



PROCESSED FOOD REGULATIONS

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Safety Issues - Hazards



- **Biological**
 - microorganisms (bacteria, viruses, parasites), plants, animals
- **Chemical**
 - allergens: especially dairy, egg, nutmeats
 - heavy metals, toxins, unapproved chemicals
- **Physical**
 - rocks, wood, plastic, metal, glass



From Kitchen to Market



- In California you cannot manufacture or hold food in your home for sale
 - exception: charity bake sales
- Issues of inspection
- Ability to manufacture under Good Manufacturing Practices
 - sanitation particularly difficult at home



Commercial Food Facilities



- **Commercial Kitchen**
 - Meets Food Code (California Retail Food Code – 10/09) requirements
 - Can register as a processing facility
- **Food Processing Plant**
 - Meets Good Manufacturing Practices Regulations
- **Co-packer**



Congress Passed S510



- Tester Amendment provides exemption for “small farmer” who sells majority of their product direct
 - 50% or more of farm product direct marketed
 - Direct markets in the same state or within 275 miles
 - Total farm sales less than \$500,000
 - Name, address and phone # provided to customer
- Applies **only** to fruits and vegetables, not meat, poultry or dairy products



Congress Passed S510



- Producers of **any size** who direct market food, as a farm or processor, are exempt from registering with FDA as a facility
 - Direct marketed food is mostly exempt from traceability requirements, as is farm identity-preserved (labeled) food—regardless of the volume
-BUT THESE ARE JUST THE FEDERAL REGULATIONS



Where will you sell?



- Make your own, only sell your own to ultimate consumer (e.g., farm gate, farmer's market)
 - Subject to County Environmental Health (each county sold)
- Others sell your product but only in California
 - Subject to State CA Dept of Public Health and/or CDFA regs
- You or others sell your product within AND outside California
 - State AND Federal (FDA and/or USDA)
- Exceptions (always—depends on type of product)



CA DPH – Food and Drug Branch



- Regulates the manufacture, storage, labeling and advertising of many foods
 - All foods and bottled water except:
meats (most) and dairy
- Laws are in the California Health and Safety Code
- Enforcement of CA and Federal food regulations



CA DPH--Processed Food Registration



- Application
 - Department of Public Health
- MUST register annually with the state as a food processor
- A separate registration is required for each place of **manufacture**, **packing**, or **holding**
- Inspection will occur PRIOR to opening business
- (Pet Foods Regulated as human food)



Fees



- Processed Food Registration Fee (\$348+)
- Food Safety Fee (\$100)
 - Exemption in certain cases (requires annual application)
 - Gross wholesale income <\$20,000
 - Requires financial records
 - Exclusively involved in:
 - Wholesale flour milling, dry bean processing, drying or milling of rice



Included products



- *Processing*, repackaging and warehousing
 - Dried fruits and vegetables (**if cut**)
 - Milling and Milled flours
 - Shelled nuts
 - Flavored nuts
- Repackaging and warehousing
 - Dried beans



Meat or Meat-Containing Products



- Fall under CDFA meat division or USDA
 - Fresh and processed meat and poultry
 - Raw products containing 3% or more by weight of meat or poultry
 - Cooked products containing 2% or more of meat or poultry



Additional Requirements



- Olive oil license (California)
 - One time registration, no fee
 - Must also register as food processor
- Organic processed product registration (Food and Drug Branch, California)
 - Will be coordinated with food processing registration (start/expiry)
- Raw agricultural commodities
 - Organic registration handled by CDFA
 - Organic certification



Additional Requirements



- Foods that are “**low acid canned**” or “**acidified and canned**” to prevent the formation of Botulism Toxin must be done in a **California-licensed cannery** regardless of whether they are direct marketed
 - Acidified food - 21 CFR Part 114
 - Thermally processed canned foods - 21 CFR 113
 - Requires training in Better Process Control School
 - Separate registration, product and process submission and evaluation, batch and record inspection

Cannery Regulations Exercise



- Is your product shelf stable (canned or bottled)?
 - YES
- Is the water activity >0.85 ?
 - YES
- Is the pH >4.6 ?
 - YES - low acid canned food
 - NO - possible acidified low acid canned food
 - E.g., pickled vegetables, salsa, relishes, pesto
- Exemptions: naturally acidic (e.g., peaches), microbially fermented (e.g., dill pickles), jams and jellies, some dressings/sauces



Acidified Low Acid Canned Foods



- Fall under cannery regulations, food service not exempt
- Low acid foods are combined with acids or acid foods to reduce the pH to <4.6
- Risk of botulism if pH is not controlled
- Process/product evaluated by the state to determine if it is under “pH control” program
- If yes, then the following applies:
 - Processor must have cannery license
 - Person who has taken BPCS must be on site during processing
 - pH must be measured for each batch
 - Records required, recall program required
 - Batch to batch release by inspectors - fee for service



Other Requirements



- Juices must be processed under Hazard Analysis Critical Control Points (HACCP)
 - 21 CFR 120
 - Additional \$250 fee
- Seafood must be processed under HACCP Requirements in 21 CFR Part 123
 - Additional \$250 fee
- Molluscan shellfish must be handled in a California “certified facility”



Special Requirements



- USDA FSIS - meats
 - Safe food handling label
- FDA - eggs
 - Safe handling
- CDFA - Milk and Dairy Foods
- Unpasteurized juices
 - Warning labels (only applies in food service settings - not in glass or cup and no product from processing facility)

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

INGREDIENTS: FRESH CARROT JUICE.



Other requirements: In-shell eggs



- Sold at Retail: Mandatory
 - Label on carton
 - “To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly”
 - Refrigeration
 - <45°F
- Sold at Certified Farmer’s Markets
 - Holding eggs at higher than 45°F is permitted if a series of conditions are met



Wrap-Up



- Know your product
- Know your process
- Understand the risks
- Understand the regulations