



July 12, 2023

Foundation FSSC

RE: Alignment of Third-Party Food Safety Standards with Food Safety Regulations

Dear Authorized Representative of Foundation FSSC:

We appreciate your efforts to advance preventive food safety practices via your voluntary participation in the Third-Party Food Safety Standards Alignment Pilot Program (as described at 85 Federal Register, 67744 (October 26, 2021)).¹ You submitted your food safety audit standard, FSSC 22000 Scheme 5.1 for Food Manufacturing plus the FSSC 22000 V5.1 FSMA PCHF Report Addendum, for review by subject matter experts at the U.S. Food and Drug Administration (FDA), to evaluate its alignment with the food safety requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (Preventive Controls for Human Food Rule), one of the regulations issued to implement the FDA Food Safety Modernization Act (FSMA).

At this time, we can inform you of our view that FSSC 22000 Scheme 5.1 for Food Manufacturing plus the FSSC 22000 Version 3 FSMA PCHF Report Addendum is in alignment with the existing requirements of the Preventive Controls for Human Food Rule.

As stated in the Federal Register Notice describing the standards alignment pilot program, this review focused on assessing third-party food safety standards, and not the overall quality of audit programs or the qualifications of auditors. As a result, we did not assess general auditing policies and practices (such as auditor training and conflict of interest policies). FDA's review does not constitute an endorsement of your food safety audit standard, or any audits conducted under that standard.

Although specific requirements of the Preventive Controls for Human Food Rule and the elements of your food safety audit standard are not identical, in general, the relevant technical components of the Preventive Controls for Human Food Rule are addressed in the FSSC 22000 Scheme 5.1 for Food Manufacturing plus the FSSC 22000 Version 3 FSMA PCHF Report Addendum.

This alignment described in this letter may help give those relying on audits conducted to the FSSC 22000 Scheme 5.1 for Food Manufacturing plus the FSSC 22000 Version 3 FSMA PCHF Report Addendum confidence that they are meeting certain requirements of the Preventive

¹ FDA, Alignment of Third-Party Food Safety Standards With Food Safety Regulations: Notice of Pilot Program, 85 Federal Register 67744 (October 26, 2020).

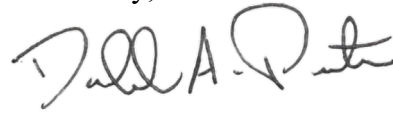
Controls for Human Food Rule. However, audits conducted under the FSSC 22000 Scheme 5.1 for Food Manufacturing plus the FSSC 22000 Version 3 FSMA PCHF Report Addendum are not a substitute for FDA or state regulatory inspections for compliance with FDA regulations, including the Preventive Controls for Human Food Rule.

As the voluntary pilot program has concluded, FDA will not be completing subsequent reviews or evaluations of audit standards at this time. The statements made in this alignment letter apply only to the specified versions of the audit standard and addendum reviewed under the pilot program and do not necessarily indicate that future versions of such audit standards will be aligned with FDA regulations. While the Agency sees value in facilitating industry's implementation of FSMA rules, and the potential of such efforts to inform risk prioritization, resources do not currently exist to establish a standing voluntary program to review additional third-party food safety standards. If additional resources become available, the Agency will evaluate the feasibility of conducting future food safety audit standard reviews.

FDA has posted this letter on [The FDA Concludes Voluntary Pilot Program to Evaluate Alignment of Third-Party Food Safety Standards with FSMA Rules webpage](#).

Again, thank you for your efforts to promote food safety.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald A. Prater". The signature is fluid and cursive, with the first name "Donald" being the most prominent.

Donald A. Prater, DVM
Acting Director
Center for Food Safety
and Applied Nutrition