



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 117

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; 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 September 17, 2015. That final rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. That final rule also revised certain definitions in our current regulation for registration of food facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for “farms.” 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: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION: In the Federal Register of Thursday, September 17, 2015 (80 FR 55908), FDA published the final rule “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” with some editorial and inadvertent errors. This action is being taken to correct inadvertent errors by making the following correcting amendments.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 117

Food packaging, Foods.

PART 1--GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Amend § 1.227 to revise the definitions of “harvesting” and “packing” to read as follows:

§ 1.227 What definitions apply to this subpart?

* * * * *

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, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

3. Amend § 1.328 to revise the definition of “harvesting” to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

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.

* * * * *

PART 117--CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS,
AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

4. The authority citation for 21 CFR part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

5. In § 117.1, revise paragraph (b) to read as follows:

§ 117.1 Applicability and status.

* * * * *

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, F, or G of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

6. Amend § 117.3 to:

a. Revise the definitions of “audit”, “harvesting”, and “packing”;

b. Revise the introductory text of paragraph (1) of the definition of “qualified end-user”;

and

c. Revise the definition of “small business”.

The revisions read as follows:

§ 117.3 Definitions.

* * * * *

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity’s food safety processes and procedures.

* * * * *

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.

* * * * *

Qualified end-user ***

(1) Is located:

* * * * *

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

* * * * *

7. In § 117.5, revise the first sentence of paragraph (a), and revise paragraph (h)(3)(v) to read as follows:

§ 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subparts C and G of this part do not apply to a qualified facility. * * *

* * * * *

(h) * * *

(3) * * *

(v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh mint, chopped dried mint);

* * * * *

8. In § 117.136, revise paragraphs (a)(2) introductory text, (a)(5), and (b)(5) to read as follows:

§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) * * *

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

* * * * *

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.

(b) * * *

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

9. In § 117.145, revise paragraph (a) to read as follows:

§ 117.145 Monitoring.

* * * * *

(a) Written procedures. You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and

* * * * *

10. In § 117.201, revise paragraphs (b)(2)(i)(B) and (b)(2)(ii) to read as follows:

§ 117.201 Modified requirements that apply to a qualified facility.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Pkwy., College Park, MD 20740; or

* * * * *

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Pkwy., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

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11. In § 117.257, revise paragraph (e) to read as follows:

§ 117.257 Contents of an order to withdraw a qualified facility exemption.

* * * * *

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287;

* * * * *

12. In § 117.264, revise paragraph (a)(1) to read as follows:

§ 117.264 Procedure for submitting an appeal.

(a) * * *

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

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Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.