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Which FSMA Rules Apply to Me?

FSMA Decision Tool Prepared for the
Almond Board of California

June 2016



Overview and Directions

Background



- The FDA Food Safety Modernization Act (FSMA) imposes new requirements for all segments of the almond industry – from growers to value added operations.
- FDA has issued four final rules that establish the new regulations:
 - Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015)
 - Preventive Controls for Animal Food, 80 Fed. Reg. 56170 (Sept. 17, 2015)
 - Produce Safety, 80 Fed. Reg. 74354 (Nov. 27, 2015)
 - Intentional Adulteration, 81 Fed. Reg. 34166 (May 27, 2016)

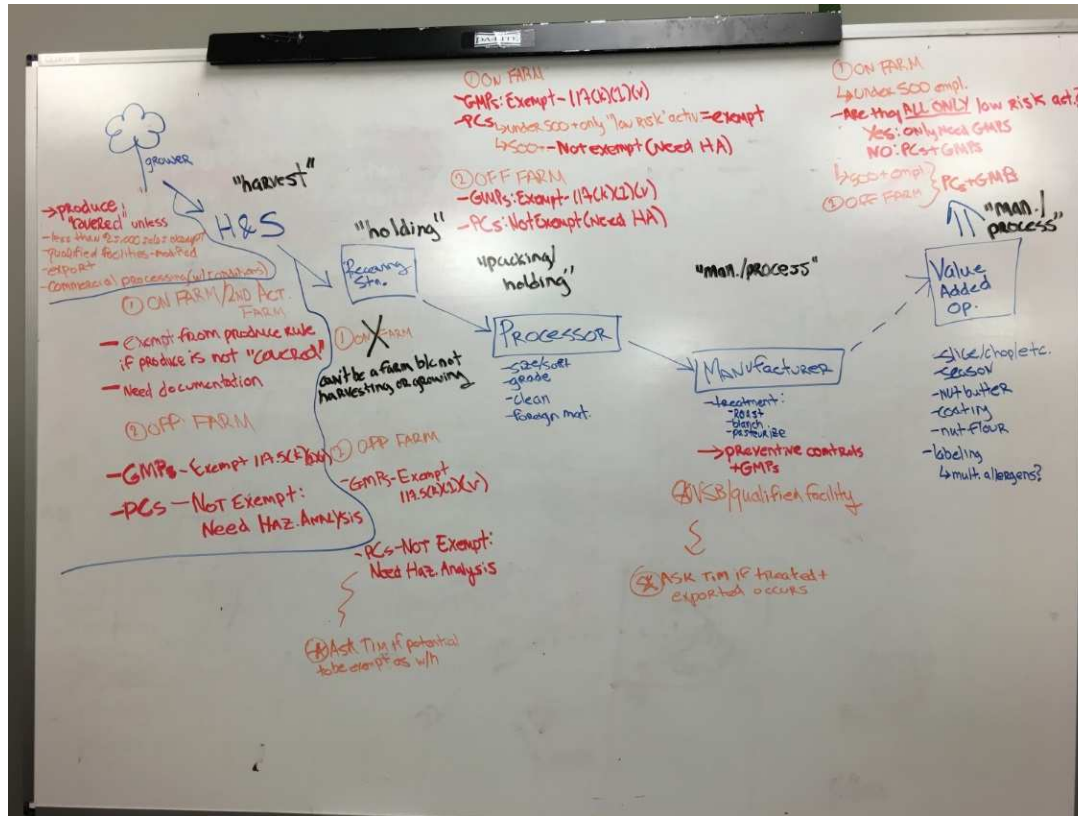


These slides explain when these FSMA regulations apply to various types of almond operations.

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, and
 - (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!



** Don't rely on this brainstorming as legal advice!

How to Use This Tool:

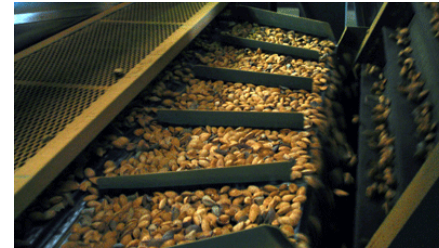
1. Determine the types of almond operations in which your company is engaged
 - See the list of types of operations and examples on the next slide
2. If you are a huller/sheller and/or processor/handler, review the “Is my operation a farm?” decision tree
3. Review the decision trees for each applicable type of operation
 - For example, if you are a grower but also engage in value-added operations, you need to consider requirements for both types of activities
4. Endpoints are outlined in gray: 

ALL activities conducted by your operation need to be considered separately!

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



Qualifiers

- This is not legal advice. These decision trees are just intended to help you understand the general FSMA framework.
- The Almond Board of California (ABC) developed this guidance as a tool for its members. ABC shall not be held liable for any inaccuracies in this information or any misunderstandings of its content.
- You are advised to consult with legal counsel for specific questions about the legal requirements for your operation.
- Forthcoming guidance from FDA may change some of the interpretations summarized in these decision trees.

Definitions



“Farm” Definition

- Primary Production Farm:
 - Operation under one management in one general (but not necessarily contiguous) location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
 - In addition to these activities, may also pack or hold raw agricultural commodities (RACs)



Farm Definition Continued..

- Secondary Activities Farm:
 - Operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of RACs
 - Provided the majority of the product harvested or packed by the secondary activities farm must have been grown by the majority owner (or joint ownership) of the secondary activities farm



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
- Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Packing



- Placing food into a container other than packaging the food
- 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)
- Does not include activities that transform a raw agricultural commodity into a processed food

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)
- 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
- Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Facility

- Domestic and foreign entities engaged in:
 - Manufacturing/Processing
 - Packing
 - Holding

Food for consumption in the United States



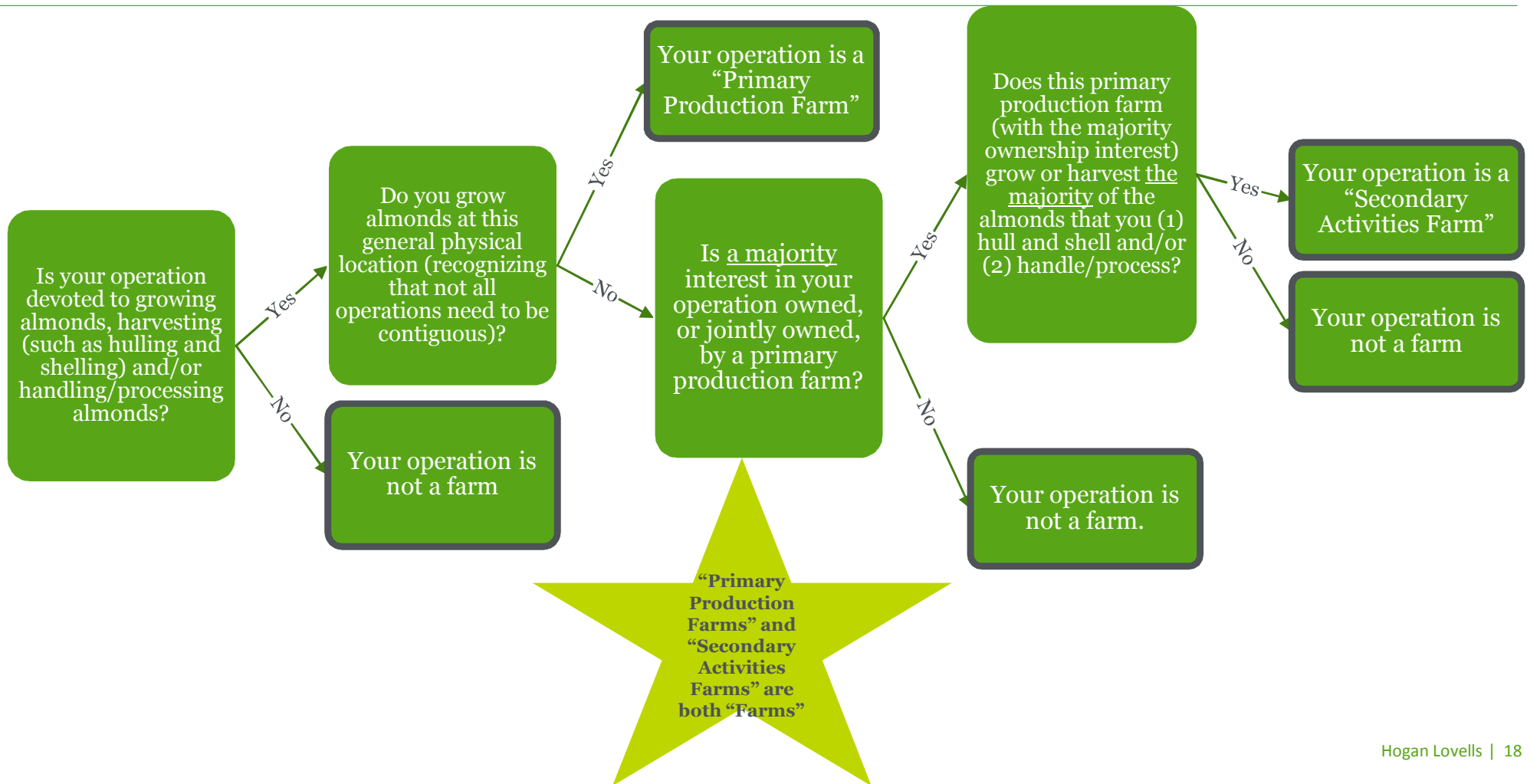
Manufacturing/Processing

- 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
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding

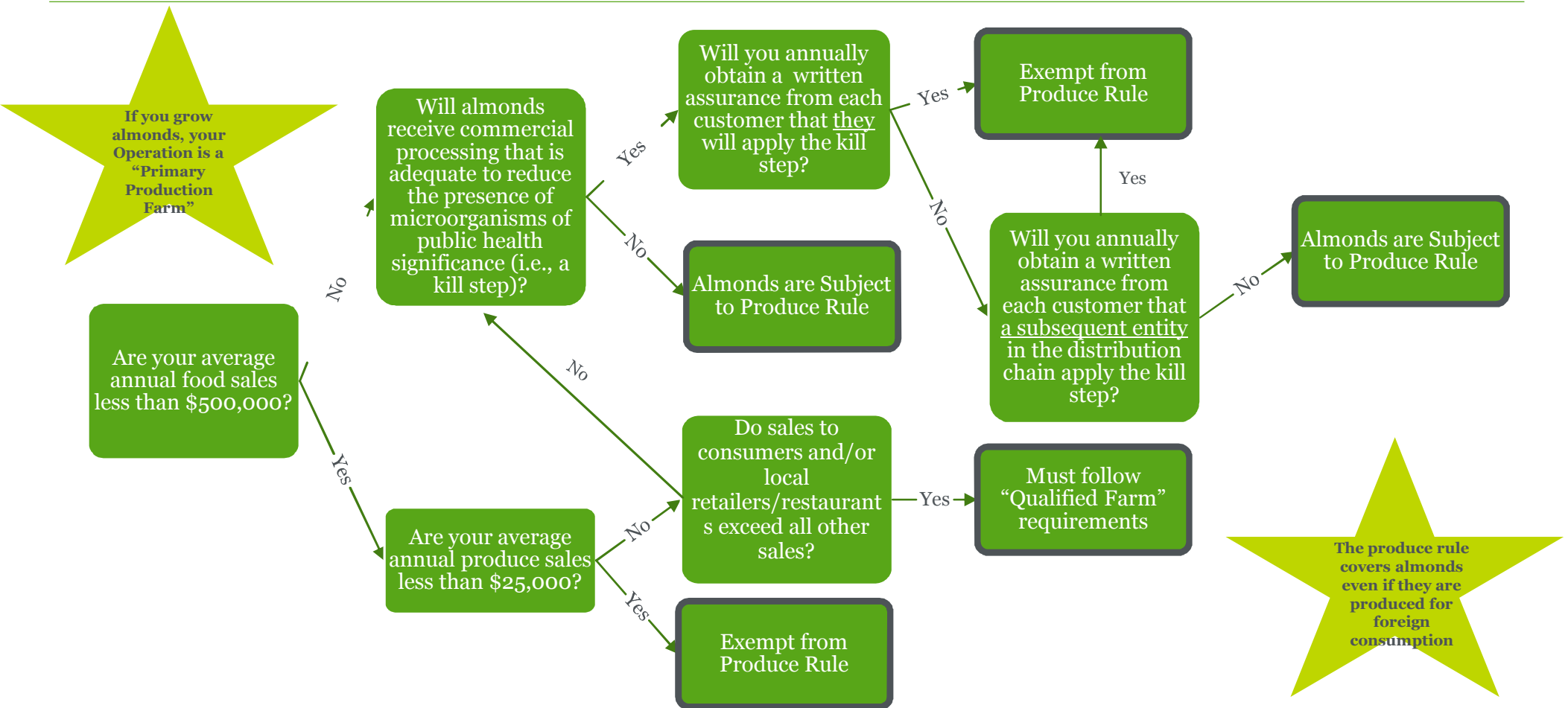


Decision Trees

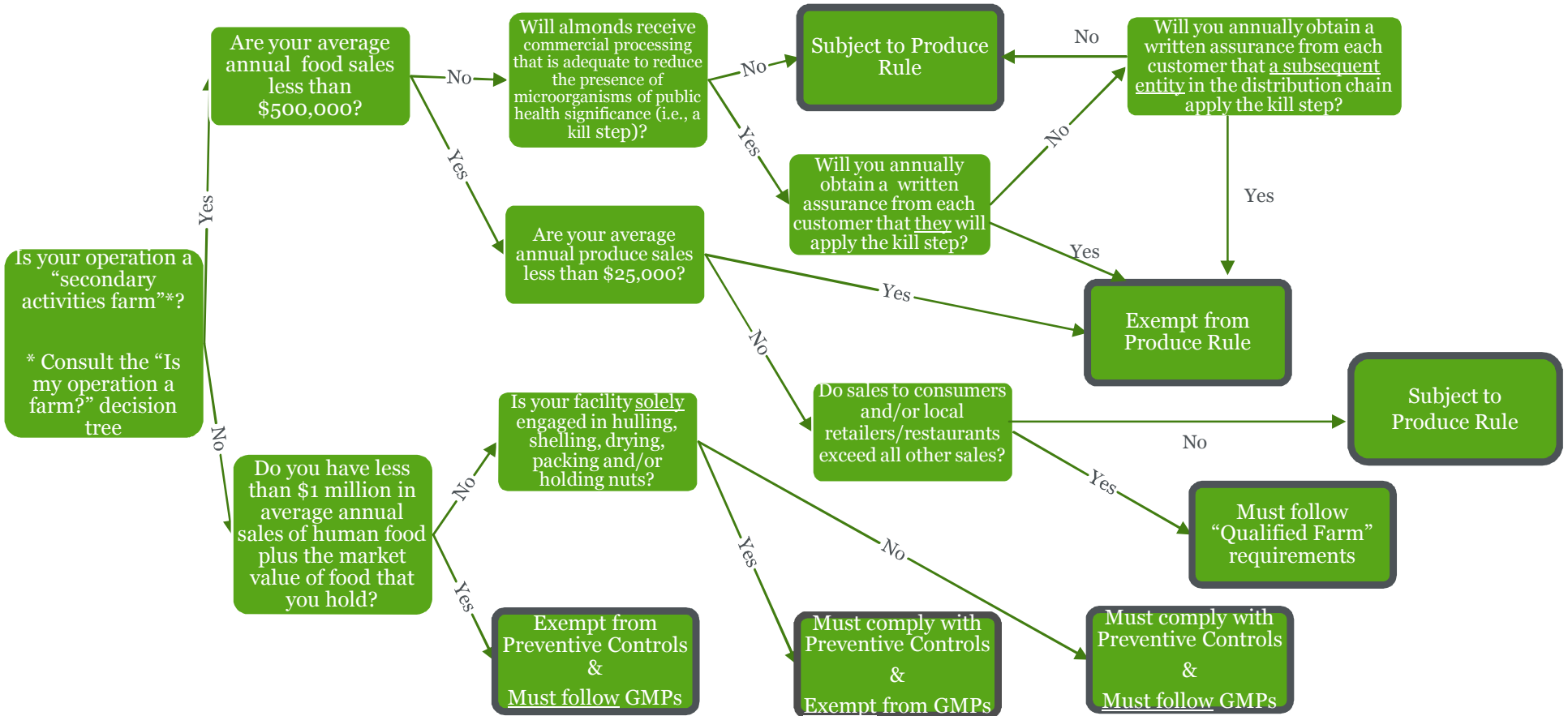
Is my operation a farm?



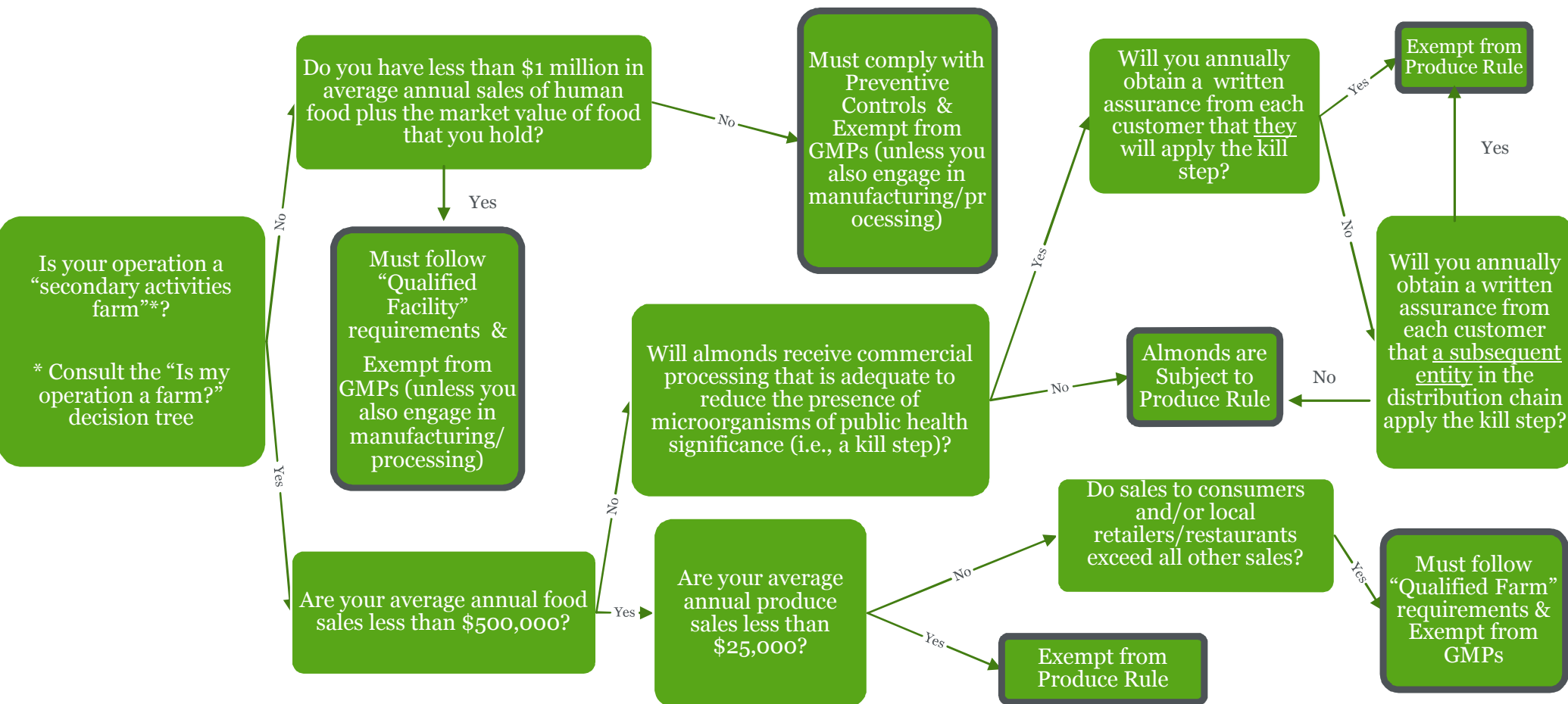
If you grow almonds:



If you hull and shell almonds:



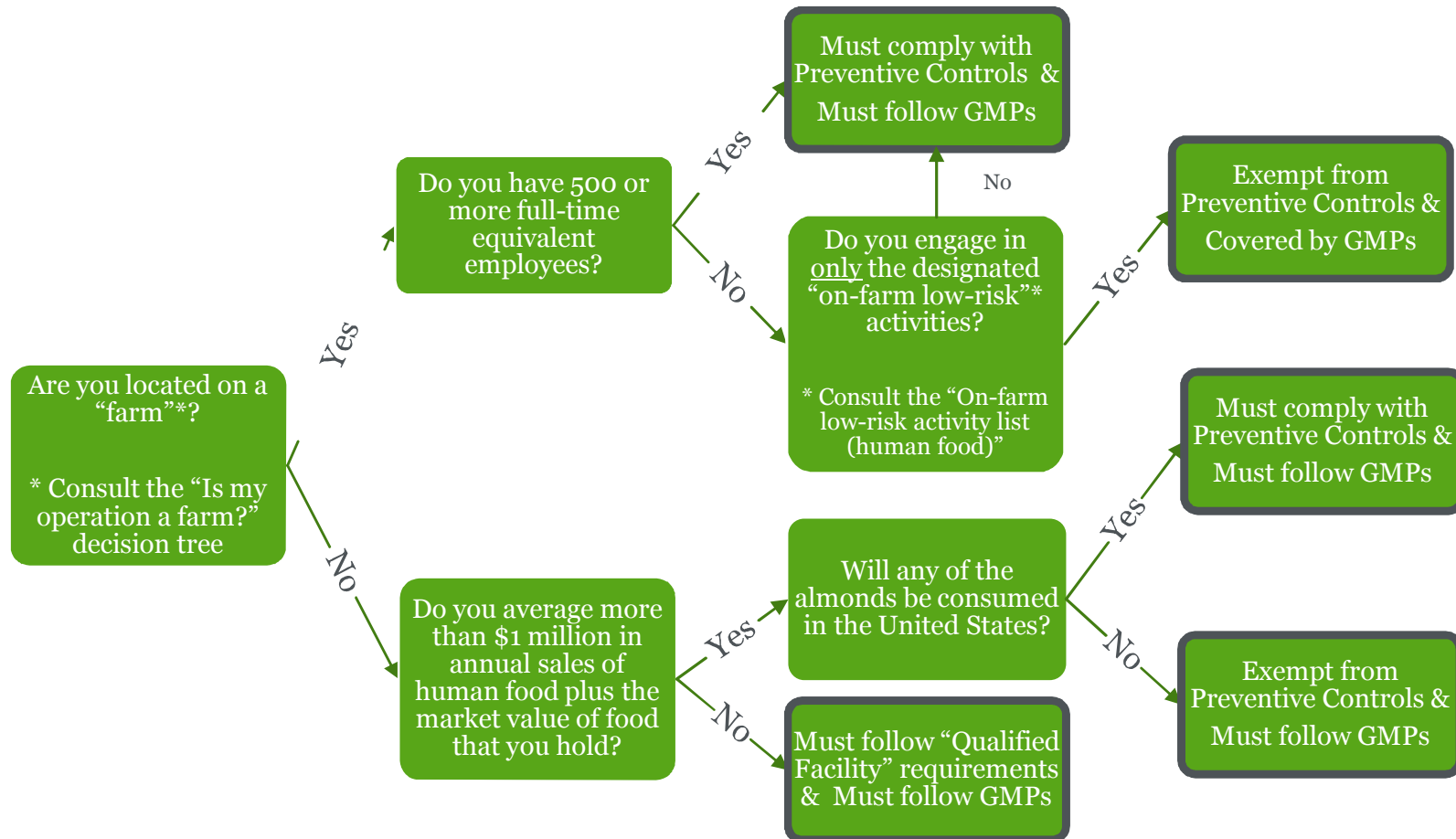
If you process/handle almonds:



If you treat/manufacture almonds:



If you have a value added operation for almonds:



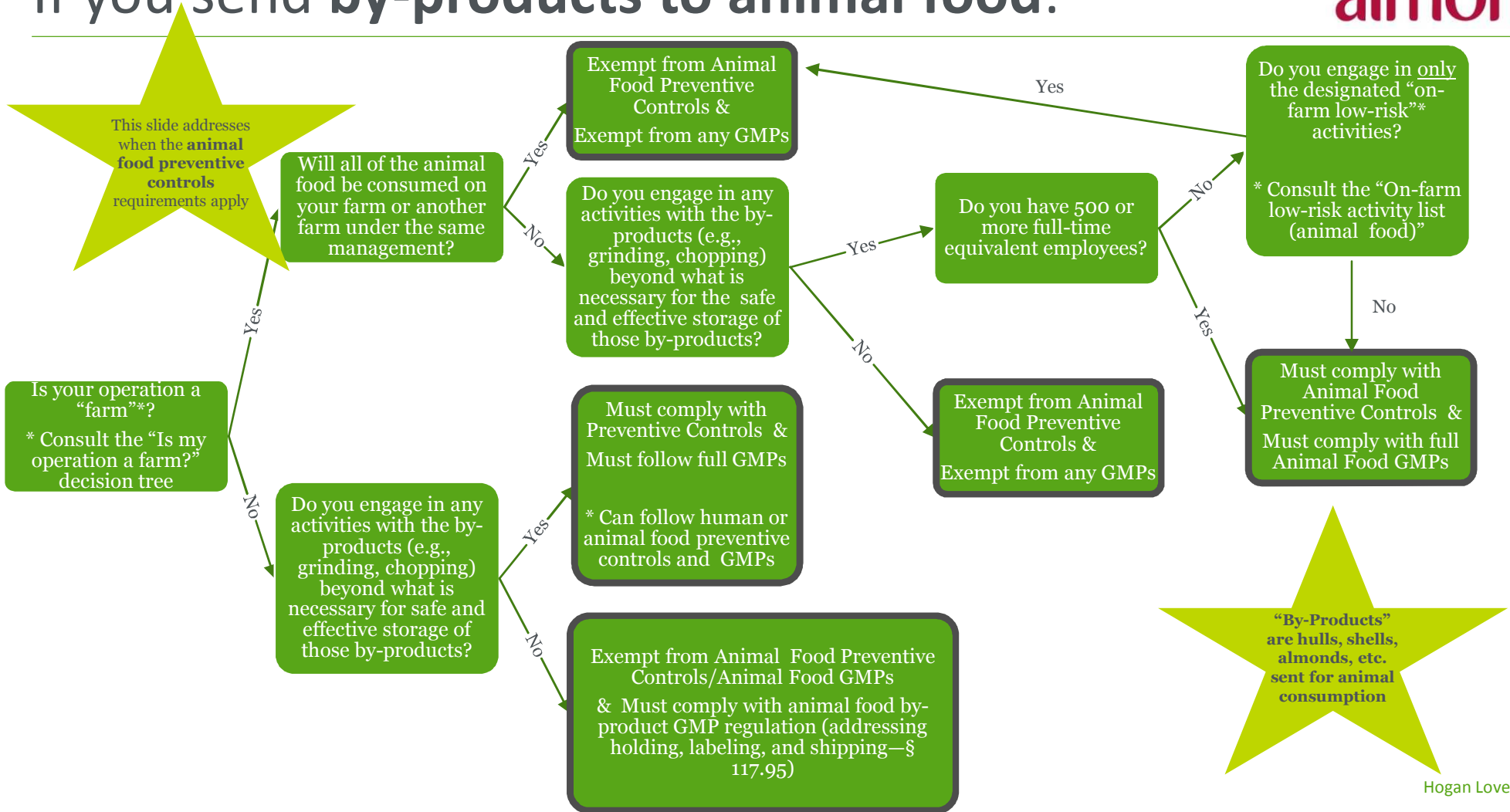
“On-Farm Low Risk” Activity List (Human Food)



This is an exhaustive list!

- **Chopping, coring, cutting, peeling, pitting, shredding, and slicing** almonds
- **Coating** dried/dehydrated almonds (*e.g.*, adding seasonings provided that the seasonings have been treated to significantly minimize pathogens)
- **Grinding/cracking/crushing/milling** almonds
- **Labeling** almond products (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (*e.g.*, roasted or seasoned whole nuts, single-ingredient almond flours))
- **Making candy** from almonds (*e.g.*, nut brittles)
- **Making trail mix and granola** from almond products, provided that almonds are treated to significantly minimize pathogens
- **Mixing** almond products
- **Packaging** almond products
- **Salting** almond products for direct consumption
- **Sifting** almond products (*e.g.*, almond flour)
- **Packing or holding** almond products

If you send by-products to animal food:



"By-Products" are hulls, shells, almonds, etc. sent for animal consumption

“On-Farm Low Risk” Activity List (Animal Food)

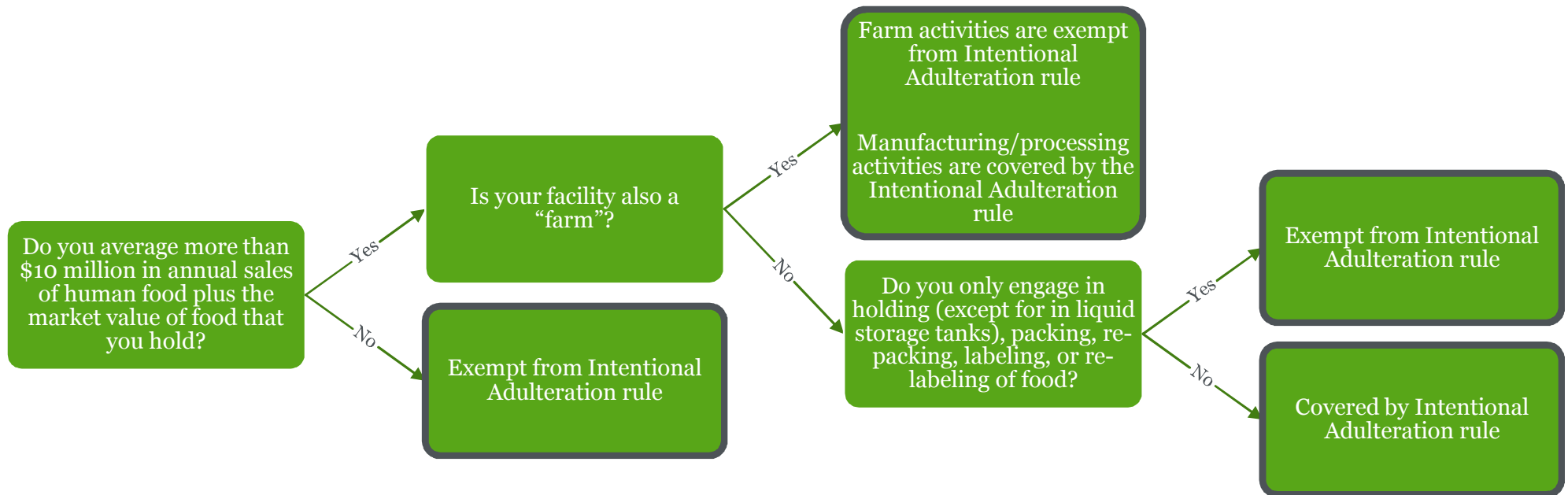


This is an exhaustive list!

These activities apply for animal food ready for consumption (e.g., hulls, shells, and roughage) or processed animal food that does not require time/temperature control for safety:

- Packing (or repacking) (including weighing or conveying incidental to packing or repacking)
- Sorting, culling, or grading incidental to packing or storing
- Storing
- Crushing, dry rolling, grinding, milling, or pulverizing
- Ensiling (including chopping, shredding, mixing, storing, or fermenting) (i.e., making silage or haylage from forage)
- Labeling
- Packaging

If you are subject to the **preventive controls rule**: (i.e., the human food preventive controls rule)



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