

Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food): Guidance for Industry

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**U.S. Department of Health and Human Services
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Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food): Guidance for Industry¹

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I. Introduction

The purpose of this guidance is to help industry subject to Title 21 of the Code of Federal Regulations (21 CFR) part 117 (part 117) or 21 CFR part 507 (part 507) determine the number of employees for purposes of the “small business” definition under parts 117 and 507.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s 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 Agency guidances means that something is suggested or recommended, but not required.

II. Background

This guidance concerns two regulations that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353). These two regulations are part 117 (published in

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the *Federal Register* on September 17, 2015, 80 FR 55907) and part 507 (published in the *Federal Register* on September 17, 2015, 80 FR 51670).

Among other things, the rulemaking to establish part 117 amended our CGMP regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, primarily in subpart B, with associated requirements in subparts A and F. Part 117 also includes new 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), primarily in subparts C and G, with associated requirements in subparts A, D, E, and F, to establish and implement hazard analysis and risk-based preventive controls for human food (the human preventive controls requirements). The rulemaking to establish part 507 created new animal food CGMP and preventive controls requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act. Requirements for CGMPs are primarily in part 507, subpart B, with associated requirements in subparts A and F (CGMP requirements). Requirements for establishing and implementing hazard analysis and risk-based preventive controls for food for animals are primarily in subparts C and E, with associated requirements in subparts A, D, and F (the animal food preventive controls requirements).

Under parts 117 and 507, whether a business is a “small business” has two main implications. First, certain small businesses (i.e., “farm mixed-type facilities,” which are establishments that are farms, but also conduct activities outside the farm definition that require the establishments to be registered) are exempt from the human food preventive controls requirements and the animal food preventive controls requirements if they are engaged only in specified low-risk activity/food combinations. Second, small businesses have later compliance dates for parts 117 and 507 than larger businesses.

III. Questions and Answers

A. Definitions

A.1 What does “small business” mean for purposes of part 117 and part 507?

A “small business” means a business (including any subsidiaries or affiliates) employing fewer than 500 full-time equivalent employees (21 CFR 117.3 and 507.3). The limit of 500 employees includes all employees of the business and is not limited to the employees at a particular facility (80 FR 55908 at 55962 and 80 FR 56170 at 56200).

A.2 What does “full-time equivalent employee” mean?

A “full-time equivalent employee” (FTE) is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business. The number of FTEs is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number. (21 CFR 117.3 and 507.3)

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A.3 What is a “subsidiary”?

A “subsidiary” means any company which is owned or controlled directly or indirectly by another company (21 CFR 117.3 and 507.3). Note that only companies can have or be subsidiaries.

A.4 What is an “affiliate”?

An “affiliate” means any facility that controls, is controlled by, or is under common control with another facility (21 CFR 117.3 and 507.3). Only facilities required to register can be affiliates.

A.5 What is a “facility”?

A “facility” means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR, part 1, subpart H (21 CFR 117.3 and 507.3).

Under 21 CFR, part 1, subpart H, a “facility” means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States (21 CFR 1.227).

B. Determining the Number of FTEs

B.1 How should you determine the number of FTEs in a business?

FDA uses the following method to calculate the number of FTEs in a business:

1. Start with a food facility required to register.
2. Determine the legal entity that the food facility is a part of.
3. Calculate the total number of FTEs in this legal entity. (See B.5 for help with calculating FTEs.)
4. Determine whether the legal entity has any subsidiaries and calculate the FTEs of all the subsidiaries.
5. Determine whether the legal entity has any affiliates and calculate the FTEs of all the affiliates.
6. Add the number of FTEs calculated for the legal entity, any subsidiaries, and any affiliates to get the total number of FTEs in a business.

B.2 How should you determine the extent of a business?

For the purpose of the small business calculation, we consider a business to consist of the legal entity that the relevant facility is part of, along with any “affiliates” and “subsidiaries” determined from the perspective of the relevant facility. Therefore, depending on your business structure, your business size calculation may not be the same for all of your facilities. For example, the business size calculation may be different for a facility that is part of a subsidiary

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than for a facility that is part of a parent company because the employees in the parent company are counted differently, depending on whether the relevant facility is part of the subsidiary or part of the parent company. The facility in the parent company should count all employees in the parent company. In contrast, the facility in the subsidiary should count only employees in the parent company that work for affiliates of the subsidiary facility (i.e., facilities required to register). Note that both facilities should count all of the employees in the subsidiary either because they work for a subsidiary (from the perspective of the facility in the parent company) or because they work for the legal entity that the facility is a part of (from the perspective of the facility in the subsidiary).

An example is shown below in Figure 1. Company A owns Company B, Company C, and Company D.

- For Facility X, the business comprises all of the employees of Company A (including the employees working at Facility X and the other employees of Company A), plus all of the employees of Companies B, C, and D, which are subsidiaries of the legal entity that Facility X is part of (Company A).
- For Facility Y, the business comprises the employees of Company B (i.e., the employees of Facility Y) and the employees working at Facilities X, Z1, and Z2, which are affiliates of Facility Y. No employees of Company C are counted because Company C cannot include any affiliates because it does not have any facilities. Employees of Company A that are not working at Facility X are not counted because Company A is not a subsidiary of Company B (Company B does not own or control Company A), nor can all of Company A be considered an affiliate because Company A has employees who do not work at a facility. Employees of Company D that are not working at Facilities Z1 or Z2 are not counted because Company D is not a subsidiary of Company B, nor can all of Company D be considered an affiliate because Company D has employees who do not work at a facility.
- For Facility Z1, the business comprises the employees of Company D (including the employees working at Facilities Z1 and Z2 and the other employees of Company D) plus the employees working at Facilities X and Y, which are affiliates of Facility Z1. No employees of Company C are counted because Company C cannot include any affiliates because it does not have any facilities. Employees of Company A that are not working at Facility X are not counted because Company A is not a subsidiary of Company D (Company D does not own or control Company A), nor can all of Company A be considered an affiliate because Company A has employees who do not work at a facility. The business size calculation would be the same for Facility Z2.

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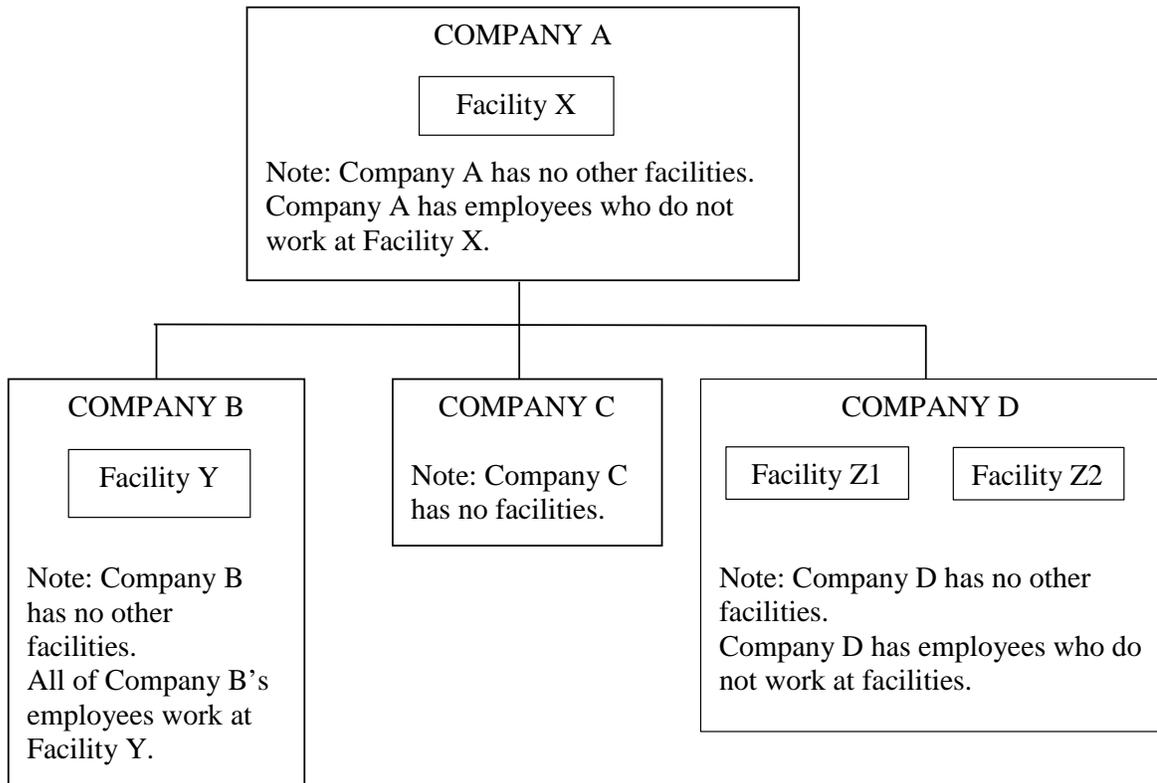


Figure 1

B.3 What food facilities are required to register?

Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. See 21 CFR 1.225 (“Who must register under this subpart?”) and 21 CFR 1.226 (“Who does not have to register under this subpart?”) and generally “Registration of Food Facilities” at <https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm>.

B.4 What are examples of legal entities that the food facility may be a part of?

Examples of a legal entity include limited liability companies, corporations, S corporations, sole proprietorships, partnerships, and cooperatives. A facility can be part of any legal entity. For example, a facility may be a division (or part of a division) of a corporation.

B.5 How do you calculate the number of FTEs?

As noted in Question A.2, the number of FTEs is calculated by dividing the total number of hours of salary or wages paid directly to employees by 2,080 hours (the number of hours of work in one year). If the result is not a whole number, round down to the next lowest whole number.

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Example B.5.1: Calculating the number of FTEs and rounding down

Your facility is part of a corporation. The corporation has 100 full-time employees who each work 40 hours per week (2,080 hours per year). It also has 150 part-time employees who each work 30 hours per week (1,560 hours per year) and 200 part-time employees who work 20 hours per week (1,040 hours per year). The corporation also has 100 seasonal workers that each work 40 hours per week for 13 weeks (520 hours per year).

Step 1. Calculate the hours for all your full-time employees.

$$100 \times 2,080 \text{ hours} = 208,000 \text{ hours}$$

Step 2. Calculate the hours for all your part-time employees.

$$(150 \times 1,560 \text{ hours}) + (200 \times 1,040 \text{ hours}) = 234,000 + 208,000 = 442,000 \text{ hours}$$

Step 3. Calculate the hours for all your seasonal employees.

$$100 \times 520 \text{ hours} = 52,000 \text{ hours}$$

Step 4. Add all the hours of your full-time, part-time, and seasonal employees.

$$208,000 \text{ hours} + 442,000 \text{ hours} + 52,000 \text{ hours} = 702,000 \text{ hours}$$

Step 5. Divide the total number of hours by 2,080 hours.

$$702,000 \text{ hours} \div 2,080 \text{ hours} = 337.5 \text{ FTEs}$$

If the corporation has no subsidiaries and/or affiliates, you are done with the FTE calculation. Round down to the next whole number. Since your facility is a business with 337 FTEs, it is a small business for purposes of part 117 and part 507.

B.6 Which employees should you count?

Example B.6.1: Counting FTEs when your facility's parent company is not a facility

Your facility is a company that manufactures food ingredients and is a subsidiary (Subsidiary A) of a parent company. Your facility is required to register with FDA under section 415 of the FD&C Act. Your parent company has two other subsidiaries (Subsidiary B and Subsidiary C) that manufacture other types of food ingredients and are also required to register. However, your parent company does not manufacture/process, pack, or hold food for consumption in the United States and therefore is not required to register with FDA. For purposes of calculating the total number of FTEs for your business, you must determine the total number of hours for all the employees in your company (Subsidiary A), as well as Subsidiary B and Subsidiary C, but you do not need to count the hours for the employees at the parent company because it is neither a subsidiary nor an affiliate of your facility. The parent company is not a subsidiary of Subsidiary A because Subsidiary A does not own or control the parent company; the reverse is true. And no part of the parent company can be an affiliate of Subsidiary A because the parent company does

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not include any registered facilities. However, Subsidiaries B and C are affiliates of Subsidiary A because they are facilities and are all under common control by the parent company.

Example B.6.2: Counting FTEs for franchisees that are facilities

Your water bottling facility (Franchisee A) is a franchisee of the company Water-Water and is made up of 400 full-time employees who each work 40 hours per week (2,080 hours per year). Water-Water has two other franchisees (Franchisee B and Franchisee C) that also bottle water and have 350 and 275 full-time employees, respectively. Included within the Water-Water company is a bottled water operation with 150 full-time employees. All of the franchisees are facilities required to register. Water-Water's water bottling operation also is a facility required to register. Each of the four entities will only need to count their own employees because there are no subsidiaries or affiliates (i.e., there are no ownership, control, or common control relationships). Therefore, your facility (Franchisee A) is a small business because it has 400 full-time-equivalent employees.

Example B.6.3: Determining the legal entity and counting FTEs for a farm mixed-type facility

Your farm mixed-type facility is legally organized as a partnership. It is also a member of a cooperative, which is a separate legal entity. The cooperative sells processed farm products including jams, jellies, baked goods, and fresh-cut produce that are made by the farm mixed-type facilities that form the cooperative. In addition to your facility, the cooperative also consists of two other members (farm mixed-type facilities), a sales division, a marketing division, and an accounting division. Step 3 in Question B.1 has you calculate the number of FTEs in the legal entity of which the facility is part. For purposes of determining which employees to include in the FTE calculation, you should add the hours for all employees of your partnership (including farm workers) but not those in the cooperative because the cooperative is a separate legal entity that is neither a subsidiary (i.e., it is not owned or controlled by your farm mixed-type facility) nor an affiliate (i.e., it is not a facility that controls, is controlled by, or is under common control with your farm mixed-type facility) of the partnership.

B.7 Should you account for employees that are not engaged in food activities covered by parts 117 or 507?

Yes, all employees of the legal entity that includes the facility, as well as its subsidiaries and affiliates, should be counted regardless of whether they are engaged in covered food activities. Examples of non-food activities employees could be engaged in include retail operations, management, accounting, or marketing.

Example B.7.1: Counting FTEs not manufacturing/processing, packing, or holding food

Your corporation (Soup Co.) includes two facilities that manufacture soup. In addition, Soup Co. has divisions for sales and marketing that are separate from either facility. When calculating

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the business size for either facility, you should include all of the employees of the legal entity (Soup Co.) that includes the facility and therefore should include employees in the sales and marketing divisions.

Example B.7.2: Counting FTEs in a more complex example

Your facility, which manufactures food, is a division of Healthy Foods Markets, Inc., a small retail chain that has 3 retail stores. See the diagram below, figure 2. In figure 2, FT represents full-time employees and PT represents part-time employees.

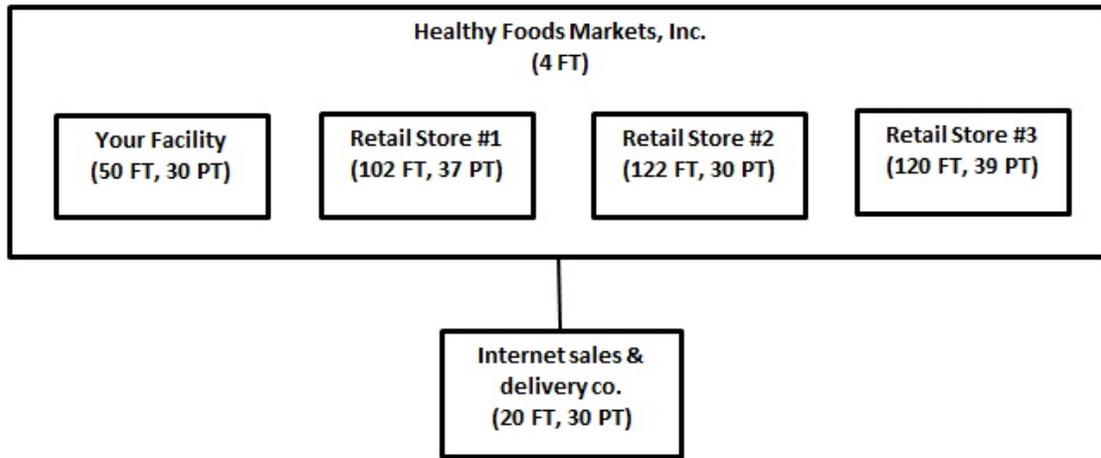


Figure 2

Your facility manufactures deli salads, sandwiches, soups, salsas, dips and cut produce for the 3 retail stores. Your facility has 50 full-time employees (40 hours per week, 2,080 hours per year) plus 30 part-time employees that work 25 hours per week (1,300 hours per year). The retail stores generally employ 100-125 full-time employees and 30-40 part-time employees (20 hours per week), with current employees shown in Table 1. The corporation has 4 additional full-time employees that are not part of a facility or a retail store. Healthy Foods Markets, Inc. also has a subsidiary that operates a home delivery service and makes Internet sales that employs 20 full-time sales representatives and 30 part-time (30 hours per week) delivery drivers.

Table 1. Retail Store Employees of Healthy Foods Markets

Retail Store	Full-time employees (40 hours / week)	Part-time employees (20 hours/week)
1	102	37
2	122	30

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3	120	39
Total	344	106

Step 1. Determine the legal entity the facility is a part of. The facility is a division of the legal entity Healthy Foods Markets, Inc.

Step 2. Calculate the hours for the full-time and part-time employees of Healthy Foods Markets, Inc.

First, calculate the hours for the full-time and part-time employees at your manufacturing facility.

$$(50 \times 2,080 \text{ hours}) + (30 \times 1,300 \text{ hours}) = 104,000 \text{ hours} + 39,000 = 143,000 \text{ hours}$$

Next, calculate the hours for the employees of Healthy Food Markets, Inc. who are not employees at your manufacturing facility or at the retail stores.

$$4 \times 2,080 \text{ hours} = 8,320 \text{ hours}$$

Next, calculate the hours for the full-time and part-time employees at each retail store.

Table 2. Calculation of Hours for Retail Employees of Healthy Foods Markets, Inc.

Retail Store	Full-time employee hours (2,080 hours/year)	Part-time employee hours (1,040 hours/year)	Total hours/year
1	102 x 2,080 = 212,160 hours	37 x 1,040 = 38,480 hours	250,640 hours
2	122 x 2,080 = 253,760 hours	30 x 1,040 = 31,200 hours	284,960 hours
3	120 x 2,080 = 249,600 hours	39 x 1,040 = 40,560 hours	290,160 hours
Total			825,760 hours

Add the hours for all the employees of Healthy Foods Markets, Inc.

$$143,000 \text{ hours} + 8,320 \text{ hours} + 825,760 \text{ hours} = 977,080 \text{ hours}$$

Step 3. Calculate the hours for the subsidiary.

$$(20 \times 2,080 \text{ hours}) + (30 \times 1,560 \text{ hours}) = 41,600 \text{ hours} + 46,800 \text{ hours} = 88,400 \text{ hours}$$

Step 4. Add the hours for all the employees of Healthy Foods Markets, Inc. and its subsidiary.

$$977,080 \text{ hours} + 88,400 \text{ hours} = 1,065,480 \text{ hours}$$

Step 5. Divide the total number of hours by 2,080 hours.

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1,065,480 hours ÷ 2,080 hours = 512.25 FTEs (round down to 512).

Since your facility is a business with a total of 512 FTEs, it is NOT a small business for purposes of part 117. (If this were an animal food business, it would not be a small business for purposes of part 507, instead.)

C. Implications of Being a Small Business Under Parts 117 and 507

C.1 Are there any exemptions for small businesses?

A small business that is a farm mixed-type facility is exempt from the human food preventive controls requirements (21 CFR part 117, subparts C and G) if the only activities that it conducts that would be subject to the preventive controls requirements in 21 CFR part 117 are the low-risk activity/food combinations listed in 21 CFR 117.5(g) and (h).

Similarly, a small business that is a farm mixed-type facility is exempt from the animal food preventive controls requirements (21 CFR part 507, subparts C and E) if the only activities that it conducts that would be subject to the preventive controls requirements in 21 CFR part 507 are the low-risk activity/food combinations listed in 21 CFR 507.5(e) and (f).

C.2 What are the compliance dates for small businesses?

FDA established staggered compliance dates based on business size for parts 117 and 507. The compliance date for a small business facility subject to 21 CFR part 117 was September 18, 2017. The compliance date for a small business facility subject to 21 CFR part 507 was September 18, 2017, for the CGMP requirements and September 17, 2018, for the animal food preventive controls requirements. Certain provisions of parts 117 and 507 were extended by a final rule published in the *Federal Register* on August 24, 2016, 81 FR 57784 and/or are the subject of an enforcement discretion policy (“Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry”) issued January 4, 2018.