Contains Nonbinding Recommendations

Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food And Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Guidance for Industry

Additional copies are available from:
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(tel) 240-701-5986
http://www.fda.gov/FoodGuidances

Policy and Regulations Staff (HFV-6)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
https://www.fda.gov/AnimalVeterinary/default.htm

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance 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 FDA–2016–D–1164.

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

September 2018

OMB Control No. 0910-0854
Expiration Date: The current expiration date can be found in Form FDA 3942a and Form FDA 3942b.
See additional PRA statement in Section V of this guidance

Table of Contents

Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food And Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals Guidance for Industry[1]

This guidance represents 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 Food Safety Modernization Act Technical Assistance Network by submitting your information at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

I. Introduction

The FDA Food Safety Modernization Act (FSMA) establishes requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans and animals. We have issued two regulations to implement these requirements. The first regulation is established in 21 CFR part 117 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (published in the *Federal Register* on September 17, 2015, 80 FR 55907). In the remainder of this guidance we refer to this regulation as "part 117." Subparts A, B, and F of part 117 include current good manufacturing practice (CGMP) requirements for domestic and foreign facilities that manufacture, process, pack, or hold human food. Subparts A, C, D, E, F, and G of part 117 include 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). The second regulation is established in 21 CFR part 507 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (published in the *Federal Register* on September 17, 2015, 80 FR 56170). In the remainder of this guidance we refer to this regulation as "part 507." For domestic and foreign facilities that are required to register under the FD&C Act, subparts A, B, and F of part 507

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition in cooperation with the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

include 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).

A facility that meets the definition of a "qualified facility" in part 117 or part 507 is subject to CGMP requirements as well as the modified requirements described in 21 CFR 117.201 or in 21 CFR 507.7, respectively. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility. Section II of this guidance explains how to determine whether your facility meets the definition of "qualified facility" under part 117 and how to submit Form FDA 3942a attesting to your status as a qualified facility that is subject to the modified requirements in 21 CFR 117.201. Section III of this guidance explains how to determine whether your facility meets the definition of "qualified facility" under part 507 and how to submit Form FDA 3942b attesting to your status as a qualified facility that is subject to the modified requirements in 21 CFR 507.7. The modified requirements also include a requirement that the facility attest to certain food safety practices. See 21 CFR 117.201(a)(2); 507.7(a)(2).

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. Frequently Asked Questions About Requirements for Qualified Facilities That Manufacture, Process, Pack, or Hold Human Food

A. Definition of Qualified Facility Under Part 117

1. How does part 117 define "qualified facility"?

Part 117 defines a qualified facility as (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- A facility that is a very small business (see definition in Question II.A.2); or
- A facility to which both of the following apply:
    - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (see definition in Question II.A.5) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

- The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

See the definition of "qualified facility" in 21 CFR 117.3.

2. How does part 117 define "very small business"?

Part 117 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than **$1,000,000**, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). See the definition of "very small business" in 21 CFR 117.3.

We believe the definition of a very small business will apply to most qualified facilities. As such, the focus of this guidance is on determining whether a facility meets the definition of a very small business, rather than on whether a facility meets the two-part definition based on sales to qualified end-users. If you have questions about sales to a qualified end-user that are not addressed in this guidance, please contact us as described in section IV of this guidance.

3. How does part 117 define "affiliate"?

Part 117 defines "affiliate" as any facility that controls, is controlled by, or is under common control with another facility. See the definition of "affiliate" in 21 CFR 117.3.

4. How does part 117 define "subsidiary"?

Part 117 defines a subsidiary as any company which is owned or controlled directly or indirectly by another company. See the definition of "subsidiary" in 21 CFR 117.3.

5. How does part 117 define "qualified end-user"?

Part 117 defines "qualified end-user" as the consumer of the food (where the term "consumer" does not include a business); or a restaurant or retail food establishment that:

- Is located:
  - In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
  - Not more than 275 miles from such facility; and
- Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

See the definition of "qualified end-user" in 21 CFR 117.3.

6. Who determines whether my facility meets the definition of a qualified facility under part 117?

You are responsible for determining whether your facility meets the definition of a qualified facility under part 117, subject to verification by FDA. We do not intend to review financial records supporting your status as a qualified facility during routine inspections. However, we may ask to review those financial records during inspections conducted "for cause" (e.g., during an inspection conducted because food produced at your facility is associated with an outbreak of foodborne illness or if we have reason to believe your facility does not meet the requirements to be a qualified facility).

7. Can a facility that is a subsidiary meet the definition of "very small business" under part 117 even if its parent company is not a very small business?

Yes. It is possible for a facility that is a subsidiary to be a very small business even if its parent company is not a very small business because not all human food sold or manufactured, processed, packed, or held without sale by the parent company is counted in a subsidiary facility's calculation of whether it is a very small business. Specifically, a subsidiary facility only includes operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary facility. For example, a subsidiary may consist of Facility A with $300,000 in annual human food sales. The subsidiary's parent company may include Facility B, a manufacturer/processor with $600,000 in annual human food sales, and Farm C with $500,000 in annual human food sales. Facility A would include Facility B's sales in its calculation because Facility B is an affiliate of Facility A. Facility A would not include Farm C's sales in its calculation because Farm C is not an affiliate (it cannot be because farms are not facilities required to register) or a subsidiary (it is part of the parent company). Therefore, Facility A would determine that it has $900,000 ($600,000 + $300,000) in annual human food sales for its business. If the average over 3 years was less than $1,000,000 adjusted for inflation for the most recent of the three years, then Facility A would be a very small business.

Facility B's calculation to determine whether it is a very small business would be different. Facility B would include, in addition to its own sales ($600,000), Farm C's sales ($500,000) because Farm C is part of the same company. Facility B would also include Facility A's sales ($300,000) because Facility A is a subsidiary of the parent company that includes Facility B. Therefore, Facility B would determine that it has $1.4 million in annual human food sales for its business. (Note, in this example none of the entities have human food manufactured, processed, packed, or held without sale that must be included in the calculation.)

8. What does "food manufactured, processed, packed, or held without sale" mean in the definition of very small business in part 117?

Food manufactured, processed, packed, or held without sale means any food for human consumption that you manufacture, process, pack or hold at your facility and do not offer for sale. This does not include food that you will sell at a later date. Examples of food manufactured, processed, packed, or held without sale include food held for a fee (e.g., by a warehouse), food processed for a fee (e.g., by a contract processor (such as a facility that irradiates spices)), and food packaged for a fee (e.g., by a contract packager).

B. Calculations to Determine Status as a Qualified Facility Under Part 117

1. How often, and when, must I make the calculation to determine my status as a qualified facility under part 117?

You must make the calculation to determine your status as a qualified facility under part 117 on an annual basis no later than July 1 of each calendar year (21 CFR 117.201(c)(1)).

2. Which products do I include in, and which products do I exclude from, the calculation of annual sales plus market value to determine my status as a qualified facility under part 117?

Include all human food, including food manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of whether the human food is subject to part 117. For example, you would include products such as seafood, juice, low-acid canned foods, and dietary supplements. Likewise, you would include raw agricultural commodities (e.g., produce, grains, milk, and eggs) and products subject to the jurisdiction of the U.S. Department of Agriculture (e.g., meat products for human consumption), regardless of whether these products are subject to part 117. You do not need to include the value of food that you have processed but not yet sold.

Do not include animal food or other items not intended for human consumption.

3. Do I include human food sold in countries other than the United States in the calculation of total sales?

Yes. Include sales of all human food in the calculation of total sales, regardless of where the food is sold. For example, if you are a domestic facility that exports food to other countries, you would include sales of food for export in your calculation of total annual sales. If you are a foreign facility, you would include sales of human food in all countries, including sales in your own country, sales in the United States, and sales in other countries.

4. How do I include human food that is manufactured, processed, packed, or held without sale (e.g., because I am a warehouse, a contract processor, or a contract packager)?

Include human food that is manufactured, processed, packed, or held without sale, through calculations of market value (see Question II.B.9).

5. How do I determine whether my average annual sales plus market value of human food manufactured, processed, packed, or held without sale is under the inflation-adjusted cut-off?

We have outlined what we believe to be the simplest method below. We will accept other methods as well (e.g., deflating average annual sales to 2011-dollars) should you choose to use a different method.

The simplest method of determining whether your annual sales plus market value of human food manufactured, processed, packed, or held without sale is below the inflation-adjusted threshold for a "very small business" is to:

- Determine which three years to include in the average;
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years;
- Calculate the average for the three years; and
- Compare to the three-year average value posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm, to determine if your three-year average is less than $1,000,000 adjusted for inflation.

6. How do I determine which three years to include for the purpose of determining the average annual sales plus market value of human food?

The definition of a very small business specifies that the average is based on the 3-year period preceding the applicable calendar year. The applicable calendar year is the current year. If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018. *Note that for the examples in this guidance, we use the years 2014, 2015, and 2016 in order to demonstrate the inflation adjustment.*

See question II.B.7 if you don't have three years of financial records to use for your calculations.

7. How do I determine average annual sales plus market value of human food if I don't have three years of financial records to use for my calculations?

The compliance date for you to keep records to support your status as a qualified facility is January 1, 2016, and the compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2018. If you began keeping applicable financial records on January 1, 2016, you would only have such records for 2 previous calendar years by September 17, 2018. Therefore, it would be reasonable for you to make the calculation based on the 2 previous calendar years. If you have records for 3 previous calendar years, you could make the calculation based on the longer time period. If we ask to see your applicable financial records during inspection in 2018, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility when you have records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years.

If you begin operations between January 1, 2017, and September 17, 2018, your applicable financial records would not cover even 2 calendar years by September 17, 2018. During the first 3 years of your operation, you should make the calculation based on the records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the first 3 years of your operation, we intend to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.

If you begin operations after January 1, 2018, you can rely on a projected estimate of revenue (or market value) at the time you begin operations. If we ask to see your applicable financial records

during your first year of operation, we intend to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees. After you have records for one or two preceding years, you should make the calculation based on records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the next two years of your operation, we intend to accept records for the preceding one or two calendar years as adequate to support your status as a qualified facility in these circumstances.

8. How do I determine annual sales of human food?

Determine your annual sales using resources such as:

- Tax Forms, e.g. Gross Receipts or Sales (Line 1a) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, e.g., Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor.

Table 1 provides an example of determining annual sales for Business D for the years 2014-2016 based on tax documents. Business D does not process, pack, or hold human food without sale, and, thus, does not calculate market value. Business D consists of a facility (Facility D) that does not have any subsidiaries or affiliates.

Table 1: Determining Annual Sales of Human Food for Business D for the Years 2014-2016

Source	2014	2015	2016
Facility D: Gross Sales of Human Food (Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility D: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*, **	N/A**	N/A**
Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	$800,000	$800,500	$900,000

*N/A = Not applicable

** There is no entry for market value of human food manufactured, processed, packed, or held without sale because Facility D does not manufacture, process, pack, or hold human food without sale.

Table 2 provides a more complex example of determining annual sales for Business E for the years 2014-2016 based on tax documents. Business E consists of Facility E and one affiliate (Affiliate E1), which produced and sold human and animal food. Neither Facility E nor Affiliate E1 manufactures, processes, packs, or holds human food without sale and, thus, neither Facility E nor Affiliate E1 calculates market value.

Table 2. Determining Annual Sales of Human Food for Business E (Facility E and its Affiliate) for the Years 2014-2016.

Source	2014	2015	2016
Facility E: Gross Sales of Human Food (Derived from Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility E: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate E1: Gross Sales of Human Food (Item 1a, IRS Form 1120)	$190,000	$200,000	$200,000
Affiliate E1: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate E1: Gross Sales of Animal Food (Derived from Item 1A, IRS Form 1120) (Not included in calculation)	$50,000 (Not included in calculation)	$55,000 (Not included in calculation)	$60,000 (Not included in calculation)
Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	$990,000	$1,000,500	$1,100,000

*There is no entry for market value of human food manufactured, processed, packed, or held without sale because neither Facility E nor Affiliate E1 manufactures, processes, packs, or holds human food without sale.

9. How do I determine the market value of human food manufactured, processed, packed, or held without sale?

Use the value of the food, not the fee for the service (e.g., for holding, processing, or packing) to calculate the market value of food that you manufacture, process, pack or hold without sale. Determine the market value of human food manufactured, processed, packed, or held without sale by considering factors such as:

- The market value of incoming food obtained from the customer for whom the food is being manufactured, processed, packed, or held;
- The amount of insurance that a warehouse holds for its products;
- The value obtained by multiplying market price by volume of food manufactured, processed, packed, or held; or
- Assets on a balance sheet.

See Section II.D of this guidance for examples of how to determine market value for human food manufactured, processed, packed, or held without sale. The examples describe the calculation for a cold storage warehouse that holds human food. In one example (Question II.D.1), the warehouse calculates market value using the value of an insurance policy. In a second example (Question II.D.2), the same warehouse calculates market value using the market value of incoming food using information or accounting documents from the customer. In these examples, the warehouse reaches the same conclusion regardless of the method used to do the calculation.

10. What conversion rate should a foreign facility use when converting annual sales plus market value of human food to U.S. dollars?

A foreign facility should use the exchange rate in effect as of the ending date of the period during which it collected the reported receipts or sales. For example, for sales during 2016 a foreign facility would use the conversion rate in effect on December 31, 2016.

11. May I subtract sales of human food to qualified end-users from my annual sales of human food when determining whether my facility meets the definition of very small business under part 117?

No. The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user.

C. Other Questions About the Human Food Preventive Controls Requirements in Part 117

1. What records must I keep to demonstrate my facility's status as a qualified facility under part 117?

Part 117 requires that you keep records that you rely upon to support the attestations you make on Form FDA 3942a, but does not otherwise specify the types of records that you must keep (21 CFR 117.205(f)). You should keep the records that you use for your calculations of annual sales. See Question II.B.8 for examples of these records. You also should keep records of the actual calculations that you make – e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value. These records are subject to the requirements in subpart F of part 117 and must be produced upon request by a duly authorized representative of the Secretary of Health and Human Services (e.g., FDA) (21 CFR 117.201(f) and 21 CFR 117.320). We do not intend to ask to review these records during routine inspections. However, we may ask to review these records during inspections conducted "for cause" (e.g., during an inspection conducted because food produced

at your facility is associated with an outbreak of foodborne illness) or if we have reason to believe your facility does not meet the requirements to be a qualified facility.

The records you are required to keep to support your attestation as to food safety practices/compliance may vary depending on how you comply with 21 CFR 117.201(a)(2). The two options are as follows:

1. Option 1: You have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards associated with the food being produced, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

2. Option 2: Your facility is in compliance with State, local, country, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

When selecting Option 1, you must keep records documenting your identification of potential hazards, the preventive controls you are implementing to address those hazards, your implementation of your preventive controls, and your monitoring of your preventive controls. (21 CFR 117.201(f)(1)). For example, you could have a document identifying the hazards and the preventive controls you will implement to address those hazards, and batch records demonstrating your implementation and monitoring of the preventive controls. If some or all of the activities you conduct are activities that we have listed as a low-risk activity/food combination in 21 CFR 117.5(g) and (h), the records documenting your identification of hazards could be as simple as a reference to the applicable activity/food combination listed in the regulation.

When selecting Option 2, you must maintain records that document your compliance with the applicable non-Federal food safety law that you are following. (21 CFR 117.201(f)(1)). For example, you could keep a record of licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency or other evidence of oversight. If the applicable food safety law does not result in a license, inspection report, certificate, or permit, you could have a printed or electronic copy of the applicable food safety law.

2. If my facility supplies raw materials or other ingredients to a manufacturer/processor covered by the human food preventive controls requirements, and my facility is responsible for controlling the potential hazards, what information should I provide to the receiving facility regarding my status as a qualified facility, or any change in status from qualified to "not a qualified facility"?

In some circumstances, when a facility supplies a raw material or other ingredient to a manufacturer/processor that is covered by the human food preventive controls requirements, it is considered a "supplier" (see definition of "supplier" in 21 CFR 117.3). The manufacturer/processor is considered a "receiving facility." A receiving facility must establish and implement a supply-chain program for raw materials and other ingredients when a hazard identified by the receiving facility is controlled by a supplier. (See 21 CFR 117.405(a)(1)). The receiving facility may rely on certain written assurances from a supplier that is a qualified

facility (see 21 CFR 117.430(c)) rather than rely on other verification methods, like an onsite audit.

If you are a supplier to a receiving facility, the receiving facility must obtain written assurance from you that you are a qualified facility before first approving you as a supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (see 21 CFR 117.430(c)(1)). The receiving facility must also obtain other written assurance from you every two years that you are producing the raw material or ingredient in compliance with applicable FDA food safety regulations (or, when applicable, the food safety regulations of a country whose food safety system FDA has recognized as comparable or equivalent). This written assurance must include either:

1. a brief description of the preventive controls you are implementing to control the applicable hazards in the food; or

2. a statement that you are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law.

(See 21 CFR 117.430(c)(2)).

If a receiving facility will rely on your written assurance that you are a qualified facility, you would provide the receiving facility with written assurance of your status as a qualified facility before the receiving facility approves you as a supplier, and on an annual basis thereafter. Because the human food preventive controls requirements require the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with you to determine the specific date within a calendar year for annual notification to the receiving facility. As a matter of a business agreement with the receiving facility, it is possible that you would provide the written assurance earlier than December 31 of each calendar year.

3. When must I submit my first attestation to FDA to comply with the modified requirements in 21 CFR 117.201?

You must submit your first attestation to FDA:

- By December 17, 2018, if your facility begins manufacturing, processing, packing, or holding food before September 17, 2018; or
- Before beginning operations, if your facility begins manufacturing, processing, packing, or holding food after September 17, 2018.

(21 CFR 117.201(c)(2)(i)).

4. How often, and when, must I re-submit Form FDA 3942a?

Beginning in 2020, you must re-submit Form FDA 3942a to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31 (21 CFR 117.205(c)(2)(ii)). Note that you must also renew your facility registration at this time (21 CFR 1.230).

5. When must I submit Form FDA 3942a to FDA if my facility's status changes from "qualified facility" to "not a qualified facility"?

If your facility's status changes from "qualified facility" to "not a qualified facility" based on the annual determination, you must submit Form FDA 3942a notifying FDA of that change in status by July 31 of the applicable calendar year (see Reference 1: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation).

(21 CFR 117.205(c)(3)).

6. Do farms need to submit Form FDA 3942a?

No, provided that they meet FDA's definition of a "farm" (21 CFR 1.227). Submission of Form FDA 3942a is only required for businesses that are required to register with FDA as a food facility, and a farm is not required to register with FDA as a food facility.

7. Do farm mixed-type facilities need to submit Form FDA 3942a?

A farm mixed-type facility that meets the definition of "qualified facility" must submit Form FDA 3942a to FDA unless it is exempt from the preventive controls requirements in subparts C and G for another reason, such as it is only engaged in low-risk packing or holding activity/food combinations (21 CFR 117.5(g)) or low risk manufacturing/processing activity/food combinations (21 CFR 117.5(h)). In that case, we consider the mixed-type facility to be exempt from subparts C and G and the modified requirements for qualified facilities.

D. Examples of Calculations to Determine Market Value of Food Held Without Sale Under Part 117

1. How can I calculate market value of human food held without sale in my warehouse using the values in my insurance policy for the warehouse?

In this example, Warehouse F is a cold storage warehouse. Its inventory turns over approximately every two months. It has an insurance policy that covers the market value of food stored at any given time. Because the inventory turns over approximately every two months, Warehouse F could multiply the value of the insurance policy times six to arrive at an approximate value of the food stored for the entire year.

See **Table** 3 for an example of how Warehouse F could do its calculation of market value on an annual basis for the years 2014, 2015, and 2016. Warehouse F can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if the three year average is less than $1,000,000 adjusted for inflation.

Table 3. Calculation of Market Value of Human Food Held Without Sale by Warehouse F Using the Value of an Insurance Policy

Item	2014	2015	2016
Value of Insurance Policy	$200,000	$225,000	$250,000
Number of time inventory turns over during the year	6	6	6
Total Market Value of human food manufactured, processed, packed, or held without sale	($200,000)(6) = $1,200,000	($225,000)(6) = $1,350,000	($250,000)(6) = $1,500,000

Warehouse F does not meet the definition of a very small business and is not a qualified facility because the three-year average value $1,350,000 is greater than $1,078,242 (inflation adjusted value of $1,000,000 in 2016).

Because an insurance policy may cover a slightly higher value than is in the warehouse at any given time, Warehouse F may decide to calculate the market value using information or accounting documents from their customer to determine the actual value of product received each year. See Question II.D.2 for an example of how one could calculate the market value using information or accounting documents from the customer.

2. How can I calculate the market value of human food held without sale as a contract processor using information or accounting documents from the customer?

In this example, Contract Processor G uses information on the value of the food received from the customer to determine the total market value of all food held without sale for each year. Using this method, Contract Processor G would add up the value of food for each shipment received throughout the year. Contract Processor G can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm.

Table 4. Calculation of Market Value of Human Food Held Without Sale by Contract Processor F Using Information from the Customer to Determine the Value of Human Food for Each Shipment

Item	2014	2015	2016
Total Market Value of human food manufactured, processed, packed, or held without sale	$870,000	$1,030,000	$1,190,000

Contract Processor G does meet the definition of a very small business and is a qualified facility because the three year average value $1,030,000 is less than $1,078,242 (inflation adjusted value of $1,000,000 in 2016).

III. Frequently Asked Questions About Requirements for Qualified Facilities That Manufacture, Process, Pack, or Hold Animal Food

A. Definition of Qualified Facility Under Part 507

1. How does part 507 define "qualified facility"?

Part 507 defines a qualified facility as (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- A facility that is a very small business (see definition in Question III.A.2.); or
- A facility to which both of the following apply:
    - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (see definition in Question III.A.4) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
    - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

See the definition of "qualified facility" in 21 CFR 507.3.

2. How does Part 507 define "very small business?"

Part 507 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than **$2,500,000**, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale). See the definition of "very small business" in 21 CFR 507.3.

We believe the definition of a very small business will apply to most qualified facilities. As such, the focus of this guidance is on determining whether a facility meets the definition of a very small business, rather than on whether a facility meets the two-part definition based on sales to qualified end-users. If you have questions about sales to a qualified end-user that are not addressed in this guidance, please contact us as described in section IV of this guidance.

3. How does part 507 define "affiliate"?

Part 507 defines "affiliate" as any facility that controls, is controlled by, or is under common control with another facility. See the definition of "affiliate" in 21 CFR 507.3.

4. How does part 507 define "subsidiary"?

Part 507 defines a subsidiary as any company which is owned or controlled directly or indirectly by another company. See the definition of "subsidiary" in 21 CFR 507.3.

5. How does part 507 define "qualified end-user"?

Part 507 defines "qualified end-user" as the consumer of the food (where the term "consumer" does not include a business); or a restaurant or retail food establishment that:

- Is located:
    - In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
    - Not more than 275 miles from such facility; and
- Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

See the definition of "qualified end-user" in 21 CFR 507.3 and the definition of "restaurant" in 21 CFR 1.227.

6. Who determines whether my facility meets the definition of a qualified facility under part 507?

You are responsible for determining whether your facility meets the definition of a qualified facility under part 507, subject to verification by FDA. We do not intend to review financial records supporting your status as a qualified facility during routine inspections. However, we may ask to review those financial records during inspections conducted "for cause" (e.g., during an inspection conducted because animal food produced at your facility is associated with an outbreak of foodborne illness or if we have reason to believe your facility does not meet the requirements to be a qualified facility).

7. Can a facility that is a subsidiary meet the definition of "very small business" under part 507 even if its parent company is not a very small business?

Yes. It is possible for a facility that is a subsidiary to be a very small business even if its parent company is not a very small business because not all animal food sold or manufactured, processed, packed, or held without sale by the parent company is counted in a subsidiary facility's calculation of whether it is a very small business. Specifically, a subsidiary facility only includes operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary facility. For example, a subsidiary may consist of Facility G with $300,000 in annual animal food sales. The subsidiary's parent company may include Facility H, a manufacturer/processor with $2 million in annual animal food sales, and Farm I with $500,000 in annual animal food sales. Facility G would include Facility H's sales in its calculation because Facility H is an affiliate of Facility G. Facility G would not include Farm I's sales in its calculation because Farm I is not an affiliate (it cannot be because farms are not facilities required to register) or a subsidiary (it is part of the parent company). Therefore, Facility G would determine that it has $2.3 million ($2,000,000 + $300,000) in annual animal food sales for

its business. If the average over 3 years were less than the inflation adjusted maximum for the most recent of the three years, then Facility G would be a very small business.

Facility H's calculation to determine whether it is a very small business would be different. Facility H would include, in addition to its own sales ($2 million), Farm I's sales ($500,000) because Farm I is part of the same company. Facility H would also include Facility G's sales ($300,000) because Facility G is a subsidiary of the parent company that includes Facility H. Therefore, Facility H would determine that it has $2.8 million in annual animal food sales for its business. (Note, in this example none of the entities have animal food manufactured/processed, packed, or held without sale that must be included in the calculation.)

8. What does "animal food manufactured, processed, packed, or held without sale" mean in the definition of very small business in part 507?

Animal food manufactured, processed, packed, or held without sale means any food for animal consumption that you manufacture, process, pack, or hold at your facility and do not offer for sale. This does not include animal food that you will sell at a later date. Examples of animal food manufactured, processed, packed, or held without sale include animal food being held for a fee (e.g., by a warehouse), animal food being processed for a fee (e.g., by a contract processor), animal food being packaged for a fee (e.g., by a contract packager), and animal food supplied by a feed mill (one which is required to register as a food facility), without sale, operating under contract farming agreements.

B. Calculations to Determine Status as a Qualified Facility Under Part 507

1. How often, and when, must I make the calculation to determine my status as a qualified facility under part 507?

You must make the calculation to determine your status as a qualified facility under part 507 on an annual basis no later than July 1 of each calendar year. (21 CFR 507.7(c)(1)).

2. Which products do I include in, and which products do I exclude from, the calculation of annual sales plus market value to determine my status as a qualified facility under part 507?

Include all animal food, including animal food manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of whether the animal food is subject to part 507. You do not need to include the value of animal food that you have processed but not yet sold.

Do not include food intended for consumption by humans or other items that are not animal food.

3. Do I include animal food that is sold in countries other than the United States, in the calculation of total sales?

Yes. Include sales of all animal food in the calculation of total sales, regardless of where the animal food is sold. For example, if you are a domestic facility that exports animal food to other

countries, you would include sales of animal food for export in your calculation of total annual sales. If you are a foreign facility, you would include sales of animal food in all countries, including sales in your own country, sales in the United States, and sales in other countries.

4. **How do I include animal food that is manufactured, processed, packed, or held without sale (e.g., because I am a warehouse, a contract processor, a contract packager, or a feed mill that supplies the animal food to a farm without sale)?**

Include animal food that is manufactured, processed, packed, or held without sale, through calculations of market value (see Question III.B.9).

5. **How do I determine whether my average annual sales plus market value of animal food manufactured, processed, packed, or held without sale is under the inflation-adjusted cut-off?**

We have outlined what we believe to be the simplest method below. We will accept other methods as well (e.g., deflating average annual sales to 2011-dollars) should you choose to use a different method.

The simplest method of determining whether your annual sales plus market value of animal food manufactured, processed, packed, or held without sale is below the inflation-adjusted threshold for a "very small business" is to:

- Determine which three years to include in the average;
- Determine annual sales and market value of animal food manufactured, processed, packed, or held without sale, or supplied to a farm without sale, for each of the three years;
- Calculate the average for the three years; and
- Compare to the three-year average value posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if your three-year average is less than $2,500,000 adjusted for inflation.

6. **How do I determine which three years to include for the purpose of determining the average annual sales plus market value of animal food?**

The definition of a very small business specifies that the average is based on the 3-year period preceding the applicable calendar year. The applicable calendar year is the current year. If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018. *Note that for the examples in this guidance, we use the years 2014, 2015, and 2016 in order to demonstrate the inflation adjustment.*

See question III.B.7 if you don't have three years of financial records to use for your calculations.

7. **How do I determine average annual sales plus market value of animal food if I don't have three years of financial records to use for my calculations?**

The compliance date for you to keep records to support your status as a qualified facility is January 1, 2017, and the compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2019. If you began keeping applicable financial records on January 1, 2017, you would only have such records for 2 previous calendar years by September 17, 2019. Therefore, it would be reasonable for you to make the calculation based on the 2 previous calendar years. If you have records for 3 previous calendar years, you could make the calculation based on the longer time period. If we ask to see your applicable financial records during inspection in 2019, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility when you have records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years.

If you begin operations between January 1, 2018, and September 17, 2019, your applicable financial records would not cover even 2 calendar years by September 17, 2019. During the first 3 years of your operation, you should make the calculation based on the records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the first 3 years of your operation, we intend to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.

If you begin operations after January 1, 2019, you can rely on a projected estimate of revenue (or market value) at the time you begin operations. If we ask to see your applicable financial records during your first year of operation, we intend to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees. After you have records for one or two preceding years, you should make the calculation based on records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the next two years of your operation, we intend to accept records for the preceding one or two calendar years as adequate to support your status as a qualified facility in these circumstances.

8. How do I determine annual sales of animal food?

Determine your annual sales using resources such as:

- Tax Forms, e.g., Gross Receipts or Sales (Line 1a) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, e.g., Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor.

Table 5 provides an example of determining annual sales for Business J for the years 2014-2016 based on tax documents. Business J does not process, pack, or hold animal food without sale, and thus, does not calculate market value. Business J consists of a facility (Facility J) that does not have any subsidiaries or affiliates.

Table 5: Determining Annual Sales of Animal Food for Business J for the Years 2014-2016

Source	2014	2015	2016
Facility J: Gross Sales of Animal Food (Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility J: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*, **	N/A**	N/A**
Total Non-Inflation Adjusted Annual Sales + Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	$800,000	$800,500	$900,000

*N/A = Not applicable

** There is no entry for market value of animal food manufactured, processed, packed, or held without sale because Facility J does not manufacture, process, pack, or hold animal food without sale.

Table 6 provides a more complex example of determining annual sales for Business K for the years 2014-2016 based on tax documents. Business K consists of Facility K and one affiliate (Affiliate K1), which also produced and sold animal food. Neither Facility K nor Affiliate K1 manufactures, processes, packs, or holds animal food without sale and, thus, neither Facility K nor Affiliate K1 calculates market value.

Table 6. Determining Annual Sales of Animal Food for Business K (Facility K and its Affiliate) for the Years 2014-2016.

Source	2014	2015	2016
Facility K: Gross Sales of Food For Animals (Item 1a, IRS Form 1120)	$900,000	$1,200,000	$1,500,000
Facility K: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate K1: Gross Sales of Animal Food (Item 1a, IRS Form 1120)	$900,000	$900,000	$1,100,000
Affiliate K1: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*

Source	2014	2015	2016
Total Non-Inflation Adjusted Annual Sales Plus Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	$1,800,000	$2,100,000	$2,600,000

*There is no entry for market value of animal food manufactured, processed, packed, or held without sale because Facility K and Affiliate K1 do not manufacture, process, pack, or hold animal food without sale.

9. How do I determine the market value of animal food manufactured, processed, packed, or held without sale?

Use the value of the animal food, not the fee for the service (e.g., for holding, processing, or packing) to calculate the market value of animal food that you manufacture, process, pack or hold without sale. Determine the market value of animal food manufactured, processed, packed, or held without sale by considering factors such as:

- The market value of incoming animal food obtained from the customer for whom the animal food is being held;
- The amount of insurance that a warehouse holds for its products;
- The value obtained by multiplying market price by volume of animal food manufactured, processed, packed, or held; or
- Assets on a balance sheet.

See Section III.D of this guidance for an example of how to determine market value for animal food manufactured, processed, packed, or held without sale. The examples describe a warehouse facility holding animal food without sale and a contract manufacturer without sales.

10. What conversion rate should a foreign facility use when converting annual sales plus market value of animal food to U.S. dollars?

A foreign facility should use the exchange rate in effect as of the ending date of the period during which it collected the reported receipts or sales. For example, for sales during 2017 a foreign facility would use the conversion rate in effect on December 31, 2017.

11. May I subtract sales of animal food to qualified end-users from my annual sales of animal food when determining whether my facility meets the definition of very small business under part 507?

No. The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user.

C. Other Questions About the Animal Food Preventive Controls Requirements in Part 507

1. What records must I keep to demonstrate my facility's status as a qualified facility under part 507?

Part 507 requires that you keep records that you rely upon to support the attestations you make on Form FDA 3942b, but does not otherwise specify the types of records that you must keep. (See 21 CFR 507.7(f)(1)). You should keep the records that you use for your calculations of annual sales. See Question III.B.8 for examples of these records. You also should keep records of the actual calculations that you make – e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value. These records are subject to the requirements in subpart F of part 507 and must be produced upon request by a duly authorized representative of the Secretary of Health and Human Services (e.g., FDA). (See 21 CFR 507.7(f)(2) and 507.200(c)). We do not intend to ask to review these records during routine inspections. However, we may ask to review these records during inspections conducted "for cause" (e.g., during an inspection conducted because animal food produced at your facility is associated with an outbreak of foodborne illness) or if we have reason to believe your facility does not meet the requirements to be a qualified facility.

The records you are required to keep to support your attestation as to food safety practices/compliance may vary depending on how you comply with 21 CFR 507.7(a)(2). The two options are as follows:

1. Option 1: You have identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards associated with the animal food being produced, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

2. Option 2: Your 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.

When selecting Option 1, you must keep records documenting your identification of potential hazards, the preventive controls you are implementing to address those hazards, your implementation of your preventive controls, and your monitoring of your preventive controls. (See 21 CFR 507.7(f)(1)). For example, you could have a document identifying the hazards and the preventive controls you will implement to address those hazards, and batch records demonstrating your implementation and monitoring of the preventive controls. If some or all of the activities you conduct are activities that we have listed as a low-risk activity/animal food combination in 21 CFR 507.5(e) and (f), the records documenting your identification of hazards could be as simple as a reference to the applicable activity/animal food combination listed in the applicable regulation.

When selecting Option 2, you must maintain records that document your compliance with the applicable non-Federal food safety law that you are following. (See 21 CFR 507.7(f)(1)). For

example, you could keep a record of licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency or other evidence of oversight. If the applicable food safety law does not result in a license, inspection report, certificate, or permit, you could have a printed or electronic copy of the applicable food safety law.

2. If my facility supplies raw materials or other ingredients to a manufacturer/processor covered by the animal food preventive controls requirements, and my facility is responsible for controlling the potential hazards, what information should I provide to the receiving facility regarding my status as a qualified facility, or any change in status from qualified to "not a qualified facility"?

In some circumstances, when a facility supplies a raw material or other ingredient to a manufacturer/processor that is covered by the animal food preventive controls requirements, it is considered a "supplier" (see definition of "supplier" in 21 CFR 507.3). The manufacturer/processor is considered a "receiving facility." A receiving facility must establish and implement a supply-chain program for raw materials and other ingredients when a hazard identified by the receiving facility is controlled by a supplier. (See 21 CFR 507.105(a)(1)). The receiving facility may rely on certain written assurances from a supplier that is a qualified facility (see 21 CFR 507.130(c)) rather than rely on other verification methods, like an onsite audit.

If you are a supplier to a receiving facility, the receiving facility must obtain written assurance from you that you are a qualified facility before first approving you as a supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (see 21 CFR 507.130(c)(1)). The receiving facility must also obtain other written assurance from you every two years that you are producing the raw material or ingredient in compliance with applicable FDA food safety regulations (or, when applicable, the food safety regulations of a country whose food safety system FDA has recognized as comparable or equivalent). This written assurance must include either:

1. a brief description of the preventive controls you are implementing to control the applicable hazards in the animal food; or

2. a statement that you are in compliance with State, local, country, tribal, or other applicable non-Federal food safety laws.

(See 21 CFR 507.130(c)(2)).

If a receiving facility will rely on your written assurances that you are a qualified facility, you would provide the receiving facility with written assurance of your status as a qualified facility before the receiving facility approves you as a supplier, and on an annual basis thereafter. Because the animal food preventive controls requirements require the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with you to determine the specific date within a calendar year for annual notification to the receiving facility. As a matter of a business agreement with the receiving facility, it is possible that you would provide the written assurance earlier than December 31 of each calendar year.

3. When must I submit my first attestation to FDA to comply with the modified requirements in 21 CFR 507.7?

You must submit your first attestation to FDA:

- By December 16, 2019, if your facility begins manufacturing, processing, packing, or holding animal food before September 17, 2019; or
- Before beginning operations, if your facility begins manufacturing, processing, packing, or holding animal food after September 17, 2019.

(See 21 CFR 507.7(c)(2)(i)).

4. How often, and when, must I re-submit Form FDA 3942b?

Beginning in 2020, you must re-submit Form FDA 3942b to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31. (See 21 CFR 507.7(c)(2)(ii)). Note that you must also renew your facility registration at this time (21 CFR 1.230).

5. When must I submit Form FDA 3942b to FDA if my facility's status changes from "qualified facility" to "not a qualified facility"?

If your facility's status changes from "qualified facility" to "not a qualified facility" based on the annual determination, you must submit Form FDA 3942b notifying FDA of that change in status by July 31 of the applicable calendar year (see Reference 1: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation).

(See 21 CFR 507.5(c)(3)).

6. Do farms need to submit Form FDA 3942b?

No, providing they meet FDA's definition of a "farm" (see 21 CFR 1.227). Submission of Form FDA 3942b is only required for businesses that are required to register with FDA as an animal food facility, and a farm is not required to register with FDA as a food facility.

7. Do farm mixed-type facilities need to submit Form FDA 3942b?

A farm mixed-type facility that meets the definition of "qualified facility" must submit Form FDA 3942b to FDA unless it is exempt from the preventive controls requirements in subparts C and E for another reason, such as being engaged in only low-risk packing or holding activity/animal food combinations (see 21 CFR 507.5(e)) or low-risk manufacturing/processing activity/animal food combinations (see 21 CFR 507.5(f)). In that case, we consider the mixed-type facility to be exempt from subparts C and E and the modified requirements for qualified facilities in 21 CFR 507.7.

D. Examples of Calculations to Determine Market Value of Animal Food Held Without Sale Under Part 507

1. How can I calculate market value of animal food held without sale in my warehouse using the market value of the product?

There are several ways in which a facility could calculate the market value of animal food held without sale. For additional examples, see section II.D. In this example, Warehouse L holds soybean meal for a fee. There are several ways Warehouse L could calculate the market value for the soybean meal that is held. This example will show how Warehouse L could calculate the market value of soybean meal held in 2014 by using the commodity price. While Table 7 shows how to calculate the value for one year, Warehouse L would need to do the calculation for the three years preceding the applicable calendar year as part of its determination of the three-year average annual sales plus market value of animal food manufactured, processed, packed, or held without sale.

To determine the market value of the soybean meal held in 2014, Warehouse L determines the volume of soybean meal held each month, multiplies that volume by the commodity value for that month, and then calculates the total for the year.

Table 7. Calculation of Market Value of Soybean Meal Held by Warehouse L in 2014

Month	Soybean Meal Price (per Metric Ton)	Volume of Soybean Meal (Metric Tons)	Market Value (before adjustment for inflation)
January 2014	$473.75	11.2	$5,306.00
February 2014	$499.36	11.5	$5,742.64
March 2014	$506.69	12.3	$6,232.29
April 2014	$533.63	11.9	$6,350.20
May 2014	$442.78	12.2	$5,401.92
June 2014	$519.27	11.8	$6,127.39
July 2014	$451.02	12.5	$5,637.75
August 2014	$447.82	11.8	$5,284.28
September 2014	$409.10	12.4	$5,072.84
October 2014	$378.82	12.2	$4,621.60
November 2014	$423.25	11.9	$5,036.68
December 2014	$418.09	12.9	$5,393.36
2014 Market Value of Soybean Meal Held for a Fee	N/A*	N/A**	$66,206.93

*This column does not have an entry in the final row of the table because the entries in this column are for price per ton, not market value.
** This column does not have an entry in the final row of the table because the entries in this column are for volume, not market value.

2. How can I calculate the market value of animal food manufactured by a contract feed mill that does not sell the animal food?

In this example, Feed Mill M provides animal food to a contract farm, without sale of the animal food. Feed Mill M can determine the market value of animal food processed without sale by using the commodity price of the product (food for broiler chickens). Table 8 shows how the market value can be calculated based on the average price per ton of broiler feed and multiplying it by the volume of broiler feed provided to a contract farm. Feed Mill M would do the same calculation for 2015 and 2016. Feed Mill M can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if the three-year average market value is less than $2,500,000 adjusted for inflation.

Table 8. Calculation of Market Value of Food for Broiler Chickens

Year	Average price per ton for broiler feed	Tons of broiler feed sent to contract farm	Market Value (before adjustment for inflation)
2014	$259.10	7,500	$1,943,250

IV. How to Contact FDA to Obtain Help with This Guidance

You can contact FDA with questions on this guidance using the FSMA Technical Assistance Network. Questions can be submitted online at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

You may also mail your questions to the address below:

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in Part 117 have been approved under OMB Control No. 0910-0751 and the collections of information in Part 507 have been approved under OMB Control No. 0910-0789.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection is 0910-0854.

VI. References

1. FDA 2016: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation. Accessible at: https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm

2. FDA 2017: Form FDA 3942a. Accessible at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm

3. FDA 2017: Form FDA 3942b. Accessible at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm