Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700. For questions regarding this draft document as it relates to animal food, 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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Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food):

Guidance for Industry [1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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 FDA Food Safety Modernization Act establishes requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans and animals. We have established regulations to implement these requirements within subparts C and G of our regulations entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR part 117) (the Preventive Controls for Human Food Rule) and within subparts C and E of our regulations entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (21 CFR part 507) (the Preventive Controls for Animal Food Rule).

A business that meets the definition of a "qualified facility" is subject to modified requirements in § 117.201 of the Preventive Controls for Human Food Rule or in § 507.7 of the Preventive Controls for Animal Food Rule. These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility. Section II of this guidance explains how to determine whether your business meets the definition of "qualified facility" under the Preventive Controls for Human Food Rule and how to submit Form FDA 3942a attesting to its status as a qualified facility under the Preventive Controls for Human Food Rule. Section III of this guidance explains how to determine whether your business meets the definition of "qualified facility" under the Preventive Controls for Animal Food Rule and how to submit Form FDA 3942b attesting to its status as a qualified facility under the Preventive Controls for Animal Food Rule.

[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.

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 Under the Preventive Controls for Human Food Rule

A. Definition of Qualified Facility Under the Preventive Controls for Human Food Rule

1. How does the Preventive Controls for Human Food Rule define "qualified facility"?

The Preventive Controls for Human Food Rule 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 very small business; 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 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 the Preventive Controls for Human Food Rule define "very small business"?

The Preventive Controls for Human Food Rule 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. 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 the Preventive Controls for Human Food Rule define "affiliate"?

The Preventive Controls for Human Food Rule 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 the Preventive Controls for Human Food Rule define "subsidiary"?

The Preventive Controls for Human Rule 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 the Preventive Controls for Human Food Rule define "qualified end-user"?

The Preventive Controls for Human Rule 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 business meets the definition of a qualified facility under the Preventive Controls for Human Food Rule?

You are responsible for determining whether your business meets the definition of a qualified facility under the Preventive Controls for Human Food Rule, subject to verification by FDA.

7. Can an affiliate or subsidiary meet the definition of "very small business" under the Preventive Controls for Human Food Rule even if the parent company does not meet the definition of very small business?

No. The total annual sales apply to each entity, regardless of whether it is the parent, the subsidiary, or the affiliate. In other words, if the total combined sales of the parent, subsidiaries, and affiliates meet the definition of very small business, the parent company, subsidiaries, and affiliates would all be subject to the modified requirements under the Preventive Controls for

Human Food Rule. However, if the parent company, a subsidiary, or an affiliate, individually or in any combination does not meet the definition of a very small business, the parent company, affiliates, and subsidiaries would all be subject to the full requirements of the Preventive Controls for Human Food Rule.

8. What does "food manufactured, processed, packed, or held without sale" mean in the definition of very small business in the Preventive Controls for Human Food Rule?

Food manufactured, processed, packed, or held without sale means any food for human consumption that you manufacture, process, pack or hold at your facility without offering it for sale. Examples include food being held for a fee (e.g., a warehouse), food being processed for a fee (e.g., a contract processor (such as a facility that irradiates spices)), and food being packaged for a fee (e.g., a contract packager).

B. Calculations to Determine Status as a Qualified Facility Under the Preventive Controls for Human Food Rule

1. How often, and when, must I make the calculation to determine my status as a qualified facility under the Preventive Controls for Human Food Rule?

You must make the calculation to determine your status as a qualified facility under the Preventive Controls for Human Food Rule 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 the Preventive Controls for Human Food Rule?

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 the Preventive Controls for Human Food Rule. For example, you would include products such as seafood, juice, low-acid canned foods, and dietary supplements. Likewise, you would include raw agricultural commodities (such as 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 the Preventive Controls for Human Food Rule.

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 calculate inflation-adjusted average annual sales plus market value of human food manufactured, processed, packed, or held without sale?

To determine the inflation-adjusted average annual sales and market value of human food manufactured, processed, packed, or held without sale, follow the steps in Questions II.B.8 through II.B.13 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;
- Adjust annual sales and market value for each year for inflation; and
- Calculate the inflation-adjusted average annual sales and market value.

6. How do I determine which three years to include for the purpose of determining the inflation-adjusted 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 2012, 2013, and 2014 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 begin 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. During inspection in 2018, when a facility has records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility.

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) and 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. 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), and 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 A for the years 2012-2014 based on tax documents. Business A has one affiliate company, which produced and sold human and animal food. Neither Business A nor its affiliate manufactures, processes, packs, or holds human food without sale and, thus, neither Business A nor its affiliate calculates market value.

Table 1. Determining Annual Sales of Human Food for Business A and its Affiliate for the Years 2012-2014.

Source	2012	2013	2014
Business A: Gross Sales of Human Food (Item 1A, IRS Form 1120)	$800,000	$800,500	$900,000
Business A: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A	N/A
Affiliate 1: Gross Sales of Human Food (Item 1A, IRS Form 1120)	$190,000	$200,000	$200,000
Affiliate 1: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A	N/A	N/A

Source	2012	2013	2014
Affiliate 1: Gross Sales of Animal Food (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
Inflation-Adjusted Sum of Annual Sales Plus Market Value (see Table 2 for methodology)	$972,538	$968,423	$1,049,433

*N/A = Not applicable

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. Determine the market value of human food manufactured, processed, packed, or held without sale by considering factors such as:

- The cost of incoming food;
- 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.1 of this guidance for an example of how to determine market value for human food manufactured, processed, packed, or held without sale. The example describes the calculation for a cold storage warehouse that holds human food.

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 the Preventive Controls for Human Food Rule?

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.

12. How do I adjust annual sales plus market value of human food products for inflation?

Use the U.S. Bureau of Economic Analysis' Implicit Price Deflators for Gross Domestic Product (GDP) to adjust the sum of annual sales plus market value for inflation, using the 2011 Implicit Price Deflator as the baseline. To do so, multiply the sum of annual sales plus market value in current U.S. dollars by the 2011 Implicit Price Deflator Index Number and then divide by the current year Implicit Price Deflator Index Number. The mathematical answer is the annual sales plus market value in 2011 dollars – i.e., inflation-adjusted sales plus market value.

Table 2 shows the calculations done by Business A and its affiliate for inflation-adjusted annual sales in 2012, 2013, and 2014. (See Table 1 for the determination of annual sales for Business A and its affiliate before adjusting for inflation.)

Table 2. Adjusting the Annual Sales of Human Food for Business A and its Affiliate for Inflation

Year	Sum of Annual Sales Plus Market Value in Current U.S. Dollars	Implicit Price Deflator Index Number	Inflation-Adjusted Sum of Annual Sales Plus Market Value
2011	N/A*	103.311	N/A
2012	$990,000	105.166	($990,000)(103.311) / 105.166 = $972,538
2013	$1,000,500	106.733	($1,000,500)(103.311) / 106.733 = $968,423
2014	$1,100,000	108.289	($1,100,000)(103.311) / 108.289 = $1,049,433

*N/A = Not applicable

We will make the Implicit Price Deflator Index Numbers for GDP available on our website at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm.

13. How do I calculate the three-year average of the inflation-adjusted annual sales plus market value of human food?

To determine the three-year average of the inflation-adjusted annual sales plus market value, add the annual inflation-adjusted sales for the previous three years and divide the sum by three. For the example shown in Table 1 and Table 2, the three year adjusted average is $996,798 as calculated below.

Three year adjusted average = (972,538 + 968,423 + 1,049,433) / 3 =$ 996,798

Business A would satisfy the definition of "qualified facility" under the Preventive Controls for Human Food Rule as a very small business, because its three-year inflation-adjusted average annual sales plus market value (including its affiliate's human food sales plus market value), is less than $1,000,000.

See Section II.D of this guidance for additional examples and calculations for determining whether your business satisfies the definition of "qualified facility" as a very small business.

C. Other Questions About the Preventive Controls for Human Food Rule

1. What records must I keep to demonstrate my facility's status as a qualified facility under the Preventive Controls for Human Food Rule?

The Preventive Controls for Human Food Rule 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 the Preventive Controls for Human Food Rule and must be produced upon request by FDA. (21 CFR 117.201(f) and 21 CFR 117.320).

2. If my facility controls a hazard in human food that it supplies to a manufacturer/processor, must I inform the manufacturer/processor of my facility's status as a qualified facility under the Preventive Controls for Human Food Rule and of any change in my status?

When a facility supplies a raw material or other ingredient to a manufacturer/processor, it is considered a "supplier." The manufacturer/processor, if subject to the requirements of the Preventive Controls for Human Food Rule, is considered a "receiving facility." A receiving facility under the Preventive Controls for Human Food Rule 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. (21 CFR 117.405(a)(1)). The receiving facility may rely on certain written assurances for a supplier that is a qualified facility (see 21 CFR 117.430(c)(2)). To do this, the receiving facility must obtain written assurance that a supplier is a qualified facility before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (21 CFR 117.430(c)(1)). Note that the receiving facility must obtain other written assurances from the supplier every two years.

If a receiving facility relies on written assurances from the supplier, the supplier would provide the receiving facility with written assurance of its status as a qualified facility before the receiving facility approves the supplier, and on an annual basis thereafter. Because the Preventive Controls for Human Food Rule only requires the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with a supplier 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 a supplier 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 Preventive Controls for Human Food Rule?

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)).

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 Appendix 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. 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" and wants to be considered as a "qualified facility" must submit Form FDA 3942a to FDA. Note that a very small farm mixed-type facility may also be exempt from all requirements for hazard analysis and risk-based preventive controls, including the modified requirements in 21 CFR 117.201, if all of its activities that would be subject to subpart C of the Preventive Controls for Human Food Rule are on-farm low-risk activity/food combinations listed in 21 CFR 117.5(g) and (h). This type of very small farm mixed-type facility may decide to not submit Form FDA 3942a even though it meets the definition of a qualified facility and instead take advantage of the exemption from all requirements for hazard analysis and risk-based preventive controls based on only conducting low risk activity/food combinations.

8. Do food hubs need to submit Form FDA 3942a?

Submission of Form FDA 3942a is only required for businesses that are required to register with FDA as a food facility. Whether a food hub must submit Form FDA 3942a depends on whether the food hub is a food facility that is required to register with FDA or does not have to register, for example, because it meets the definition of "farm" in 21 CFR 1.227. Under the "farm" definition in 21 CFR 1.227, a business operation (such as a food hub) can be a "secondary activities farm" if it is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

D. Examples of Calculations to Determine Market Value of Food Held Without Sale Under the Preventive Controls for Human Food Rule

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 A 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 A 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 A could do its calculation of market value on an annual basis for the years 2012, 2013, and 2014. See Table 4 for an example of how Warehouse A could adjust its annual sales for inflation**.**

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

Item	2012	2013	2014
Value of Insurance Policy	$2,000,000	$2,250,000	$2,500,000
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	($2,000,000)(6) = $12,000,000	$13,500,000	$15,000,000

Table 4. Adjusting the Annual Market Value of Human Food Held Without Sale by Warehouse A for Inflation

Year	Total Annual Market Value in Current Value	Implicit Price Deflator Index Number	Total Market Value Adjusted for Inflation
2011	N/A*	103.311	N/A
2012	$12,000,000	105.166	($12,000,000)(103.311)/105.166 = $11,788,335
2013	$13,500,000	106.733	($13,500,000)(103.311)/106.733 = $13,067,172
2014	$15,000,000	108.289	($15,000,000)(103.311)/108.289 = $14,310,456

*N/A = Not applicable

To determine the three-year average of the inflation-adjusted market value, Warehouse A adds the annual inflation-adjusted market value for the previous three years and divides the sum by three. For the example shown in Table 3 and Table 4, the three year adjusted average is $13,055,321 as calculated below:

Three year adjusted average = ($11,788,335 + $13,067,172 + $14,310,456)/3 = $13,055,321

Based on these calculations, Warehouse A does not meet the definition of a qualified facility under the Preventive Controls for Human Food Rule.

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

2. How can I calculate the inflation-adjusted market value of human food held without sale in my warehouse using the market value of incoming food from invoices or accounting documents?

In this example, Warehouse A is a cold storage warehouse that uses invoices for food received to determine the total market value of all food held without sale for each year. Using this method, Warehouse A would add up the value of food for each shipment received throughout the year and then calculate the three-year average of the inflation-adjusted market value.

Table 5. Calculation of Market Value of Human Food Held Without Sale by Warehouse A Using Invoices for the Value of Human Food for Each Shipment

Item	2012	2013	2014
Total Market Value of human food manufactured, processed, packed, or held without sale	$8,700,000	$10,300,000	$11,900,000

Table 6. Adjusting the Annual Market Value of Human Food Held Without Sale by Warehouse A for Inflation

Year	Total Annual Sales in Current Value	Implicit Price Deflator Index Number	Total Annual Sales Adjusted for Inflation

2011	N/A*	103.311	N/A
2012	$11,200,000	105.166	$11,002,446
2013	$10,900,000	106.733	$10,550,532
2014	$13,900,000	108.289	$13,261,023

*N/A = Not applicable

Three year adjusted average ($11,200,000 + $10,900,000 + $13,900,000) /3 = $11,604,667

Based on these calculations, Warehouse A still does not meet the definition of a qualified facility under the Preventive Controls for Human Food Rule.

III. Frequently Asked Questions About Requirements for Qualified Facilities Under the Preventive Controls for Animal Food Rule

A. Definition of Qualified Facility Under the Preventive Controls for Animal Food Rule

1. How does the Preventive Controls for Animal Food Rule define "qualified facility"?

The Preventive Controls for Animal Food Rule defines a qualified facility as (when including the sales by an subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- A very small business; 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 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 the Preventive Controls for Animal Food Rule define "very small business"?

The Preventive Controls for Animal Food Rule 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. 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 the Preventive Controls for Animal Food Rule define "affiliate"?

The Preventive Controls for Animal Food Rule 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 the Preventive Controls for Animal Food Rule define "subsidiary"?

The Preventive Controls for Animal Food Rule 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 the Preventive Controls for Animal Food Rule define "qualified end-user"?

The Preventive Controls for Animal Food Rule 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 business meets the definition of a qualified facility under the Preventive Controls for Animal Food Rule?

You are responsible for determining whether your business meets the definition of a qualified facility under the Preventive Controls for Animal Food Rule subject to verification by FDA.

7. Can an affiliate or subsidiary meet the definition of "very small business" under the Preventive Controls for Animal Food Rule even if the parent company does not meet the definition of very small business?

No. The total annual sales apply to each entity, regardless of whether it is the parent, the subsidiary, or the affiliate. In other words, if the total combined sales of the parent, subsidiaries, and affiliates meet the definition of very small business, the parent company, subsidiaries, and affiliates would all be subject to the modified requirements of 21 CFR 507.7 under the Preventive Controls for Animal Food Rule. However, if the parent company, a subsidiary, or an affiliate individually or in any combination does not meet the definition of a very small business, the parent company, affiliates, and subsidiaries would all be subject to the full requirements of the Preventive Controls for Animal Food Rule.

8. What does "animal food manufactured, processed, packed, or held without sale" mean in the definition of very small business in the Preventive Controls for Animal Food Rule?

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 without offering it for sale. Examples include animal food being held for a fee (e.g., a warehouse), animal food being processed for a fee (e.g., a contract processor), animal food being packaged for a fee (e.g., 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 the Preventive Controls for Animal Food Rule

1. How often, and when, must I make the calculation to determine my status as a qualified facility under the Preventive Controls for Animal Food Rule?

You must make the calculation to determine your status as a qualified facility under the Preventive Controls for Animal Food Rule 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 the Preventive Controls for Animal Food Rule?

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 the Preventive Controls for Animal Food Rule.

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 calculate inflation-adjusted average annual sales plus market value of animal food manufactured, processed, packed, or held without sale?

To determine the inflation-adjusted average annual sales and market value of animal food manufactured, processed, packed, or held without sale, follow the steps in Questions III.B.8 through III.B.13 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 for each of the three years;
- Adjust annual sales and market value for each year for inflation; and
- Calculate the inflation-adjusted average annual sales and market value.

6. How do I determine which three years to include for the purpose of determining the inflation-adjusted 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 2012, 2013, and 2014 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 begin 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. During inspection in 2019, when a

facility has records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility.

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) and 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. 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), and 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 plus market value of animal food manufactured, processed, packed, or held without sale?

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 7 provides an example of determining annual sales for Business A for the years 2012-2014 based on tax documents. Business A has one affiliate company, which also produced and sold animal food. Neither Business A nor its affiliate manufactures, processes, packs, or holds animal food without sale and, thus, neither Business A nor its affiliate calculates market value.

Table 7. Determining Annual Sales of Animal Food for Business A and its Affiliate for the Years 2012-2014.

Source	2012	2013	2014
Business A: Gross Sales of Food For Animals	$900,000	$1,200,000	$1,500,000
Affiliate 1: Gross Sales of Food for Animals	$900,000	$900,000	$1,100,000

Source	2012	2013	2014
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
Inflation-Adjusted Sum of Annual Sales Plus Market Value (see Table 8 for methodology)	$1,768,250	$2,032,671	$2,480,479

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. Determine the market value of animal food manufactured, processed, packed, or held without sale by considering factors such as:

- The cost of incoming animal food;
- 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 the Preventive Controls for Animal Food Rule?

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.

12. How do I adjust annual sales plus market value of animal food for inflation?

Use the U.S. Bureau of Economic Analysis' Implicit Price Deflators for Gross Domestic Product (GDP) to adjust the sum of annual sales plus market value for inflation, using the 2011 Implicit Price Deflator as the baseline. To do so, multiply the sum of annual sales plus market value in

current U.S. dollars by the 2011 Implicit Price Deflator Index Number and then divide by the current year Implicit Price Deflator Index Number. The mathematical answer is the annual sales plus market value in 2011 dollars – i.e., inflation-adjusted sales plus market value.

Table 8 shows the calculations done by Business A and its affiliate for inflation-adjusted annual sales in 2012, 2013, and 2014. (See Table 7 for the determination of annual sales for Business A and its affiliate before adjusting for inflation.)

Table 8. Adjusting the Annual Sales of Animal Food for Business A and its Affiliate for Inflation

Year	Total Annual Sales in Current Value	Implicit Price Deflator Index Number	Total Annual Sales Adjusted for Inflation
2011	N/A*	103.311	N/A
2012	$1,800,000	105.166	($1,800,000)(103.311)/105.166 = $1,768,250
2013	$2,100,000	106.733	($2,100,000)(103.311)/106.733 = $2,032,671
2014	$2,600,000	108.289	($2,600,000)(103.311)/108.289 = $2,480,479

* N/A = Not applicable

We will make the Implicit Price Deflator Index Numbers for GDP available on our website at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm.

13. How do I calculate the three-year average of the inflation-adjusted annual sales plus market value of animal food?

To determine the three-year average of the inflation-adjusted annual sales plus market value, add the annual inflation-adjusted sales for the previous three years and divide the sum by three. For the example shown in Table 7 and Table 8, the three year adjusted average is $2,093,800 as calculated below.

Three year adjusted average = ($1,768,250 + 2,032,671 + $2,480,479) / 3 =$ 2,093,800

Business A would satisfy the definition of "qualified facility" under the Preventive Controls for Animal Food Rule as a very small business, because its three-year inflation-adjusted average annual sales plus market value (including its affiliate's animal food sales plus market value) is less than $2,500,000.

See Section III.D of this guidance for additional examples and calculations for determining whether your business satisfies the definition of "qualified facility" as a very small business.

C. Other Questions About the Preventive Controls for Animal Food Rule

1. What records must I keep to demonstrate my facility's status as a qualified facility under the Preventive Controls for Animal Food Rule?

The Preventive Controls for Animal Food Rule 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. (21 CFR 507.7(f)(1)). You should keep the records that you use for your calculations of annual sales. See Question III.A.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 the Preventive Controls for Animal Food Rule and must be produced upon request by FDA. (21 CFR 507.7(f)(2) and 507.200(c)).

2. If my facility controls a hazard in animal food that it supplies to a manufacturer/processor, must I inform the manufacturer/processor of my facility's status as a qualified facility under the Preventive Controls for Animal Food Rule and of any change in my facility's status?

When a facility supplies a raw material or other ingredient to a manufacturer/processor, it is considered a "supplier." The manufacturer/processor, if subject to the requirements of the Preventive Controls for Animal Food Rule, is considered a "receiving facility." A receiving facility under the Preventive Controls for Animal Food Rule 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. (21 CFR 507.105(a)(1)). The receiving facility may rely on certain written assurances for a supplier that is a qualified facility (see 21 CFR 507.130(c)(2)). To do this, the receiving facility must obtain written assurance that a supplier is a qualified facility before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (21 CFR 507.130(c)(1)). Note that the receiving facility must obtain other written assurances from the supplier every two years.

If a receiving facility relies on written assurances from the supplier, the supplier would provide the receiving facility with written assurance of its status as a qualified facility before the receiving facility approves the supplier, and on an annual basis thereafter. Because the Preventive Controls for Animal Food Rule only requires the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with a supplier 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 a supplier 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 Preventive Controls for Animal Food Rule?

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.

(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.

(21 CFR 507.7(c)(2)(ii)).

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 Appendix 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 507.5(c)(3)).

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

No. 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" and wants to be considered as a "qualified facility" must submit Form FDA 3942b to FDA.

Note that a very small farm mixed-type facility may also be exempt from all requirements for hazard analysis and risk-based preventive controls, including the requirements in 21 CFR 507.7, if all of its activities that would be subject to subpart C of the Preventive Controls for Animal Food Rule are on-farm low-risk activity/animal food combinations listed in 21 CFR 507.5(e) and (f). This type of very small farm mixed-type facility may decide not to submit For FDA 3942b even though it meets the definition of a qualified facility and instead take advantage of the exemption from all requirements for hazard analysis and risk-based preventive controls based on only conducting low-risk activity/food combinations.

D. Examples of Calculations to Determine Market Value of Food Held Without Sale Under the Preventive Controls for Animal Food Rule

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

In this example, Warehouse A holds soybean meal for a fee. There are several ways you could calculate the market value for the soybean meal that is held. This example will show how you could calculate the market value of soybean meal held in 2014 by using the commodity price. While the example below shows how to calculate the value for one year, you would need to do the calculation for the three years preceding the applicable calendar year as part of your determination of the three year average annual sales plus market value of food manufactured, processed, packed, or held without sale.

To determine the market value of the soybean meal held in 2014, determine the volume of soybean meal held each month and multiply it by the commodity value for that month and then add the total for the year.

Table 9. Calculation of Market Value of Soybean Meal Held by Warehouse A in 2014

Month	Soybean Meal Price (per Metric Ton)	Volume of Soybean Meal (Metric Tons)	Market Value
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

*N/A = Not applicable

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

In this example, Feed Mill B provides animal food to a contract farm, without sale of the animal food. The profits come from the sale of edible animal products for human consumption, in this case, broiler chickens. Feed Mill B can determine the market value of animal food processed without sale by using the commodity price of the product (food for broiler chickens). Table 9

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.

Table 10. 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

Table 11 shows how the market value calculated in Table 10 would be adjusted for inflation.

Table 10. Adjusting the Market Value of Animal Food Held Without Sale by Feed Mill B for Inflation

Year	Market Value (before adjustment for inflation)	Implicit Price Deflator Index Number	Market Value Adjusted for Inflation
2011	N/A*	103.311	N/A
2014	$1,943,250	108.289	($1,943,250)(103.311)/108.289 = $1,853,920

*N/A = Not applicable

To determine the three-year average of the inflation-adjusted market values, Feed Mill B should calculate the market value adjusted for inflation for the three previous years, add the annual inflation-adjusted market values for the previous three years and divide the sum by three.

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 http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

You may also mail your questions to the address below:

Food and Drug Administration
5100 Paint Branch Parkway
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

V. Appendices

1. FDA 2016: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food0: Instructions for Submitting Your Attestation. Accessible at:

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/ucm496263.htm

2. FDA 2016: Draft Form FDA 3942a. Accessible at: http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/UCM496262.pdf

3. FDA 2016: Draft Form FDA 3942b. Accessible at: http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/UCM496261.pdf