

UNITED STATES FOOD & DRUG ADMINISTRATION

Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption

OMB Control No. 0910-0816

August 2023

Request for Non-substantive Change:

The Food and Drug Administration (FDA) is requesting a nonmaterial/non-substantive change request (83-C) to OMB control no. 0910-0816, “*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.*” This ICR includes recommendations found in the draft guidance “*Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations*” (January 2017 draft guidance). With this 83-C we are finalizing this guidance in part and changing the title of the guidance to “*Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption*” to make it more concise and to promote clarity.

Consistent with our Good Guidance Practice regulations at 21 CFR part 10.115 we are finalizing recommendations from the January 2017 draft guidance in response to comments. Non-substantive changes to the guidance include: clarifying the recommendations regarding the frequency of cleaning and sanitizing; providing additional recommendations on seed for sprouting, including seed treatment and corrective actions; removing language on voluntary periodic sampling and testing of sprouts, and clarifying our expectations for corrective actions after an operation detects *Listeria* spp. or *Listeria monocytogenes* in an environmental sample.

We also received general comments that requested we shorten and simplify the guidance. As a result, we removed section III (“General Sprout Production,” as it appeared in the January 2017 draft guidance) because most of the language in this section was repeated elsewhere.

We are also issuing for additional comment a revision to the January 2017 draft guidance that contains revised information in the sections entitled “Equipment, Tools and Buildings” (titled “Buildings, Tools and Equipment” in the January 2017 draft guidance) and “Sampling and Testing of Spent Sprout Irrigation Water (or In-Process sprouts)” (sections IV and V, respectively, which were sections IV and VIII in the January 2017 draft guidance) and consolidates information on personnel qualifications, training, and hygienic practices into a new standalone section.

Finally, we are requesting an update to the title of the ICR to correct the erroneous use of the word “packaging”. The requested title is “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”.