

Value-Added On-Farm Processing

REGULATORY CONSIDERATIONS



This resource aims to aid farmers interested in producing value-added products in understanding the multiple state and federal regulatory requirements for selling processed food products.



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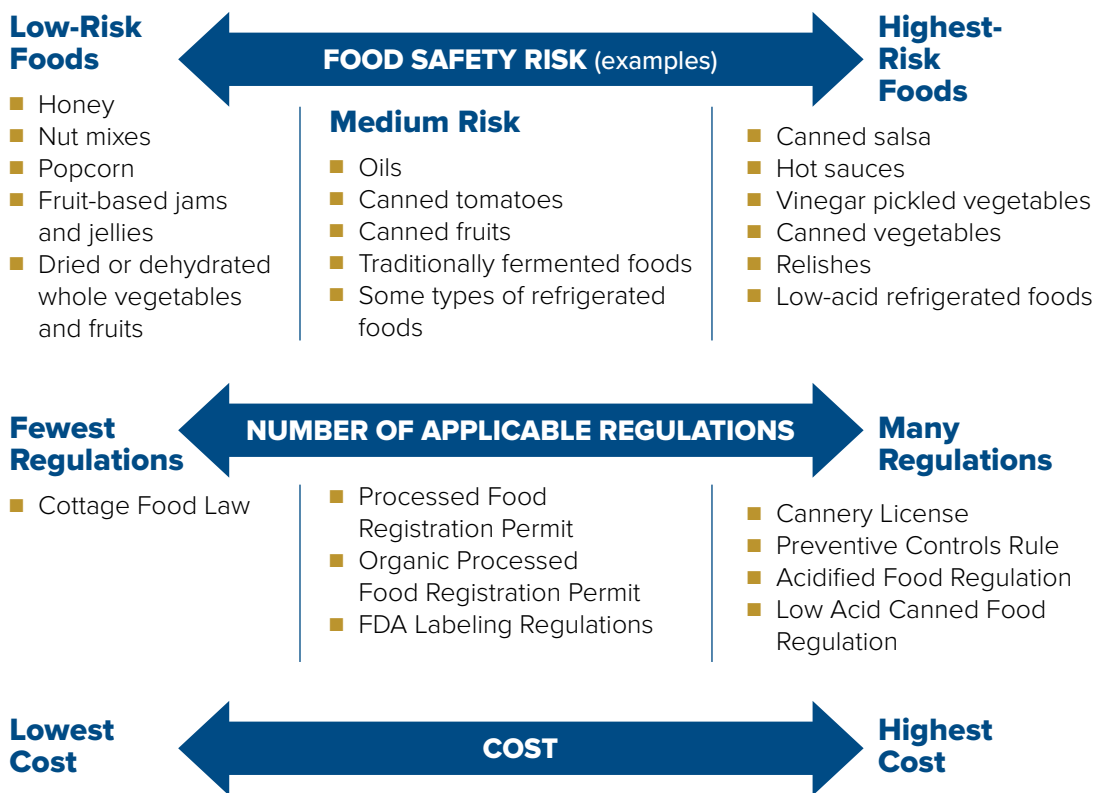
interested in producing value-added products in understanding the multiple state and federal regulatory requirements for selling processed food products. Producers of a value-added product need to navigate the various state and federal regulations and determine which of them apply to their situation.

Relevant regulations include:

- California Cottage Food Law
- California Processed Food Registration
- California Cannery License Program
- U.S. Food and Drug Administration Food Safety Modernization Act
- U.S. Food and Drug Administration Low Acid Canned Food Regulation
- U.S. Food and Drug Administration Acidified Food Regulation

Getting Started

When starting a processed food business it is important to understand that different categories of processed foods inherently possess varying levels of food safety risks. Generally, categories of processed foods that present the greatest potential risk to human health if not processed properly will be subject to the most rigorous regulatory oversight. If an individual chooses to process a high risk food, it is important to understand that this correlates to increased capital investment and long-term operating costs. The diagram below provides an overview of the three related spectrums – food safety risk, regulations, and cost – to consider when bringing a new processed food product to market.



California Cottage Food Law

The California Cottage Food Law allows individuals to prepare and/or package certain non-potentially-hazardous foods in private home kitchens referred to as “cottage food operations” (CFOs). There are currently 32 approved foods for in-home production on the California Cottage Food list. All cottage food operators have to meet specified requirements stated in the California Health and Safety Code. This is the most cost effective option for starting a food processing business. However, you are only allowed to process foods on the approved list and the annual gross revenue from a cottage food business is capped at \$50,000.

If your product or business does not meet the requirements of the Cottage Food Law, the next option for consideration is the Processed Food Registration (PFR). Foods that can be produced under a PFR include those on the Cottage Food Law approved list, refrigerated products, olive oil,



traditionally fermented products, and other processed foods that are considered “low risk”. In the state of California, low-risk food processing establishments (that are not CFOs) must file a Processed Food Registration (PFR) with the state and have the food production facility inspected on a regular basis by the California Department of Public Health’s Food and Drug Branch (CDPH-FDB). In addition, if you are storing processed foods in a separate location from where they are produced, that storage location will also require a PFR.

Acidified Canned Food Production

Acidified canned food production (high risk food types) requires a cannery license in the state of California. That is because these products are higher risk compared to those produced under the PFR. These products, if not acidified correctly, may cause a deadly toxin (produced by the bacteria *Clostridium botulinum*) to be present in the product that is impossible to see, smell or taste. Examples of acidified canned foods include vinegar pickles, salsas and tomato sauces with added vegetables. The production of shelf stable versions of these products requires submitting forms with the state, inspection of the facility prior to operations, and batch inspection and release of product produced in the facility by inspectors of the CDPH-FDB. If your storage facility for these products is in a different location than where you produced them (and have the Cannery License), then you need to get a PFR for that storage facility. A specific federal regulation also applies to the production of shelf stable acidified foods, 21 CFR Part 114. There are prescriptive requirements for the production of these types of foods, FDA registration of the food processing facility is required, and the operating supervisor needs to attend the Better Process Control School or Acidified Foods Manufacturing School.

Low Acid Canned Food Production

Shelf stable low acid canned foods, including canned vegetables, soups, and many others, are the highest risk category of processed foods. Like shelf stable acidified foods, the production of these products requires submitting forms with the state, inspection of the facility prior to operations, and batch inspection and release of product produced in the facility by the CDPH-FDB. The canning of these products must be done in a calibrated pressure canner or retort and



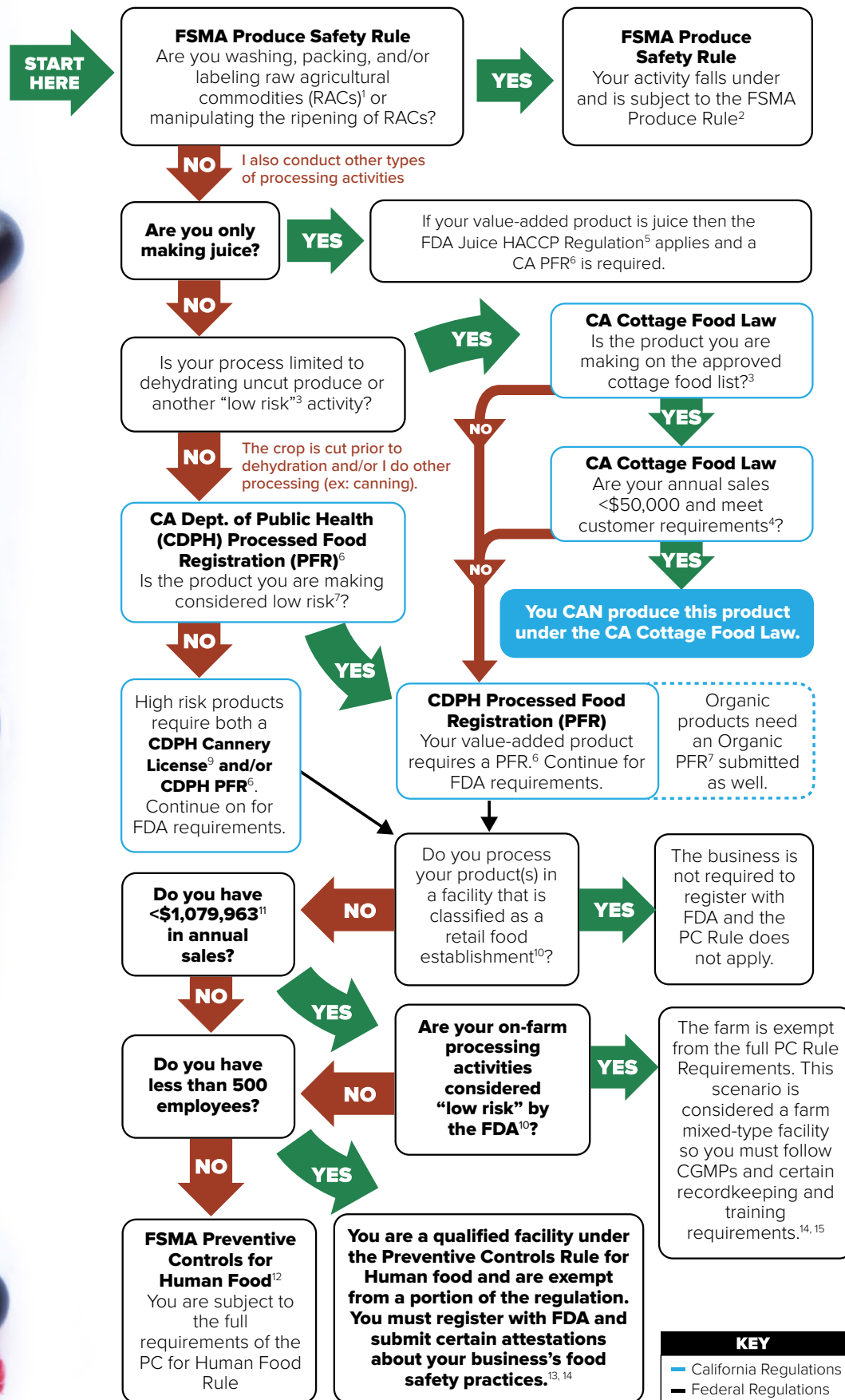
the scheduled process (recipe, processing temperature, processing time, container size, container fill weight, etc.) must always be followed to ensure food safety. A federal regulation also is in place to regulate the production of low acid canned foods, 21 CFR Part 113. This regulation requires registration of the facility with FDA, outlines specific requirements for the production of low acid canned foods, and mandates that operating supervisors attend the Better Process Control School.

Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act (FSMA) is the largest overhaul in U.S. food safety regulations in over 70 years. FSMA contains rules that pertain to on farm food production and food processing and the FDA enforces the regulations (21 CFR 117). Both the Produce Safety Rule (PSR) and the Preventive Controls for Human Food (PC) Rule will likely impact small farmers producing value added products. Training specific to the PSR and PC Rule is required for those farms and processing facilities covered by the regulation, respectively. There are some exemptions and modified requirements that may apply based on the type of food or size of the business. Even if a business is determined to meet the requirements of a qualified facility, they will still be required to be compliant with the portion of the PC rule related to Current Good Manufacturing Practices (CGMPs). Likewise, the PSR provides modified requirements for some farms eligible for a qualified exemption; however, those farms will also need to meet certain requirements defined in the regulation.

Follow the flowchart on the next page to determine what state and federal regulations your product(s) will be subject to. The flowchart is focused on value-added products composed of vegetables and fruits and does not cover value-added dairy, meat, or egg products (cheese, yogurt, charcuterie) which are subject to additional and/or alternative regulations. This resource covers value added food product regulations for foods regulated by the FDA at the federal level. At the time of publication this flowchart reflects the current understanding of the federal regulations. FDA may release guidance documents with further clarification on implementation of the regulations.

Food Safety Regulation Flow Chart



Processed Food Regulatory Bodies and Program Oversight at a Glance

LOCAL: County Environmental Health Department

- Cottage Food Operations
- Restaurants
- Temporary Permits for Farmer's Markets
- Retail Food Establishments

STATE: CA Department of Public Health Food and Drug Branch

- Processed Food Registration
- Organic Processed Food Registration (if applicable)
- Cannery License
- Enforcement of federal regulations

FEDERAL: Food and Drug Administration

- HACCP (juice and seafood)
- Food Safety Modernization Act (FSMA)
- Acidified Food Regulations
- Low Acid Canned Food Regulations
- Labeling Requirements





Resources

This resource focuses on the regulations required when processing raw agricultural products into value added products such as salsa and jam. To learn more about food safety regulations for raw produce on farms visit these resources:

**The California Department of Food and Agriculture
Small Farm Food Safety Guidelines:**

https://www.cdfa.ca.gov/is/i_&c/sffsg.html

UC Davis Food Safety web pages:

<http://ucfoodsafety.ucdavis.edu/>

Community Alliance with Family Farmers web pages:

<https://www.caff.org/programs/foodsafety/>

If your product(s) is organic, there are additional regulatory permits to obtain and possibly steps to take with your organic certifying body (ex: CCOF, Oregon Tilth). This is not a comprehensive resource for organic value added products, refer to the Processed Food Registration and Cannery Timeline resources in this series for more information.

If the regulatory burden is too great for your business you can choose to work with a co-packer. A co-packer is a business that will process your product for a fee. There are pros and cons to working with a co-packer. The main pro is that the co-packer company will deal with making sure all the regulatory permits are in order. The main cons are the additional cost of having to pay the co-packer to make your product and that most co-packers do not allow you to bring in the produce/ingredients for the product. Learn more about co-packers here: http://ucfoodsafety.ucdavis.edu/Food_Industry_Contacts/Co-Packers/



Footnotes

1. Food, Drug, and Cosmetic Act, subchapter two on definitions, including raw agricultural commodities. (<http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section321&num=0&edition=prelim>)
2. FSMA Produce Safety Rule (<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>) Helpful National Sustainable Agriculture Produce Rule Guidebook can be found at (<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-PRODUCE-RULE-FINAL.pdf>)
3. California Cottage Food Law (<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CottageFoodOperations.aspx>)
4. Cottage Food Law Permit Requirements, including Class A and Class B permits (<https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/CottageFood/RegistrationPermitRequirements.pdf>).
5. Juice HACCP (<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/Juice.aspx>)
6. CA Processed Food Registration (<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/ProcessedFoodRegistration.aspx>)
7. CA Organic Processed Food Registration (<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8593.pdf>)
8. Acidified Food Regulation and Low Acid Canned Food Regulation (<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm>)
9. CA Cannery License Program (<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CanneryInspectionProgram.aspx>)
10. Retail Food Establishment and FDA “low-risk” processing criteria explained in this resource: <http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>
11. FDA Tables for Inflation Adjusted Numbers <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>
12. FSMA Preventive Controls for Human Food (<https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>)
13. FSMA Preventive Controls for Human Food Qualified Facility Definition:
21 CFR section 117.3
 - Business averaging less than \$1,000,000 (adjusted for inflation) per year, over a three year period, in sales of human food plus the market value of any food manufactured, processed, packed, or held without sale
 - A facility in which both conditions apply: during the three year period preceding the applicable calendar year
 - The average annual monetary value of the food manufactured, processed, packed, or held that is sold directly to qualified end-users exceeds the average annual monetary value of the food sold by such a facility to all other purchasers
 - The average annual monetary value of all food sold during the three year period preceding the applicable calendar year was less than \$500,000 adjusted for inflation
14. National Sustainable Agriculture Coalition’s Guide to the Preventive Controls Rule has information on Farm Mixed-Type Facilities and Qualified Facilities (<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>)
15. FDA Guidance on Farm Mixed-Type Facilities (<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517575.pdf>)

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