food defense for which FDA has not yet issued a regulation). 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.

What Should SQF-Certified Facilities Do Now? As the food industry looks to protect customers and their brand as well as be in compliance with the proposed new rules, our analysis indicates that being SQF level 2 certified to today's SQF standards is a very strong start. This said 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.).

Conclusion: Companies will want to stay abreast of the on-going rule-making process, the issuance of the final rule, as well as new FDA regulations as the agency continues to implement FSMA to ensure that they are ready to fully

implement the final preventive controls rules while continuing to meet SQF requirements.