



July 12, 2023

GLOBALG.A.P. North America Inc.

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

Dear Authorized Representative of GLOBALG.A.P. North America Inc.:

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, GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist. Version 5.4-GFS plus the GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule Add-on Module Version 1.2, 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 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (Produce Safety 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 GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist. Version 5.4-1-GFS plus the GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule Add-on Module Version 1.3 is in alignment with the existing requirements of the Produce Safety Rule.

At the time of pilot submissions, 21 CFR Part 112, Subpart E, related to Agricultural Water,² was under reconsideration for produce (other than sprouts); therefore, the applicability of this subpart to non-sprout produce was not included in our review for alignment. In addition, GLOBALG.A.P. did not include Subpart M requirements, related to sprouts, in its standard because the standard is directed towards auditing produce other than sprouts. Therefore, we did not include Subpart M, related to sprouts, in our review.

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

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

² See 86 Federal Register 69120 (December 6, 2021).

constitute an endorsement of your food safety audit standard, or any audits conducted under that standard.

Although specific requirements of the Produce Safety Rule and the elements of your food safety audit standard are not identical, in general, the relevant technical components of the Produce Safety Rule are addressed in the GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist. Version 5.4-1-GFS plus the GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule Add-on Module Version 1.3.

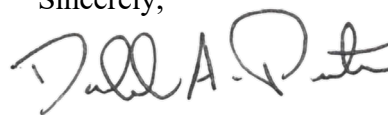
This alignment described in this letter may help give those relying on audits conducted to GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist. Version 5.4-1-GFS plus the GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule Add-on Module Version 1.3 confidence that they are meeting certain requirements of the Produce Safety Rule. However, audits conducted under GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist. Version 5.4-1-GFS plus the GLOBALG.A.P. Food Safety modernization Act Produce Safety Rule Add-on Module Version 1.3 are not a substitute for FDA or state regulatory inspections for compliance with FDA regulations, including the Produce Safety 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 add-on module 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 being the most prominent.

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