

grain, culled fruits and vegetables, or roughage;

(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;

(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and

(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

(g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to any of the following:

(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and

(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) *Electronic submission.* To submit electronically, go to <http://www.fda.gov/furls> and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from <http://www.fda.gov/pcafrule>;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

§ 507.10

21 CFR Ch. I (4–1–17 Edition)

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By *December 16, 2019* for a facility that begins manufacturing, processing, packing, or holding animal food before *September 17, 2019*;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after *September 17, 2019*; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016; 81 FR 49897, July 29, 2016]

§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

(a) Subparts C and E of this part do not apply to a facility 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.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if: