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.
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.

Low-Risk Foods
- Honey
- Nut mixes
- Popcorn
- Fruit-based jams and jellies
- Dried or dehydrated whole vegetables and fruits

Medium Risk
- Oils
- Canned tomatoes
- Canned fruits
- Traditionally fermented foods
- Some types of refrigerated foods

Highest-Risk Foods
- Canned salsa
- Hot sauces
- Vinegar pickled vegetables
- Canned vegetables
- Relishes
- Low-acid refrigerated foods

Lowest Cost
- Cottage Food Law
- Processed Food Registration Permit
- Organic Processed Food Registration Permit
- FDA Labeling Regulations

Highest Cost
- Cannery License
- Preventive Controls Rule
- Acidified Food Regulation
- Low Acid Canned Food Regulation

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.
START HERE

FSMA Produce Safety Rule
Are you washing, packing, and/or labeling raw agricultural commodities (RACs) or manipulating the ripening of RACs?

NO
I also conduct other types of processing activities

Are you only making juice?

NO

If your value-added product is juice then the FDA Juice HACCP Regulation applies and a CA PFR is required.

CA Cottage Food Law
Is the product you are making on the approved cottage food list?

YES

CA Cottage Food Law
Are your annual sales <$50,000 and meet customer requirements?

NO

You CAN produce this product under the CA Cottage Food Law.

CA Dept. of Public Health (CDPH) Processed Food Registration (PFR)
Is the product you are making considered low risk?

YES

CDPH Processed Food Registration (PFR)
Your value-added product requires a PFR. Continue for FDA requirements.

NO

Do you have <1,079,963 in annual sales?

NO

Do you have less than 500 employees?

NO

FSMA Preventive Controls for Human Food
You are a qualified facility under the Preventive Controls Rule for Human food and are exempt from a portion of the regulation. You must register with FDA and submit certain attestations about your business’s food safety practices.

YES

The business is not required to register with FDA and the PC Rule does not apply.

The farm is exempt from the full PC Rule Requirements. This scenario is considered a farm mixed-type facility so you must follow CGMPs and certain recordkeeping and training requirements.

See footnotes on inside back cover
### Processed Food Regulatory Bodies and Program Oversight at a Glance

<table>
<thead>
<tr>
<th>LOCAL: County Environmental Health Department</th>
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<tbody>
<tr>
<td>- Cottage Food Operations</td>
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<tr>
<td>- Restaurants</td>
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<td>- Temporary Permits for Farmer’s Markets</td>
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<td>- Retail Food Establishments</td>
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<tr>
<th>STATE: CA Department of Public Health Food and Drug Branch</th>
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<tr>
<td>- Processed Food Registration</td>
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<td>- Organic Processed Food Registration (if applicable)</td>
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<tr>
<td>- Cannery License</td>
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<td>- Enforcement of federal regulations</td>
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<th>FEDERAL: Food and Drug Administration</th>
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<tr>
<td>- HACCP (juice and seafood)</td>
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<tr>
<td>- Food Safety Modernization Act (FSMA)</td>
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<tr>
<td>- Acidified Food Regulations</td>
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<td>- Low Acid Canned Food Regulations</td>
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<td>- Labeling Requirements</td>
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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/sffsq.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 do bring in the produce/ingredients for the product. Learn more about co-packers here: http://ucfoodsafety.ucdavis.edu/Food_Industry_Contacts/Co-Packers/
Footnotes


3. California Cottage Food Law ([https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CottageFoodOperations.aspx](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](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](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](https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/ProcessedFoodRegistration.aspx))


9. CA Cannery License Program ([https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CanneryInspectionProgram.aspx](https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CanneryInspectionProgram.aspx))


11. FDA Tables for Inflation Adjusted Numbers [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm](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](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.


Acknowledgements

Erin DiCaprio, M.S., Ph.D.
Assistant Specialist in Cooperative Extension
Department of Food Science and Technology, UC Davis

Kali Feiereisel, M.P.H.
Food Safety Specialist
Community Alliance with Family Farmers

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