

## EXECUTIVE SUMMARY: SQF and FSMA's Produce Safety Rule and Good Agricultural Practices

### OVERVIEW

Global food safety and quality standards, in part spearheaded by the Global Food Safety Initiative (GFSI) and its approved benchmarked schemes such as SQF, have become a leading driver of significant food safety improvements, including implementation of industry best practices in preventive controls across the food industry.

As we know, the Food Safety Modernization Act (FSMA) was signed into law January 2011. The new legislation expands the authority of FDA, and places new requirements on growers, manufacturers, processors, importers, and to certain degrees retailers, warehouses and distributors and transporters. FSMA and the proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the "Produce Safety Rule," "Produce Rule," "PS Rule" or "the Proposed Rule") represents a paradigm shift in food safety thinking from a regulatory perspective and in many ways aligns FDA's approach with the philosophy of prevention already in place on many farms and in many produce facilities. Given the obvious parallels between GFSI and the Produce Rule, there have naturally been several questions related to the comparability of FDA's proposed requirements and the practices and processes already in place in facilities certified to the GFSI benchmarked scheme.

As such, the Safe Quality Food Institute (SQFI) engaged The Acheson Group, LLC (TAG) to compare the elements of SQF Level 2 Module 7 to the proposed Produce Safety Rule. The comparison was also conducted in against the guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fruits and vegetables issued under the "Guidance for Industry – Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" ("the GAPs Guide"). The purpose of this exercise was 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

Our analysis showed that generally the SQF Code aligned well to the proposed Produce Safety Rule requirements. There are several areas addressed by SQF that have not been addressed in the proposed rule or GAPS or have been addressed to a lesser extent. In these areas, SQF specific requirements exceed that of the proposed rule and GAPS.

Since SQF is a global program that is not intended to be US/FDA-centric, or product specific, it is not surprising to learn that there are a few areas where SQF elements are less prescriptive than those found in FDA's proposed Produce Safety Rule. For example, with respect to irrigation water, the proposed Produce Safety Rule is more prescriptive with respect to specific

agricultural water testing requirements, e.g. specific levels of detection for microbes is set forth (e.g. *no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water under specific circumstances*) and requires a specific quantitative method be used for conducting such testing. Further, the proposed rule has detailed and special requirement for sprouts. The SQF Code does not contain this level of specificity; however, the SQF Code does require that agricultural water be drawn from a known clean source and treated to make it “suitable for use.” Thus, the Produce Safety Rule goes farther in defining, or putting quantifiable criteria around, SQF’s requirement of “suitable use”—which is a more subjective, general definition.

A summary of our primary observations are captured below. The tables found in the full report sets forth the full comparative analysis of the SQF Modules 7 and proposed Produce Safety Rule as well as the GAPS.

### **SQF vs. Produce Safety Rule Observations**

#### SQF Strengths/Produce Rule Weaknesses:

*Chillers and Cold Storage Safety:* The Produce Rule doesn’t address Chillers and Cold Storage areas and their respective requirements separately. Rather, it addresses some cooling equipment (hydro coolers), but it doesn’t robustly address the specific complications that can come from trying to maintain proper cold storage safety like SQF’s 7.2.3 requirements do.

*Pest Management:* SQF has a more prescriptive and stronger pest management set of requirements. In comparison the Proposed Produce Safety Rule’s requirements are weaker.

*GMPs:* The Produce Rule should consider suggesting that farmers consider adopting some CGMP measures where appropriate. While none of the following regulations applies to fruits and vegetables at the point at which FDA proposes to regulate such food by this regulation (during growing, harvesting, packing, and holding on farms), they are instructive as models and were referenced by FDA in designing the Proposed Rule. Although others were consulted the CGMPs most relevant to this observation are “The existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation (current 21 CFR part 110; “Food CGMP regulation”); and (2) the Hazard Analysis and Critical Control Point (HACCP) Systems (“juice HACCP”) regulation (21 CFR part 120).

*Lack of Guidance:* FDA says it will leave a lot of the specific requirements for guidance documents. For example, the worker hygiene section simply says at the end that there will be more information provided in the guidance documents. So by itself, the proposed Produce Rule requirements are not clear, and will not be until guidance documents are published. (See 7.3.3.1 comment.)

#### SQF Opportunities for Enhancements:

*More Specificity:* Instead of focusing on an end condition, SQF may desire to take guidance from FDA and identify specific ways in which the end result should be achieved. For example, SQF requires that “All buildings used to store equipment, field chemicals, field packing materials, or field product shall be designed and constructed so as to permit compliance to good hygiene practices and avoid product contamination.” SQF should identify which practices are necessary to achieve good hygiene practices and avoid contamination. If a requirement is too broad it is not as impactful to achieve the desired outcome (See SQF 7.2.1.1 Field and Storage Buildings).

Another specificity issue is found in SQF section 7.3.1 -- Personnel practices. This element simply states to make sure personnel ensure appropriate personal practices, and if they don't, then a corrective action has to happen. With this broad statement it is difficult to know what personnel need to do in order to achieve the required outcome.

Lastly, in SQF, there seems to be ambiguity in the distinction between processing water, irrigation water, and agricultural water. These definitions aren't as distinctly laid out as they are in the Produce Rule and thus could warrant revisiting and potential revision.

*More Flexibility Where Appropriate:*

The Produce Rule includes several places where you can show alternatives to the standard rule. In this regard, the Produce Rule is easier for a farm to implement based on unique attributes such as water availability/quality in certain geographic locations. While SQF is a risk based standard and allows for alternative control measures by demonstration through a risk analysis, SQF may benefit in revisiting areas that should allow more flexibility and alternatives but not compromise food safety. (e.g. See 7.5.2.1 Irrigation water.)

**SQF v. GAPs Observations:**

SQF Strengths/ The “Gaps” in GAPs:

GAPs are not as explicit in terms of written plans, setting corrective actions, and verification requirements as is SQF. Notwithstanding this apparent “gap”, the language at the conclusion of the GAPs Guide does embrace the importance of these critical factors in ensuring food safety and establishes the right tone--one that is commensurate with the "guidance" style of the GAPs guide. Specifically to this point, the conclusion states:

“Once good agricultural and manufacturing practices are in place, it is important that the operator ensure that the process is working correctly. Operators should follow up with supervisors or the person in charge to be sure that regular monitoring takes place, equipment is working, and good agricultural and management practices are being followed. Without accountability to ensure the process is working, the best attempts to minimize microbial food safety hazards in fresh fruits and vegetables are subject to failure.”

In essence, this is basically saying that once you assess the risks and establish good agricultural practices (specified quite well in the guide), then you have to monitor them on a continuous

basis and correct them when they aren't working. So, although it is a much "softer" guidance versus a more prescriptive requirement, the general tone of the GAPs Guide seems to ultimately expect—or assume—similar levels of monitoring, verification, and documentation that we see in the SQF requirements.

Other 'gaps' in GAPs include:

- Calibration of equipment (For example: See SQF Element 7.2.8.4 Maintenance Protocol)
- The need for written plans: (For example: In SQF Element 7.2.7.1 Maintenance Protocol: This is a good example of an SQF Requirement that requires a written plan, whereas the equivalent GAPs requirement is simply a more general statement about the importance of maintenance without a specific written plan requirement. See also, 7.5.8.2 where the requirements are the same, except SQF "requires" a written plan and GAPs uses the term "consider.")
- Validation of soil amendment of animal origin
- Corrective Actions

#### SQF Opportunities for Enhancement / Where GAPs May Have an Edge:

Although SQF is comparable to or exceeds GAPs in most areas, one area where GAPs may have an edge up is explaining *why* growers/farmers need to have these requirements. While SQF gives a better treatment of the "what" that is required, SQF may be able to be even more effective at actually improving food safety if it also added more of the "why" behind its requirements, as does the otherwise more general GAPs Guide. Because of the great variability of farms (more so than manufacturing facilities), both SQF and GAPs need to be concerned about balancing rigid standards with flexibility. So when you have a situation where there is a lot of leeway in implementing a certain requirement, understanding the "why" behind the requirement helps to make sure that farms are less apt to miss the mark on implementing a key food safety control. See Table 1 in the GAPs comparative analysis for more details on where SQF exceeds, is comparable and may differ from the GAPs standards.

#### CONCLUSION

For the few elements that are different, being SQF level 2 certified to today's SQF Code will elevate facilities to meet the proposed Produce Safety Rule requirements. It will not take SQFI long to gain full alignment with the proposed rule which is a laudable goal that reflects SQFI's commitment to continuous improvement and leading practices in global food safety assessment standards practices. 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 Produce Safety Rule while continuing to meet SQF requirements.