



# FSMA: Food Safety and Almonds

Almond Conference

December 6, 2016



# Agenda

- Determining Your Compliance Obligations
  - Draft Guidance on Classification of Activities
  - General Framework & Decision Trees
- Case Studies
- Written Disclosures & Assurances
- Compliance Date Extensions
- Preparation





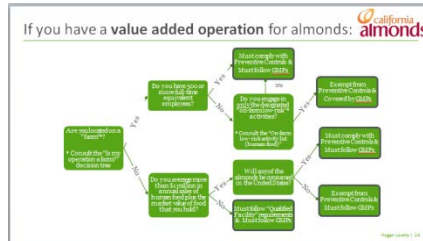
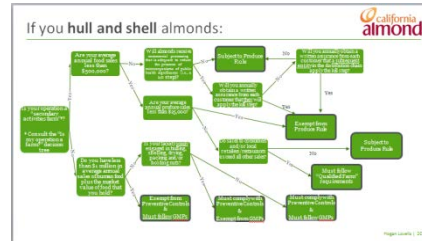
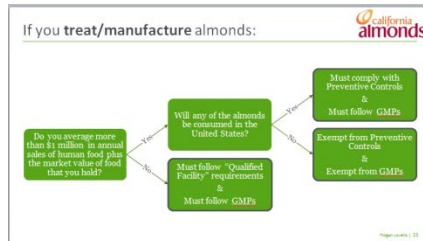
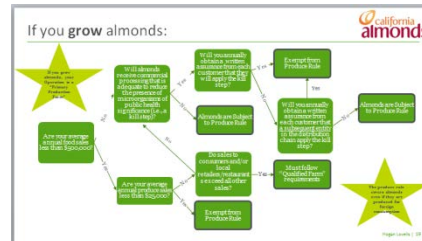
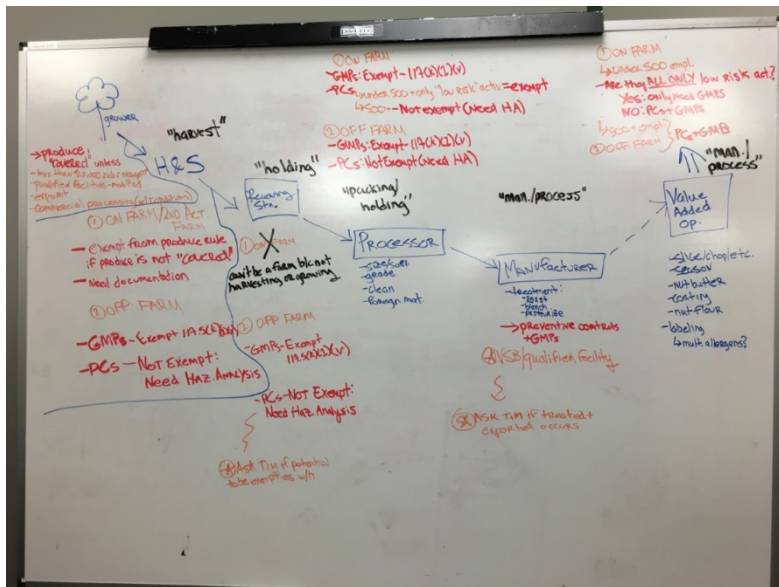
# Determining Your Compliance Obligations

# What FSMA Means for You

- Determining the regulations that apply to your business and what you need to do to comply, is very case-specific
  - Consider applicability
    - (1) GMPs
    - (2) Preventive Controls
    - (3) Produce Safety
- Key issues include:
  - Location of the operation
  - Ownership structure
  - Company size
  - Activities performed
    - Growing
    - Hulling and Shelling
    - Handling
    - Manufacturing
- **Note: Conducting multiple activities can change your compliance obligations!**



# It's Complicated!



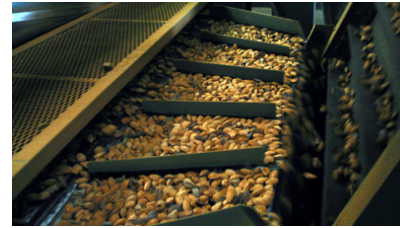
\*\* This just an illustration, not advice!

# How to Get Started

- To determine your FSMA obligations, you need to start by determining how the activities you conduct are classified by FDA
  - Need to do this before you use the decision trees, because the decision trees assume you know whether your operation is a “farm” or a “facility” (or a “farm mixed type facility”)
- In late August, FDA released a draft guidance document intended to help operations determine whether or not the activities they perform fall within in the “farm” definition
  - Remember, for “farm mixed type facilities” some activities will be “farm” activities and others “facility” activities
- **Importantly, activities may be classified in different ways, depending on the circumstances**
- To determine where your activities fall:
  - Start with whether the activity is “growing”
  - Then consider whether the activity meets the definition of “harvesting”
  - If not, consider whether the activity falls within the definition of “packing”
  - Then consider whether it is classified as “holding”
  - If the activities cannot be classified into any of the above categories, consider whether they are “manufacturing/processing”

# Types of Almond Operations

- Growers
- Hullers and Shellers
- Processors / Handlers
  - Sizing, sorting, grading
  - Cleaning (separating out foreign material)
  - Bulk packing
- Manufacturers
  - Treat almonds through pasteurization, roasting, and/or blanching
- Value Added Operations
  - Slicing, chopping
  - Seasoning, coating
  - Making nut butters, nut flour
  - Labeling
  - Packaging



**→ Many operations fall into more than one category**

## Key Definitions

- 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
- 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.



## Key Definitions Continued...

- **Facility** means any establishment, structure, or structures under one ownership at one general physical location . . . that manufactures/processes, packs, or holds food for consumption in the United States. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership.
- A **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 (e.g., a “farm mixed-type facility” which is an establishment that is a farm, but that also conducts activities that require it to be registered).

# Harvesting

- 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
  - Includes hulling and shelling, sorting/culling/grading
  - Importantly, **harvesting relates to a place where RACs were grown or raised – it requires a connection to such a place**; either:
    - By location (same general physical location where RACs are grown (though the RACs grown don't have to be the same RACs or same type of RACs harvested)) OR
    - By Ownership (see definition of a secondary activities farm)
- Hulling and shelling where almonds are grown (same general physical location) = within the primary production farm definition
  - Hullers and shellers that are primary production farms can hull/shell any amount of almonds from other farms
- Open questions:
  - Are all hullers/shellers farms because they harvest in the same region where almonds are grown? What does “same general physical location” entail?
  - How does FDA determine whether an operation is growing RACs?

# Packing

- Placing food into a container other than packaging the food (i.e., placing food into containers that are not consumer containers)
- 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 also can include hulling/shelling when done for the safe and effective packing (such as to pack only the desired portion of the nut)
- Does not include activities that transform a raw agricultural commodity into a processed food
- Note that “packaging” and labeling are manufacturing/processing activities (e.g., putting almonds into bags that the consumer receives)

# Holding

- 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)
  - Other activities within the definition of holding include aeration and turning for safe and effective storage
- 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 or activities optionally performed to add value
  - Blending must take place on foods that are the same (e.g., almonds with almonds)
  - Also includes sorting, culling, grading, weighing, conveying, and sampling when they are a practical necessity for the distribution of the food
- Holding facilities could include warehouses and storage silos
- Note: hulling, shelling, packaging, re-packing are NOT holding activities

# Manufacturing/Processing

- Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients
  - Examples include: Baking, boiling, cooking, cooling, cutting, formulating, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, washing, chopping, slicing, hulling, shelling, crushing, sorting, culling, grading, weighing, conveying
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding



## Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Hulling/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>• Hulling/shelling RACs on a farm is a harvesting activity</li><li>• Hulling/shelling for safe/effective packing (such as hulling almonds to pack just the desired part of the RAC) is a packing activity</li><li>• Hulling/shelling almonds at a facility that chops the almonds is a manufacturing/processing activity</li></ul>

## Examples of Activities Classified Multiple Ways

Activity	Classification	Details
Sorting Culling 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 pasteurization) are manufacturing/ processing activities</li></ul>

## Implications of Activity Classification

- 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
  - The activities that trigger the registration requirement (those that are not within the farm definition) may be subject to GMPs and Preventive Controls, 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
  - All of your operations may be subject to GMPs and Preventive Controls

## Examples – Handlers

- Handlers size, sort, grade, and pack almonds
- Handler that grows almonds = primary production farm
- Handler that does not grow almonds and is not owned by growers = facility
- Handler owned by two growers that supply the majority of almonds sized, sorted, graded, and packed = secondary activities farm
  - If this handler also chops some of the almonds = farm mixed-type facility
- Handler owned by two growers that do not supply the majority of almonds packed = facility
- Handler who pasteurizes the almonds = facility

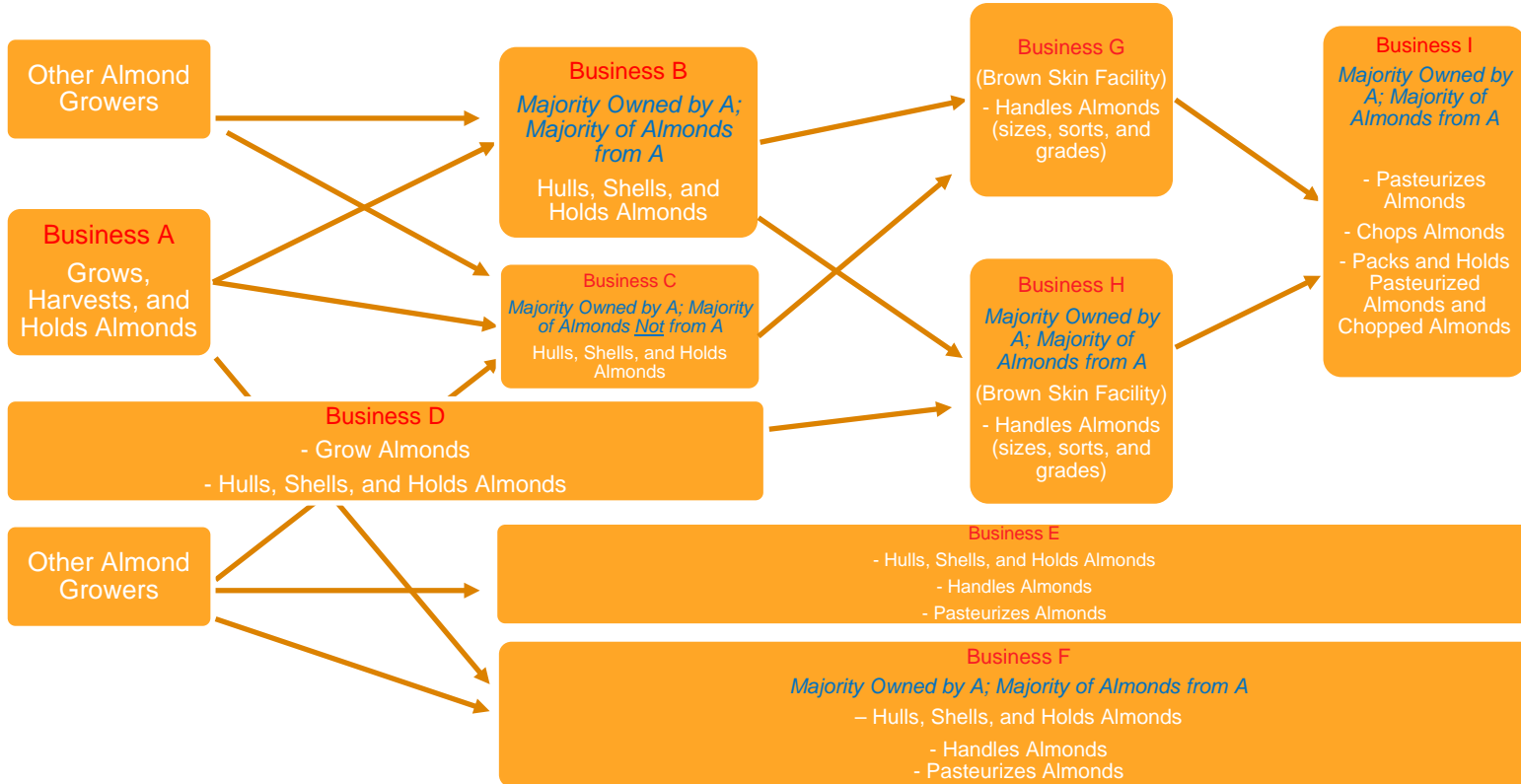
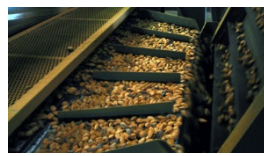
## Examples – Hullers/Shellers

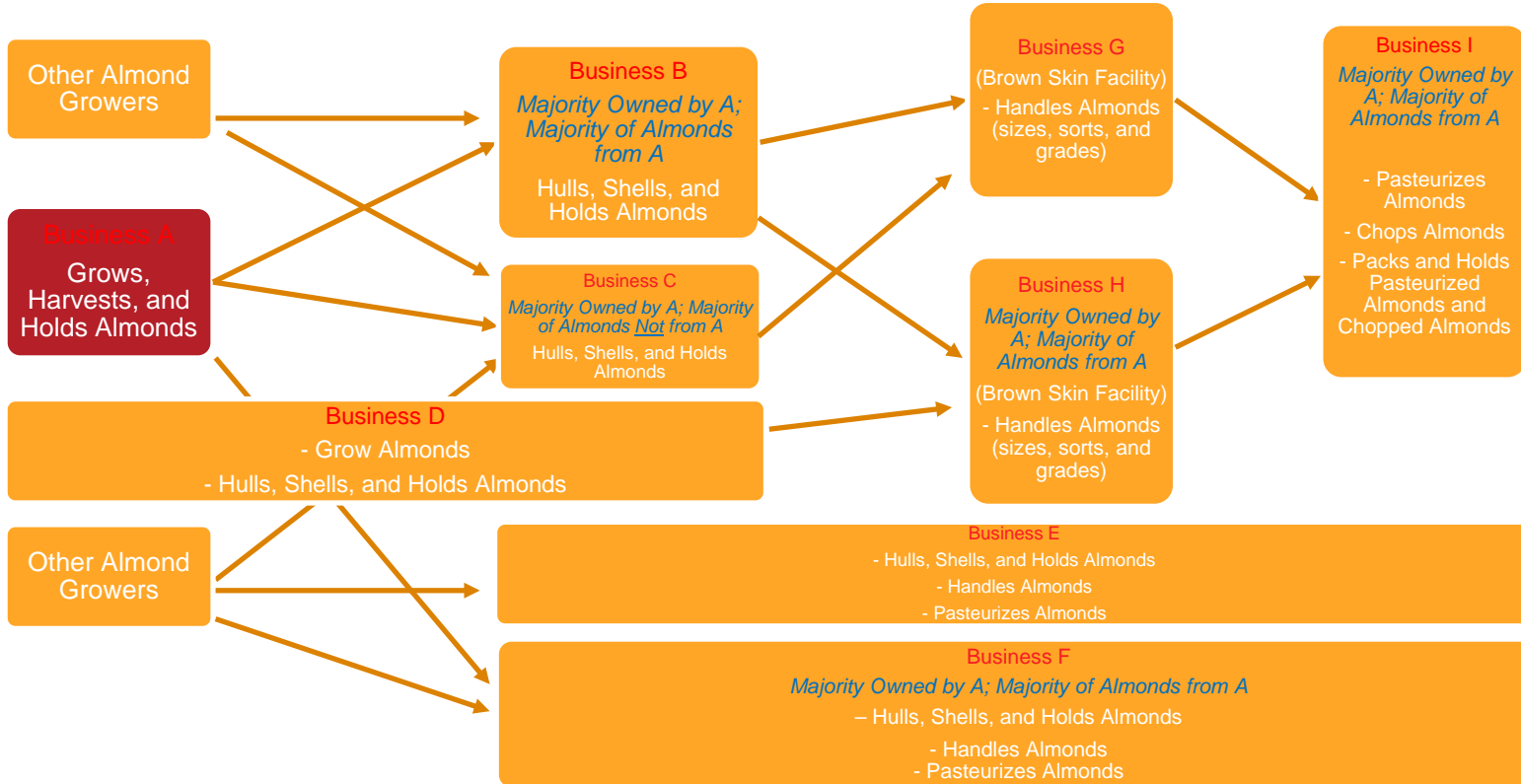
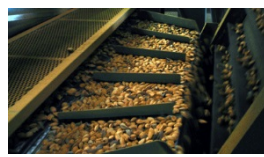
- Huller/sheller that grows almonds = primary production farm
- Huller/sheller that grows walnuts = primary production farm
- Huller/sheller that does not grow almonds and is not owned by growers, but is in the same general physical location where almonds are grown = primary production farm (but need FDA concurrence to be certain)
- Huller/sheller that does not grow almonds and is not owned by growers, but is in the same general physical location where other RACs are grown = primary production farm (but need FDA concurrence to be certain)
- Huller/sheller owned by two growers that supply the majority of almonds sized, sorted, graded, and packed = secondary activities farm
- Huller/sheller that does not grow almonds, is not owned by growers, and is not in the same general physical location where almonds are grown = facility



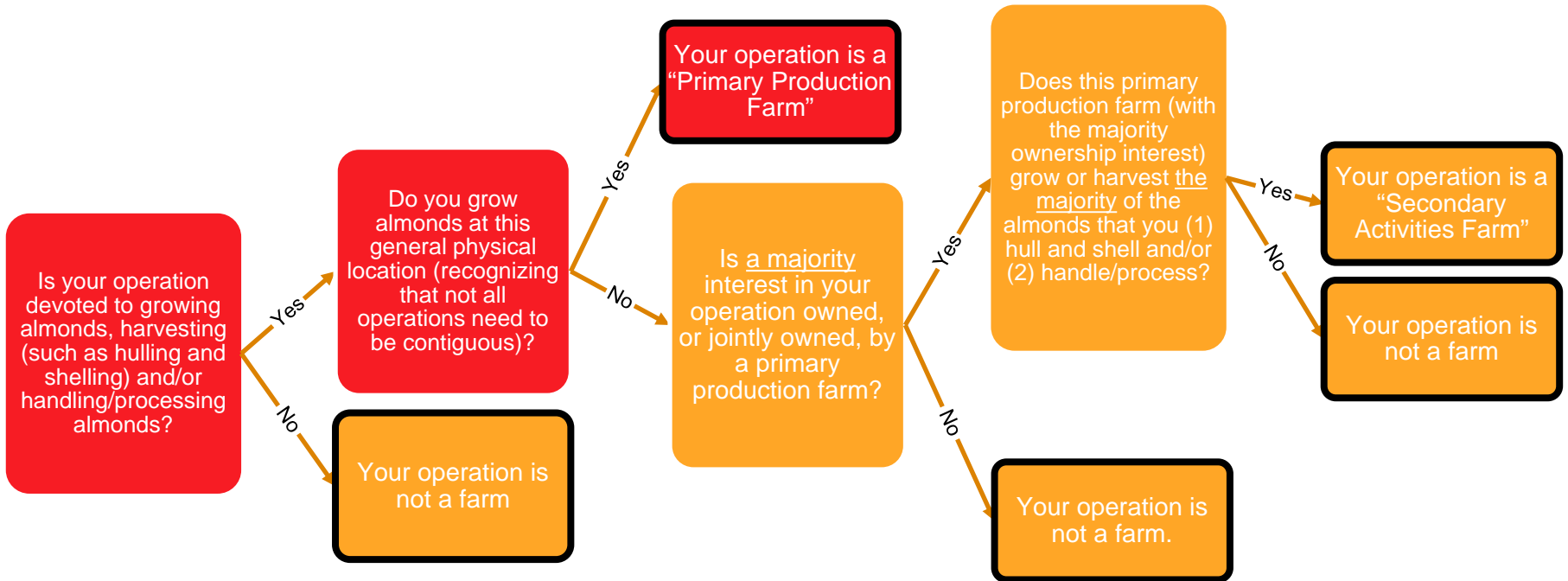
## Case Studies





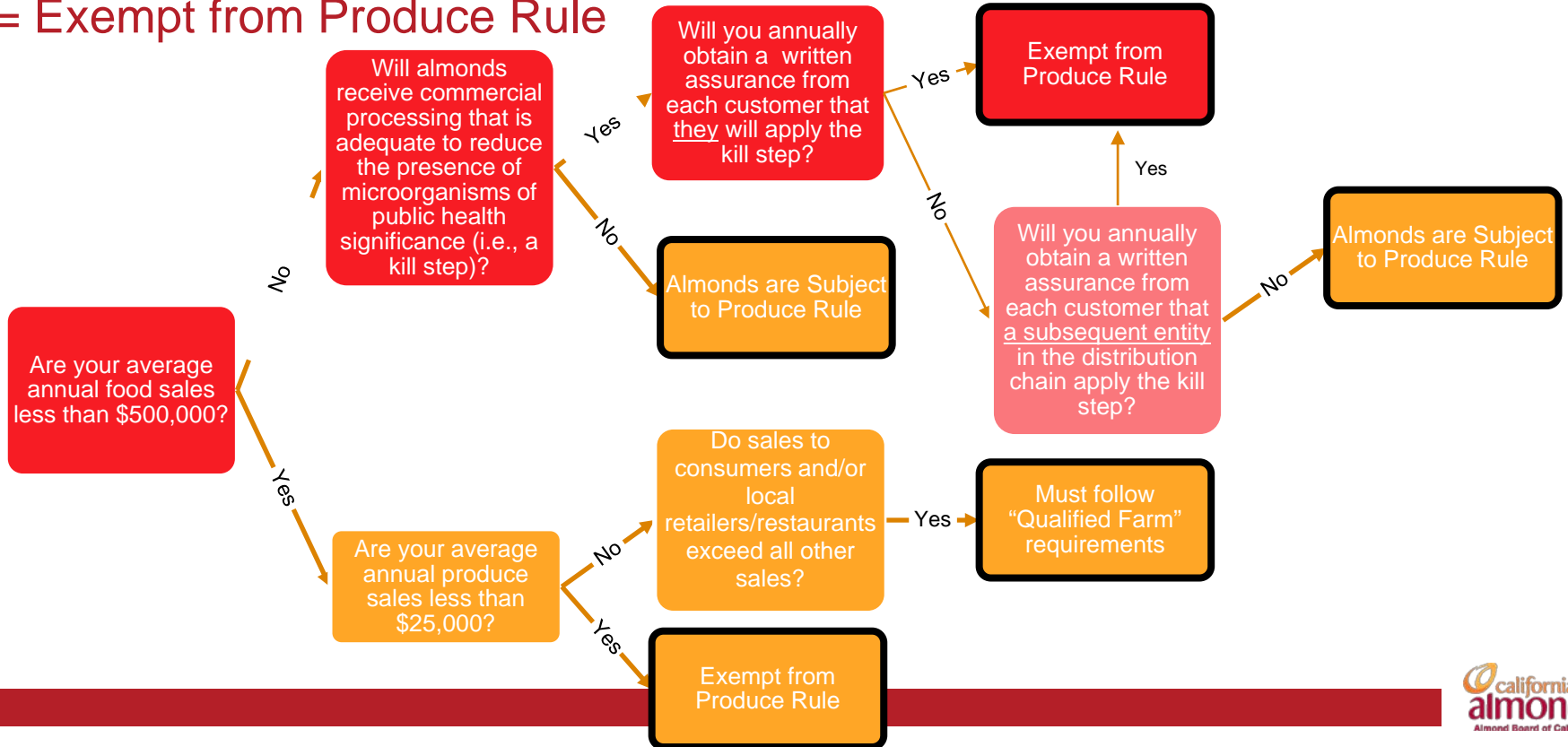


# Business A: Grows, Harvests, and Holds Almonds (Grower) = Primary Production Farm



# Business A: Grows, Harvests, and Holds Almonds (Grower)

= Primary Production Farm + *Obtains Written Assurances*  
= Exempt from Produce Rule

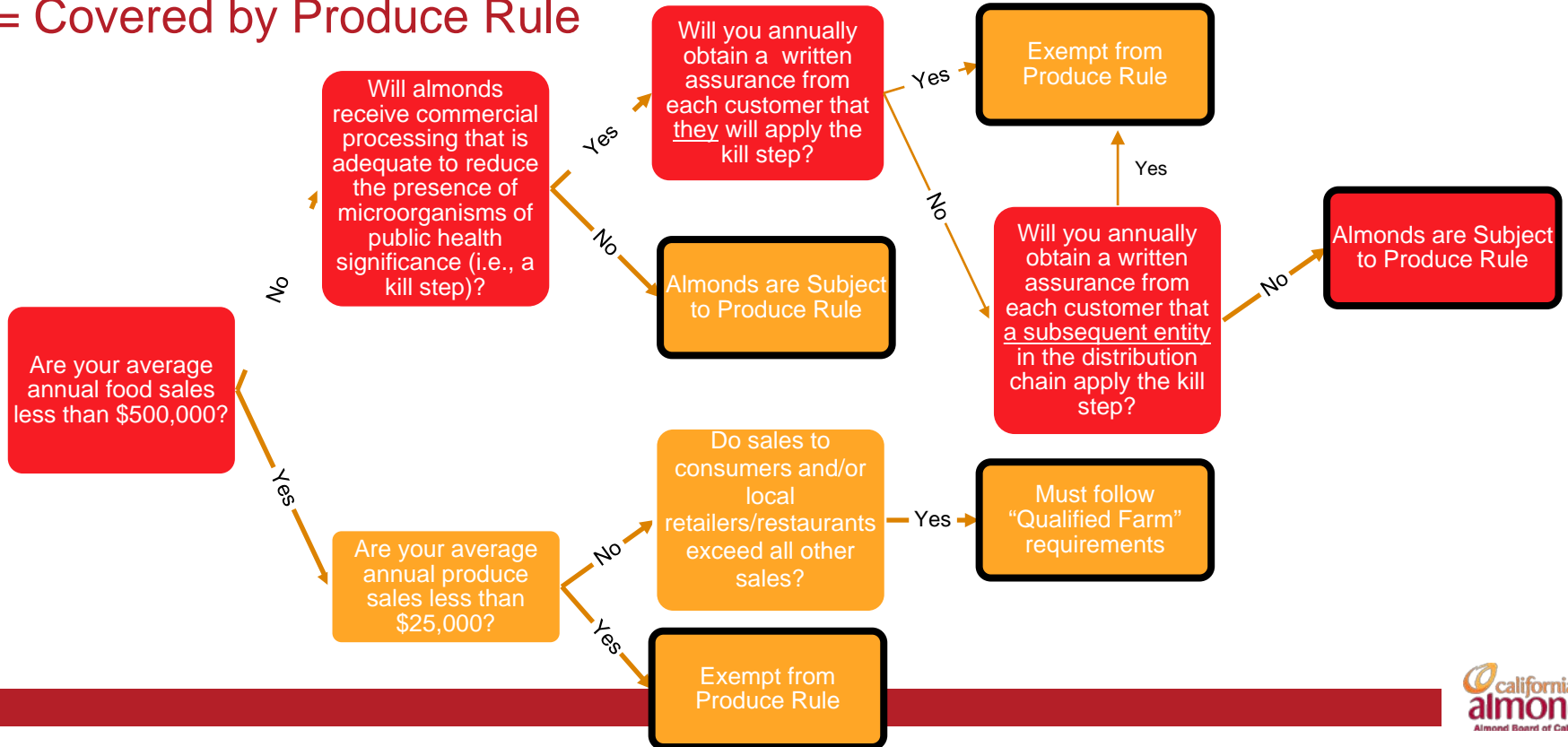


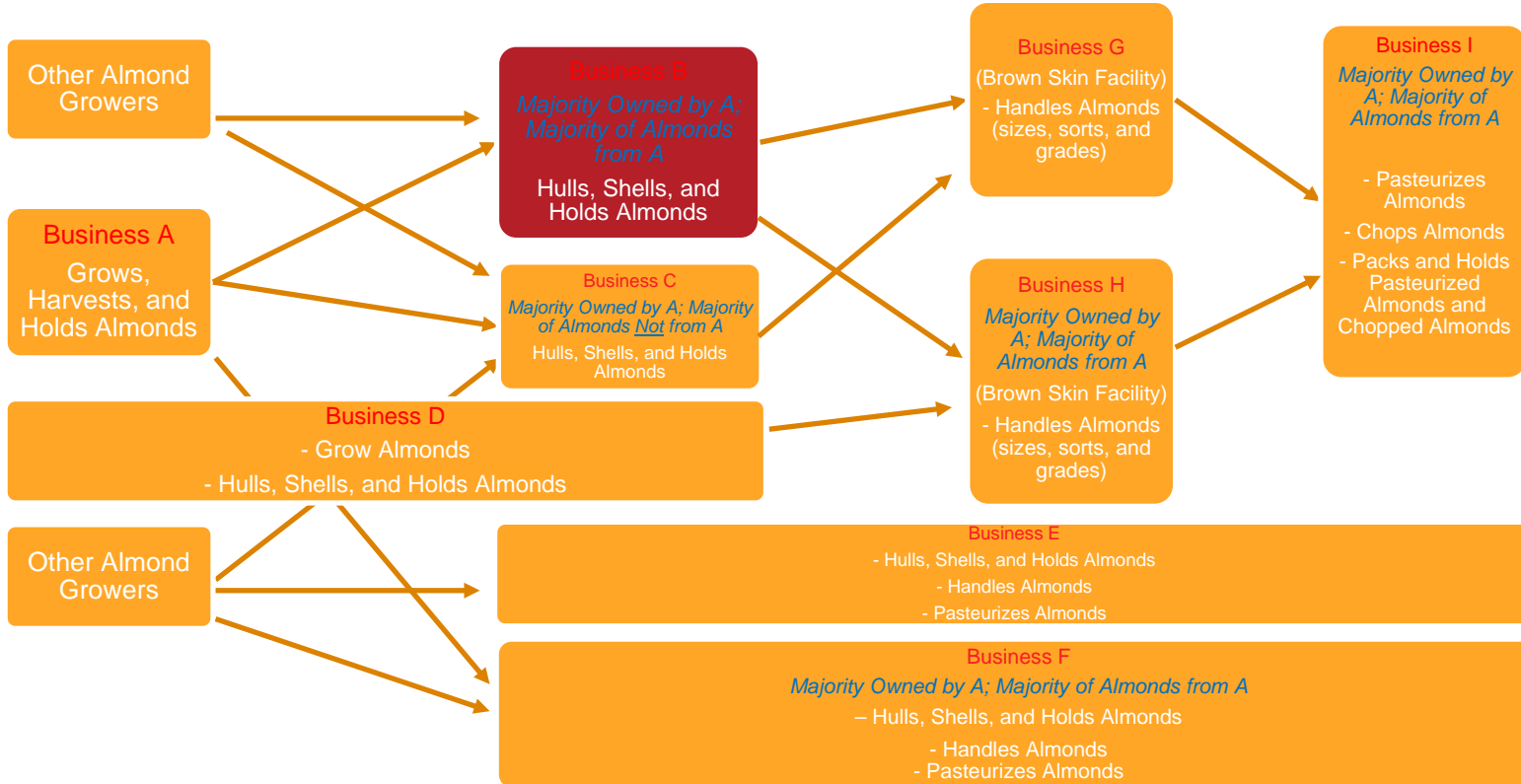
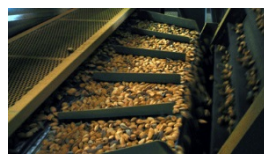


# Business A: Grows, Harvests, and Holds Almonds

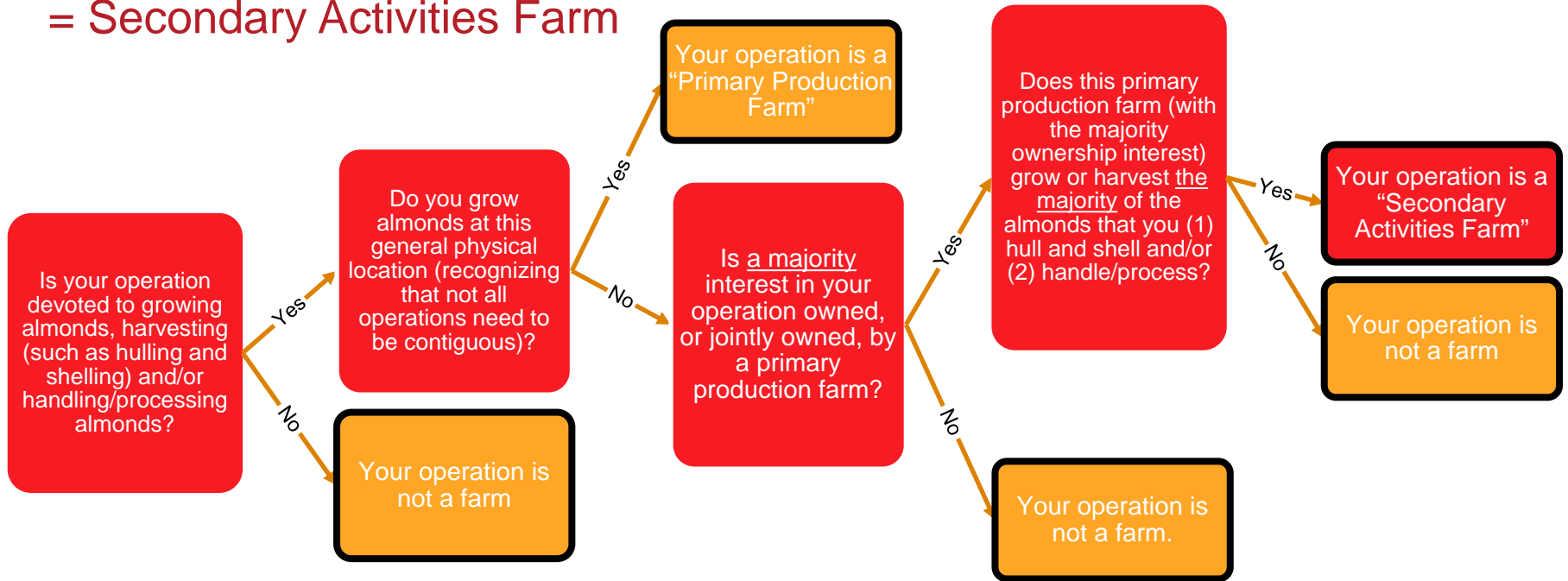
= Primary Production Farm + Does Not Obtain Written Assurances

= Covered by Produce Rule

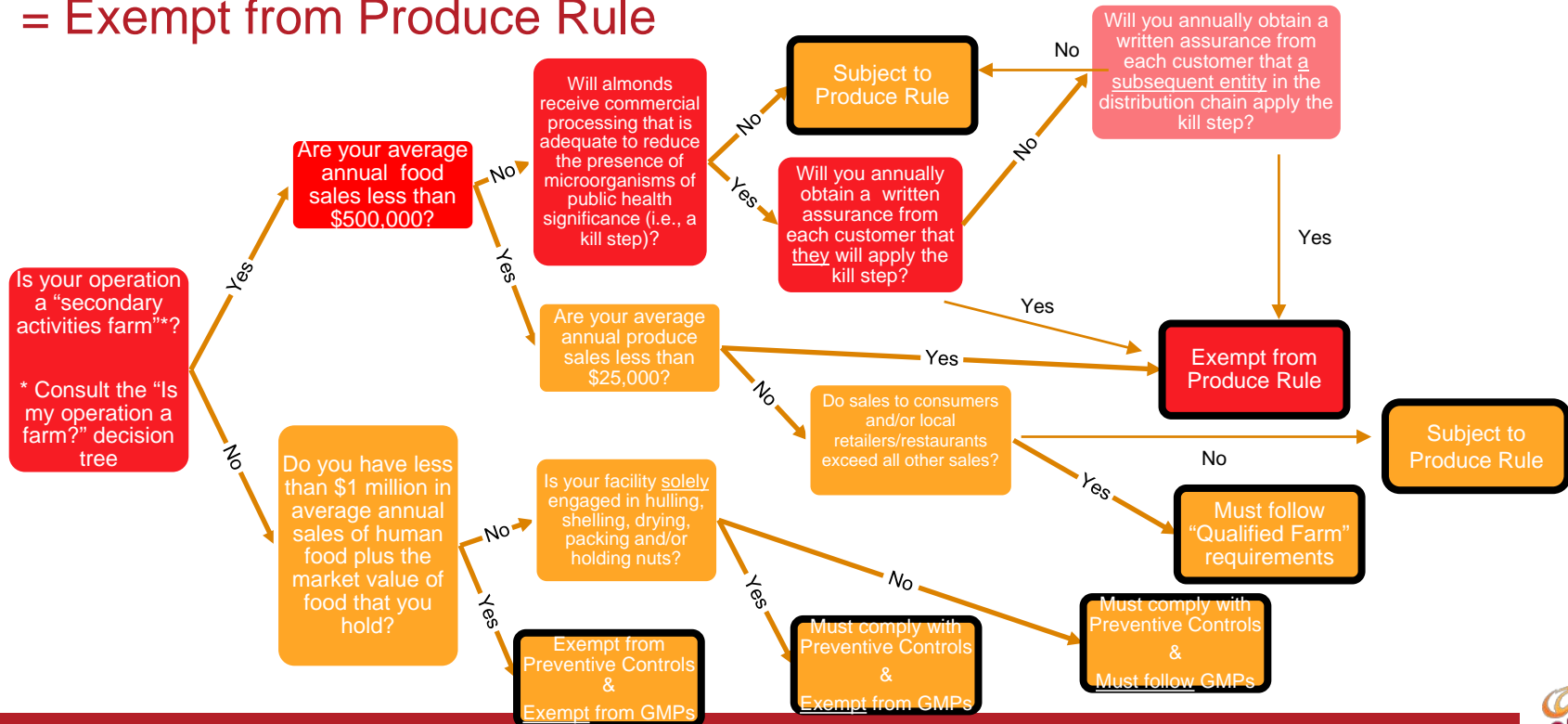


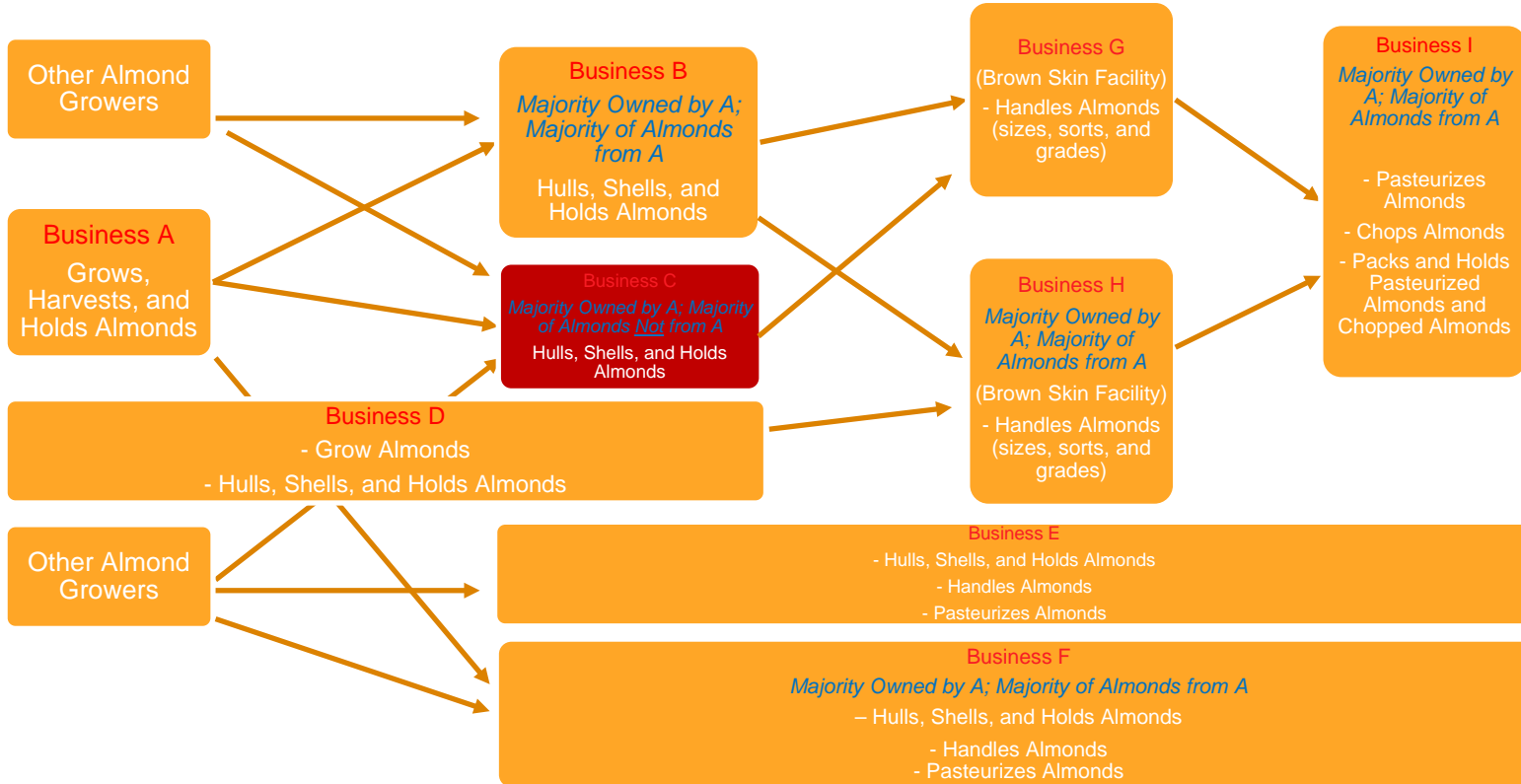


# Business B: Hulls, Shells, and Holds Almonds and *Majority Owned by A with Majority of Almonds from A (Huller/Sheller)* = Secondary Activities Farm

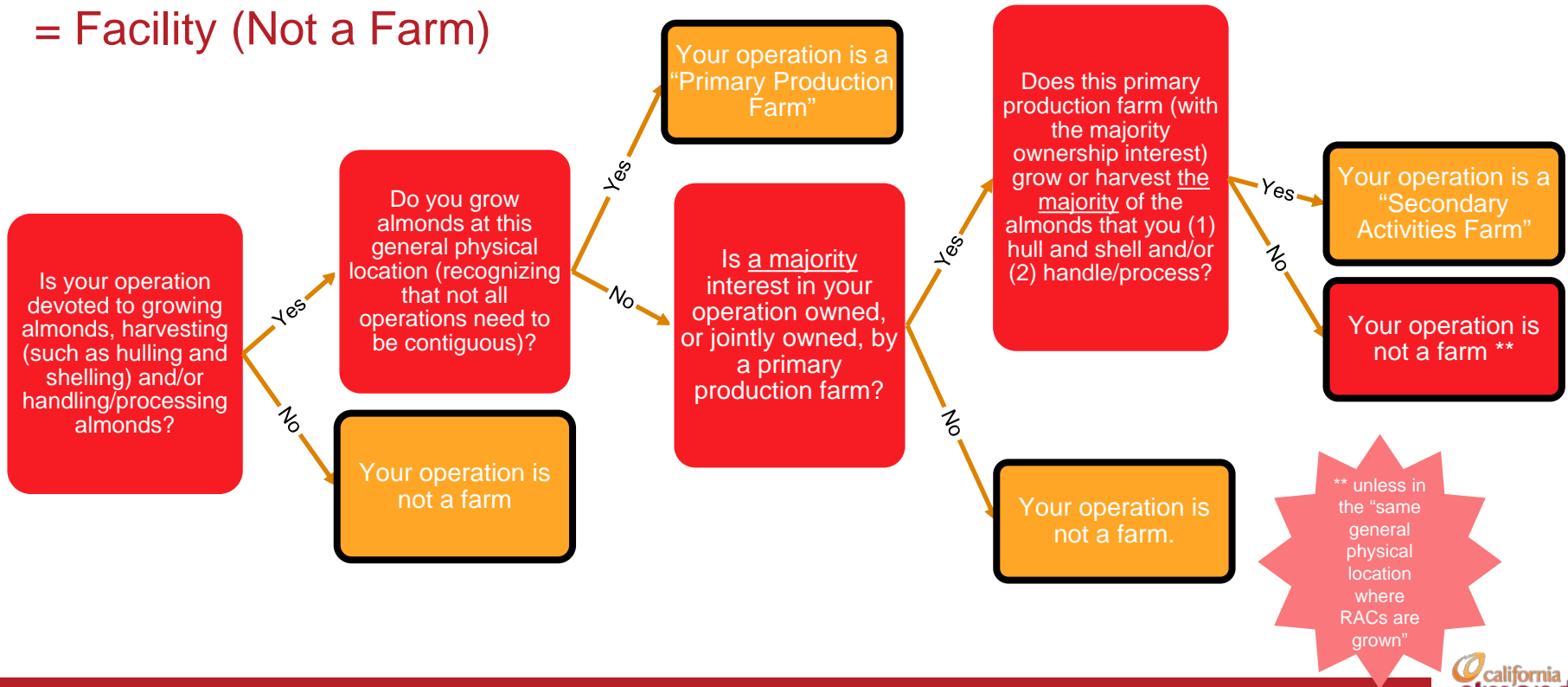


# Business B: Hulls, Shells, and Holds Almonds and Majority Owned by A with Majority of Almonds from A + Obtains Written Assurances = Exempt from Produce Rule





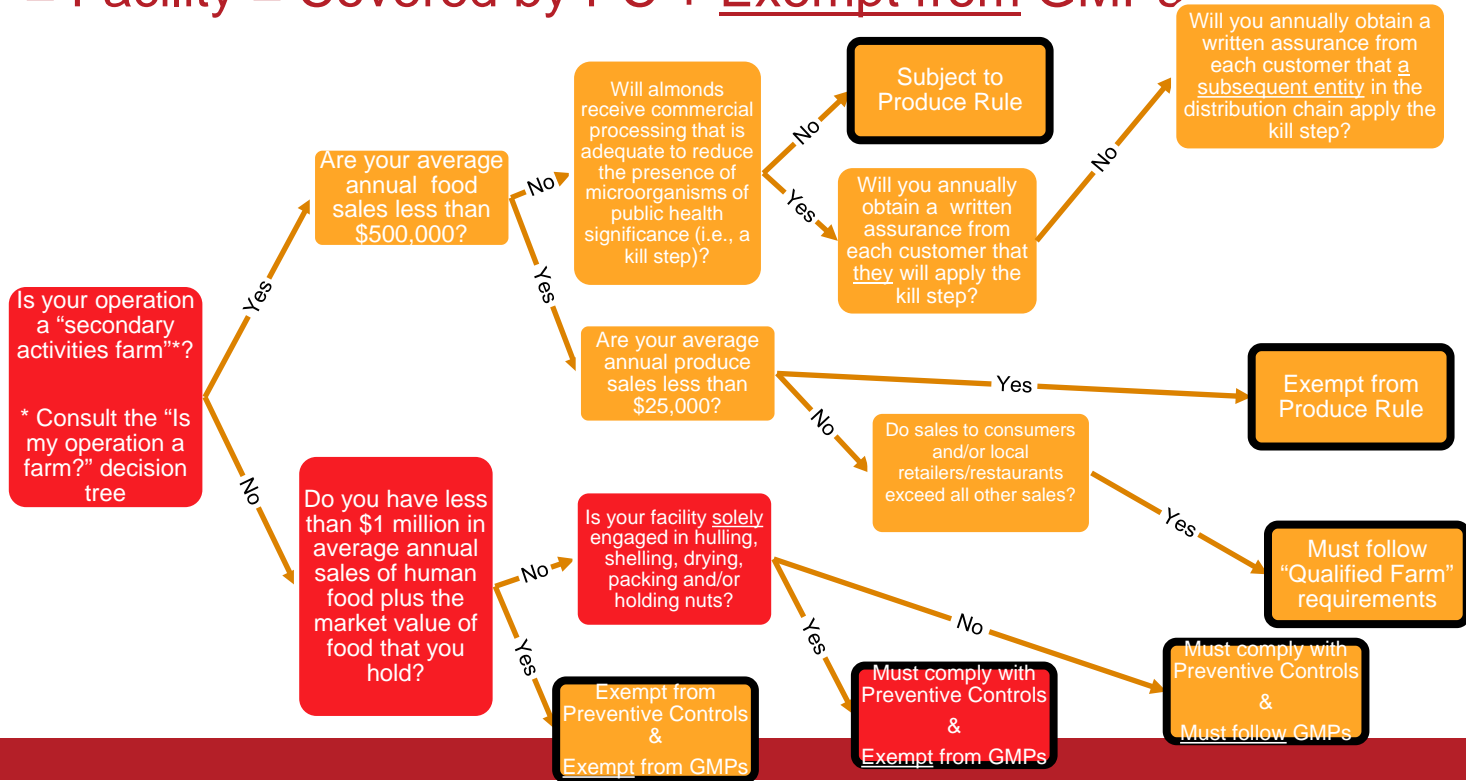
# Business C: Hulls, Shells, and Holds Almonds and *Majority Owned by A with Majority of Almonds NOT from A (Huller/Sheller)* = Facility (Not a Farm)

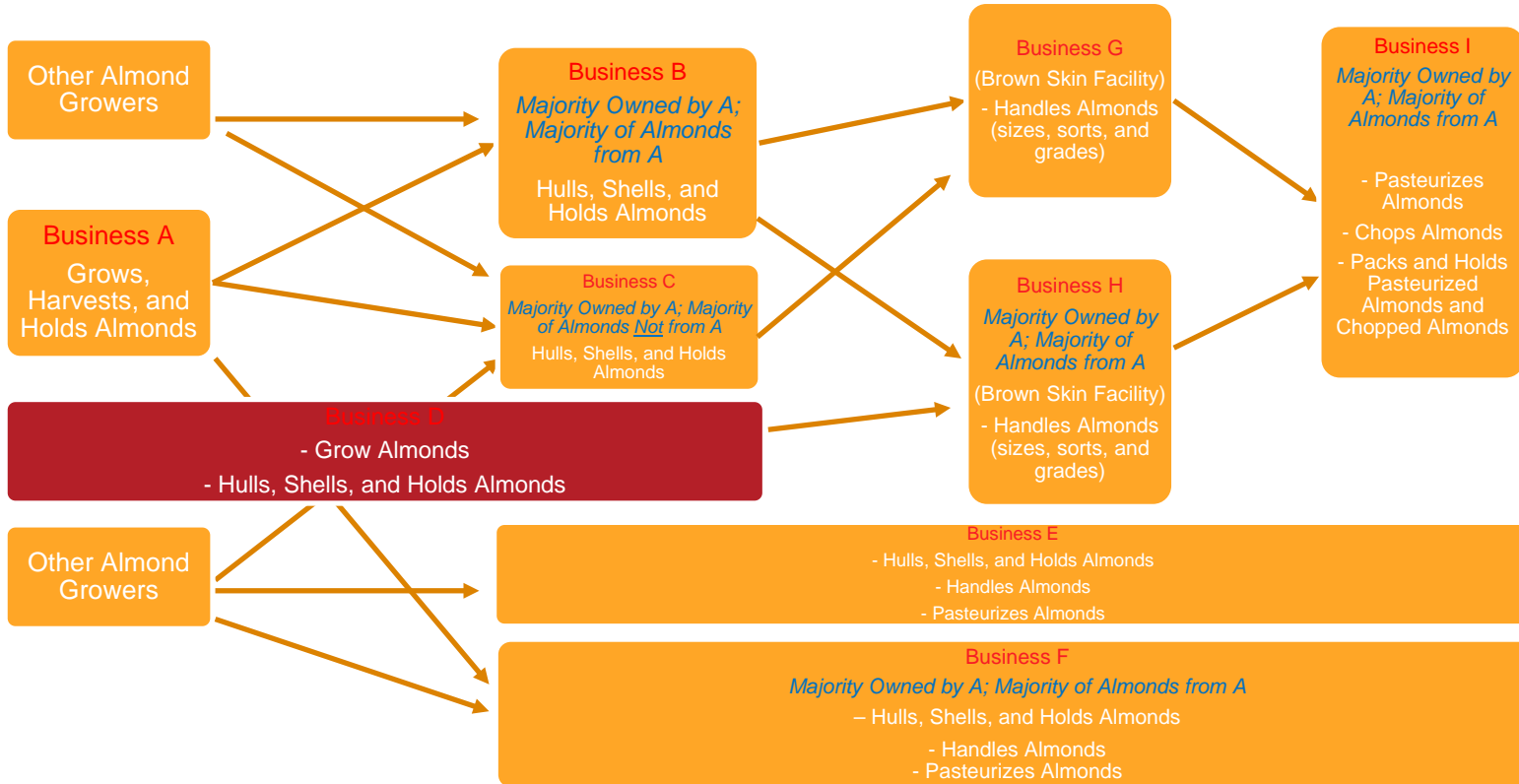
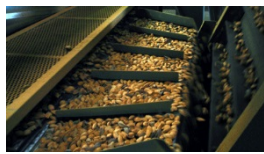


\*\* unless in the "same general physical location where RACs are grown"

# Business C: Hulls, Shells, and Holds Almonds and *Majority Owned by A with Majority of Almonds NOT from A (Huller/Sheller)*

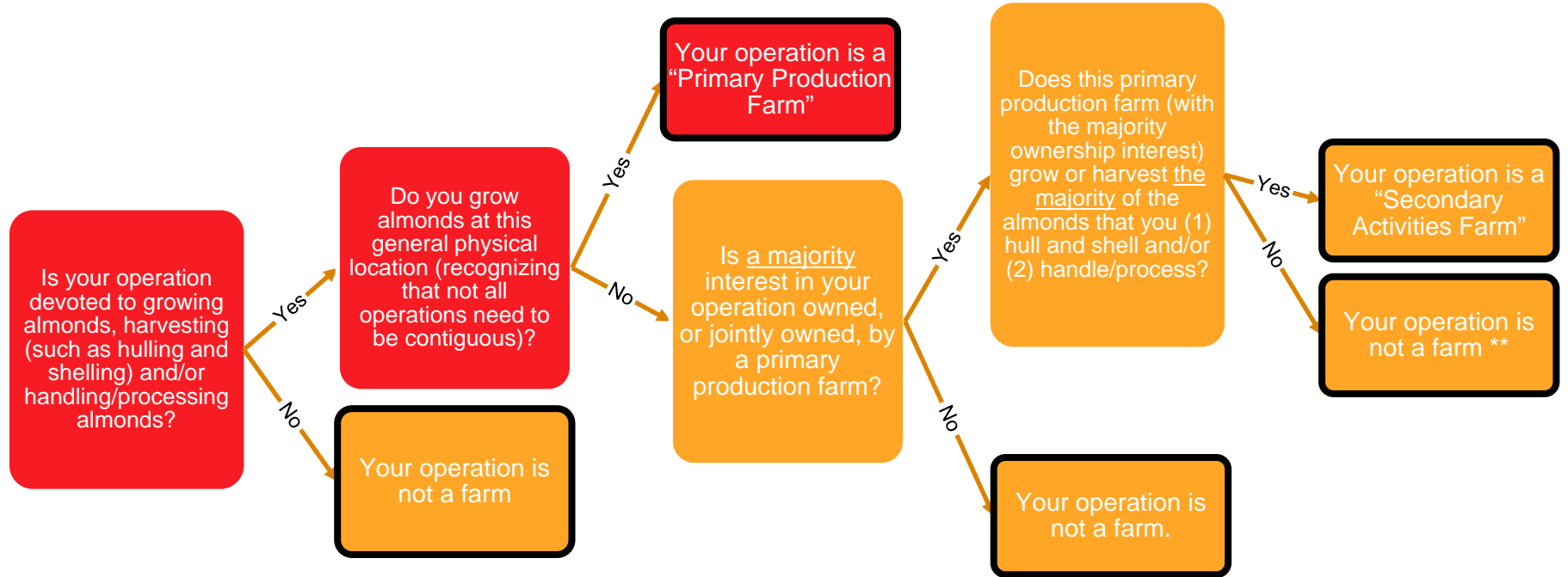
= Facility = Covered by PC + Exempt from GMPs



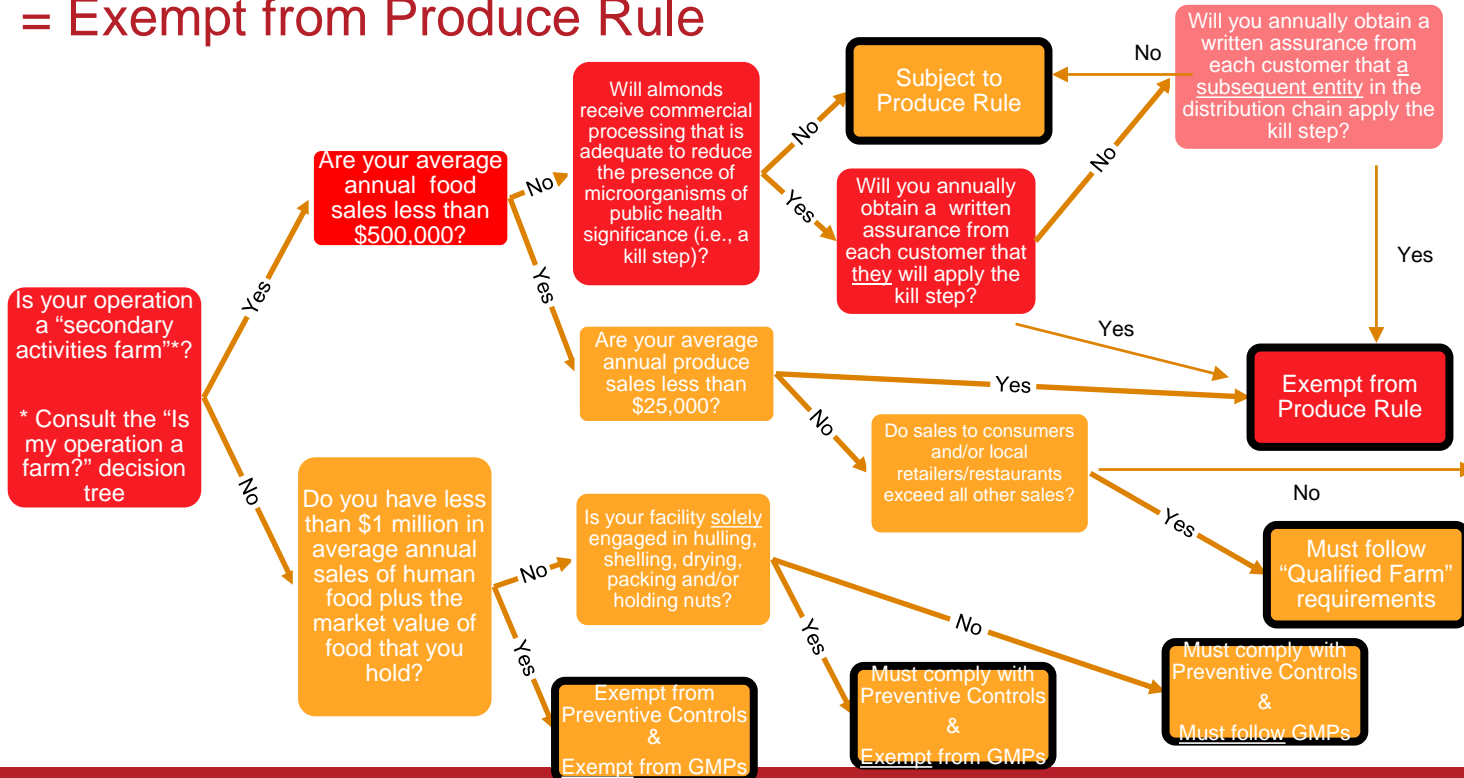


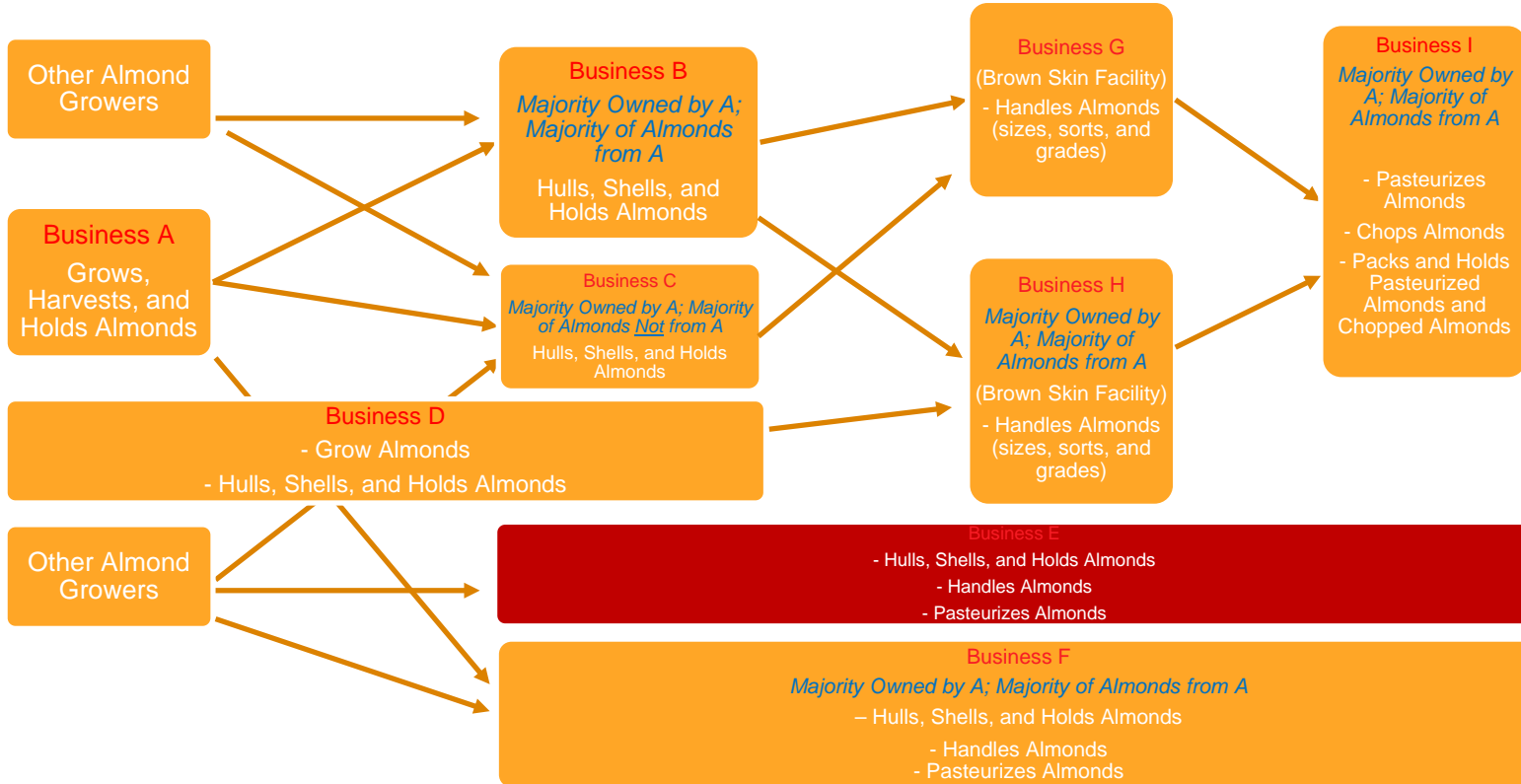
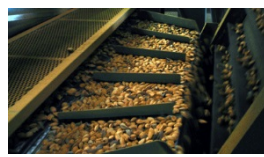


# Business D: Grows, Hulls, and Shells Almonds (Grower & Huller/Sheller) = Primary Production Farm

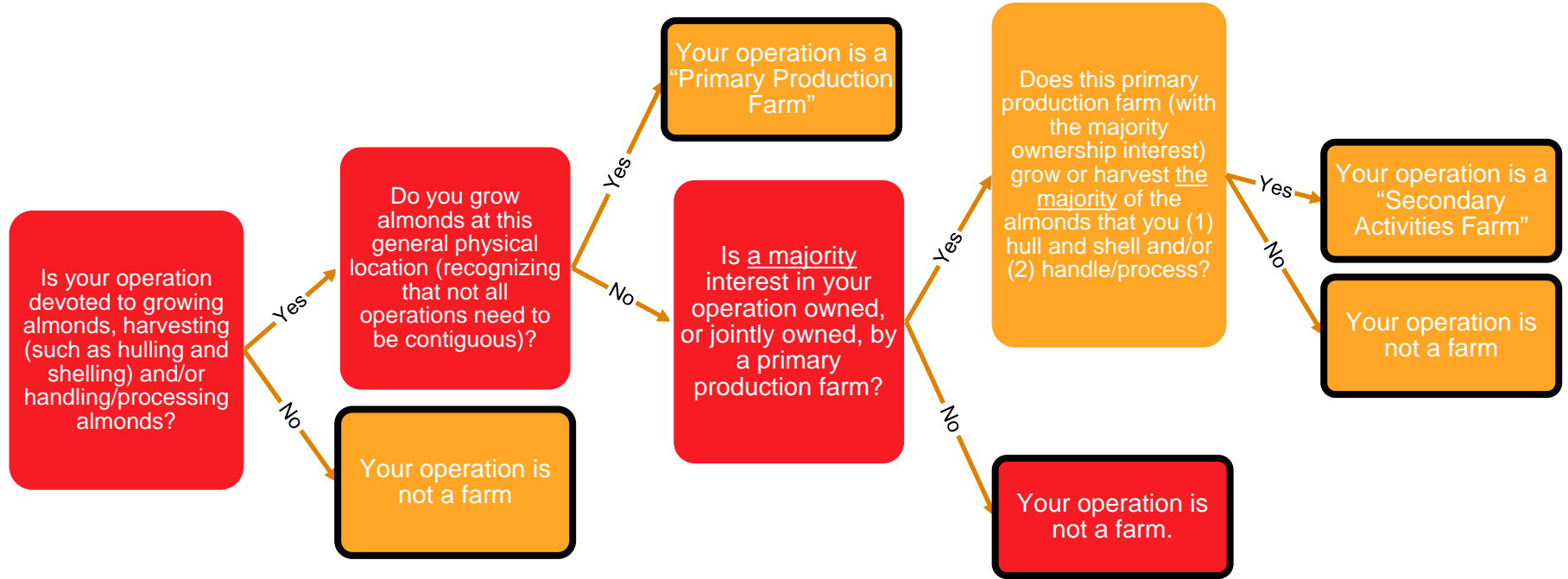


# Business D: Grows, Hulls, and Shells Almonds (Grower & Huller/Sheller) + Obtains Written Assurances = Exempt from Produce Rule

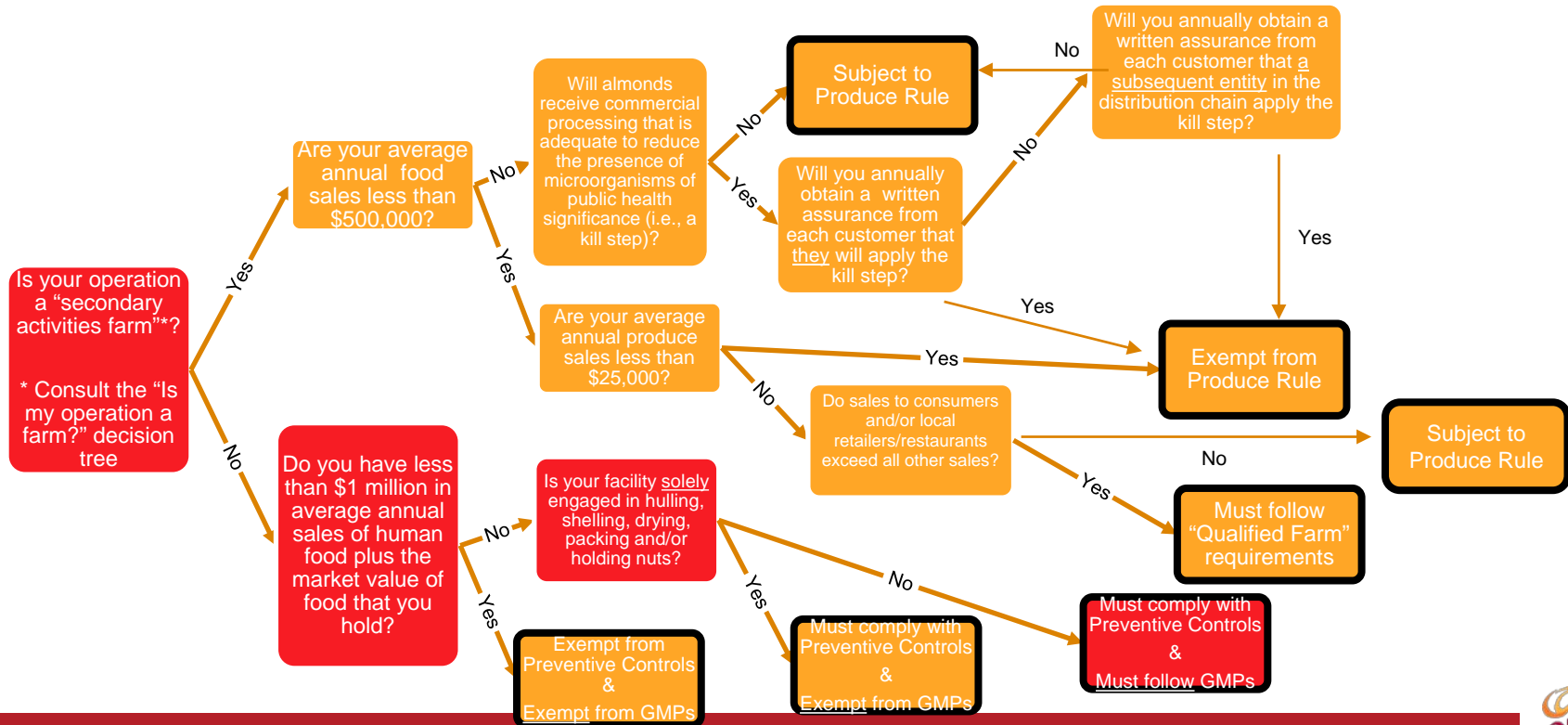


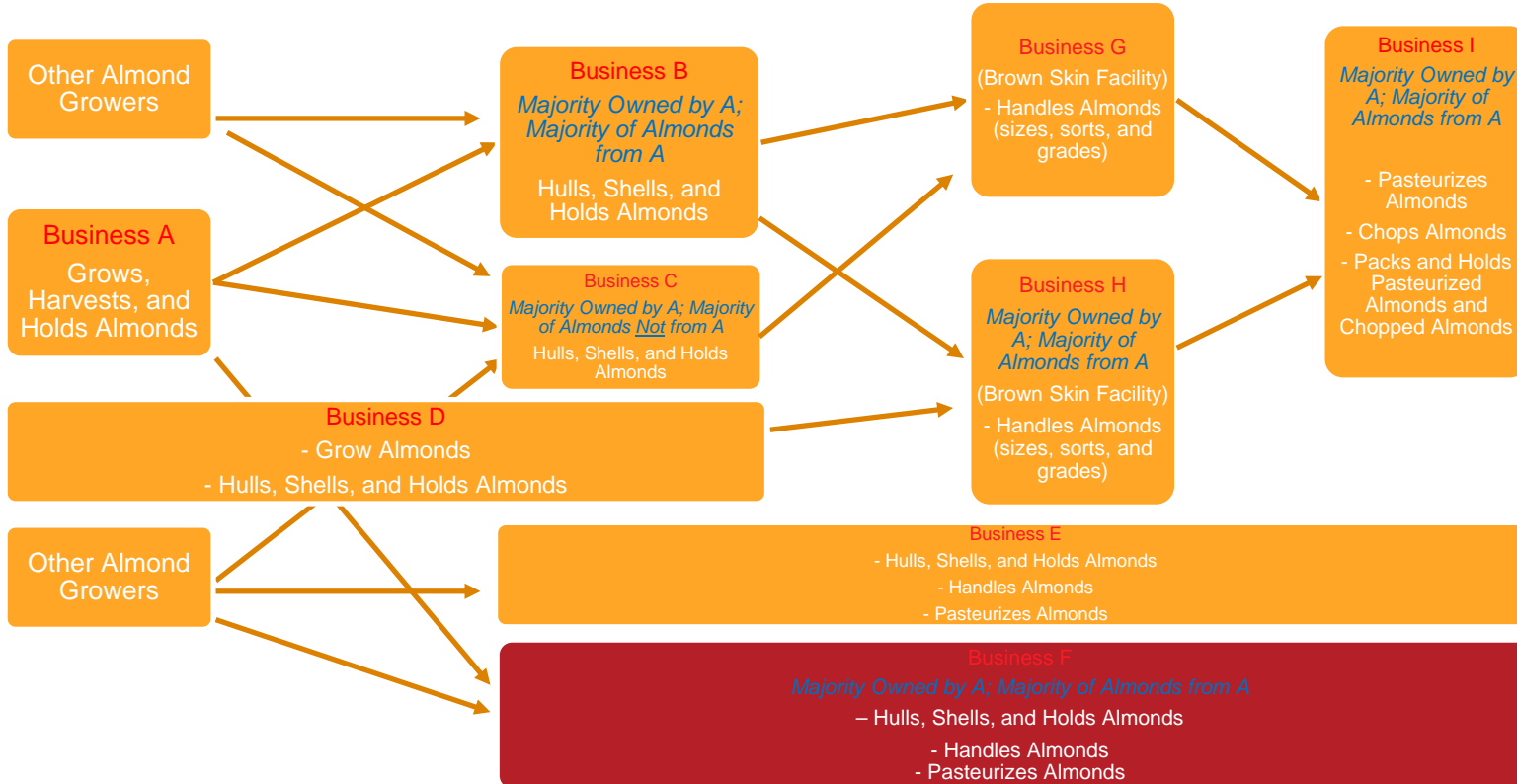
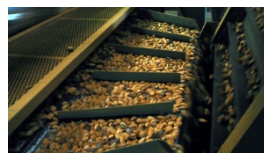


# Business E: Hulls, Shells, and Holds Almonds + *Pasteurizes Almonds* (Huller/Sheller & Processor) = Facility (Not a Farm)



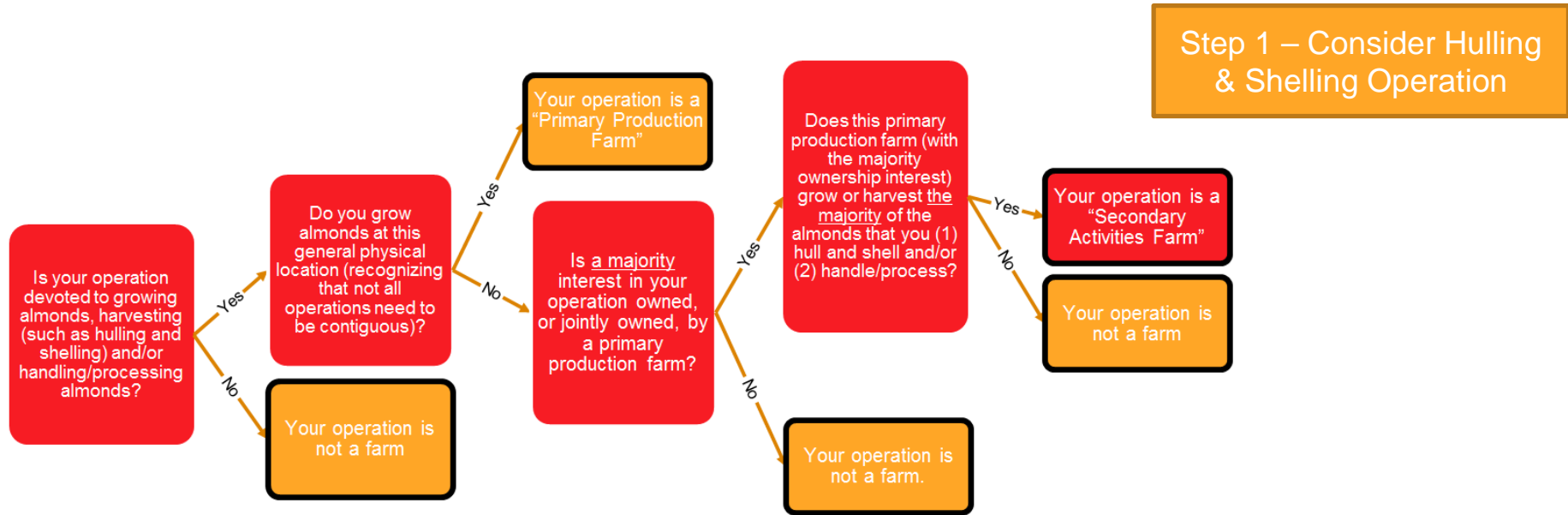
# Business E: Hulls, Shells, and Holds Almonds + *Pasteurizes Almonds* = Covered by Preventive Controls and GMPs





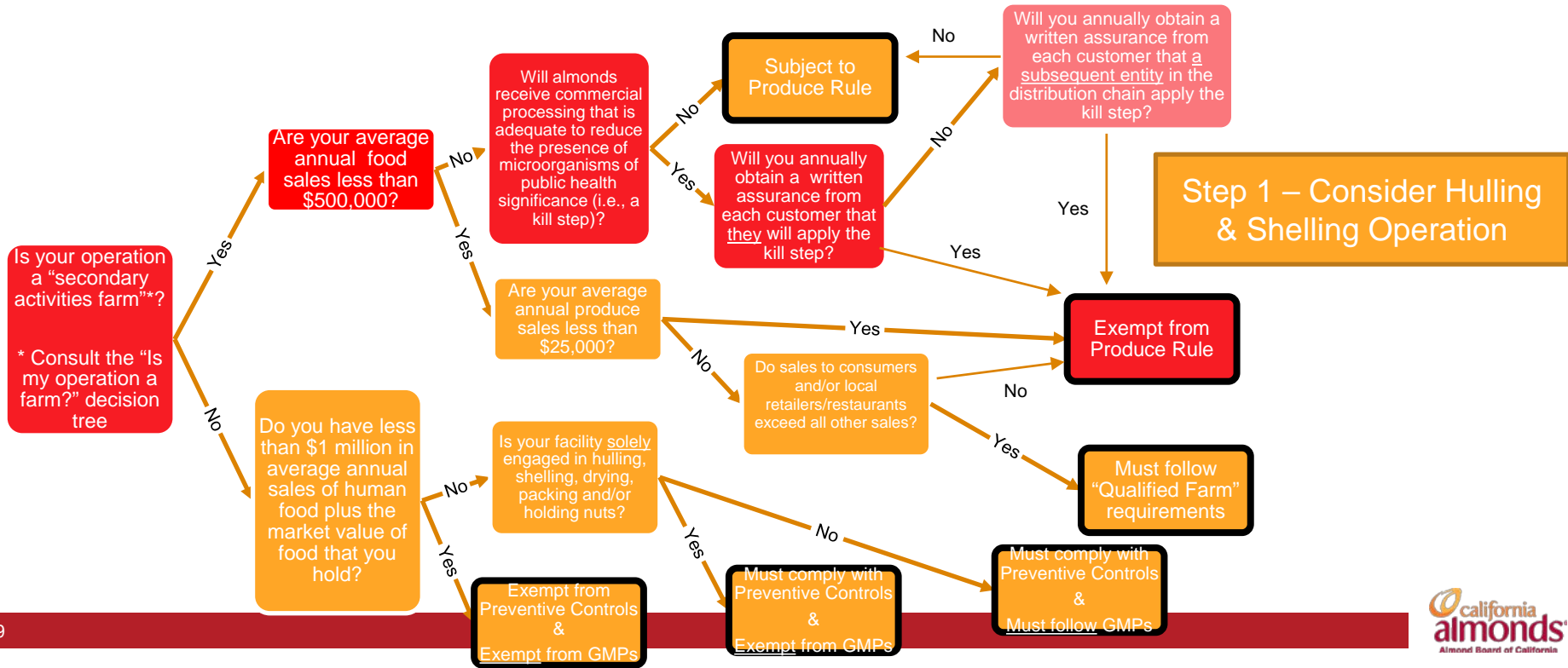
# Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A

= Farm Mixed-Type Facility = Consider both Produce and PC rules



# Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A

= Farm Mixed-Type Facility = Consider both Produce and PC rules

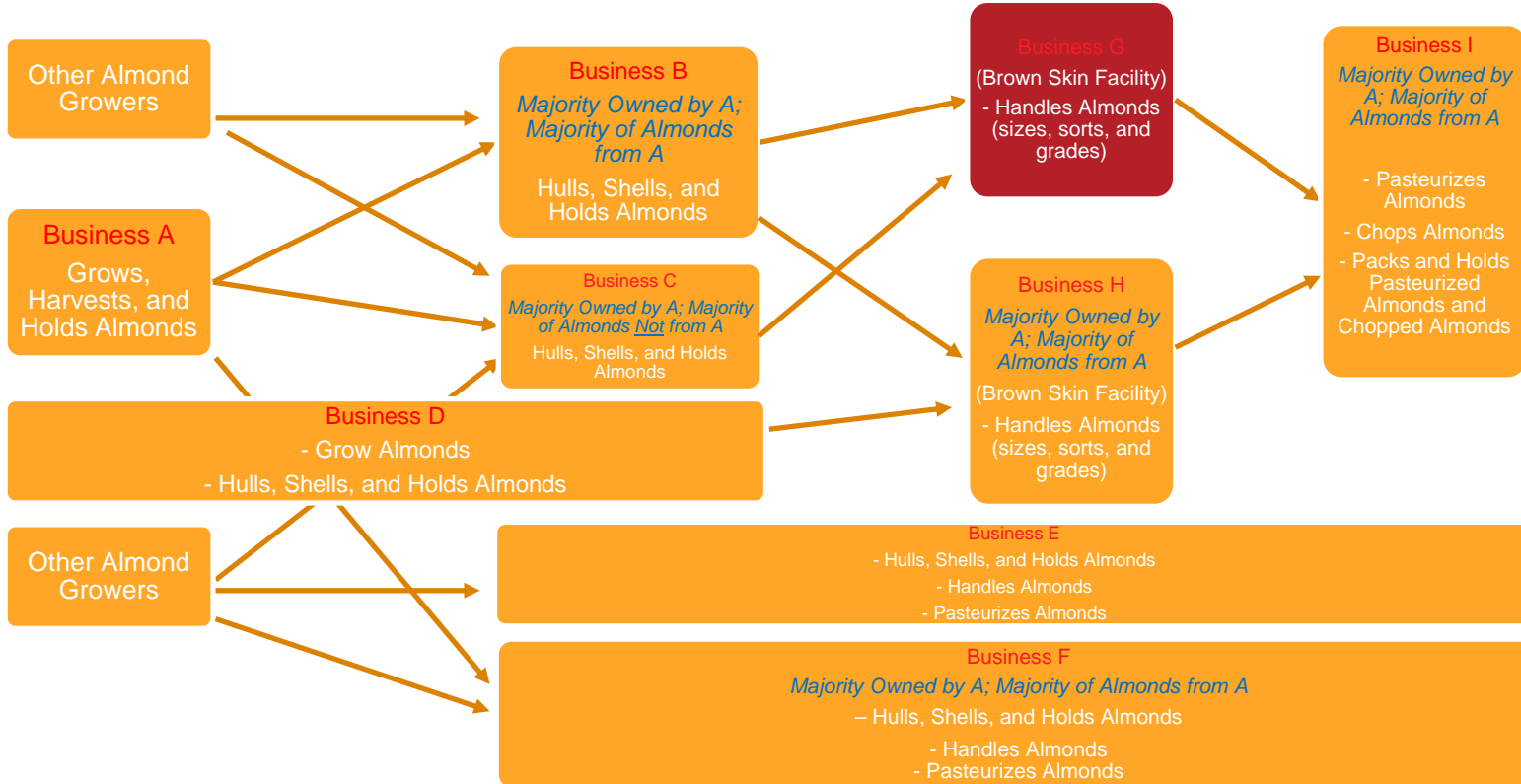
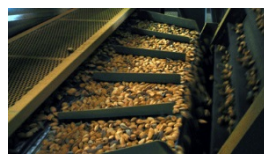




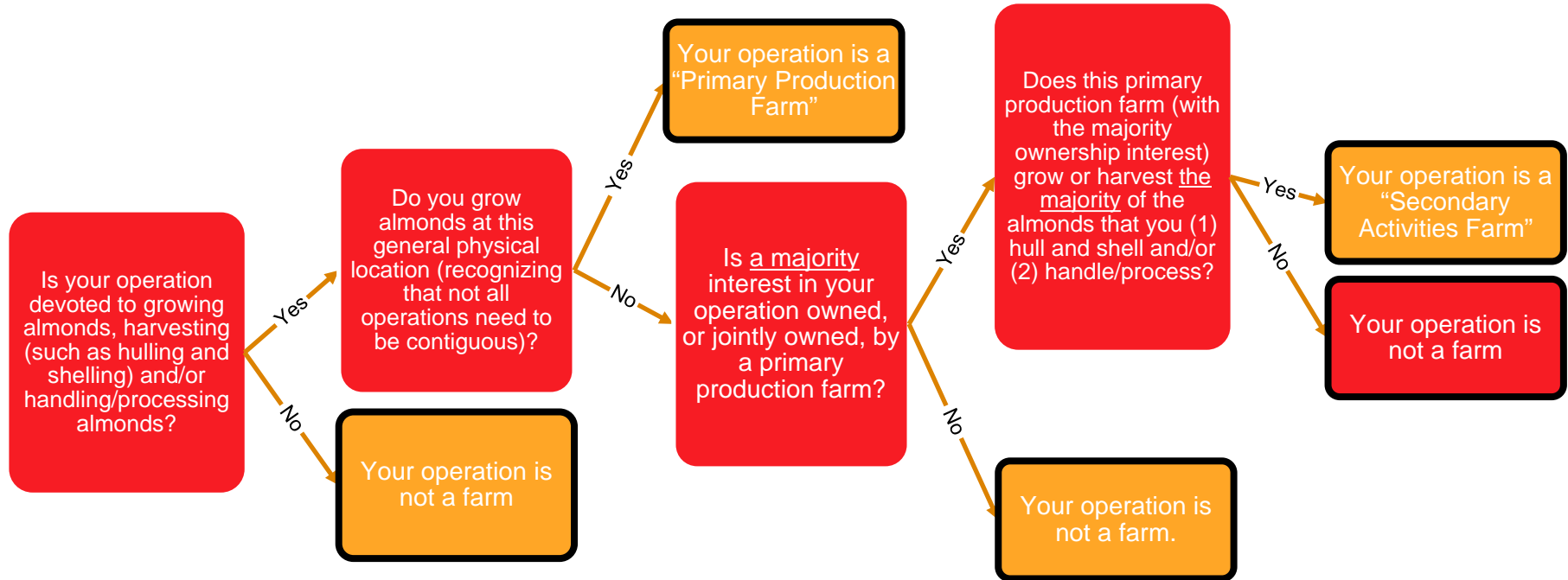
**Business F: Hulls, Shells, and Holds Almonds + Pasteurizes Almonds + Majority Owned by A with Majority of Almonds from A**  
**= Farm Mixed-Type Facility = Consider both Produce and PC rules**



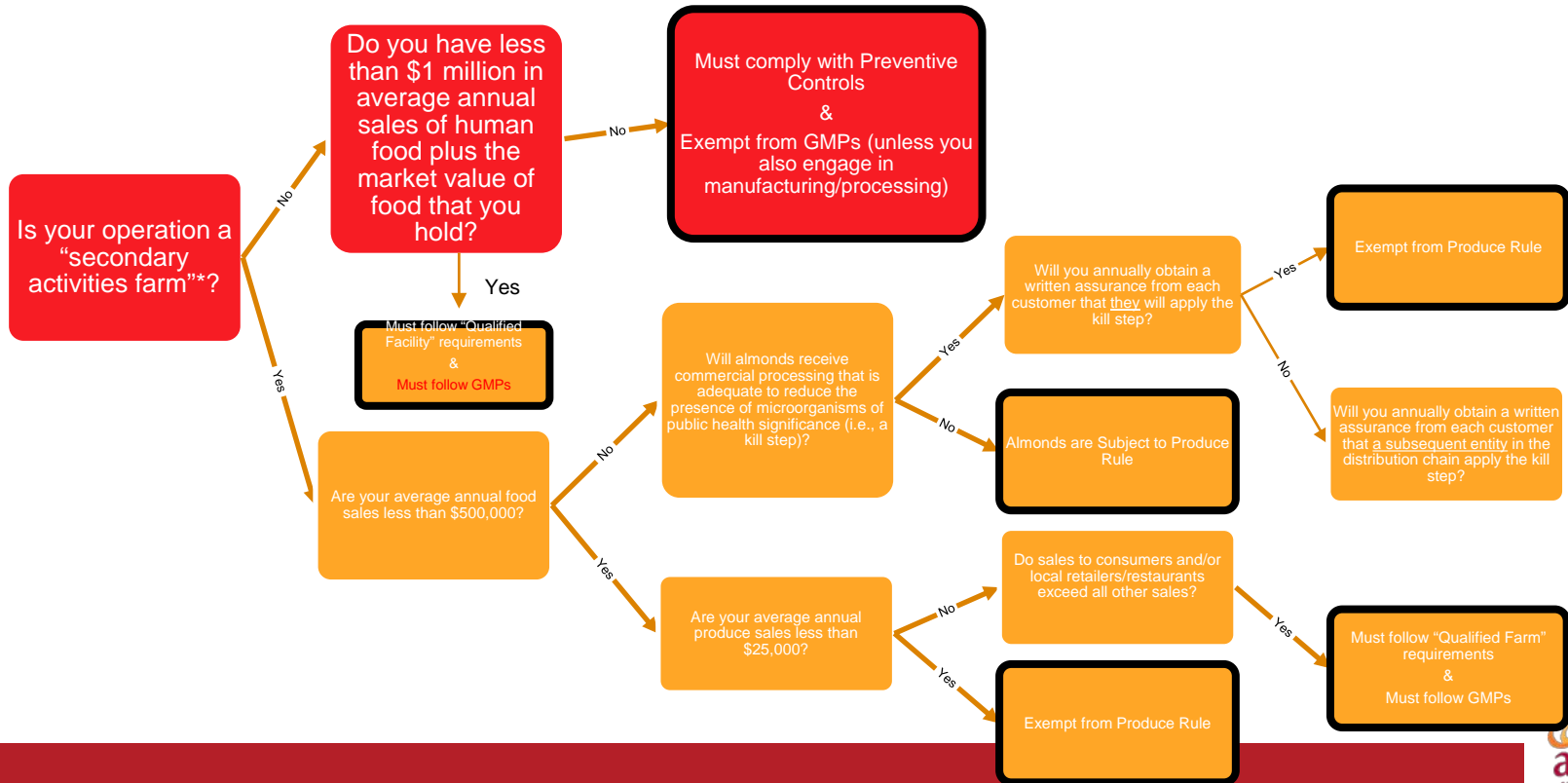
Step 2 – Consider  
"Manufacturing" Operation

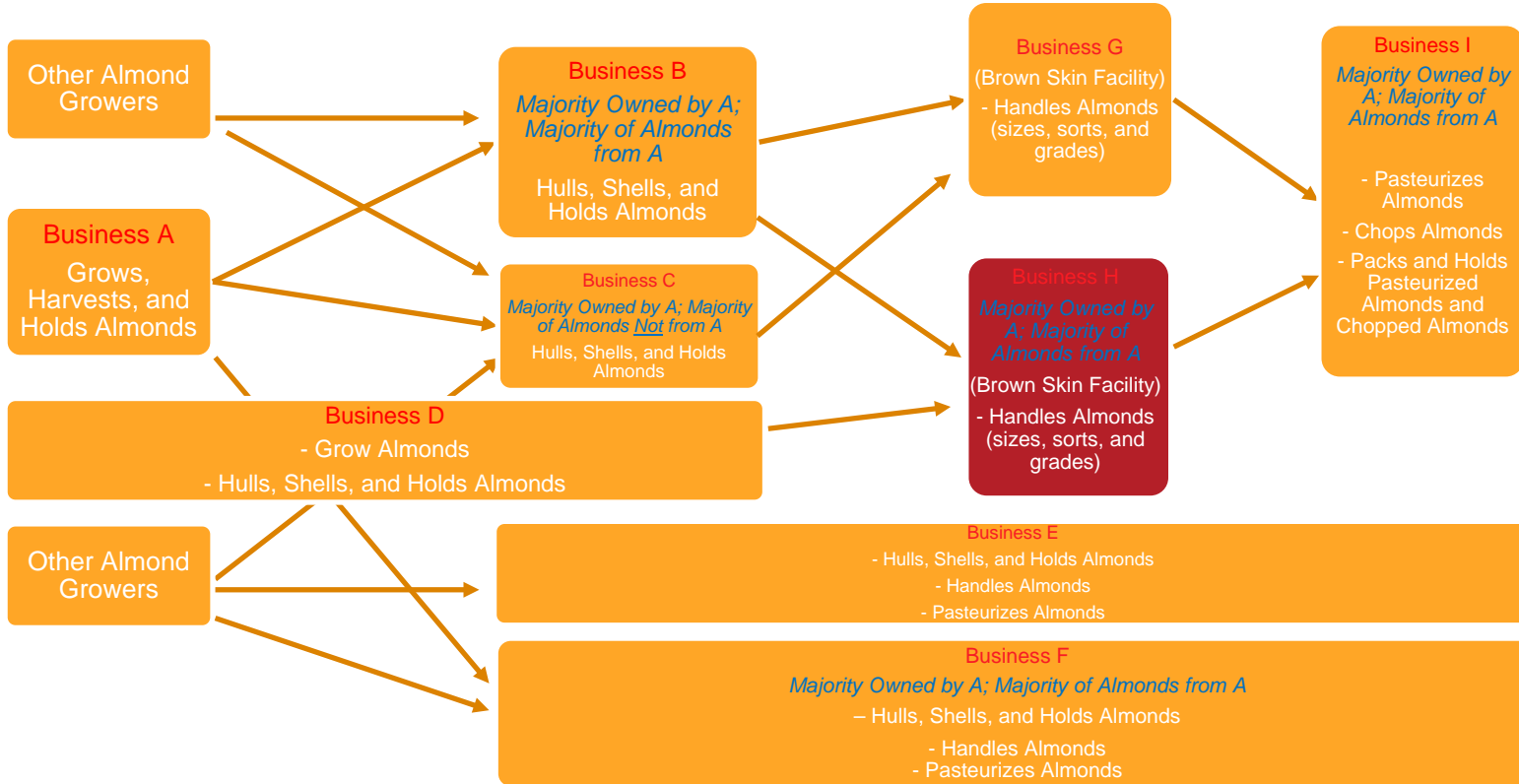
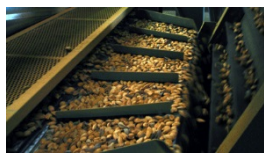


# Business G: Sizes, Sorts, and Grades Almonds (Brown Skin Facility) = Facility



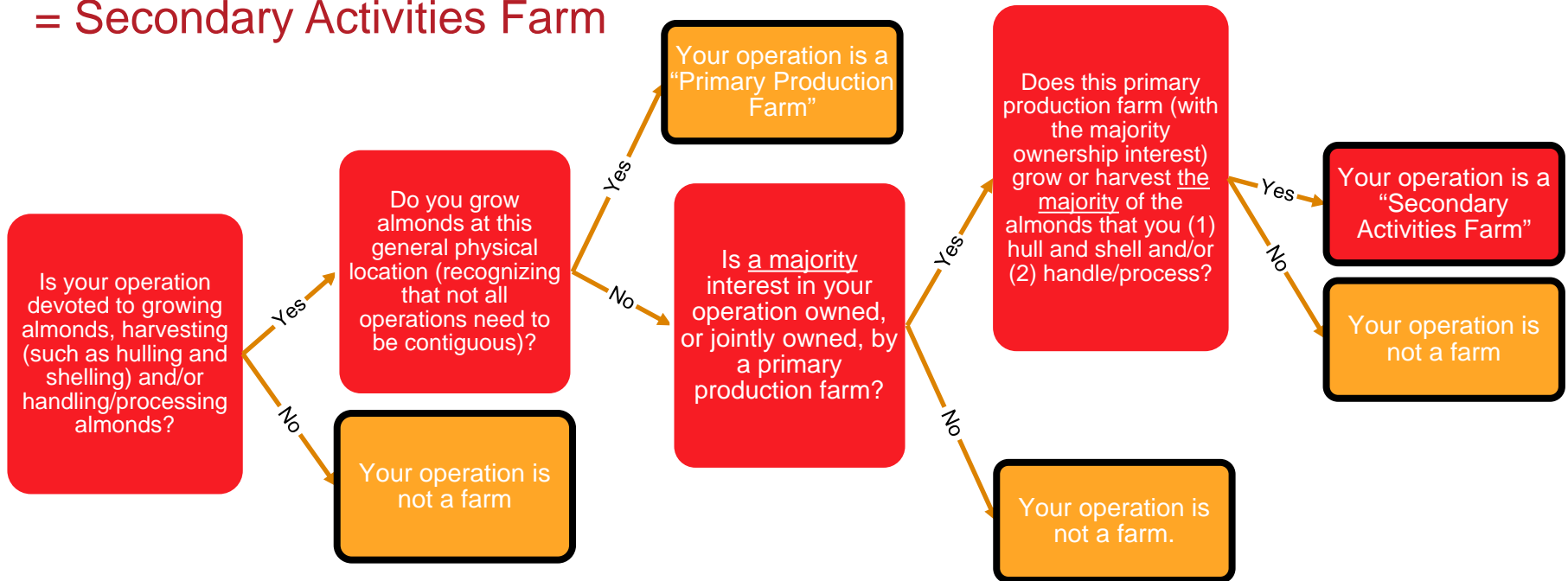
# Business G: Sizes, Sorts, and Grades Almonds (Brown Skin Facility) = Facility = Follow PCs and Exempt from GMPs





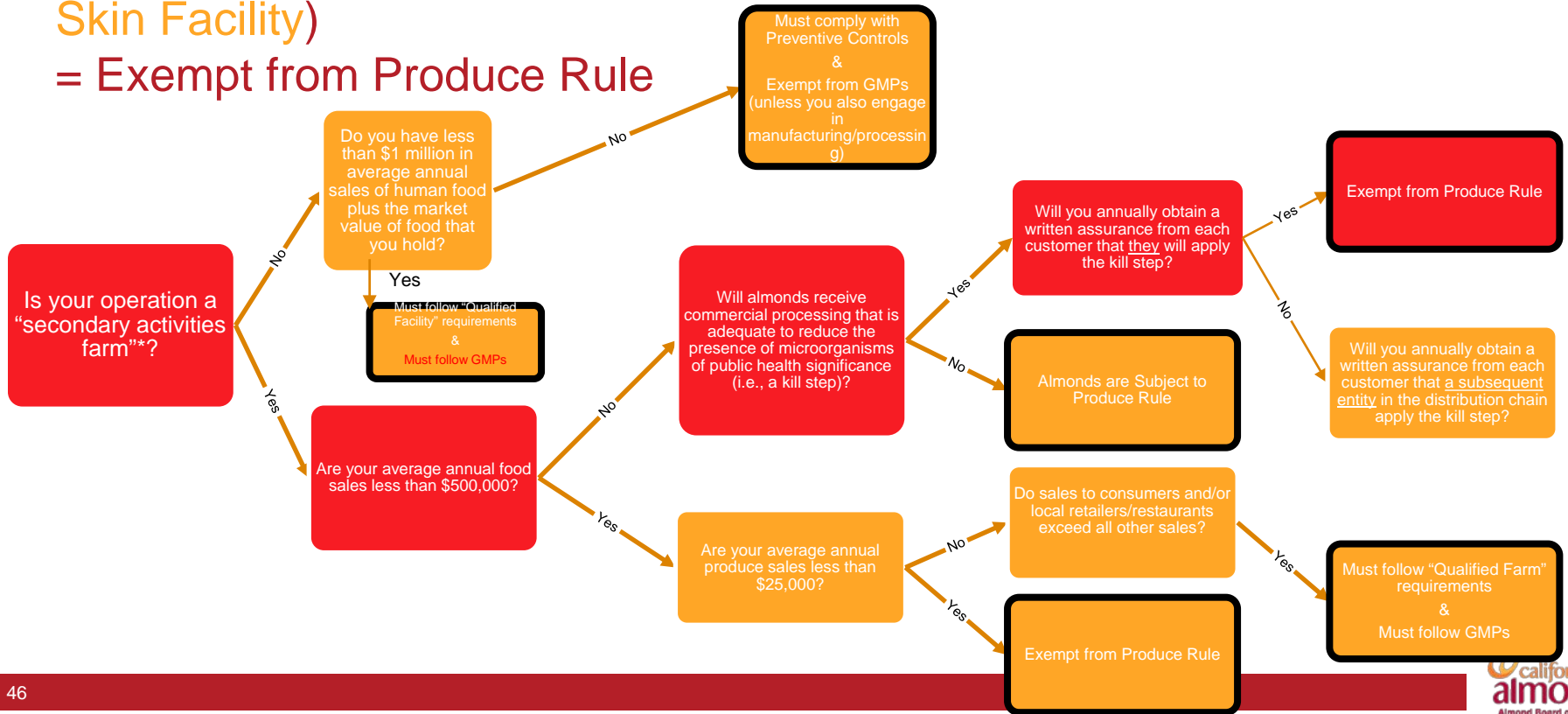
# Business H: Sizes, Sorts, and Grades Almonds and Majority Owned by A with Majority of Almonds from A + Obtains Written Assurances (Brown Skin Facility)

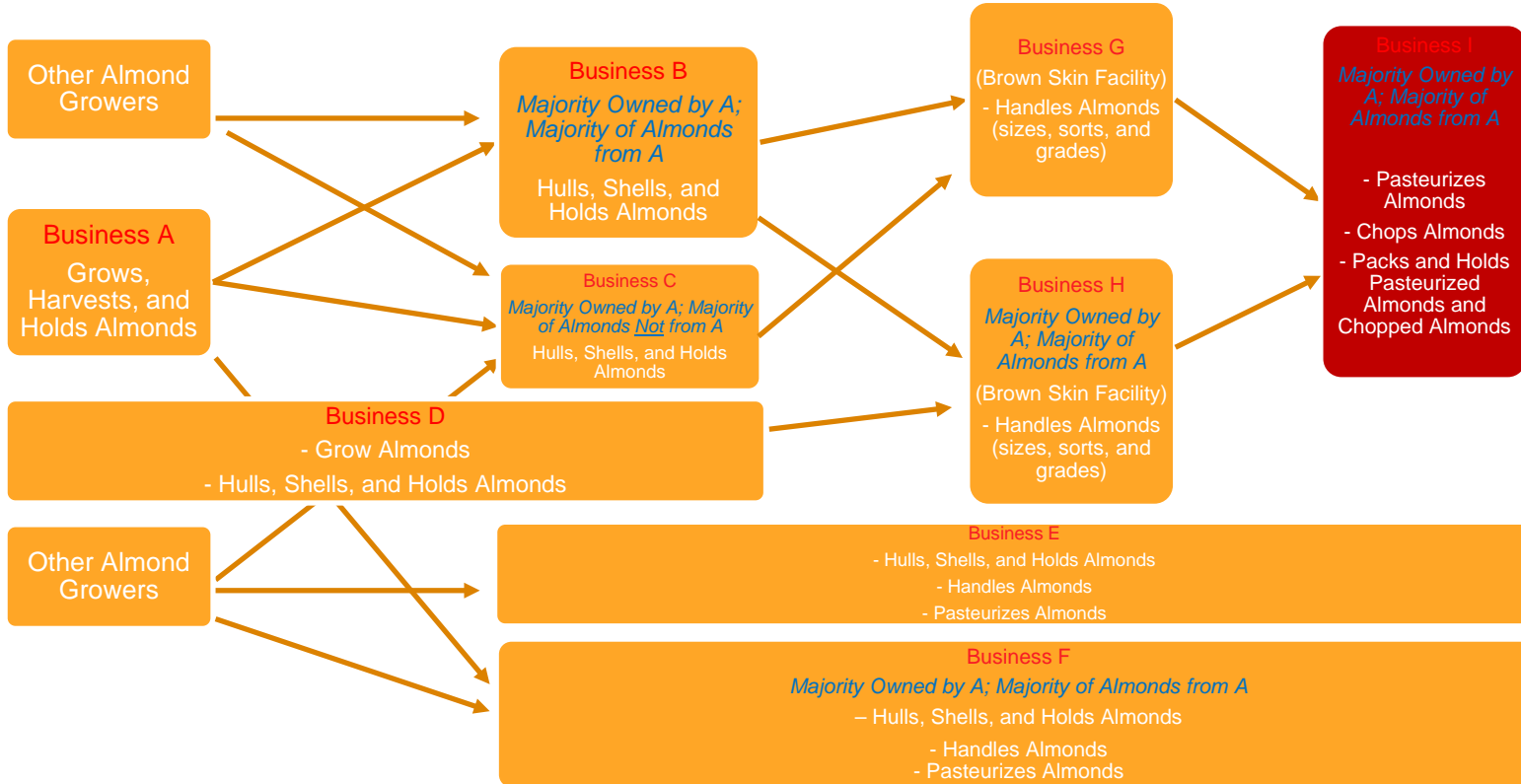
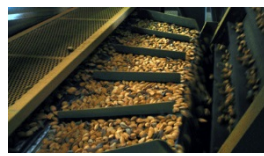
= Secondary Activities Farm



# Business H: Sizes, Sorts, and Grades Almonds and Majority Owned by A with Majority of Almonds from A + Obtains Written Assurances (Brown Skin Facility)

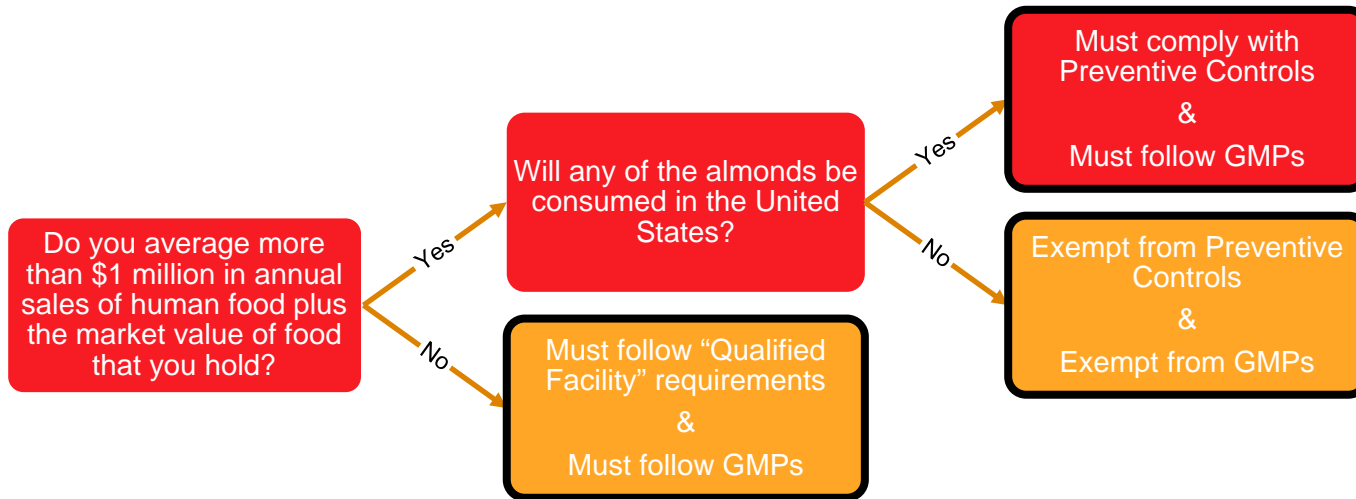
= Exempt from Produce Rule







Business I: Pasteurizes and Chops Almonds + *Majority Owned by A;*  
*Majority of Almonds from A*  
= Facility (Covered by Preventive Controls + GMPs)



# Written Disclosures & Written Assurances



# Customer Assurance Provisions

- The PC Rule provides that when a manufacturer identifies a hazard requiring a preventive control, does not control the hazard, and relies on an entity in its distribution chain to address the hazard, it must:
  1. Provide documentation to its direct customer that the food is “not processed to control [identified hazard]”; and
  2. Annually obtain a written assurance from their customer that the customer is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements, or will only sell the food to someone who agrees to do so

→ For example, if a huller and sheller is a “facility,” they likely will be covered by this provision

# Customer Assurance Provisions

- The Produce Safety rule provides that farms are exempt from the rule if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided that:
    1. The farm provides documentation accompanying the produce that the food is not processed to adequately reduce the presence of the microorganisms of public health concern; and
    2. Annually obtains written assurance from its customer that either the customer or another entity performs commercial processing that adequately reduces the presence of microorganisms
- Growers need to either comply with this provision or comply with the produce safety rule

# FDA's Draft Guidance on Written Disclosure Statements

- FDA recently issued a draft guidance on the disclosure statement requirements under the PC and Produce Safety rules
- The guidance provides recommendations on:
  - How to describe the identified hazards; and
  - What constitutes “documents accompanying the food, in accordance with the practice of trade”



# Disclosure Statement Guidance – How to Describe the Hazard



- The **Produce Safety rule** requires a disclosure that the food “is not processed to adequately reduce the presence of microorganisms of public health significance”
  - FDA will consider a farm to be in compliance if it discloses that its produce is “not processed to adequately reduce the presence of microbial pathogens,” or uses a similar phrase
  
- The **PC rule** requires the statement disclose that the food is “not processed to control [identified hazard]”
  - In practice, FDA expects disclosure statements will be used mostly for biological hazards
  - For **biological** hazards, FDA provides flexibility by allowing the hazard to be described by a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than naming a specific biological hazard (i.e., *Salmonella* or *Listeria monocytogenes*)



# Disclosure Statement Guidance – How to Communicate the Hazard

- Disclosure statements for each of the rules require the statements to be made in documents “accompanying” the food, “in accordance with the practice of trade”



– FDA notes this requirement can be satisfied in a wide variety of documents that accompany food, “such as labels, labeling, bill of lading, shipment-specific certificate of analysis, and other documents or paper associated with the shipment that a food safety manager for the customer is likely to read”



– FDA’s position is that it is not sufficient to reference a website in a document of the trade without including the disclosure statement, itself, in the document of the trade

- It would be permissible to use labeling that includes a disclosure statement such as “not processed to control microbial pathogens” and then direct the recipient to a website for additional information about those microbial pathogens



– Further, FDA does not recommend that documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the disclosure statement

- FDA’s position is that such documents are not specific to a particular shipment, and some of these documents may not be available to the customer’s food safety manager

# Almond Board Recommended Strategy for Compliance

- Based on discussions with FDA and the draft guidance, the Almond Board recommends taking the following approach for written assurances:
  - Grower provides written disclosure to handler:
    - “Almonds are not processed to adequately reduce the presence of microorganisms of public health significance”
  - Handler provides written assurance to grower:
    - Assurance must explain that the almonds will be subject to processing (following procedures under the Marketing Order that adequately reduce the presence of microorganisms of public health significance), or otherwise they will be exported with a disclosure that they are “not processed to adequately reduce the presence of microorganisms of public health significance”
  - Handlers can put the written assurance in their annual contract with the grower
  - No further documentation needed for hullers/shellers, DV users, customer processors, or export customers.
- Guidance document from Almond Board coming soon!
- Note that FDA has not formally sanctioned this approach and it is not entirely aligned with the regulations



# How Growers Can Avoid Disclosures & Assurances

- Growers are only required to comply with the written disclosure/assurance provisions if they want to be exempt from the Produce Safety rule
- The Almond Board conducted a gap assessment for the Produce Safety rule and found that most of the requirements can be addressed through enhanced training programs for workers, but that the agricultural water standards may pose challenges

Privileged and Confidential - May Only Be Used for Reporting Chart Communication

**Almond Board of California  
Produce Safety Rule Gap Assessment  
June 9, 2016**

Topic	Requirements of FDA's Final Rule	Current Practices	Identified Gaps/Areas for Follow-Up
§ 112.21 – (What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?)	<p><b>Subject C – Personnel Qualifications and Training</b></p> <p>Personnel who handle (contact) covered produce or food contact surfaces are subject to all of the following requirements:</p> <p>(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive <b>adequate training</b>, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.</p> <p>(b) All personnel (including temporary, part time, seasonal, and contracted persons) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a <b>combination of education, training, and experience necessary to perform the person's assigned duties</b> in a manner that ensures compliance with this part.</p> <p>(c) Training must be conducted in a <b>manner that is easily understood</b> by personnel being trained.</p> <p>(d) Training must be <b>repeated as necessary and appropriate</b> in light of observations or information indicating that personnel are not meeting FDA's produce safety standards.</p>	<p><b>Concerns that even truck drivers, irrigation workers need training (re: touching product, eating allergens, personal hygiene)</b></p> <p><b>Implications for contract harvesters: handlers will be asking for information on allergen practices</b></p> <p><b>Tailgate training is common</b></p>	<p><b>May need to reemphasize to industry members the importance of personnel training</b></p> <p><b>Potential for more standardized training across industry?</b></p>
§ 112.22 – (What minimum requirements apply for training personnel who conduct a covered activity?)	<p>(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:</p> <p>(1) <b>Principles of food hygiene and food safety.</b></p> <p>(2) <b>The importance of health and personal hygiene for all personnel and</b></p>		<p><b>May need to incorporate additional training on new FDA produce safety rule requirements into existing training</b></p> <p><b>Need to complete the Produce Safety Alliance training, for small growers it may make sense to outsource (ISA, training, requirements to third parties)</b></p>



# Extension of Certain FSMA Compliance Deadlines

# Extension of Certain FSMA Compliance Deadlines

- In September, FDA issued a final rule extending certain compliance deadlines for four of the seven final FSMA regulations: Human Food Preventive Controls (PC), Animal Food PC, Foreign Supplier Verification Program (FSVP), and Produce Safety rules
  - These are not blanket extensions of the compliance deadlines for the FSMA rules
  - The following three\* categories of compliance date extensions may affect the almond industry:
    - 1) The requirement to obtain customer assurances for food that will be subject to further processing;
    - 2) Compliance with PC rules for facilities solely engaged in packing and/or holding activities conducted on nut hulls and shells; and
    - 3) Compliance with PC rules for facilities that would qualify as “secondary activities farms” except for ownership of the facility
- \* The guidance also contains a clarification on the meaning of the compliance date for the agricultural water testing provision



# 1. New Compliance Dates for Customer Assurance Provisions

- The new compliance dates for the customer assurance provision under the Human Food PC rule are:
  - **September 19, 2018** for businesses with 500+ full-time equivalent employees
  - **September 18, 2019** for small businesses (less than 500 full-time equivalent employees)
- The new compliance dates for the customer assurance provisions under the Produce Safety rule are:
  - **January 28, 2019** for businesses with over \$500,000 in average produce sales
  - **January 27, 2020** for small businesses (\$250,000-\$500,000 in average produce sales)
  - **January 26, 2022** for very small businesses (\$25,000-\$250,000 in average produce sales)



# 1. Scope of Customer Assurance Provisions Extension

- The original compliance dates remain in effect for the requirement under the PC Rule to disclose and provide documentation that a hazard has not been controlled when relying on a subsequent entity to control the hazard
  - For example, if a huller and sheller that is a “facility” ships raw almonds to another company that will perform the kill step, the huller and sheller must provide documentation that the food is “not processed to control *Salmonella*.”
- You cannot separate the facility registrations for your manufacturing/processing and hulling/shelling/handling operations in order to take advantage of the compliance date extension.
  - Even if a business has different structures engaging in different activities, it would still be considered one facility if the ownership is the same



## 2. Facilities Engaged in Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

- Certain off-farm operations, such as facilities that hull, shell, pack, and/or hold nuts, are subject to the PC rule, rather than the Produce Safety rule
    - E.g., a huller and sheller that does not meet the definition of “secondary activities farm”
  - FDA is extending the compliance date for “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells”
- This extension covers almond brown skin facilities that only size, sort, grade, or pack almonds, as well as facilities that only hull and shell almonds
- As long as the facility does not engage in manufacturing or processing activities (i.e., chopping, grinding, mixing, roasting, pasteurizing, salting) then it can take advantage of the compliance date extension



## 2. Facilities Engaged in Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

- The new compliance dates for the PC rule for these facilities will align with the compliance date for the Produce Safety rule
  - These facilities now have the same time to understand the applicable provisions of the Produce Safety regulation as “farms” that conduct similar packing and holding activities
  - FDA expects that these facilities will draw from the provisions of the [P]roduce [S]afety regulation in developing [their] food safety plan,” so the extension gives them the same amount of time as farms to understand the produce rule
  
- It’s notable that FDA expects these facilities to adopt the same type of food safety practices under its Food Safety Plan as it would be required to implement under the Produce Safety rule

## 2. New Compliance Dates for Packing/Holding Produce RACs or Nut Hulls and Shells under PC Rule

- The new compliance dates for the human PC rule for facilities that pack, hold, shell, or hull nuts are:
  - **January 26, 2018** for businesses with 500+ full-time equivalent employees
  - **January 28, 2019** for small businesses (under 500 full-time equivalent employees)
  - **January 27, 2020** for very small businesses (under \$1 million in average sales/value of food held)





### 3. Facilities that Qualify as Secondary Activities Farms Except for Ownership of Facility

- Facilities that meet the definition of “secondary activities farms” except for the ownership criterion can take advantage of an extension for compliance with the PC rule if:
  - 1) The operation is not located on the primary production farm;
  - 2) The operation is devoted to harvesting, packing, and/or holding of RACs (including operations that hull, shell, and/or dry nuts without additional manufacturing); and
  - 3) The operation is under **common ownership** with the primary production farm that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the operation
    - Examples of common ownership include:
      - An operation owned by (or that owns) one or more primary production farms (e.g., a packing house owned by a cooperative of individual farms)
      - Operations that are managed within the same business structure as the primary production farm (e.g., the farm and packinghouse are separate operations owned by parents and their children, respectively, and both operations are part of the same business jointly owned by the parents and the children)

### 3. New Compliance Dates for Facilities that Qualify as Secondary Activities Farms Except for Ownership of Facility

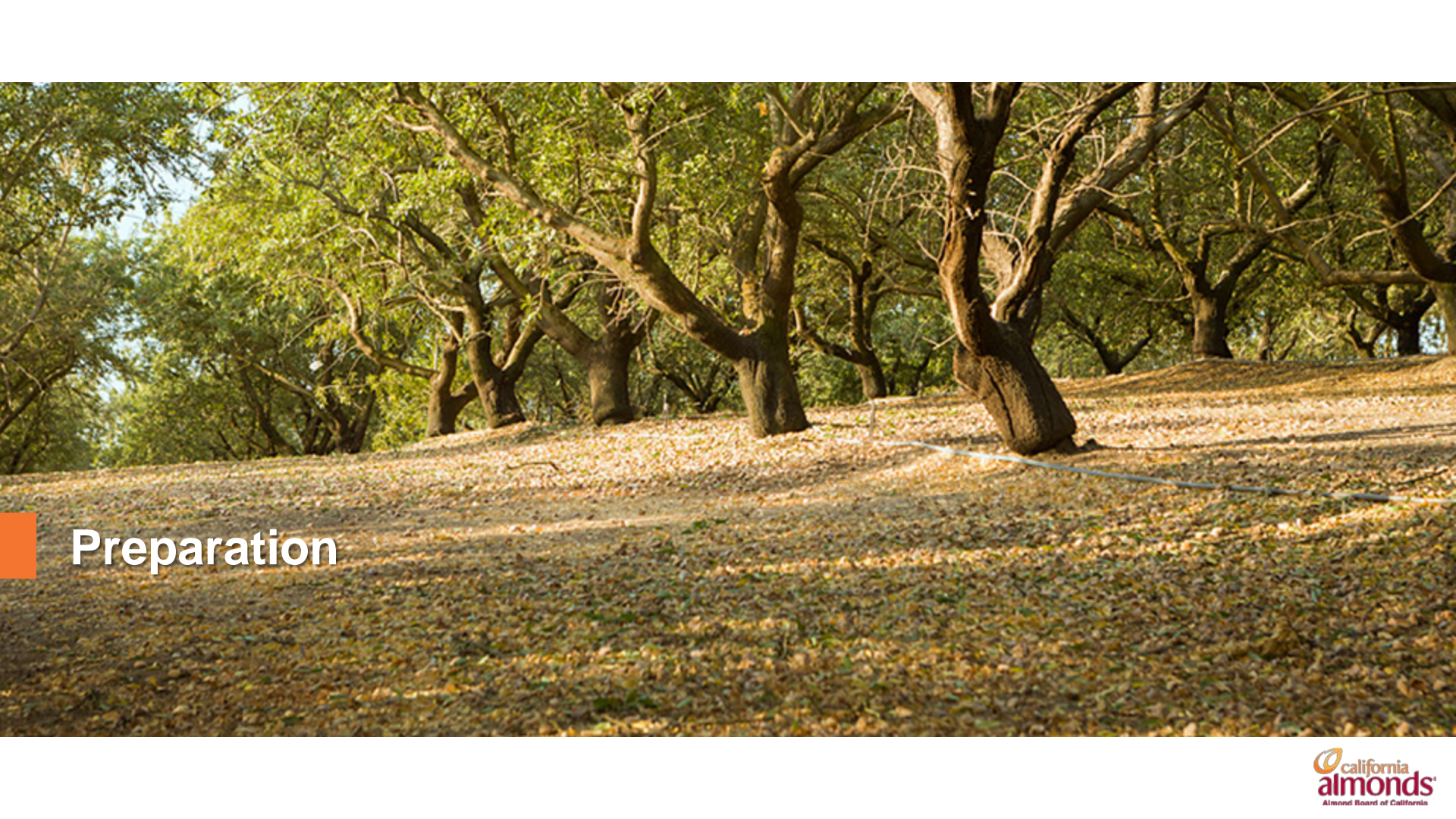
- For operations satisfying the criteria, the new compliance dates for the human food PC rule are:
  - **January 26, 2018** for businesses with 500+ full-time equivalent employees
  - **January 28, 2019** for small businesses (under 500 full-time equivalent employees)
  - **January 27, 2020** for very small businesses (under \$1 million in average sales/value of the food held)

→ The compliance date extensions match the compliance dates for businesses in the same size categories in the produce safety rule, as well as other extended compliance dates related to the farm definition



# FDA's Clarification Regarding the Agricultural Water Testing Provision

- FDA's guidance also contained a clarification regarding its intent of the meaning of the compliance dates for certain agricultural testing requirements in the Produce Safety rule
  - The guidance provides that farms are allowed discretion as to both the number of samples they take in their initial survey to develop a microbial quality profile for untreated surface water directly applied to growing produce, provided that the total is 20 or more samples
  - FDA is also allowing discretion as to the time period over which the samples are taken, provided that it is at least two years, and no more than four years
- This only affects you if you're a grower that opts to comply with the Produce Safety rule rather than obtaining written assurances



# Preparation

## Prepare Now!

- Although we have some compliance date extensions, they're narrow:
  - Customer assurances
  - Huller/shellers and handlers that are “facilities” and also do not “manufacture” food
  - Facilities that are *almost*, but not quite, secondary activities farms
- It's essential to start preparing now, rather than waiting until the 11<sup>th</sup> hour
- The FSMA regulations require significant changes that will take time to implement—no matter where you're located in the supply chain





# Where to Start

- Determine which rule(s) apply to your operation and your compliance
  - Leverage the tools developed by the Almond Board!
  - Start by making a list of the activities you perform
- Growers:
  - Assess obligations under produce rule, or plan for written disclosures and written assurances
- Hullers & Shellers and Processors/Handlers:
  - Assess obligations under produce rule, or plan for written disclosures and written assurances
  - Develop a Food Safety Plan
    - Conduct and document hazard analysis
    - Plan for written disclosures and written assurances for biological hazards
- Manufacturers:
  - Develop a Food Safety Plan
    - Improve documentation under existing HACCP plan
    - Train PCQI(s)
    - Plan for providing written assurances to suppliers
    - Develop or improve supplier verification program



# Renewal of Food Facility Registration

- Remember to renew your facility's registration—if you're still required to register!
  - Food facilities are required to renew their registration biennially between October 1 and December 31 of every even-numbered year
  - If a facility fails to renew its registration, it is considered expired and will be removed by FDA
- Registration renewal is not required if a facility's legal requirement to register has changed as a result of FSMA
  - Farms are not required to register!



# Questions?





## Contact Information

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