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The Safe Quality Food Institute (SQFI) contracted with The Acheson Group, LLC (TAG) to compare the elements of SQF Level 2 Module 7 to the proposed U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). The comparison was with the Produce Safety Rule requirements as well as 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.

The SQF program is recognized by the Global Food Safety Initiative (GFSI) and given the obvious parallels between GFSI and the produce rules, 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.

GAPs has served as significant guidance to the produce industry since 1997. However, produce has experienced increased scrutiny in recent years due to several recalls and susceptibility to microbiological contamination. As early as May of 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent a report to the President that identified produce as an area of concern. Later that year, President Clinton announced a plan entitled "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (the "Produce Safety Initiative") to provide further assurance that fruits and vegetables consumed by Americans, whether grown domestically or imported from other countries, meet the highest health and safety standards. As part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue updated good agricultural practices guidance and to increase food safety controls over produce.

Ultimately these initiatives resulted in FSMA--signed into law by the U.S. President in January 2011—and more specifically the proposed FSMA Produce Safety Rule and the most recent GAP's Guide. FSMA is the most sweeping overhaul of the food-safety system in the United States since the Food, Drug, and Cosmetic Act of 1938. The new legislation expands the authority of FDA, and places new requirements on growers, manufacturers, processors, importers, and to some degree retailers, warehouses and distributors and transporters. FSMA and the proposed Produce Safety 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 in many food facilities.

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 have been addressed to a lesser extent. In these areas, SQF specific requirements exceed that of the proposed rule (recognizing some items may be covered by existing regulations or are covered by other areas of FSMA and will be addressed in forthcoming rules / regulations.)



There are a few areas where SQF elements are less prescriptive than those found in FDA's proposed Produce Safety Rule. This is not unexpected since SQF is a global program that is not intended to be US or FDA-centric. 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 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 or treated to make it suitable for use. Thus, the Produce Safety Rule goes farther in defining "suitable use"—a more general definition. The table found in the full report sets forth a full comparative analysis of the SQF Modules 7 and proposed Produce Safety Rule.

The primary purpose of this project was to allow SQFI to identify any Module elements that may be absent from or less prescriptive than its counterpart in the proposed Produce Safety Rule, and address and close that gap so that companies could feel secure that implementation of SQF Code helps them meet or exceed the corresponding Produce Safety Rule requirement. The project was also to help SQFI determine differences in any Module elements as against the Good Agricultural Practices (GAPs) requirements.

As the food industry looks to protect customers and their brands as well as be in compliance with new requirements, our analysis indicates that being SQF level 2 certified to today's SQF Code will elevate facilities to meet the proposed Produce Safety Rule requirements. For the few elements that are different, 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.

Sincerely

A handwritten signature in black ink, appearing to read 'David W K Acheson'.

David W K Acheson, M.D. President and CEO,

The Acheson Group, LLC