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# **Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry**

## ***Draft Guidance***

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

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

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# **Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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

## **I. Introduction**

The purpose of this guidance is to help you to determine whether the activities that you perform are within the “farm” definition. The regulatory framework for determining whether your business is a “farm” depends in large part on certain definitions (i.e., the definitions for “farm,” “mixed-type facility” (including a “farm mixed-type facility”), “harvesting,” “packing,” “packaging,” “holding” and “manufacturing/processing”) that are established in our regulation for Registration of Food Facilities (21 CFR part 1, subpart H).<sup>2</sup> For your convenience, we copied these definitions that are established in [21 CFR 1.227](#) into sections II.B and II.C of this guidance.

The guidance includes several examples of hypothetical operations that conduct various activities. We developed the hypothetical examples to make certain points about the regulatory framework for determining whether the activities that you perform are within the “farm” definition. To make these points, in some cases our hypothetical examples describe activities that may not be common in today’s farming operations. It would not be possible to address every conceivable circumstance that may be relevant to determining whether the activities that

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<sup>1</sup> 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.

<sup>2</sup> The definition of “manufacturing/processing” includes “packaging” as an example of a “manufacturing/processing” activity. In this guidance, we often discuss packaging separately from manufacturing/processing even though packaging is a manufacturing/processing activity. This is because “packaging” is common on farms and the “farm” definition specifically provides for “packaging” as a manufacturing/processing activity that is within the “farm” definition.

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you perform are within the “farm” definition. However, our intent was to provide information that will be helpful to you in evaluating your own operations.

Determining whether the activities you perform are within the “farm” definition plays a key role in determining whether your business is exempt from registration as a food facility under Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d) and 21 CFR 1.226(b) because your business is a “farm.”<sup>3</sup> Farms are not subject to the requirements for hazard analysis and risk-based preventive controls (in 21 CFR part 117 for human food and in 21 CFR part 507 for animal food), which apply only to facilities required to register.<sup>4</sup> Some key provisions in our regulation for Registration of Food Facilities applicable to determining whether your operation is a facility that is required to register are:

- [21 CFR 1.225](#) – Who must register under this subpart?
- [21 CFR 1.226](#) – Who does not need to register under this subpart?
- [21 CFR 1.227](#) – What definitions apply to this subpart?

We intend to provide additional guidance relating to our regulation for Registration of Food Facilities in the near future.

This guidance is also intended for you if your business is a farm mixed-type facility required to register, to help you determine which activities that you perform are outside the “farm” definition and therefore potentially subject to the requirements for hazard analysis and risk-based preventive controls (in 21 CFR part 117 for human food and in 21 CFR part 507 for animal food)<sup>4</sup> and/or the requirements for Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR 121).

This guidance is also intended for you if you need to determine whether you are exempt from:

- Current good manufacturing practice (CGMP) requirements for human food (in 21 CFR Part 117, Subpart B) or for animal food (21 CFR Part 507, Subpart B), based on:
  - the exemptions for farms and the activities of farm mixed-type facilities that fall within the definition of “farm” in 21 CFR 117.5(k)(1)(i) (as limited by 21 CFR 117.5(k)(2)), 21 CFR 117.5(k)(1)(iv), and 21 CFR 507.5(a);
  - the exemptions for establishments that are “solely engaged” in the holding and/or transportation of one or more raw agricultural commodities (RACs) in 21 CFR 117.5(k)(iii) and 21 CFR 507.5(h)(1);
  - the exemptions for establishments that are “solely engaged” in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) in 21 CFR 117.5(k)(1)(v) and 21 CFR 507.5(h)(2);

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<sup>3</sup> There are other exemptions from the facility registration requirement in addition to the exemption for farms. See 21 CFR § 1.226. The applicability of these other exemptions are outside the scope of this guidance, which relates only to the exemption for farms in § 1.226(b).

<sup>4</sup> There are various exemptions from the hazard analysis and preventive controls requirements potentially available to facilities required to register. See 21 CFR §§ 117.5, 117.7, 507.5, 507.10, and 507.12). The applicability of many of these exemptions is outside the scope of this guidance.

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- the exemption for establishments that are “solely engaged” in ginning of cotton (without additional manufacturing/processing, such as extracting oil from cotton seed) in 21 CFR 507.5(h)(3); and/or
- Requirements for hazard analysis and risk-based preventive controls in 21 CFR Part 117, Subparts C and G (for human food) or 21 CFR Part 507, Subparts C and E (for animal food), and certain modified requirements (such as 21 CFR 117.201 or 21 CFR 507.7) based on the exemptions for:
  - on-farm packing or holding of food by a small or very small business, if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are identified low-risk activity/food combinations in 21 CFR 117.5(g) and 21 CFR 507.5(e);
  - on-farm manufacturing/processing of food for distribution into commerce by a small or very small business, if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are identified low-risk activity/food combinations in 21 CFR 117.5(h) and 21 CFR 507.5(f);
  - facilities that are “solely engaged” in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing in 21 CFR 117.5(j) and 21 CFR 507.5(g); and/or
  - facilities that are “solely engaged” in the storage of unexposed packaged food (with modified requirements where the food requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, pathogens) in 21 CFR 117.7 and 21 CFR 507.10.

In general, this guidance is directed at classification of activities associated with crops (plants or plant products) rather than with animal products. However, some of the information in this guidance may be of interest to you if you produce shell eggs. For example, you may find it useful to know that “washing” can be classified as a “harvesting,” “packing,” or “manufacturing/processing” activity. Likewise, some of the information in this guidance may be of interest to you if you raise game animals. For example, you may find it useful to know that we classify slaughtering and smoking as “manufacturing/processing” activities.

This guidance is intended to help you determine which activities that you perform are within the “farm” definition. It is not directed to interpreting other aspects of the “farm” definition (such as an interpretation of “under one management” or “in one general (but not necessarily contiguous) physical location”), or other definitions in our regulation for Registration of Food Facilities (such as “retail food establishment”), even though these other aspects and definitions may be relevant to determining whether your business must register as a food facility and the applicability of other requirements, such as those in 21 CFR Parts 112, 117, and 507. Certain aspects of the “farm” definition, such as “under one management” and “in one general (but not necessarily contiguous) physical location,” are very fact-specific, and therefore we are not issuing guidance focused on these topics at this time but are instead addressing them on a case-by-case basis. However, some of the examples we provide in this document do describe operations in terms of both management and/or location. You may find these examples helpful in understanding these aspects of the “farm” definition.

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

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viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **II. Background on Farm-Related Definitions**

### **A. Rulemaking to Revise Farm-Related Definitions**

Section 103(c) of the FDA Food Safety Modernization Act (FSMA) directed us to conduct rulemaking to clarify the on-farm activities that would, in part, determine when an establishment is required to register with us as a “facility,” or is not required to register with us because the establishment is a “farm.” To do so, we conducted rulemaking to revise and add farm-related definitions to our existing regulation for Registration of Food Facilities in the same rulemaking documents that we issued to establish Part 117, containing the CGMP and preventive controls requirements for human food. (See the final rule at 80 FR 55908, September 17, 2015.) For the purposes of this guidance, we call that rulemaking “the farm definition rulemaking.” The farm definition rulemaking:

- Revised the “farm” definition to provide for two types of farms:
  - Primary production farms; and
  - Secondary activities farms;
- Revised three definitions associated with the “farm” definition (i.e., the definitions of “packing,” “holding,” and “manufacturing/processing”) and added more examples of activities in each of these definitions; and
- Established a new definition associated with the “farm” definition (i.e., the definition of “harvesting”) and included examples of harvesting activities in the definition.

### **B. Definitions of “Farm” and “Mixed-Type Facility”**

The following definitions of “farm” and “mixed-type facility” are excerpts from our updated regulation for Registration of Food Facilities as published in the Title 21 of the Code of Federal Regulations, part 1, subpart H (21 CFR 1.227). The “farm” definition is formatted according to styles associated with the Code of Federal Regulations, including numbering styles not otherwise associated with this document.

*Farm* means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

- (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(I) of this definition; and

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(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm 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. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraph (1)(ii) and (iii) of this definition.

*Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

We note that one result of the farm definition rulemaking is that there are two types of farms – “primary production farm” and “secondary activities farm.” We provided for these two types of farms to reflect the current reality of what it means to be a farm. For example, the two types of farms provide for a packinghouse that is managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual primary production farms) to be within the “farm” definition under certain circumstances. For a fuller discussion of our reasons for revising the “farm” definition to provide for two types of farms, see Comment and Response 25 in the farm definition rulemaking (80 FR 55908 at 55927-55929).

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**C. Definitions of “Harvesting,” “Packing,” “Packaging,” “Holding,” and “Manufacturing/Processing”**

The following definitions of “harvesting,” “packing,” “packaging,” “holding,” and “manufacturing/processing” are excerpts from our updated regulation for Registration of Food Facilities as published in the Title 21 of the Code of Federal Regulations, part 1, subpart H (21 CFR 1.227).

*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

*Packing* means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

*Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

*Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating,



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labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

#### **D. Manufacturing/Processing Activities That Are Allowed Within the Farm Definition**

A key factor in whether your business is a “farm” is whether the activities you perform fall within the activities that we included in the “farm” definition. You can do the following manufacturing/processing activities and still be within the “farm” definition, as long as you don’t do manufacturing/processing that goes beyond these activities:

- Drying/dehydrating raw agricultural commodities (RACs) to create a distinct commodity (such as drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling the dried/dehydrated commodities, without additional manufacturing/processing activities (such as chopping or slicing the fresh or dried herbs);
- Treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas), and packaging and labeling the treated RACs, without additional manufacturing/processing activities (such as by chopping or slicing the untreated or treated RACs); and
- Packaging and labeling RACs, without additional manufacturing/processing activities (such as by irradiating the RACs or packaged RACs).

#### **E. “Packing,” “Packaging,” and Stickers/Labeling Activities That Are Allowed Within the “Farm” Definition**

Note that our definitions distinguish between “packing” and “packaging.” The first key distinction is that we use the term “packaging” to mean placing food into a container that directly contacts the food and that the consumer<sup>5</sup> receives, but we use the term “packing” when food is placed into containers that are not consumer containers. For example, placing strawberries into consumer containers that directly contact the food (e.g., plastic “clamshells”) is “packaging,” but placing apples into boxes and sending them to distribution centers or retailers is “packing.” The second key distinction is that we classify “packaging” as a manufacturing/processing activity, but we do not classify “packing” as a “manufacturing/processing” activity.

Importantly, one of the changes we made during the farm definition rulemaking is to allow “packaging” RACs to be within the “farm” definition even though packaging is a manufacturing/processing activity. As a result, if you place RACs into a container, it makes no difference whether that activity is “packing” or “packaging” the RACs – for the purpose of determining whether your business is a “farm,” you can do either. Refer to section II.B of this guidance for the “farm” definition at (1)(i) (packing RACs); (1)(iii)(B)(3) (packaging RACs);

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<sup>5</sup> The term “consumer” does not include businesses. For example, pet owners and other individuals purchasing animal food from a retail facility are consumers but a farm operation purchasing animal food for its livestock is not a consumer. See 68 FR 58894 at 58914.

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and (2) (Secondary Activities Farms may pack RACs and conduct the same additional activities in (1)(iii) as a Primary Production Farm).

Similarly, we consider labeling, including stickering, to be a “manufacturing/processing” activity. However, you can also place labels (e.g., stickers) directly on RACs, on boxes or other containers holding packed RACs, or on consumer packages containing RACs, and still be within the “farm” definition. See “farm” definition at (1)(iii)(B)(3) (labeling RACs).

By contrast, however, packaging and labeling of processed foods is “manufacturing/processing” that is not specifically included within the “farm” definition (see “farm” definition at (1)(iii)(B)) unless done for consumption on farm (see “farm” definition at (1)(iii)(A)) or performed on certain types of dried/dehydrated processed foods specified in the farm definition (see “farm” definition at (1)(iii)(B)(1)). Also, only certain “packing” of processed foods is within the farm definition. See “farm” definition at (1)(ii) (packing of processed foods limited to processed foods consumed on that farm or another under the same management, and processed foods identified in (1)(iii)(B)(1)). See Table 1 for a summary of those “packing,” “packaging,” and “stickering/labeling” activities that are within the “farm” definition and those “packing,” “packaging,” and “stickering/labeling” activities that are not within the “farm” definition.

**Table 1. Summary of “Packing,” “Packaging,” and “Stickering/Labeling” Activities**

	<b>Packing</b>	<b>Packaging</b>	<b>Stickering/labeling</b>
RAC	Within the “farm” definition	Within the “farm” definition	Within the “farm” definition
Processed food	Not within the “farm” definition, unless consumed on that farm or another farm under the same management, or is performed on processed food identified in (1)(iii)(B)(1)	Not within the “farm” definition, unless consumed on that farm or another farm under the same management, or is performed on processed food identified in (1)(iii)(B)(1) with no additional manufacturing/processing	Not within the “farm” definition, unless consumed on that farm or another farm under the same management, or is performed on processed food identified in (1)(iii)(B)(1) with no additional manufacturing/processing

## **F. Distinguishing “Blending” Activities from “Mixing” Activities**

For the purposes of this guidance, we use the term “blending” when the foods involved are the same. One example of a type of food that is blended is grain, such as wheat. For example, we consider the activity of “blending” different lots of wheat to meet a customer’s quality specifications to be a practical necessity for product distribution and, thus, to be within the definition of “holding” (see 79 FR 58524 at 58537, and 80 FR 55908 at 55933). Holding RACs is within the “farm” definition (see “farm” definition at (1)(i) and (2)) and therefore blending lots of the same RAC on a farm does not make an operation a facility required to register.

For the purposes of this guidance, we use the term “mixing” when the foods involved are different. Depending on the circumstances, mixing can be classified in different ways.

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For example, we consider the activity of “mixing” corn and oats in the production of animal food, or mixing various seeds to produce bird food, to be manufacturing/processing, because the animal food produced by mixing ingredients is a processed food (see 79 FR 58524 at 58537, and 80 FR 55908 at 55933). Because this type of manufacturing/processing is not specifically included in the “farm” definition (see “farm” definition at (1)(iii)(B)), this kind of mixing makes an operation a facility required to register (unless an exemption applies).

On the other hand, when mixing different intact RACs together does not create a processed food, we classify such mixing as part of “packing,” “packaging,” or “holding,” as applicable. For example, we classify the activity of mixing intact produce RACs (such as oranges and grapefruit) in a packing container such as a box for further distribution as “packing” the RACs. We classify mixing intact produce RACs (such as apples, oranges, and tangerines) in a net bag that directly contacts the food and that a consumer would receive, and mixing three different colored intact bell pepper RACs in a plastic bag that directly contacts the food and that a consumer would receive, “packaging” the RACs. These activities are within the “farm” definition and therefore these kinds of mixing of RACs on a farm do not make an operation a facility required to register.

## **III. Discussion**

### **A. Significance of Activity Classification**

The regulatory text of each definition associated with the farm definition includes examples of activities included within that definition. Importantly, the fact that we included a particular activity in one definition does not mean that it cannot also be included as an example in another definition. Depending on the circumstances, activities may be classified in different ways, and there may even be more than one possible classification of an activity for a single circumstance. We recommend that, in considering classification of an activity, businesses consider first whether the activity is growing (for farms) or fits the definition of “harvesting,” “packing,” or “holding.” If the activity is not growing and does not fall within one or more of the “harvesting,” “packing,” or “holding” definitions, the activity is likely to be “manufacturing/processing.” There are various limitations on growing, harvesting, packing, and holding. By contrast, the definition of manufacturing/processing is very broad, capturing anything that does not fall within one or more of the other definitions. The limitations on growing, harvesting, packing, and holding, compared to the breadth of manufacturing/processing, help explain why some activities may be classified in different ways depending on the specific situation.

For example, we included “trimming of outer leaves” as an example in the definition of “harvesting,” but we also included “trimming” as an example in the definition of “manufacturing/processing.” This is because trimming RACs can be harvesting when done on a farm (whether this is done in the growing area or elsewhere on a farm, such as in a packing house), or can be manufacturing/processing, for example, when done during the production of processed produce (such as fresh-cut mixed salad greens) in a food processing facility. We also consider that “trimming” can in some cases fit the definition of “packing,” both on and off-farm, when trimming is incidental to packing (i.e., when it is done for the purpose of safe or effective packing of food). This is true even though we did not include “trimming” as an example of a

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“packing” activity in the definition. For example, if a RAC must be trimmed before the RAC is packed in a container to remove damaged portions that could promote pathogen growth, or if part of the RAC (e.g., foliage, husks, roots or stems) must be removed to pack only the desired RAC in the container, such trimming may be incidental to packing. On the other hand, if an operation trims a RAC such as a head of lettuce to remove damaged portions before the operation washes the lettuce, chops it, bags the chopped lettuce in consumer packages, and then packs the bags into shipping boxes, the trimming in this case would not be incidental to packing. Other activities performed by the operation after the trimming make clear that the purpose of the trimming is not merely for safe or effective packing. For example, the intervening chopping, which is a manufacturing/processing activity, prevents the trimming from being considered incidental to packing.

The definition of “manufacturing/processing” specifies that, “[f]or farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.” This means that because trimming on a farm may be “harvesting” or (in some cases) “packing,” it is not “manufacturing/processing” in such cases. Off-farm, trimming may be “packing” as described above, and is otherwise likely to be “manufacturing/processing” when it does not fit the definition of “packing.”

For a farm mixed-type facility, activity classification is relevant to determining which activities are within the “farm” definition, and which activities are not within the “farm” definition and therefore make an operation a facility required to register (unless an exemption applies), and which may in turn be subject to CGMP and/or preventive controls requirements (as applicable) under Parts 117 or 507. For example, if you grow apples for human food, harvest the apples, and manufacture/process the apples by slicing them, your operation is a “farm mixed-type facility” and you must register as a food “facility” (unless an exemption applies) because you are performing manufacturing/processing that is outside the “farm” definition (i.e., slicing apples). The growing and harvesting activities are within the “farm” definition and, thus, are not subject to the preventive controls requirements in Part 117 (see 78 FR at 3677 (Jan. 16, 2013), and 21 CFR 117.5(f), (g)(1), and (h)(1)). In addition, those activities are exempt from the CGMP requirements in Part 117 (Subpart B) under 21 CFR 117.5(k)(1)(iv). On the other hand, your apple growing and harvesting activities are potentially subject to the produce safety requirements in Part 112 (as applicable). In addition, the manufacturing/processing activity of slicing the apples is potentially subject to the CGMP and preventive controls requirements of Part 117 (as applicable). Apple culls and cores resulting from the production of human food that are by-products for animal food use may be subject to the CGMP and preventive controls requirements of Part 507 (or the holding and distribution provision of 21 CFR 117.95, if the by-product meets the requirements of 21 CFR 507.12).

For an establishment (such as a warehouse) that performs activities on RACs but is not a “farm,” the activity classification can have important consequences beyond making the establishment a facility required to register. For example, under 21 CFR 117.5(j) and 507.5(g) for human food and animal food, respectively, a facility that is solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing is not subject to the requirements for hazard analysis and risk-based preventive controls in those regulations. In this case, the facility would need to determine whether all the activities it performs fall within the definition of “holding.” As an example, depending on the activities performed at the facility, as discussed in section II.F of this guidance, the difference between “blending” (which is an

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example of a “holding” activity), “mixing” that creates a processed food (which is an example of a “manufacturing/processing” activity), and “mixing” that does not create a processed food (which may be “packaging,” “packing,” or “holding,” depending on the circumstances) could be relevant in determining whether the requirements for hazard analysis and risk-based preventive controls are applicable. As another example, an establishment can be exempt from CGMP requirements if it is solely engaged in hulling, shelling, drying, packing, and/or holding nuts<sup>6</sup> (without additional manufacturing/processing, such as roasting nuts) (21 CFR 117.5(k)(1)(v) and 507.5(h)(2) for human and animal food, respectively). In this case, to determine whether the CGMP requirements apply, the facility would need to determine whether the activities it performs (in addition to hulling, shelling, and drying) are included in the definitions of “packing” or “holding.”

Some farm operations use different terms (such as “post-harvest,” “pre-packing,” or “post-packing”) for some of the activities we classify as “harvesting,” “packing,” “packaging,” or “holding.” While farms may classify activities for their own purposes, our definitions for regulatory purposes may not align with how farms think of various activities for non-regulatory purposes. In particular, our definition of “harvesting” may be broader than what many farms or other businesses think of as harvesting. Our definition of harvesting is not limited to the act of, for example, gathering RACs from a growing area (e.g., picking apples off of trees), but also includes activities traditionally performed on farms for purposes of removing RACs from the place they were grown or raised and preparing them for use as food. This breadth is intended to reflect the reality of what it means to be a farm. See section III.B of this guidance for examples of activities that can be classified as “harvesting.” On the other hand, our definitions of “packing” and “holding” may be narrower than what some businesses consider to be packing or holding. Our emphasis on the definitions we have established in the relevant regulations is important to preserve the intended scope and applicability of various regulatory requirements.

During the farm definition rulemaking, we received comments asking us to classify several specific activities so that an operation that performs these activities can determine whether performing that specific activity is within the “farm” definition. To address these questions, in the remainder of this guidance we:

- Provide examples of “harvesting,” “packing,” “packaging,” “holding,” and “manufacturing/processing” activities in addition to those examples established in the definitions in our regulation for Registration of Food Facilities;
- Explain why some activities (such as washing RACs) are classified in more than one way;
- Provide some examples explaining which activities would be within the “farm” definition, and which activities would not, for hypothetical farms, farm mixed-type facilities, and facilities conducting various activities.

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<sup>6</sup> For animal food, the exemption in 21 CFR 507.5(h)(2) includes “hulling, shelling, drying, packing, and/or holding nuts and hulls.”

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#### **B. Activities Classified as “Harvesting”**

Note that the definition of “harvesting” makes this definition applicable only to farms and farm mixed-type facilities.

Importantly, as defined, “harvesting” relates to a place where RACs were grown or raised. The examples in this section are primarily intended to demonstrate how the definition of “harvesting” requires connection to such a place, and the type and degree of connection that is sufficient. The examples in this section focus on a single activity – washing apples – to illustrate the impact of changes to the type and degree of the connection to a place where RACs were grown or raised.

As we noted in section III.A, activities may be classified in different ways, and there may even be more than one possible classification of an activity for a single circumstance. In this section of this document, we focus on circumstances in which an activity could be classified as “harvesting,” even if the activity could also be classified another way under the same circumstances (for example, as “packing,” as shown in these examples).

- Operation A grows and harvests apples in one general physical location, so Operation A is a primary production farm. Operation A also washes the apples as they are removed from the trees, in the growing area. The washing can be classified as “harvesting” because it is occurring on a farm in the same general physical location as where the apples were grown. (In addition, if some or all of Operation A’s washing is performed for the safe or effective packing of the apples (e.g., to prevent unwanted debris from being packed along with the apples), the washing may also be classified as “packing.” Because both harvesting RACs and packing RACs are inside the farm definition, the overlap has no practical consequence for Operation A’s regulatory status.)
- Operation B grows and harvests apples in one general physical location, so Operation B is a primary production farm. Operation B also washes the apples in a packing house that is separate from the growing area but still on the same farm. The washing can be classified as “harvesting” because it is occurring on a farm in the same general physical location as where the apples were grown. (In addition, if some or all of Operation B’s washing is performed for the safe or effective packing of the apples, the washing may also be classified as “packing.”)
- Operation C grows and harvests apples in one general physical location, so Operation C is a primary production farm. Operation C also washes the apples in a packing house that is separate from the growing area but still on the same farm. It also receives apples from another farm under separate management and washes those apples in the same packing house. The washing can be classified as “harvesting.” For the apples the operation grew, this is because the washing is occurring on a farm in the same general physical location as where the apples were grown. For the other farm’s apples, this is because the washing is occurring on a farm in the same general physical location where the farm’s own RACs were grown or raised, and we have removed distinctions from the farm definition that limited what activities farms could perform on RACs from other farms. An activity a farm performs on others’ RACs can be classified the same way as the same activity would be classified when performed on the farm’s own RACs. (In addition, if some or all of Operation C’s washing is performed for the safe or effective packing of the apples, the

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washing may also be classified as “packing.” This is true for both the apples Operation C grew and those received from other farms.)

- Operation D does not grow any apples (or grow/raise any other RACs) but receives apples from multiple farms under separate management and washes them. The operation is majority owned by the primary production farms that grow the majority of the apples it washes. Operation D is a secondary activities farm. While the washing in this case does not take place in the same general physical location as where any of the apples (or any other RACs) were grown, this is the type of arrangement FDA intended to establish as within the farm definition through the addition of secondary activities farms to that definition. Thus, we consider that in such cases, the criteria in the secondary activities farm definition linking the farms where the RACs were grown to the secondary activities farm (through both the RACs themselves and the majority ownership requirement) make it appropriate to classify such an operation’s washing of apples as “harvesting” even though it is not done in the same general physical location as where the apples (or any other RACs) were grown. (In addition, if some or all of Operation D’s washing is performed for the safe or effective packing of the apples, the washing may also be classified as “packing.”)
- Operation E does not grow any apples (or grow/raise any other RACs) but receives apples from multiple other farms under separate management and washes them. The operation is **not** majority owned by the primary production farms that supply the apples it washes and therefore Operation E is not a secondary activities farm. In this case, the washing cannot be classified as “harvesting” because it is not performed on a farm in the same general physical location as where the apples or other RACs were grown or raised, and the criteria in the secondary activities farm definition that might otherwise satisfy the needed connection are not met. If some or all of Operation E’s washing is performed for the safe or effective packing of the apples, the washing may be classified as “packing.” Otherwise, this washing should be classified as “manufacturing/processing.” Regardless of whether the washing is classified as “packing” or “manufacturing/processing,” Operation E is a facility that is required to register (unless an exemption applies), and it may be subject to Part 117 (unless an exemption applies). Also, this operation is not a primary production farm that only harvests apples based on an argument that washing can be classified as “harvesting” in some cases where washing is not done in the same general physical location as where those specific RACs were grown or raised (such as for Operations C and D above). FDA considers “harvesting” to be limited to the general physical locations of farms (and farm mixed-type facilities) where RACs are grown or raised, except for operations meeting the specific criteria required to be secondary activities farms. The definition of “harvesting” is not so limited that it applies only to the specific RACs grown on a single farm (see Operation C above), but it is not so extensive as to allow any activity that might be considered “harvesting” on a farm to bring an operation that does not grow crops/raise animals, or harvest RACs in the same general physical location where they were grown or raised, into the farm definition.
- Operation F travels to farms under separate management to wash apples on-site at the growing farm. Sometimes the washing is done in the field where the apples were grown, and sometimes it is done elsewhere on the growing farm (not in the growing area but still in the same general physical location where the apples were grown). Operation F is **not**

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majority owned by the primary production farms that supply the apples it washes and therefore Operation F is not a secondary activities farm. In this case, the washing can be classified as “harvesting” because it is performed on farms (the growing farms) in the same general physical locations as where the apples were grown. Operation F is a primary production farm that harvests, but does not grow, the apples. Operation F is a different type of primary production farm than Operations A, B, and C, because Operation F is a primary production farm that harvests, but does not grow or raise, RACs. (In addition, if some or all of Operation F’s washing is performed for the safe or effective packing of the apples, the washing may also be classified as “packing.”)

- Operation G travels to farms under separate management to pick apples from trees, and then takes the apples off-site to a different location under its own management to be washed. While the washing location is not on any of the growing farms, it is half a mile down the road - near enough that it is still in the same general physical location as those farms. In this case, picking apples from the trees where they were grown can be classified as “harvesting.” Performing this activity makes Operation G a primary production farm (or a farm mixed-type facility, depending on the scope of activities it performs). Like Operation F, Operation G is a primary production farm that harvests, but does not grow or raise, RACs. The washing in this case can also be classified as “harvesting” even though it is not performed on the growing farms. As for Operation C above, this is because the washing is occurring on a farm (in this case, Operation G) in the same general physical location as where the apples were grown, and we have removed distinctions from the farm definition that limited what activities farms could perform on RACs from other farms. An activity a farm performs on others’ RACs can be classified the same way as the same activity is classified when performed on the farm’s own RACs. (In addition, if some or all of Operation G’s washing is performed for the safe or effective packing of the apples, the washing may also be classified as “packing.”)
- Operation H travels to farms under separate management to pick apples from trees, and then takes the apples off-site to a separate location under its own management to be washed. In this case the washing location is not on any of the growing farms, and is **not** in the same general physical location as those farms – it is in a different region of the country. Because a primary production farm is limited to “one general (but not necessarily contiguous) physical location,” the washing location is not considered to be part of the same operation that picked the apples (regardless of the fact that common management controls Operation H’s picking and washing). Thus, the washing operation should be separately analyzed from the picking operation. In this case, just as for Operation G, picking apples from the trees where they were grown can be classified as “harvesting.” Performing this activity makes the picking operation a primary production farm (or a farm mixed-type facility, depending on the scope of activities it performs). Like Operations F and G, Operation H’s picking operation is a primary production farm that harvests, but does not grow or raise, RACs. In this case, the picking operation (which is a primary production farm) owns a majority interest in the washing operation and the picking operation supplies all of the washing operation’s apples. Thus, the washing operation meets the criteria to be a secondary activities farm. We consider that in such cases, the criteria in the secondary activities farm definition linking the farm where the RACs were harvested to the secondary activities farm (through both the RACs



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themselves and the majority ownership requirement) make it appropriate to classify such an operation's washing of apples as "harvesting" even though it is not done in the same general physical location as where the apples (or any other RACs) were grown. (In addition, if some or all of Operation H's washing is performed for the safe or effective packing of the apples, the washing may also be classified as "packing.")

The examples above demonstrate how "harvesting" relates to a place where RACs were grown or raised. To summarize, we interpret "harvesting" to occur only (1) in the same general physical location as where RACs are grown or raised (though the RACs grown/raised in that location need not be the same RACs, or same type(s) of RACs, harvested in that location); or (2) at operations that meet the criteria in the secondary activities farm definition linking the farm where the RACs were harvested to the secondary activities farm (through both the RACs themselves and the majority ownership requirement).

The examples above also illustrate how some activities may be classified in more than one way depending on the facts, and why they are, for example, provided both as examples of "harvesting" and as examples of "manufacturing/processing" in those definitions. Some activities, such as washing RACs, may be classified as "harvesting" on a farm or farm mixed-type facility but "manufacturing/processing" when performed elsewhere. Some activities, such as washing RACs, can also be classified as "packing" both on- and off-farm under appropriate circumstances (i.e., when performed for the safe or effective packing of a food). Some activities, such as washing RACs, may be simultaneously classified in two or more different ways (e.g., washing RACs can simultaneously be both "harvesting" and "packing" if both definitions fit). Washing RACs is only an example of one such activity. There are other activities, such as trimming RACs, that have the same or similar properties.

Also, as mentioned earlier, our classifications for regulatory purposes may not always align with how farms think of various activities for non-regulatory purposes. We consider that many activities on farms and farm mixed-type facilities can be classified as "harvesting" even though they may not be performed in the growing area itself (provided, as illustrated above, that there is a sufficient connection to the growing area) or at the same time that the crop is removed from the plant. Thus, we consider that both Operation A's washing apples and Operation B's washing apples (see above) can be classified as "harvesting," even though Operation B's washing occurs in a packing house that is on the same farm (and therefore in the same general physical location as the growing area) but separate from the growing area. Moreover, the amount of time that has passed since the apples were removed from the growing area is not, in and of itself, determinative. Thus, for example, it does not matter to the outcome for Operation B whether the apples are washed right after being picked and then packed into boxes, or if the apples are washed weeks after they are picked, just before they are packed into boxes. In either case, we still consider that the washing can be classified as "harvesting" because it is performed on RACs on a farm, does not transform those RACs into processed food, and is an activity farms have traditionally performed for the purpose of removing RACs from the place they were grown and preparing them for use as food. Some farms may consider Operation B's washing to be "packing" considering the on-farm packing house location or temporal connection to packing. As described above, if some or all of Operation B's washing is performed for the safe or effective packing of the apples (e.g., to prevent unwanted debris from being packed along with

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the apples), the washing may also be classified as “packing” (in addition to “harvesting”). Because both harvesting RACs and packing RACs are inside the farm definition, the overlap has no practical consequence for Operation B’s regulatory status. On the other hand, if an operation were to wash apples, slice them, and then pack the sliced apples, the washing could not be considered incidental to packing because the circumstances demonstrate that the washing is not merely for the purpose of safe or effective packing of the apples. The intervening slicing, which is a manufacturing/processing activity, prevents the washing from being considered part of the later packing activity.

See the first column in Table 2 for examples of activities that we included in the definition of “harvesting” in our regulation for Registration of Food Facilities. See the second column in Table 2 for additional examples of activities that can be classified as “harvesting” on farms and farm mixed-type facilities, even though we did not include the activity in the definition of “harvesting.”

**Table 2. Examples of Harvesting Activities**

Examples of “Harvesting” Activities Included in the Definition	Additional Examples of “Harvesting” Activities
<ul style="list-style-type: none"> <li>• Cutting (or otherwise separating) the edible portion of the RAC from the crop plant</li> <li>• Removing or trimming part of the RAC (e.g., foliage, husks, roots, or stems)</li> <li>• Cooling</li> <li>• Field coring</li> <li>• Filtering</li> <li>• Gathering</li> <li>• Hulling</li> <li>• Shelling</li> <li>• Sifting</li> <li>• Threshing</li> <li>• Trimming of outer leaves</li> <li>• Washing</li> </ul>	<ul style="list-style-type: none"> <li>• Aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans</li> <li>• Blending (e.g., blending different lots of the same RAC together)</li> <li>• Braiding (e.g., garlic)</li> <li>• Bunching (e.g., garlic, onions)</li> <li>• Cleaning seeds that are the harvested crop including removal of leaves, stems, and husks, such as for flax seeds</li> <li>• Drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating grains in the growing area)</li> <li>• Hydro-cooling and icing</li> <li>• Maintaining hydration</li> <li>• Sorting/culling/grading</li> <li>• Trimming the tops or roots of bunches of allium crops (such as leeks, chives, or garlic) and root crops (such as carrots, beets, turnips, parsnips)</li> <li>• Using pesticides in wash water</li> </ul>

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**C. Activities Classified as “Packing” or “Packaging”**

See the first column in Table 3 for examples of activities that we included in the definition of “packing” in our regulation for Registration of Food Facilities. See the second column in Table 3 for additional examples of activities that can be classified as “packing” even though we did not include the activity in the definition of “packing.”

Although packaging RACs is within the “farm” definition, “packaging” is distinct from “packing.” We consider “packaging” to be “manufacturing/processing,” but we have specifically provided that packaging and labeling RACs, when this activity does not involve additional manufacturing/processing, is within the “farm” definition. See farm definition at (1)(iii)(B)(3) and (2)). See Table 4 for examples of activities that can be classified as “packaging.” Note that the definition of “packaging” in our regulation for Registration of Food Facilities does not include any examples of packaging activities.

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**Table 3. Examples of Packing Activities**

<b>Examples of “Packing” Activities Included in the Definition</b>	<b>Additional Examples of “Packing” Activities</b>
<ul style="list-style-type: none"><li>• Activities performed incidental to packing or re-packing a food - e.g., activities performed for the safe or effective packing of that food<ul style="list-style-type: none"><li>○ Sorting</li><li>○ Culling</li><li>○ Grading</li><li>○ Weighing or conveying</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Blending different lots of the same food together for the purpose of safe or effective packing of that food (e.g., combining lots of the same food to fill a packing container with the desired amount of food)</li><li>• Cooling (including hydro-cooling and icing) for safe/effective packing</li><li>• Filtering for safe/effective packing (e.g., filtering honey to remove hive debris)</li><li>• Mixing intact RACs in a packing container without creating a processed food (such as putting intact oranges and grapefruits together into a box for further distribution)</li><li>• Hulling for safe/effective packing (such as hulling walnuts to pack only the desired part of the RAC)</li><li>• Removing or trimming parts of RACs for safe/effective packing (e.g., removing stems/husks, trimming outer leaves, trimming tops or roots of bunches of allium crops (such as leeks, chives, or garlic) and root crops (such as carrots, beets, turnips, parsnips))</li><li>• Shelling for safe/effective packing (such as shelling walnuts to pack only the desired part of the RAC)</li><li>• Sifting for safe/effective packing (such as sifting grains to remove plant debris such as pieces of stalks to pack only the desired grain)</li><li>• Washing for safe/effective packing (e.g., washing RACs to remove dirt, including using pesticides in wash water)</li></ul>

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**Table 4. Examples of Packaging Activities**

<b>Examples of Packaging Activities</b>
<ul style="list-style-type: none"><li>• Putting strawberries into clamshells that directly contact the food and that the consumer receives</li><li>• Putting cilantro into plastic bags that directly contact the food and that the consumer receives</li><li>• Putting apples into plastic bags that directly contact the food and that the consumer receives</li><li>• Putting citrus fruit into net bags that directly contact the food and that the consumer receives</li><li>• Putting bell peppers into plastic bags that directly contact the food and that the consumer receives</li><li>• Putting three different colored bell peppers into plastic bags that directly contact the food and that the consumer receives (“mixing” the different colored bell peppers in the package)</li><li>• Putting tree nuts into plastic or net bags that directly contact the food and that the consumer receives</li></ul>

**D. Activities Classified as “Holding”**

*1. Activities performed incidental to storage of a food (e.g., for safe or effective storage of the food)*

The definition of holding provides that holding includes “activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity)... but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.” Below, we add as additional examples of activities performed for the safe or effective storage of food that do not transform a RAC into processed food, which may therefore be classified as “holding”:

- aeration for safe or effective storage (e.g., to manipulate grain temperatures);
- coating RACs for safe or effective storage (e.g., coating grains with diatomaceous earth to control insects during storage, coating fruits and vegetables with wax/oil/resin for safe or effective storage (including using wax as a carrier of fungicides or anti-oxidants for safe or effective storage));
- cooling (e.g., refrigerating, maintaining already-frozen food in a frozen state) for the purpose of safe/effective storage (including to preserve quality);
- heat treatment for purposes of pest control (i.e., for safe/effective storage) that does not change a RAC into processed food (e.g., heating mangoes by immersion in hot water for a specified time as a quarantine treatment for fruit flies; heating already dried herbs to control insects); and

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- turning for safe or effective storage (e.g., turning grain to monitor grain condition and quality, turning grain to manage grain temperature and moisture).

#### *2. Activities performed as a practical necessity for distribution of a food*

In addition to including activities incidental to storage (e.g., performed for safe or effective storage of food), the definition of holding provides that “[h]olding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.” We emphasize that “activities performed as a practical necessity for the distribution of [a] food” are limited to only those activities that are truly necessary, as a practical matter, to any holding and distribution of the food in question. It would not be appropriate to consider activities optionally performed to add value to a food product as “holding” on this basis, because such activities are not truly necessary to the distribution of the food.

Further, any activity that changes a RAC into processed food is explicitly excluded from “holding.”

In keeping with these limitations, we have identified only a few activities as examples of “holding” based on a conclusion that they are practical necessities for distribution of certain foods. For example, we consider that blending of the same RAC (e.g., blending different lots of the same grain to meet a customer’s quality specifications), and breaking down pallets (e.g., unwrapping and disassembling a pallet containing multiple cartons of food so that the cartons may be stored and/or sold separately) may be practical necessities for distribution of foods. Below, we add as additional examples of this kind:

- aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans;
- loading food into a vehicle, or placing food in a building or its associated fixtures or equipment as a practical necessity for distribution of the food;
- sampling food (such as sugar) for grading or quality control purposes as a practical necessity for distribution of the food;
- screening grain (e.g., using scalpels and shakers to remove rocks and other extraneous material) as a practical necessity for distribution of the food;
- sorting/culling/grading as a practical necessity for distribution of the food; and
- weighing or conveying as a practical necessity for distribution of the food (e.g., to hold only a given weight in a storage bin or to distribute a given weight of food).

We note that we are **not** including in this list of examples “repacking and blast freezing... when product is not exposed to the environment,” despite our statement in the farm definition rulemaking that such activities would be considered practical necessities for distribution and therefore “holding.” See 80 FR at 55934 (Comment/Response 44) and 80 FR at 56192 (Comment/Response 39). Our prior statements were incorrect and we hereby withdraw them.

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Neither “repacking” nor “blast freezing” should be considered a “holding” activity. We have thought more about what should be considered a “practical necessity” and are explaining our thinking more here.

Repacking is “packing.” Packing has a separate definition from holding and is not within the definition of holding. We understand, however, that some activities that industry might think of as putting food in a container are practical necessities for distributing food, and we wish to clarify that some such activities are considered “holding” for our purposes. We do not consider placing food inside a building, or its associated fixtures or equipment, to be “packing.” For example, we consider placing grain in a silo to be a practical necessity for distribution of the grain, and therefore “holding” grain. Placing grain in a silo is not “packing” grain, even though a silo might in some sense be considered a “container.” Similarly, we consider that loading food into a vehicle is not “packing,” even though a vehicle might in some sense be considered a “container.” Loading food into a vehicle as a practical necessity for distribution of the food is “holding” (regardless of whether the food being loaded is in a container(s), or is loaded directly into the vehicle “in bulk”).

Blast freezing, to the extent this activity involves freezing food that is not already frozen, is manufacturing/processing. Freezing changes RACs into processed food and therefore cannot be “holding,” because the definition of “holding” excludes activities that change RACs to processed food. However, as noted above, maintaining already-frozen food in a frozen state (such as by holding such food in a freezer) is “holding” because it is performed for the safe or effective storage of the already-frozen food.

#### *3. Examples of activities that are not “holding”*

We consider that the following activities may not be classified as “holding,” even though they do not necessarily transform RACs into processed food, because they are not incidental to storage (e.g., for safe or effective storage) and they are not practical necessities for distribution of food:

- filtering;
- hulling;
- labeling (including stickering);
- mixing two different foods together;
- packing or re-packing;
- packaging;
- removing or trimming parts of RACs;
- shelling;
- sifting; and
- washing.

This list is not exhaustive. For example, any activity that transforms a RAC into processed food may not be classified as “holding,” because as noted above, the definition of “holding” excludes activities that change RACs to processed food.

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4. *Summary*

See the first column in Table 5 for examples of activities that we included in the definition of “holding” in our regulation for Registration of Food Facilities. See the second column in Table 5 for additional examples of activities that can be classified as “holding” even though we did not include the activity in the definition of “holding.”

**Table 5. Examples of Holding Activities**

<b>Examples of “Holding” Activities Included in the Definition</b>	<b>Additional Examples of “Holding” Activities</b>
<ul style="list-style-type: none"> <li>• Storing food</li> <li>• Activities performed incidental to storage of a food - e.g., activities performed for the safe or effective storage of that food               <ul style="list-style-type: none"> <li>○ Fumigating food during storage</li> <li>○ Drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)</li> </ul> </li> <li>• Activities performed as a practical necessity for the distribution of that food               <ul style="list-style-type: none"> <li>○ Blending of the same RAC</li> <li>○ Breaking down pallets</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Aeration for safe or effective storage (e.g., to manipulate grain temperatures)</li> <li>• Aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans</li> <li>• Coating RACs for safe or effective storage (e.g., coating grains with diatomaceous earth to control insects during storage, coating fruits and vegetables with wax/oil/resin for safe or effective storage (including using wax as a carrier of fungicides or anti-oxidants for safe or effective storage))</li> <li>• Cooling (e.g., refrigerating, maintaining already-frozen food in a frozen state) for the purpose of safe/effective storage (including to preserve quality)</li> <li>• Heat treatment for purposes of pest control (i.e., for safe/effective storage) that does not change a RAC into processed food (e.g., heating mangoes by immersion in hot water for a specified time as a quarantine treatment for fruit flies; heating already dried herbs to control insects)</li> <li>• Loading food into a vehicle, or placing food in a building or its associated fixtures or equipment as a practical necessity for distribution of the food</li> <li>• Sampling food (such as sugar) for grading or quality control purposes as a practical necessity for distribution of the food</li> <li>• Screening grain (e.g., using scalpels and shakers to remove rocks and other extraneous material) as a practical</li> </ul>



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Examples of “Holding” Activities Included in the Definition	Additional Examples of “Holding” Activities
	<p>necessity for distribution of the food</p> <ul style="list-style-type: none"><li>• Sorting/culling/grading as a practical necessity for distribution of the food</li><li>• Turning for safe or effective storage (e.g., turning grain to monitor grain condition and quality, turning grain to manage grain temperature and moisture)</li><li>• Weighing or conveying as a practical necessity for distribution of the food (e.g., to hold only a given weight in a storage bin or to distribute a given weight of food)</li></ul>

**E. Activities Classified as “Manufacturing/Processing”**

See the first column in Table 6 for examples of activities that we included in the definition of “manufacturing/processing” in our regulation for Registration of Food Facilities. See the second column in Table 6 for additional examples of activities that can be classified as “manufacturing/processing” even though we did not include the activity in the definition of “manufacturing/processing.” A given activity may be manufacturing/processing but not transform a RAC into a processed food. As discussed in the farm definition rulemaking, the activities that transform a RAC into a processed food are not coextensive with the definition of “manufacturing/processing.” Transforming a RAC into processed food involves altering the general state of the commodity, sometimes referred to as transformation of the RAC into a new or distinct commodity. Examples of activities that may be manufacturing/processing without transforming a RAC into a processed food include coloring, washing, and waxing. See 78 FR 3646 at 3679 (Jan. 16, 2013) (proposed rule). On the other hand, because any activity that does transform a RAC into processed food is explicitly excluded from the definitions of harvesting, packing, and holding, such activities are always classified as manufacturing/processing. Manufacturing/processing is outside the farm definition except as specifically provided in the farm definition (see farm definition at (1)(iii) and (2)).

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**Table 6. Examples of Manufacturing/Processing Activities**

<b>Examples of “Manufacturing/Processing” Activities Included in the Definition</b>	<b>Additional Examples of “Manufacturing/Processing” Activities</b>
<ul style="list-style-type: none"> <li>• Baking</li> <li>• Boiling</li> <li>• Bottling</li> <li>• Canning</li> <li>• Cooking</li> <li>• Cooling</li> <li>• Cutting</li> <li>• Distilling</li> <li>• Drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins)*</li> <li>• Evaporating</li> <li>• Eviscerating</li> <li>• Extracting juice</li> <li>• Formulating</li> <li>• Freezing</li> <li>• Grinding</li> <li>• Homogenizing</li> <li>• Irradiating</li> <li>• Labeling*</li> <li>• Milling</li> <li>• Mixing</li> <li>• Packaging (including modified atmosphere packaging)*</li> <li>• Pasteurizing</li> <li>• Peeling</li> <li>• Rendering</li> <li>• Treating to manipulate ripening*</li> <li>• Trimming</li> <li>• Washing</li> <li>• Waxing</li> </ul>	<ul style="list-style-type: none"> <li>• Bleaching (e.g., walnuts)</li> <li>• Chopping</li> <li>• Coating for purposes other than storage/transport (e.g., coating strawberries with chocolate)</li> <li>• Coloring (e.g., adding color to the skin of oranges)</li> <li>• Coring (e.g., in the production of fresh-cut lettuce)</li> <li>• Cracking (e.g. corn)</li> <li>• Crushing</li> <li>• Extracting oils</li> <li>• Extruding</li> <li>• Fermenting fruits and vegetables</li> <li>• Flaking</li> <li>• Hulling</li> <li>• Infusing</li> <li>• Mashing</li> <li>• Pearling</li> <li>• Pelleting</li> <li>• Pitting</li> <li>• Roasting</li> <li>• Salting</li> <li>• Shelling</li> <li>• Shredding</li> <li>• Sifting</li> <li>• Slaughtering and post-slaughter operations</li> <li>• Slicing</li> <li>• Smoking</li> <li>• Sorting, culling, grading (e.g., as an initial step in a processing facility before canning)</li> <li>• Using pesticides in wash water (e.g., in the production of fresh-cut lettuce)</li> <li>• Wafering</li> <li>• Weighing or conveying ingredients to be used during manufacturing/processing at the same facility (e.g., weighing ingredients to be used in the facility’s production of baked goods)</li> </ul>

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\*At least some types of the listed manufacturing/processing activity are specifically allowed within the “farm” definition as manufacturing/processing (i.e., such activities are within the farm definition even though they are not otherwise classified as growing, harvesting, packing, or holding).

**F. Activities Classified in More Than One Way**

If you compare Table 2, Table 3, Table 5, and Table 6, you will see that several activities can be classified in more than one way. See Table 7 for examples of activities that may be classified in more than one way. Please note that, as discussed above, in some cases these examples overlap (i.e., an activity can simultaneously be classified in more than one way, such as being both harvesting and packing when performed on a farm), and that these are only examples (not an exhaustive list of possibilities).

**Table 7. Examples of Activities That May Be Classified in More Than One Way**

<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans	<ul style="list-style-type: none"><li>• Harvesting</li><li>• Holding</li></ul>	<ul style="list-style-type: none"><li>• Aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans on a farm is a harvesting activity.</li><li>• Aging/curing/fermenting/oxidizing that occurs passively over time, e.g., cocoa beans, coffee beans, and vanilla beans during storage is a holding activity.</li></ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Blending (the same food)	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Holding</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Blending different lots of the same RAC together on a farm is a harvesting activity.</li> <li>• Blending different lots of the same food together for the purpose of safe or effective packing of that food (e.g., combining lots of the same food to fill a packing container with the desired amount of food) is a packing activity.</li> <li>• Blending different lots of the same grain to meet a customer's quality specifications as a practical necessity for product distribution is a holding activity.</li> <li>• Blending that does not fall into harvesting, packing, or holding (e.g., combining lots of the same flour at a facility that uses the flour to bake bread) is a manufacturing/processing activity.</li> </ul>
Coating	<ul style="list-style-type: none"> <li>• Holding</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Coating for safe or effective storage (e.g., coating grain RACs with diatomaceous earth to control insects during storage, coating fruits and vegetables with wax/oil/resin for safe or effective storage, including using wax as a carrier of fungicides or anti-oxidants for safe or effective storage) is a holding activity.</li> <li>• Coating in the production of chocolate-covered strawberries or caramel-coated apples is a manufacturing/processing activity.</li> </ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Cooling	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Holding</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Cooling RACs on a farm (e.g., hydro-cooling cherries as they are picked in the growing area, hydro-cooling cantaloupes in an on-farm packing house) is a harvesting activity.</li> <li>• Cooling (including hydro-cooling and icing (e.g., hydro-cooling broccoli)) for the purpose of safe/effective packing is a packing activity.</li> <li>• Cooling (e.g., refrigerating, maintaining already-frozen food in a frozen state) during storage for the purpose of safe/effective storage (including to preserve quality) is a holding activity.</li> <li>• Cooling that does not fall into harvesting, packing, or holding (e.g., a cooling step in a production process used to remove heat from a cooked food prior to packaging) is a manufacturing/processing activity.</li> </ul>
Coring	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• “Field coring” on a farm (e.g., removing the core from lettuce at the same time that the stem is cut and wrapper leaves removed) is a harvesting activity.</li> <li>• Coring lettuce at a facility that chops the lettuce to produce fresh-cut lettuce is a manufacturing/processing activity.</li> </ul>
Cutting	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Cutting (or otherwise separating) the edible portion of the RAC from the crop plant on a farm is a harvesting activity.</li> <li>• Cutting lettuce in the production of fresh-cut lettuce is a manufacturing/processing activity.</li> </ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Drying/ dehydrating RACs	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Holding</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Drying/dehydrating RACs on a farm when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating grains in the growing area on a farm) is a harvesting activity.</li> <li>• Drying/dehydrating RACs for purposes of safe or effective storage when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa) is a holding activity.</li> <li>• Drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins) is a manufacturing/processing activity.</li> </ul>
Filtering	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> </ul>	<ul style="list-style-type: none"> <li>• Filtering RACs (e.g., filtering raw milk to remove straw, hair, etc.) on a farm is a harvesting activity.</li> <li>• Filtering RACs for safe/effective packing (e.g., filtering honey to remove hive debris) is a packing activity.</li> </ul>
Hulling	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Hulling RACs on a farm is a harvesting activity.</li> <li>• Hulling for safe/effective packing (such as hulling walnuts to pack just the desired part of the RAC) is a packing activity.</li> <li>• Hulling walnuts at a facility that chops the walnuts is a manufacturing/processing activity.</li> </ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Mixing (different foods)	<ul style="list-style-type: none"><li>• Packing</li><li>• Manufacturing/processing</li></ul>	<ul style="list-style-type: none"><li>• Mixing intact RACs in a packing container without creating a processed food (e.g., placing three different colored bell peppers in a box for further distribution) is a packing activity.</li><li>• Mixing intact RACs in a container that directly contacts the food and that the consumer receives without creating a processed food (e.g., placing three different colored bell peppers directly into a plastic bag that the consumer receives) is packaging, which is a manufacturing/processing activity.</li><li>• Mixing different RACs together in a manner that creates a processed food (e.g., mixing corn and oats in the production of animal food) is a manufacturing/ processing activity.</li><li>• Mixing performed on processed foods (e.g., mixing roasted nuts, chocolate, and dried fruits to make trail mix) is a manufacturing/processing activity.</li></ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Removing or trimming parts of RACs	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Removing or trimming parts of RACs (e.g., removing stems/husks, trimming outer leaves, trimming tops or roots of bunches of allium crops (such as leeks, chives, or garlic) and root crops (such as carrots, beets, turnips, parsnips)) on a farm is a harvesting activity.</li> <li>• Removing or trimming parts of RACs for safe/effective packing is a packing activity.</li> <li>• Removing or trimming parts of RACs at a facility that chops the RACs to produce a fresh-cut salad mix is a manufacturing/processing activity.</li> </ul>
Shelling	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Shelling RACs on a farm is a harvesting activity.</li> <li>• Shelling for safe/effective packing (such as shelling walnuts to pack just the desired part of the RAC) is a packing activity.</li> <li>• Shelling walnuts at a facility that chops the walnuts is a manufacturing/processing activity.</li> </ul>
Sifting	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Sifting RACs (e.g., hand threshing of wheat) on a farm is a harvesting activity.</li> <li>• Sifting for safe/effective packing (such as sifting grains to remove plant debris such as pieces of stalks to pack only the desired grain) is a packing activity.</li> <li>• Sifting flour as part of making baked goods is a manufacturing/processing activity.</li> </ul>



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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Sorting, culling, and grading	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Holding</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Sorting, culling, and grading RACs on a farm are harvesting activities.</li> <li>• Sorting, culling, and grading performed for the safe or effective packing of the food incidental to packing are packing activities.</li> <li>• Sorting, culling, and grading performed as a practical necessity for distribution of the food are holding activities.</li> <li>• Sorting, culling and grading that does not fall into harvesting, packing, or holding (e.g., when performed as an initial step in a processing facility before canning) are manufacturing/processing activities.</li> </ul>
Washing (including using pesticides in wash water)	<ul style="list-style-type: none"> <li>• Harvesting</li> <li>• Packing</li> <li>• Manufacturing/processing</li> </ul>	<ul style="list-style-type: none"> <li>• Washing RACs on a farm (e.g., washing RACs to remove dirt, including using pesticides in wash water) is a harvesting activity.</li> <li>• Washing for safe/effective packing (e.g., washing RACs to remove dirt, including using pesticides in wash water) is a packing activity.</li> <li>• Washing at a facility before canning fruit or vegetables, or during the production of a fresh-cut salad mix, including using pesticides in wash water, is a manufacturing/processing activity.</li> </ul>

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<b>Activity</b>	<b>Classifications</b>	<b>Discussion</b>
Weighing or conveying	<ul style="list-style-type: none"><li>• Packing</li><li>• Holding</li><li>• Manufacturing/processing</li></ul>	<ul style="list-style-type: none"><li>• Weighing for the purpose of safe or effective packing (e.g., to pack items of a similar weight) is a packing activity</li><li>• Weighing as a practical necessity for distribution of food (e.g., to hold only a given weight in a storage bin or to distribute a given weight of food) is a holding activity</li><li>• Weighing ingredients to be used during processing at the same facility (e.g., weighing ingredients to be used in the facility’s production of baked goods) is a manufacturing/processing activity</li></ul>

The following examples describe the practical implications for some situations in which activities can be classified in more than one way, including whether the specific classification of an activity is likely to matter.

- If all of the activities you perform are within the “farm” definition, it generally makes no difference whether you classify an activity as harvesting, packing, or holding, or as one of the manufacturing/processing activities (such as packaging) listed in the farm definition. Thus, for example, if it might be possible to consider a particular activity that you perform on a particular food to be either “harvesting” or “packing” within the meaning of those definitions, the decision is unlikely to affect your operation’s regulatory status in a meaningful way.
- If your business is a “primary production farm” or a “secondary activities farm”, but you also perform at least one activity that falls outside the “farm” definition, your business is a “farm mixed-type facility” and you may be required to register as a food facility (see 21 CFR 1.225 and 1.226). The activities that trigger the registration requirement (those that are not within the farm definition) may be subject to the requirements of 21 CFR Part 117 or 507 (for human food or animal food, respectively) as applicable.
- If your operation is not a “primary production farm” or a “secondary activities farm,” you may be required to register as a food facility (see 21 CFR 1.225 and 1.226). All of the activities you perform are potentially subject to the requirements of 21 CFR Part 117 or 507 (for human food or animal food, respectively), or Part 121, as applicable.

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**G. Activity Classification on a Farm Mixed-Type Facility that Grows, Harvests, Packs, and Processes Lettuce**

Business I grows lettuce and other types of salad greens and harvests lettuce and other types of salad greens from the field by cutting the stems, field coring the lettuce, trimming outer leaves of the lettuce/greens, and washing the intact lettuce/greens. The business then packs some of the lettuce in an intact form for distribution, and also produces some fresh-cut lettuce/greens (e.g., by chopping a single variety of lettuce and bagging it or by chopping and bagging mixes of salad greens). The business also stores all of its products (intact and fresh-cut lettuce/greens) for at least some time in refrigerated storage.

- Business I’s growing and harvesting operations (growing the lettuce/greens, cutting the stems, field coring the lettuce, trimming outer leaves of the lettuce/greens, and washing the intact lettuce/greens) are within the “farm” definition. Business I’s packing of RACs (packing intact lettuce for distribution) and storing of RACs (storing intact lettuce/greens under refrigeration) are also within the “farm” definition. These activities are not subject to the requirements of Part 117 or Part 507. Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule), as applicable.
- When Business I chops lettuces/salad greens to create fresh-cut lettuce/greens, this changes the intact RACs into distinct commodities, which means they become processed foods and are no longer RACs. This is a manufacturing/processing activity (note that the definitions of harvesting, packing, and holding all explicitly exclude activities that change RACs into processed foods, which leaves only manufacturing/processing as an appropriate classification for such activities). This manufacturing/processing activity is not specifically included in the farm definition (see farm definition at (1)(iii)(B)) unless done for consumption on farm (see farm definition at (1)(iii)(A)). In this example, the chopped lettuce/greens are for distribution into commerce and not for on-farm consumption, so this activity is outside the farm definition. Assuming that no exemptions from the registration requirement apply (see 21 CFR 1.225 and 1.226), Business I is required to register as a food facility. Because Business I is a farm (see paragraph above), but also conducts some activities outside the farm definition that require it to be registered, Business I is a “farm mixed-type facility.” Business I’s chopping of lettuce/greens is potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively), as applicable.
- Business I also packages the chopped lettuces/greens by placing them in bags that directly contact the food and that the consumer receives (whether as a single chopped lettuce variety or as a mix of chopped salad greens). This is packaging, which is a manufacturing/processing activity, and it is performed on a processed food. This manufacturing/processing activity (packaging a processed food) is not specifically included in the farm definition (see farm definition at (1)(iii)(B)) unless done for consumption on farm (see farm definition at (1)(iii)(A)) or performed on certain types of dried/dehydrated processed foods specified in the definition (see farm definition at (1)(iii)(B)(1)). In this example, the chopped lettuce/greens are for distribution into commerce and not for on-farm consumption, so this activity is outside the farm definition and as discussed above, Business I is a “farm mixed-type facility.” Business I’s

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packaging of chopped lettuce/greens is potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively), as applicable.

- Business I also stores its chopped, bagged lettuce/greens for at least some time in refrigerated storage. This is a holding activity, and it is performed on a processed food. This holding activity (holding a processed food) is only within the farm definition if done for consumption on farm or performed on certain types of dried/dehydrated processed foods specified in the definition (see farm definition at (1)(ii)). In this example, the chopped lettuce/greens are for distribution into commerce and not for on-farm consumption, and they are not the dried/dehydrated processed foods specified in the farm definition, so this activity is outside the farm definition. As discussed above, Business I is a “farm mixed-type facility.” Business I’s holding of chopped, bagged lettuce/greens is potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively), as applicable.

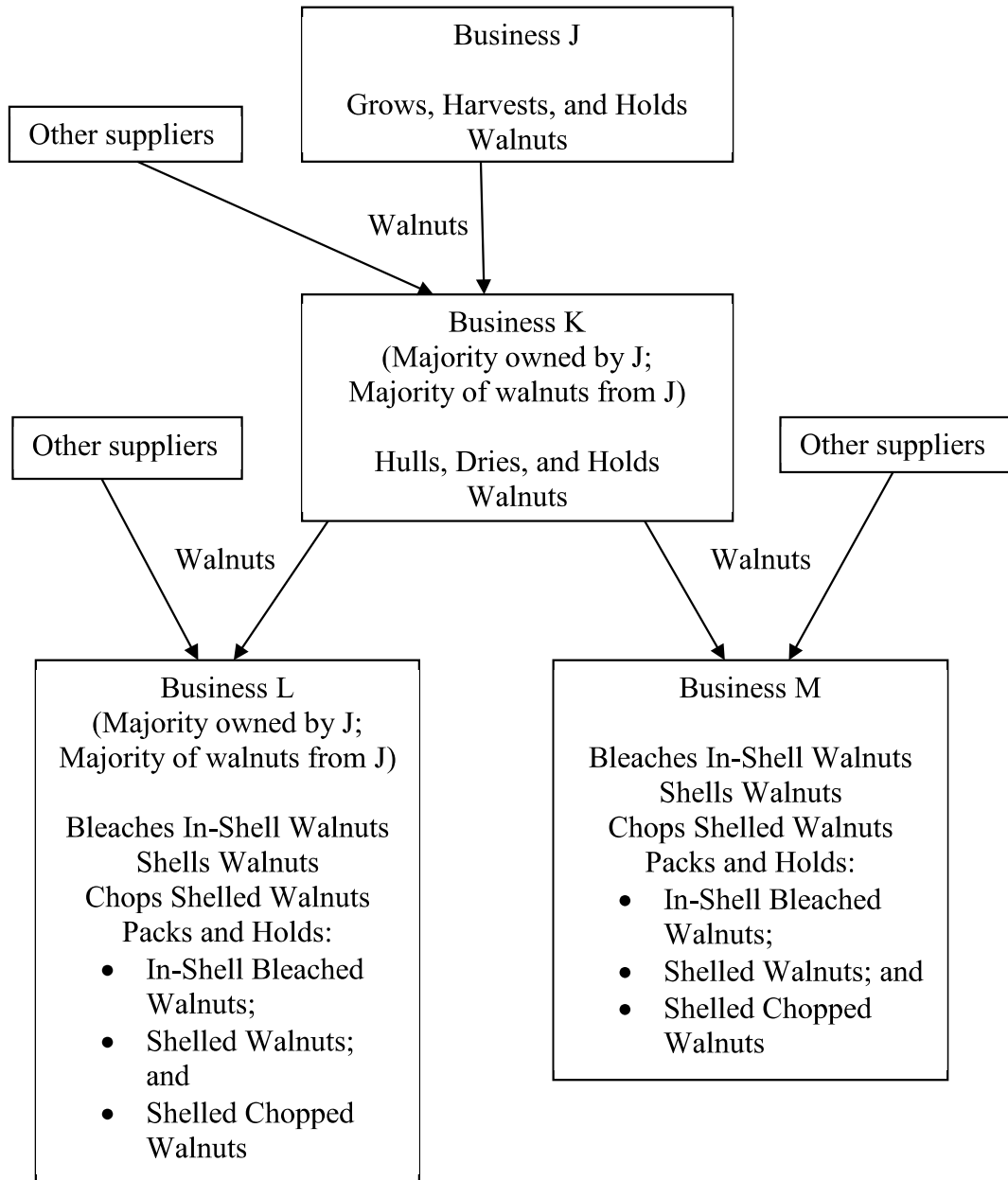
## **H. Activity Classification in the Production of Walnuts**

Business J grows and harvests walnuts, holds them, and ships them in bulk (loading walnuts directly into trucks) to Business K. Business K hulls and dries the walnuts, holds them, and ships them in bulk to Businesses L and M. Business L and Business M shell walnuts, but also have manufacturing/processing operations that bleach in-shell walnuts and chop shelled walnuts. Businesses L and M also pack and hold the in-shell bleached walnuts, shelled walnuts, and shelled chopped walnuts for distribution (into large fabric bags and boxes used as shipping containers, which consumers do not receive). Business J owns a majority interest in Businesses K and L, but does not own a majority interest in Business M. More than half of the walnuts that Business K hulls and dries are grown by Business J. More than half of the walnuts that Business L shells are grown by Business J. Business M buys walnuts to shell from several different farms including Business J.

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**Figure 1.—Schematic Representation of the Business Relationship Between Walnut Businesses J, K, L, and M**



- Business J is a primary production farm. Business J’s bulk shipping of walnut RACs (loading the walnuts into trucks) is a holding activity. Its growing, harvesting, and holding of walnut RACs are all within the “farm” definition, and are therefore not subject to the requirements in 21 CFR Parts 117 or 507 (for human or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule) as applicable.

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- Business K is majority owned by Business J, which is a primary production farm, and gets more than half of its RACs from Business J. Business K hulls and dries walnuts (drying which does not create a distinct commodity). While these activities occur in a different physical location from where the walnuts were grown, the ownership and product connection of Business K to the primary production farm (Business J) means that these activities of Business K may be considered harvesting activities. It may also be reasonable to consider Business K's drying of walnuts to be a holding activity because the drying is for the purpose of safe or effective storage of the walnuts. Regardless of whether the drying is classified as a harvesting activity or a holding activity, Business K is a secondary activities farm that harvests and holds walnut RACs and meets the ownership and product criteria in the secondary activities farm definition. Business K's bulk shipping of walnut RACs (loading the walnuts into trucks) is a holding activity. Its hulling, drying, and holding of walnut RACs are all within the "farm" definition, and are therefore not subject to the requirements in 21 CFR Parts 117 or 507 (for human or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule) as applicable.
- Business L is majority owned by Business J, which is a primary production farm, and gets more than half of its RACs from Business J (via Business K). Business L's walnut shelling occurs in a different physical location from where the walnuts were grown, but as for Business K, the ownership and product connection of Business L to the primary production farm (Business J) means that the walnut shelling activities of Business L may be considered harvesting activities. Business L is a secondary activities farm that shells walnut RACs (which may be considered, in this case, a harvesting activity) and meets the ownership and product criteria in the secondary activities farm definition. Business L's shelling of walnuts, and its packing and holding of shelled (not chopped) walnuts, are inside the farm definition and are therefore not subject to the requirements in 21 CFR Parts 117 or 507 (for human or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule), as applicable. However, Business L also conducts some activities that are not within the farm definition. Its walnut bleaching and chopping are manufacturing/processing activities. It also packs and holds shelled chopped walnuts, which are a processed food. These packing and holding activities (packing and holding a processed food) are only within the farm definition if done for consumption on farm or performed on certain types of dried/dehydrated processed foods specified in the definition (see farm definition at (1)(ii)). In this example, the chopped walnuts are for distribution into commerce and not for on-farm consumption, and they are not the dried/dehydrated processed foods specified in the farm definition, so these activities are outside the farm definition. Business L also packs and holds in-shell bleached walnuts. The bleaching step, as described above, is outside the farm definition, making Business L's later packing and holding of the in-shell bleached walnuts also outside the farm definition. Assuming that no exemptions from the registration requirement apply (see 21 CFR 1.225 and 1.226), Business L is required to register as a food facility. Because Business L is a farm (see above), but also conducts some activities outside the farm definition that require it to be registered, Business L is a "farm mixed-type facility." Business L's bleaching, chopping, packing, and holding of the bleached in-shell walnuts

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and the shelled chopped walnuts are potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively), as applicable.

- Business M does not meet the ownership or product criteria in the secondary activities farm definition, so its shelling of walnuts is not harvesting because it is not performed on a farm in the same general physical location as where the walnuts or other RACs were grown or raised, and the criteria in the secondary activities farm definition that might otherwise satisfy the needed connection are not met. This business's shelling can be classified in different ways depending on its specific purpose. When Business M shells walnuts and packs the shelled walnuts for distribution, the shelling might reasonably be classified as a packing activity because it is done for the safe/effective packing of the shelled walnuts (to pack only the desired portion of the RAC). The same shelling might also reasonably be classified as manufacturing/processing activity. On the other hand, when Business M shells walnuts, chops the shelled walnuts, and packs the shelled chopped walnuts, the shelling is not merely for the purpose of safe/effective packing and therefore may not be considered "packing." The intervening chopping, which is a manufacturing/processing activity, prevents this shelling from being considered "packing." This shelling is therefore only reasonably classified as a manufacturing/processing activity. Business M's bleaching and chopping of walnuts are also manufacturing/processing activities. Business M also packs and holds all the products described here. Assuming that no exemptions from the registration requirement apply (see 21 CFR 1.225 and 1.226), Business M is required to register as a food facility. Business M is not a farm mixed-type facility. All of its activities are packing, holding, or manufacturing/processing activities that are potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively), as applicable.

## **I. Activity Classification in the Production of Tomatoes**

In this example, we first describe five different businesses (Business N, O, P, Q, and R) and then explain how each business is classified (as a primary production farm, secondary activities farm, or a facility).

### *1. Description of the businesses*

- Business N packs and holds tomatoes grown and harvested from its own fields in the same general physical location as the packing house and also packs and holds tomatoes that it buys from other tomato farms, Business O and Business P.
- Businesses O and P are two separate operations that grow, harvest, and hold tomatoes, but do not pack tomatoes.
- Business Q packs and holds only tomatoes grown and harvested by Business O and Business P, and Businesses O and P together own more than 50 percent of Business Q.
- Business R buys tomatoes from several farms (Business O, Business P and others), and packs and holds those tomatoes. Business R does not grow any tomatoes and is not owned by the farms that supply the tomatoes it packs.

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2. *Classification of the business*

- Business N is a primary production farm. Its growing, harvesting, packing and holding of tomatoes are within the “farm” definition, and are therefore not subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule) as applicable.
- Businesses O and P are each primary production farms. Their growing, harvesting, and holding of tomatoes are within the “farm definition,” and are therefore not subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule) as applicable.
- Business Q is a secondary activities farm because it is majority owned by primary production farms (Businesses O and P) and all of the tomatoes packed by Business Q come from the primary production farms. Business Q’s packing and holding of tomatoes are therefore not subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively). Because these activities are performed on a farm on produce RACs, they may be subject to the requirements of Part 112 (the produce safety rule) as applicable.
- Business R is not a farm. Business R is a facility and, assuming that no exemptions from the registration requirement apply (see 21 CFR 1.225 and 1.226), it is required to register as a food facility. Its packing and holding of tomatoes are potentially subject to the requirements of Part 117 or Part 507 (for human food or animal food, respectively).