



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending a final rule that published in the Federal Register of November 27, 2015. That final rule established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. FDA established these standards as part of our implementation of the FDA Food Safety and Modernization Act. The final rule published with some editorial and inadvertent errors. This document corrects those errors.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION: In the Federal Register of Friday, November 27, 2015 (80 FR 74354), FDA published the final rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” with some editorial and inadvertent errors. This action is being taken to correct inadvertent errors in the preamble to the final rule and to improve the accuracy of the provisions added to the Code of Federal Regulations.

On page 74357, the table with the heading “COMPLIANCE DATES” is corrected to read as follows:

Compliance Dates						
Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
		Time periods starting from the effective date of this rule				Time periods starting from the effective date of this rule
Very small business	3 years (January 26, 2019)	6 years (January 26, 2022)	4 years (January 26, 2020)	Effective date of rule (January 26, 2016)	January 1, 2020	4 years for farms not producing sprouts (January 26, 2020)/ 3 years for farms producing sprouts (January 26, 2019)
Small business	2 years (January 26, 2018)	5 years (January 26, 2021)	3 years (January 26, 2019)			3 years for farms not producing sprouts (January 26, 2019)/ 2 years for farms producing sprouts (January 26, 2018)
All other businesses	1 year (January 26, 2017)	4 years (January 26, 2020)	2 years (January 26, 2018)			N/A

Section 112.3 is revised to collapse paragraphs (a), (b), and (c) into a single paragraph.

The definition of “farm” is revised to use the same indent numbering as in the definition of “farm” under 21 CFR 1.227 established in the final rule, “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (80 FR 55908; September 17, 2015).

The definition of “covered activity” is revised to replace the reference to 21 CFR part 110 with a reference to 21 CFR part 117.

The definition of “harvesting” is revised consistent with the revision to the definition of “harvesting” in § 1.227 as published in “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Technical Amendment” (81 FR 3714; January 22, 2016).

The definition of “packing” is revised to remove a duplicative reference to section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)) and to add the term “re-packing” in multiple places, so that the definition is consistent with the definition of “packing” in § 117.3 as published in “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Technical Amendment” (81 FR 3714);

The definitions of “small business” and “very small business” are revised to remove paragraph references that are no longer needed due to the rearrangement of § 112.3 into a single section and to follow the structure of the other definitions in § 112.3.

In the definition of “qualified end-user,” paragraphs (i) and (ii) are redesignated as paragraphs (1) and (2).

Section 112.55(b) is revised to add a liquid weight basis for sampling, consistent with table 18 in the final rule “Standards for the Growing, Harvesting, Packing, and Holding of

Produce for Human Consumption” (80 FR 74354 at 74475) and discussion under Comment 291 in the same document (80 FR 74354 at 74472 to 74473).

List of Subjects in 21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

PART 112--STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

2. Amend § 112.3 by:

a. Removing paragraphs (a) and (b) and (c) introductory text and adding introductory text;

b. In the definition of “Qualified end-user”, redesignating paragraphs (i) and (ii) as paragraphs (1) and (2);

c. Revising the definitions of “Covered activity”, “Farm”, “Harvesting”, and “Packing”; and

d. Adding in alphabetical order the definitions of “Small business” and “Very small business”.

The revisions and additions read as follows:

§ 112.3 What definitions apply to this part?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

\* \* \* \* \*

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 117 of this chapter.

\* \* \* \* \*

Farm means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

\* \* \* \* \*

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by

drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

\* \* \* \* \*

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

\* \* \* \* \*

Small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in this section.

\* \* \* \* \*

Very small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$250,000.

\* \* \* \* \*

3. In § 112.55, revise paragraph (b) to read as follows:

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

\* \* \* \* \*

(b) Salmonella species are not detected using a method that can detect three MPN Salmonella species per 4 grams (or milliliter, if liquid is being sampled) of total solids; and less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids.

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09768 Filed: 5/2/2016 8:45 am; Publication Date: 5/3/2016]