

*Contains Nonbinding Recommendations
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Application of the “Solely Engaged” Exemptions in Parts 117 and 507: Guidance for Industry

Draft Guidance

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Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number 2017-D- 6333 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food,” contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2166.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals,” contact the Center for Veterinary Medicine (CVM) at 240-402-6246.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to help establishments and facilities subject to Title 21 of the Code of Federal Regulations (21 CFR) part 117 (part 117) or 21 CFR part 507 (part 507) determine whether they are “solely engaged” in certain activities. Establishments and facilities “solely engaged” in certain activities are exempt from some or all requirements in parts 117 or 507.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

This guidance concerns two regulations that we have established in 21 CFR as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353).² These two regulations are part 117 (published in the *Federal Register* on September 17, 2015, 80 FR 55907) and part 507 (published in the *Federal Register* on September 17, 2015, 80 FR 51670).

¹ This guidance has been jointly prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Office of Foods and Veterinary Medicine in the Office of the Commissioner at the U.S. Food and Drug Administration.

² For more information on the Agency's implementation of FSMA, see <http://www.fda.gov/fsma>.

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Requirements for establishments³ that manufacture, process, pack, or hold human food to follow current good manufacturing practices (CGMPs) are found in subparts A, B, and F of part 117. Requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements) are found in subparts A, C, D, E, F, and G of part 117.

For domestic and foreign facilities that are required to register, subparts A, B, and F of part 507 include animal food CGMP requirements and subparts A, C, D, E and F of part 507 include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements).

Parts 117 and 507 contain exemptions specific to establishments and facilities “solely engaged” in certain activities. These exemptions refer to the primary subparts that contain CGMP and preventive controls requirements: subpart B (CGMPs), subparts C and G (human preventive controls) and subparts C and E (animal food preventive controls). Exemption from the primary subparts necessarily includes exemption from the associated subparts. For example, when subpart B is not applicable, then the associated CGMP requirements in subparts A and F are not applicable.

The relevant exemptions are outlined below.

Exemption from human food CGMP requirements

Part 117, subpart B does not apply to the following:

- Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities (RACs) (21 CFR 117.5(k)(1)(iii))
- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) (21 CFR 117.5(k)(1)(v))

Exemption from human food preventive controls requirements

Part 117, subparts C and G do not apply to:

- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (21 CFR 117.5(j))
- Facilities solely engaged in the storage of unexposed packaged food (21 CFR 117.7(a))

Exemption from animal food CGMP requirements

Part 507, subpart B does not apply to the following:

- Establishments solely engaged in the holding and/or transportation of one or more RACs (21 CFR 507.5(h)(1))

³ In this guidance we use the term “establishments” in the context of the CGMP requirements and “facilities” in the context of the preventive controls requirements (or both requirements in some circumstances) to reflect differences in the regulatory text.

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- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts) (21 CFR 507.5(h)(2))
- Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed) (21 CFR 507.5(h)(3))

Exemption from animal food preventive controls requirements

Part 507, subparts C and E do not apply to:

- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (21 CFR 507.5(g))
- Facilities solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (21 CFR 507.10(a))

The terms “facility,” “holding,” “packing,” “raw agricultural commodity,” “unexposed packaged food,” and “unexposed packaged animal food” are defined in 21 CFR 117.3 and 507.3.

III. Discussion

A. Exemption from CGMP Requirements

The human food CGMP regulations in part 110⁴ include an exemption for “[e]stablishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the [FD&C Act], which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.” (See 21 CFR 110.19.) This provision has been called the “RAC exemption.” Modified RAC exemptions have been codified in parts 117 and 507 (see 21 CFR 117.5(k)(1)(iii) and (v) and 21 CFR 507.5(h)).

Although the RAC exemption from CGMPs in part 110 is written to apply to establishments that are solely engaged in harvesting, storing, or distributing RACs, FDA has long interpreted this exemption as applying to establishments that are doing any one or more of these activities (e.g., both harvesting and storing). This interpretation is reflected in the modified RAC exemptions in parts 117 and 507 (i.e., holding and/or transportation of RACs; hulling, shelling, drying, packing, and/or holding nuts [and, for animal food, hulls]). Note that 21 CFR 117.5(k)(1)(iii) and 21 CFR 507.5(h)(1) provide an exemption for “holding and/or transportation of RACs” but do not refer to “harvesting,” which falls within the “farm” definition (see 21 CFR 1.227). Farms, as defined in 21 CFR 1.227, are exempt from the human food and animal food CGMP requirements. (See 21 CFR 117.5(k)(1)(i) and (iv) and 21 CFR 507.5(a).) Activities of a farm that is part of a farm mixed-type facility need not be considered when determining whether an establishment is solely engaged in the activities specified in the exemptions.

An establishment engaged in any combination of the activities listed in 21 CFR 117.5(k)(1)(iii) and (v) and 507.5(h), and not engaged in any other activities subject to CGMPs, qualifies for the

⁴ Part 110, promulgated before FSMA was enacted, will be removed from 21 CFR on September 17, 2018.

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RAC exemption and is not subject to the CGMP requirements in part 117, subpart B, or part 507, subpart B. However, if an establishment engages in any activity subject to the CGMP requirements (e.g., certain manufacturing/processing), in addition to those activities covered by a CGMP exemption, then the establishment is subject to the CGMP requirements.

Examples

1. An establishment that holds and transports RACs for human and animal food use, hulls and shells nuts, and does not engage in any additional activities covered by the CGMP requirements is exempt from the CGMP requirements in parts 117 and 507.
2. An establishment that holds and transports RACs, hulls and shells nuts, and grinds the shells, all for animal food use, is not “solely engaged” in activities exempt from the CGMP requirements. Therefore, the establishment must comply with the CGMP requirements in part 507.

B. Exemption from Preventive Controls Requirements

Section 418(m) of the FD&C Act allows exemptions from the preventive controls requirements for facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further processing and distribution, or the storage of packaged foods that are not exposed to the environment. We have issued regulations based on this section in 21 CFR 117.5(j) and 117.7, and 21 CFR 507.5(g) and 507.10. We believe it is reasonable to implement § 418(m) and the associated regulations consistent with our well-established implementation of the RAC exemption for CGMPs. This allows a facility that is storing RACs (other than fruits and vegetables) intended for further processing and distribution, storing packaged food that is not exposed to the environment and does not require time/temperature control, or storing both types of food, to be exempt from the preventive controls requirements. We also note that the relevant portions of § 418(m) do not distinguish between human and animal food; we interpret this section to allow a facility to store both types of food and still qualify for exemptions from the preventive controls requirements.

However, as explained in the preamble to the part 117 regulation (80 FR 55907 at 55984-85 and 55994), if a facility performs any activity subject to preventive controls requirements (such as certain manufacturing/processing) in addition to those activities described in the preventive controls exemptions, then the activities that would have been subject to the exemptions are no longer exempt and the facility is subject to preventive controls requirements.

Examples

3. A facility that stores unexposed packaged human and animal food that does not require time/temperature control, stores grain RACs intended for further processing and distribution, and does not engage in any additional activities covered by the preventive controls requirements is exempt from the preventive controls requirements in parts 117 and 507.
4. A facility that stores unexposed packaged human food that does not require time/temperature control but also cuts vegetables (i.e., manufactures/processes food) is

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not “solely engaged” in activities exempt from the preventive controls requirements. Therefore, the facility must comply with the preventive controls requirements in part 117.

5. A facility that stores unexposed packaged human food, including unexposed packaged food that requires time/temperature control, but also stores fruits and vegetables for human consumption that are exposed to the environment (e.g., stored in vented containers) is not “solely engaged” in activities exempt from the preventive controls requirements. Therefore, the facility must comply with the preventive controls requirements in part 117.

C. Exemption from Both CGMP and Preventive Controls Requirements

A facility can be exempt from both CGMP and preventive controls requirements, for part 117 or part 507 or both parts, as long as it is engaged in any combination of activities that are exempt from CGMP and preventive controls requirements, and not engaged in activities that would be subject to those requirements. If any part of a facility is engaged in an activity subject to CGMPs or preventive controls requirements, then the entire facility is subject to the CGMP requirements, the preventive controls requirements, or both.

Examples

6. A facility consisting of a grain elevator that holds grain RACs for human and animal food use and does not engage in any other activities covered by the CGMP or preventive controls requirements is exempt from the CGMP and preventive controls requirements in parts 117 and 507.

7. A facility consisting of both a grain elevator that holds grain RACs for animal food use and a feed mill that manufactures animal food is not “solely engaged” in activities exempt from either the CGMP or preventive controls requirements. Therefore, the facility is subject to the CGMP and preventive controls requirements in part 507.

D. Conclusion

In summary, if all of the activities performed by an establishment are exempt under one or more CGMP exemptions, then the establishment is not subject to the part 117 and/or part 507 CGMPs, as applicable. Similarly, if all the activities performed by a facility are exempt under one or more preventive controls exemptions, then the facility is not subject to the part 117 and/or part 507 preventive controls requirements, as applicable. If all of the activities performed by a facility are exempt under one or more CGMP exemptions and one or more preventive controls exemptions, then the facility is not subject to the CGMP or preventive controls requirements in part 117 and/or part 507, as applicable. However, if any part of a facility is engaged in an activity subject to the CGMP or preventive controls requirements, then the entire facility is subject to CGMPs, the preventive control requirements, or both. This framework is summarized in Table 1.

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Table 1: Summary of CGMP and Preventive Controls Exemption Framework

	All Activities Covered by PC Exemptions	All Activities not Covered by PC Exemptions
All Activities Covered by CGMP Exemptions	Facility exempt from CGMP and PC requirements	Facility exempt from CGMP requirements only
All Activities not Covered by CGMP Exemptions	Facility exempt from PC requirements only	Facility not exempt from CGMP and PC requirements