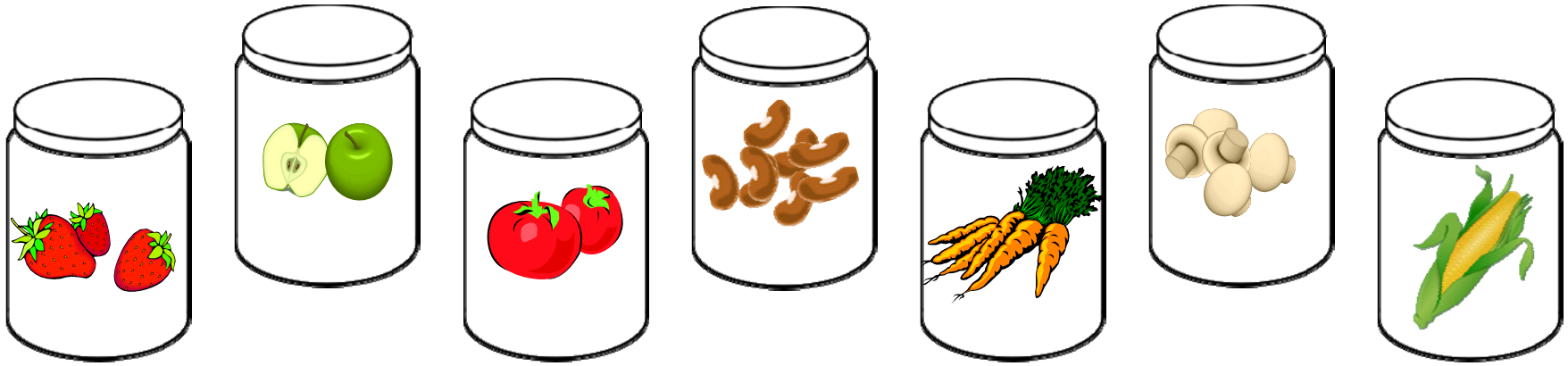
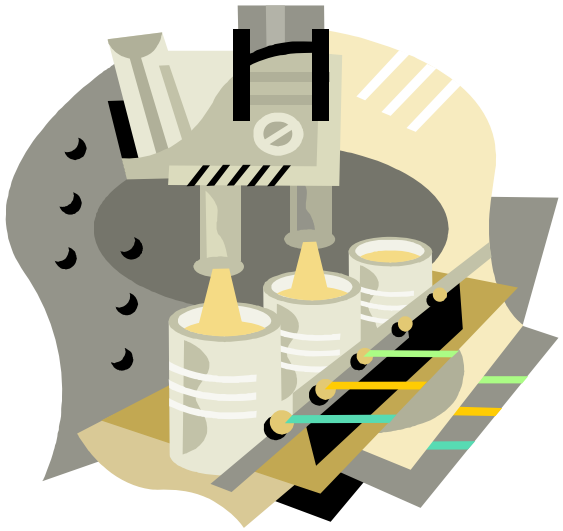


Staying Safe and Legal: Food Safety and Regulations

Linda J. Harris, Ph.D.
Specialist in Cooperative Extension



UCDAVIS
FOOD SCIENCE AND TECHNOLOGY

Basic Food Laws

- Food shall not be contaminated
  - No unsafe ingredients
  - Not missing valuable components
  - Not spoiled
  - Meets standards if there are ones

Food Regulations

- ~~Can seem~~ are a little complicated
  - Based on history
  - Protecting public health
    - Often in response to outbreaks

National/State Food Agencies Pertaining to Food

Federal Agency	Corresponding State Agency
US Food and Drug Administration (FDA) Advisory through Pasteurized Milk Ordinance (FDA)	California Department of Public Health Food and Drug Branch (CDPH FDB) California Department of Food and Agriculture Milk and Dairy Food Safety Branch
US Department of Agriculture Food Safety and Inspection Service (FSIS) Agricultural Marketing Service (AMS)	California Department of Food and Agriculture Meat Branch (USDA/FSIS) (Leafy Greens Marketing Agreement Audits)
Environmental Protection Agency	California Environmental Protection Agency
US Food and Drug Administration (FDA) Food Code (advisory)	County Departments of Environmental Health (CDPH FDB is also advisory)
Many Others	Many Others

Authority for Rules/Regulation - Federal

- Acts of Congress
  - Federal Meat Inspection Act (1906)
  - Food Drug and Cosmetic Act (1938)
  - Public Health Services Act (1944)
  - Poultry Products Inspection Act (1957)
  - Egg Products Inspection Act (1970)
  - Bioterrorism Act (2002)
  - Food Safety Modernization Act (2011)

Small processors – key regulations

- 21 CFR 101-102
  - Labeling
- 21 CFR 110
  - Current Good Manufacturing Practices
- 21 CFR 117 (August 2015)
  - Part of Food Safety Modernization Act
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- 21 CFR 114
  - Acidified low acid foods
  - (California pH control)
- 21 CFR 120
  - Juice Hazard Analysis and Critical Control Points
- 9 CFR
  - Animals and animal products

CFR = Code of Federal Regulations

21 = FDA

9 = USDA

Good Manufacturing Practices
21 CFR 117

- Cover the basics of producing safe food
  - Facility (buildings and equipment)
  - Sanitation
  - Human Hygiene
  - Processes and controls*
  - Pest Control
  - Training
  - Records*

*New regulations greater emphasis

Ingredients – Regulatory Authority

USDA-FSIS

Meat Inspection Act 1906

Meats

Poultry

Amenable Species

FDA

Food Drug and Cosmetic Act 1938
Food Safety Modernization Act 2011

Oil/Oil seeds

Tree nuts, Fruits, Vegetables

Seafood

Cereals and Grains

Dairy

Additives/preservatives ingredients

Legumes

Juices

+ Everything Else

Meat or Meat-Containing Products

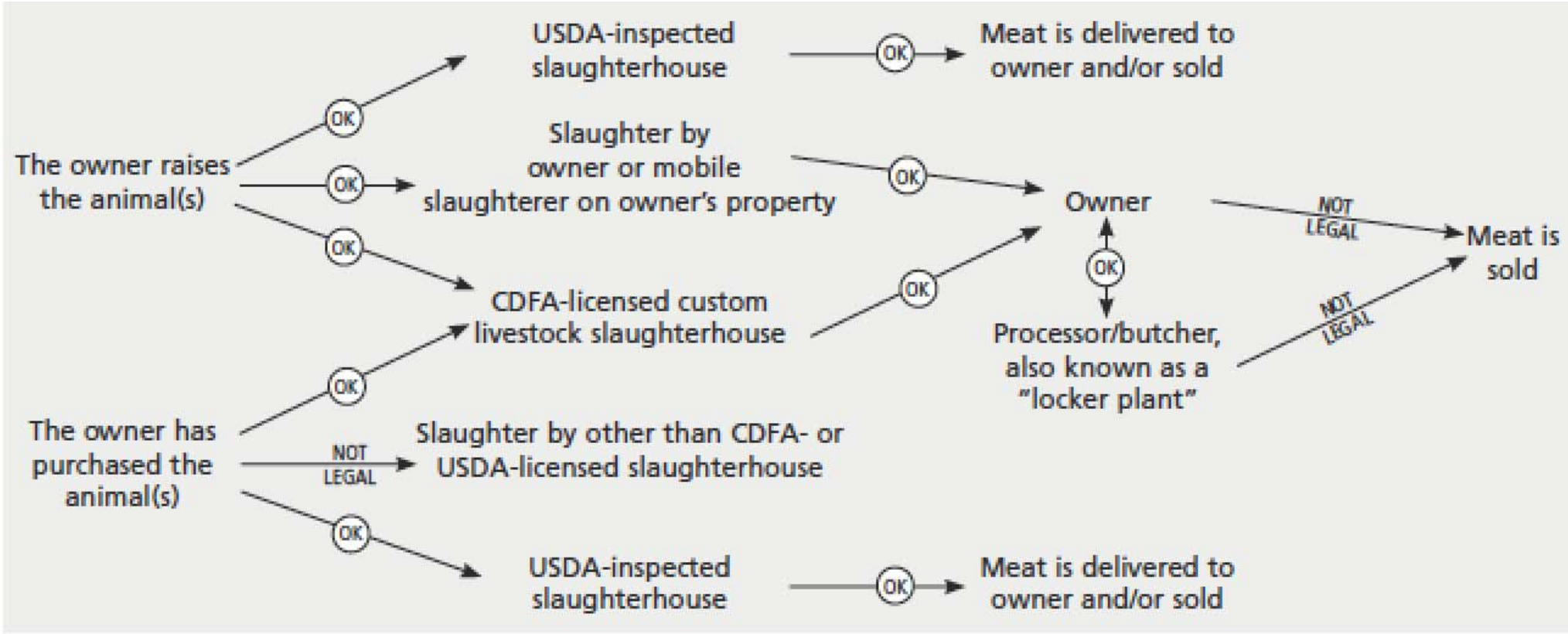
- Fresh and processed meat and poultry
- Raw products
  - containing 3% or more by weight of meat or poultry
- Cooked products
  - containing 2% or more of meat or poultry
- Meat ingredients must be
  - Slaughtered under USDA-FSIS inspection
  - Less likely CDFA meat division
- Manufacturing of meat-containing product
  - Under USDA-FSIS inspection

PUBLICATION 8146

Selling Meat and Meat Products

http://ucfoodsafety.ucdavis.edu/files/26481.pdf

LINDA J. HARRIS is Cooperative Extension Specialist in Microbial Food Safety, Department of Food Science and Technology, UC Davis, and **HSU LING TAN** is Planning Analyst, Strategic and Business Development, Sutter Health.



Other Exceptions

- Seafood or seafood-containing products
  - 21 CFR

- Juices
  - 21 CFR 120

- Fluid dairy products

Manufacturing Options

- Commercial Food Facility
  - Commercial Kitchen (County Environmental Health)
    - Meets Food Code (Cal Code) requirements
    - Usually can qualify as a food processing facility
  - Food Processing Facility (CDPH FDB)
    - Meets Good Manufacturing Practices Regulations
    - May not meet standards of commercial kitchen

Manufacturing Options

- Co-packer
  - Registered food processing facility
    - Contract processor
- Must match product to facility
- May have minimum lot requirements
- More information:
  - http://ucfoodsafety.ucdavis.edu/Food_Processing/
  - http://ucfoodsafety.ucdavis.edu/Food_Industry_Contacts/Co-Packers/

Who will sell your product?

- Make your own, sell your own to ultimate consumer (e.g., farmer's market)
  - Commercial kitchen
    - Rent or own
- License: County Environmental Health
  - Inspected like a restaurant
  - CalCode (Food Code)
- Exceptions
  - Meats/meat-containing products
  - Shelf stable acidified foods – e.g. acidified pickles

Who will you sell your product?

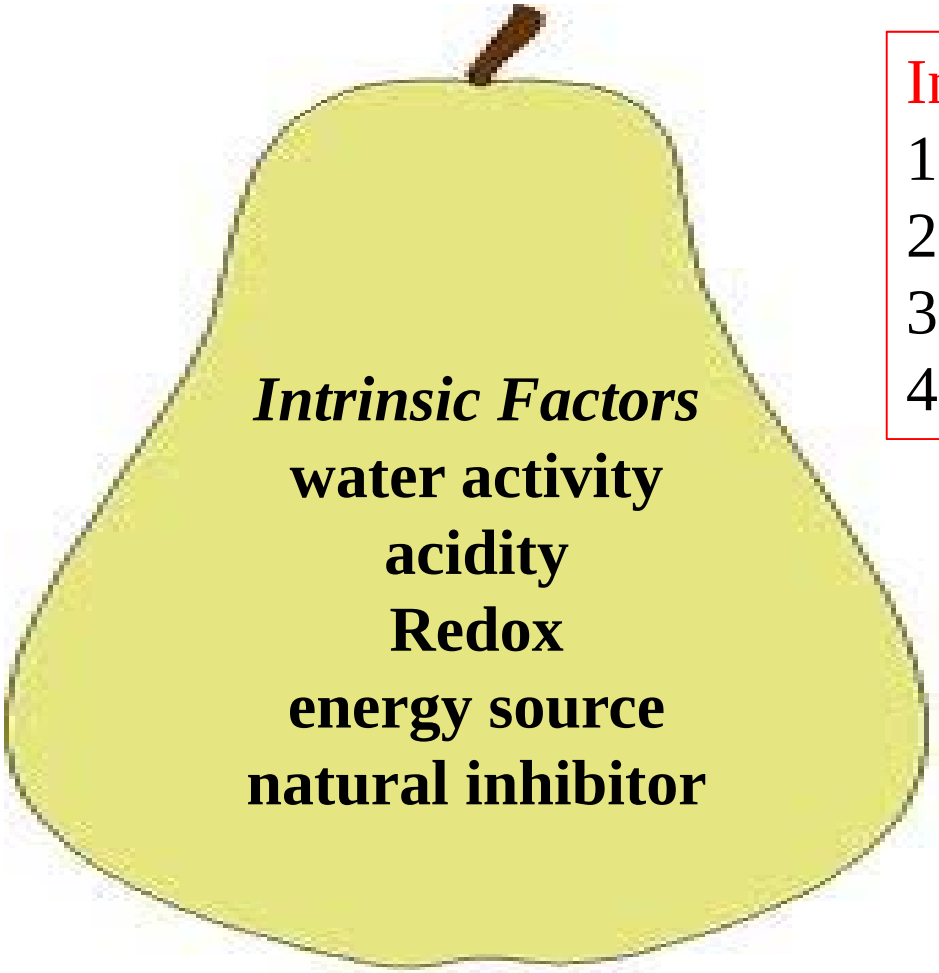
- Others sell your product z
  - (in addition to you or rather than you)
- Food processing facility
    - Rent or own, can be a commercial kitchen
- Registration as a food processor
- Exceptions
  - Meats/meat-containing products (USDA registration)
  - Shelf stable acidified foods
    - e.g. acidified pickles (CA only) (Cannery License)
  - Pet foods (Pet Food Processor License)

Processed Food Registration

- STATE of CA: MUST register annually as a food processor
  - CA Department of Public Health Food and Drug Branch
  - https://www.cdph.ca.gov/certlic/manfprocdistrib/Pages/Food.aspx
  - A separate registration is required for each place of manufacture, packing, or holding
  - Inspection will occur PRIOR to opening business
    - And roughly annually thereafter
- Federal: MUST register initially and every even year (e.g., 2016)
  - US Food and Drug Administration
  - http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm

The Food System

Extrinsic Factors - Storage Conditions
temperature, atmosphere, relative humidity



Interplay of:
1) Intrinsic factors
2) Extrinsic factors
3) Processing
4) Packaging

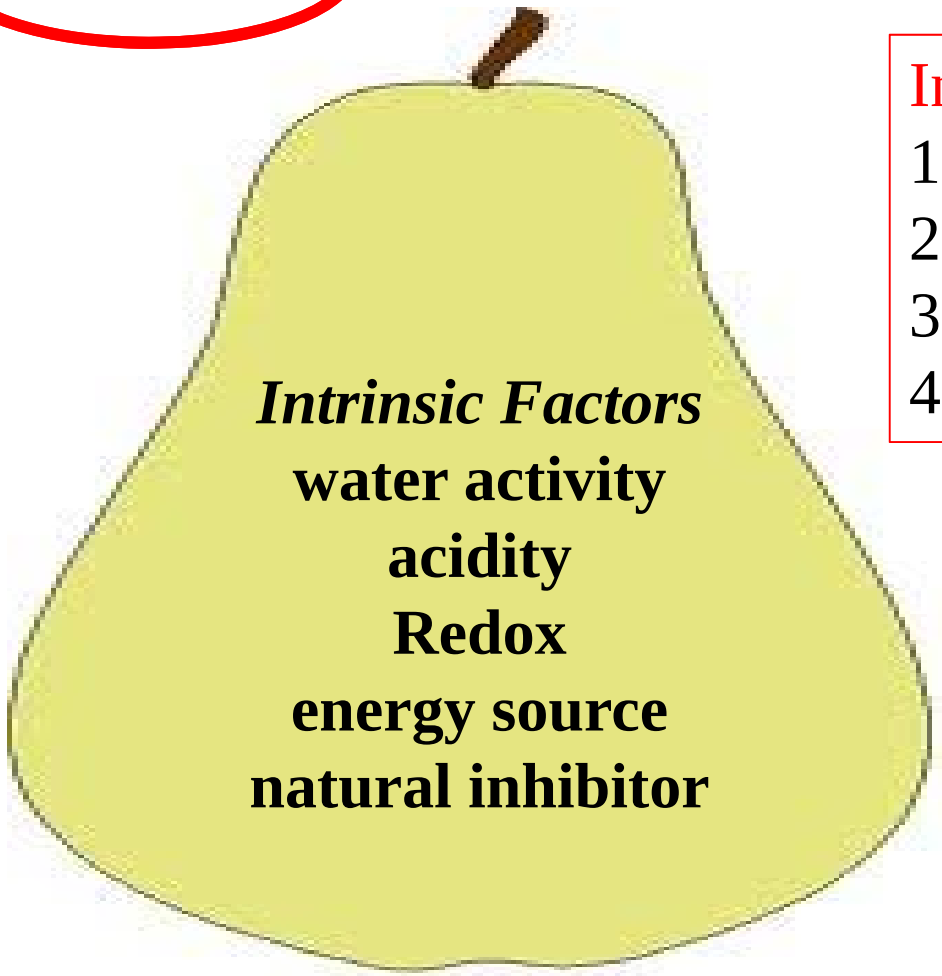
Packaging
atmosphere,
relative humidity,
physical protection

Processing
Physical-heat
Chemical - acid, or
other preservatives,
fermentation

The Food System

Extrinsic Factors - Storage Conditions

temperature, atmosphere, relative humidity



Interplay of:

1) Intrinsic factors
2) Extrinsic factors
3) Processing
4) Packaging

Packaging

atmosphere, relative humidity, physical protection

Processing

Physical-heat

Chemical - acid, or other preservatives, fermentation

Processed Food Registration

- Refrigerated Foods
  - IF: pathogen growth controlled only by temperature
  - THEN: RECOMMENDED secondary barrier
  - Labeling requirement “Perishable Keep Refrigerated”

- Frozen Foods
  - Pathogen *growth* controlled by temperature
  - Pathogens SURVIVE freezing very well

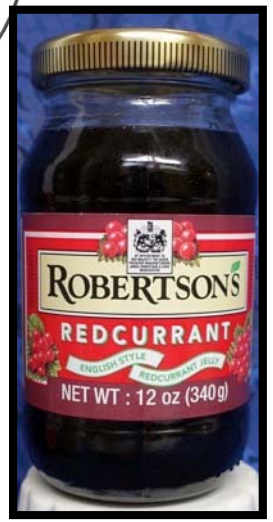
Processed Food Registration

- Shelf Stable Foods
  - Baked
  - Dried

- Exceptions
  - Baked goods that need refrigeration
  - Some dried fruits

Processed Food Registration

- Shelf Stable Foods
  - "Canned"
    - Acid food
      - Naturally acidic
    - Many fermented fruits/vegetables
      - E.g., many green olives, sauerkraut, cucumber pickles fermented in a salt brine
    - Jams and jellies made from fruit



- Exemptions
  - Shelf stable acidified foods – e.g. acidified pickles

California Canning License: Botulism Control Program

- Shelf Stable Foods
  - "Canned"
    - Low acid foods
    - Acidified low acid food
- Exceptions
  - Low water activity products (pH <0.85)
    - E.g., jams/jellies
  - Others:
    - small amounts of low acid (some dressings)
  - Naturally acidic
    - E.g., peaches, apples
  - Traditional fermented
    - E.g., sauerkraut, fermented dill
- http://www.cdph.ca.gov/programs/Pages/fdbCAN.aspx

The Food System

Extrinsic Factors: Storage Conditions

temperature, atmosphere, relative humidity

Interplay of:

1) Intrinsic factors
2) Extrinsic factors
3) Processing
4) Packaging

Packaging

atmosphere, relative humidity, physical protection

Processing

Physical-heat

Chemical - acid, or other preservatives, fermentation

Intrinsic Factor: Moisture

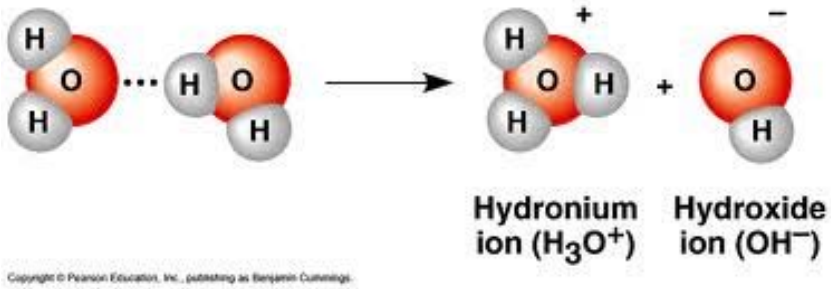
- Amount AND availability of moisture
- Manipulated by:
  - Removing water (e.g., drying, concentrating)
  - Binding water with solutes (e.g., sugars or salts)
- Influences microbial growth
- Water activity A_w (Equilibrium Relative Humidity)
  - A measure of available moisture
  - Value between 0 and 1
    - E.g., 0.98, 0.65, 0.47

~Water Activity (A_w) of Some Foods

Food	~Water Activity	Microbial Growth Limits
Fresh meat, milk, fruits, vegetables	>0.95	Most microorganisms grow
Cheese spread	0.95	Some bacteria inhibited
10% salt	0.93	*Clostridium botulinum* inhibited
Fudge sauce	0.85	All growth of pathogenic bacteria growth inhibited
Soft moist pet food	0.83	Some yeasts inhibited
Salami	0.82	
Soy sauce (16 to 17% salt)	0.80	
Peanut butter (15% total moisture)	0.70	
Milk powder (8% total moisture)	0.70	
Jam	0.65	Most yeasts and molds inhibited

Intrinsic Factor: pH

- pH is a measure of acidity
- pH = -log [H^+ ions]
- Log scale ranges from 0 to 14



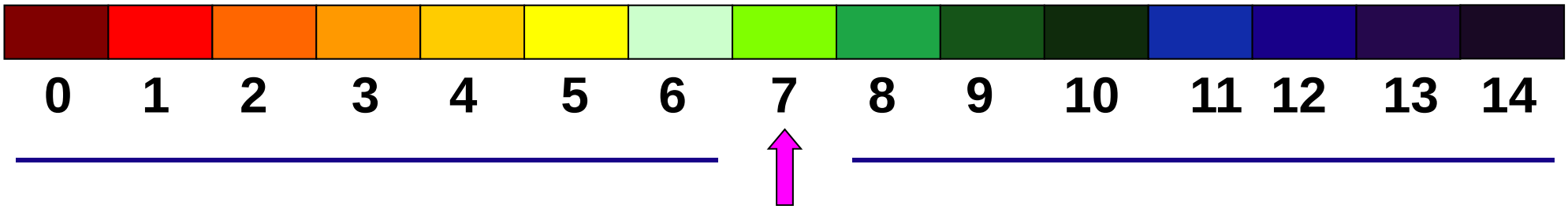
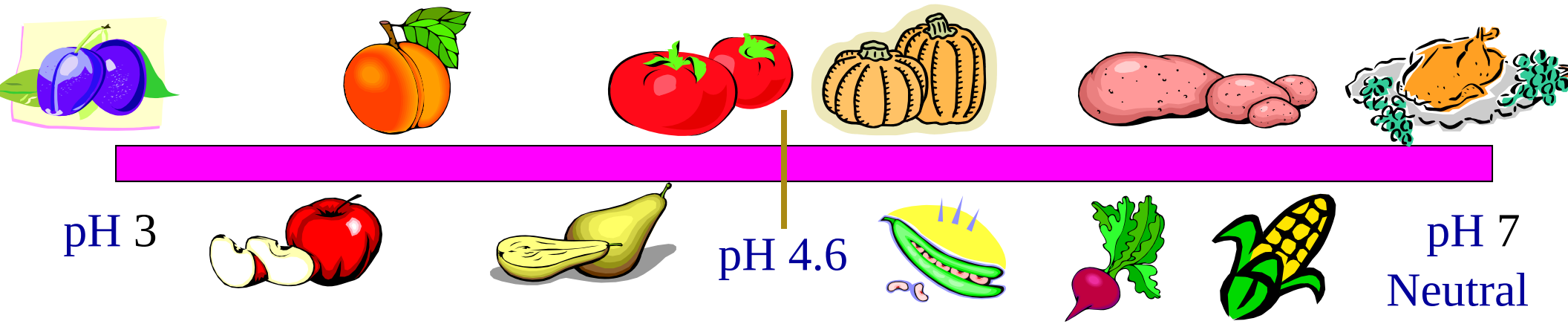


Image: kentsimmons.uwinnepeg.ca

pH Examples of Some Foods



pH 3

pH 4.6

pH 7
Neutral

pH Scale

High acid foods

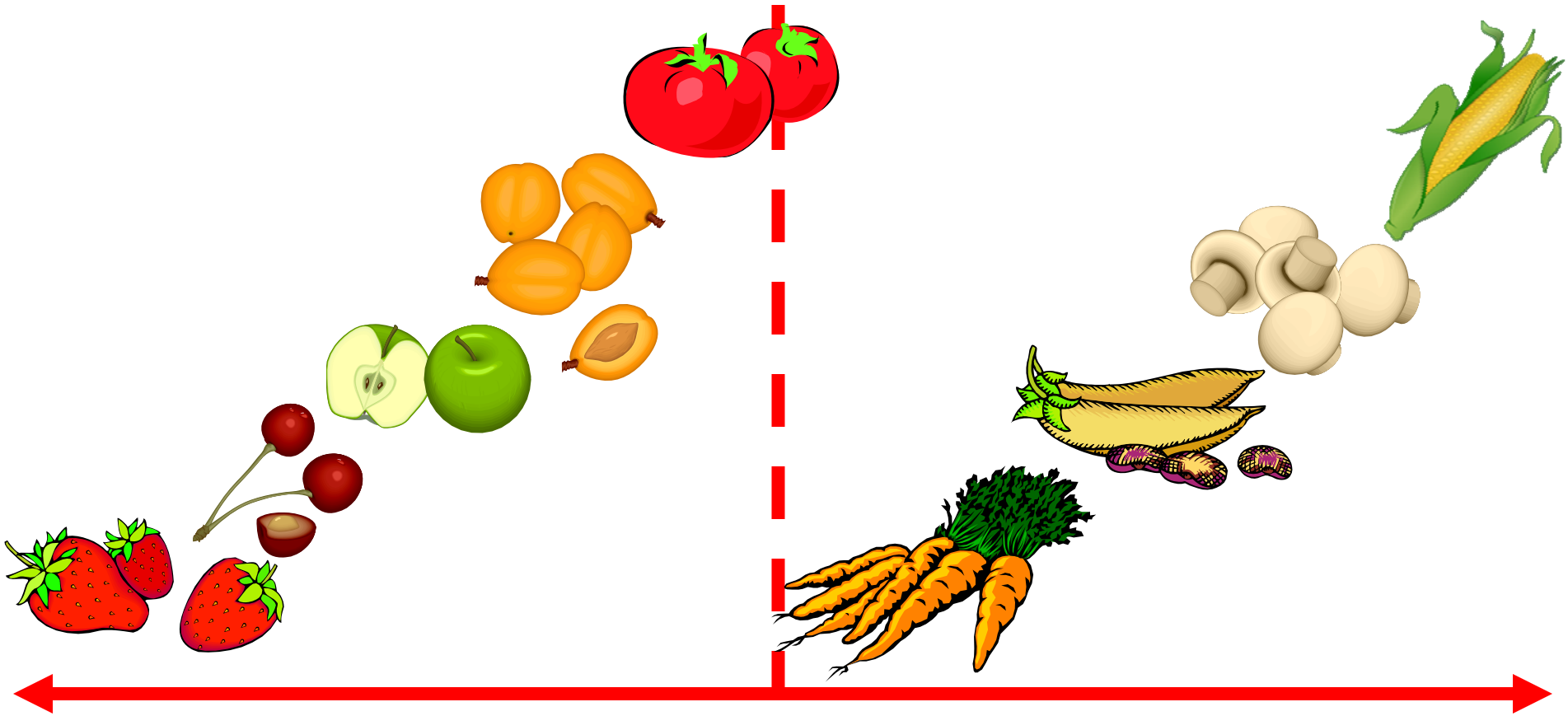
Low acid foods

Few microbes grow

Most microbes grow

Clostridium botulinum inhibited at pH 4.6

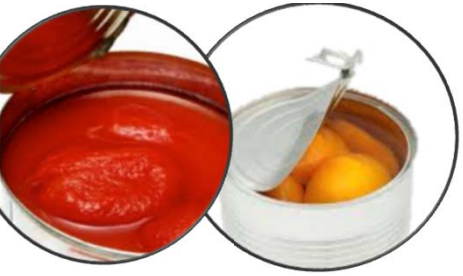
pH and Food Processing



pH 4.6

High acid food

Low acid food



pH & Canning

MILDER HEAT
Atmospheric heating

1) Pathogens destroyed
2) *Clostridium botulinum* survives
3) Botulism prevented by pH control

HIGH HEAT
Pressure processing

1) Pathogens destroyed
2) *Clostridium botulinum* destroyed

pH 3 — pH 4.6 — pH 7

High acid food — ***Low acid food***

Acidified Low Acid Foods

- Foods that are "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
  - Requires training in Better Process Control School or Acidified School
  - Separate facility registration
  - Product and process submission and evaluation,
    - "S" letter that must be filed with FDA
  - Batch and record inspection
    - At manufacturer cost

Exempt from 21 CFR 114

Maybe exempt

- **Acid foods** that contain <u>small amounts</u> of low- acid foods foods and have a resultant finished equilibrium pH that does not differ from that of the <u>predominant acid or acid food</u>
  - SMALL AMOUNTS - rule of thumb less than 10%
  - PREDOMINANT ACID OR ACID FOOD determined by quantity/amount of acidit ingredient characterizes food

FDA Guidance: "Water-based liquid"

- Newer Guidance "Proposed"
  - Acidified low acid foods:
    - Beverages, dietary supplements
    - Water is predominant ingredient PLUS
      - Fruit flavors
      - Extracts
      - Herbs
      - Vitamins, minerals or other nutrients
    - NOT fruit juice or milk-based liquids

Process – HEAT

Process

1. Heated in a kettle, filled hot and inverted
2. Heated, filled then pasteurizer tunnel or hot water bath
3. Not heated, filled, then pasteurizer tunnel or hot water bath

Info Needed to Evaluate

1. Cook time/temp; Fill temp; Lid/Headspace sterilization
2. Fill temp; 'Pasteurizer temp' and Process time
3. Container size; Product characteristics; Heat penetration data, IT, 'Pasteurizer' temp, Time in heated conditions (may be belt speed if pasteurizer)

Process – COLD FILL

- Heated then filled cold
- Not heated, just filled cold
- Challenge study to determine how long it takes to get a 5-log reduction of vegetative pathogens
  - HOLD TIME and TEMPERATURE
    - usually 10°C/50°F and 20°C/70°F

California Botulism Control Program
21 CFR 114 – California version

- The State of California is the PROCESS AUTHORITY for low-acid and acidified foods made in California
- The UCLRFP (University of California Laboratory for Research in Food Preservation) is the 'consulting laboratory' for the State of California

UC LABORATORY FOR RESEARCH IN
FOOD PRESERVATION DEPARTMENT OF
FOOD SCIENCE AND TECHNOLOGY

Label Regulations

http://www.cdph.ca.gov/programs/Documents/fdblabel.pdf

Label Regulations

Principal Display Panel

Must be
•Legible (1/16 inch minimum)
•English

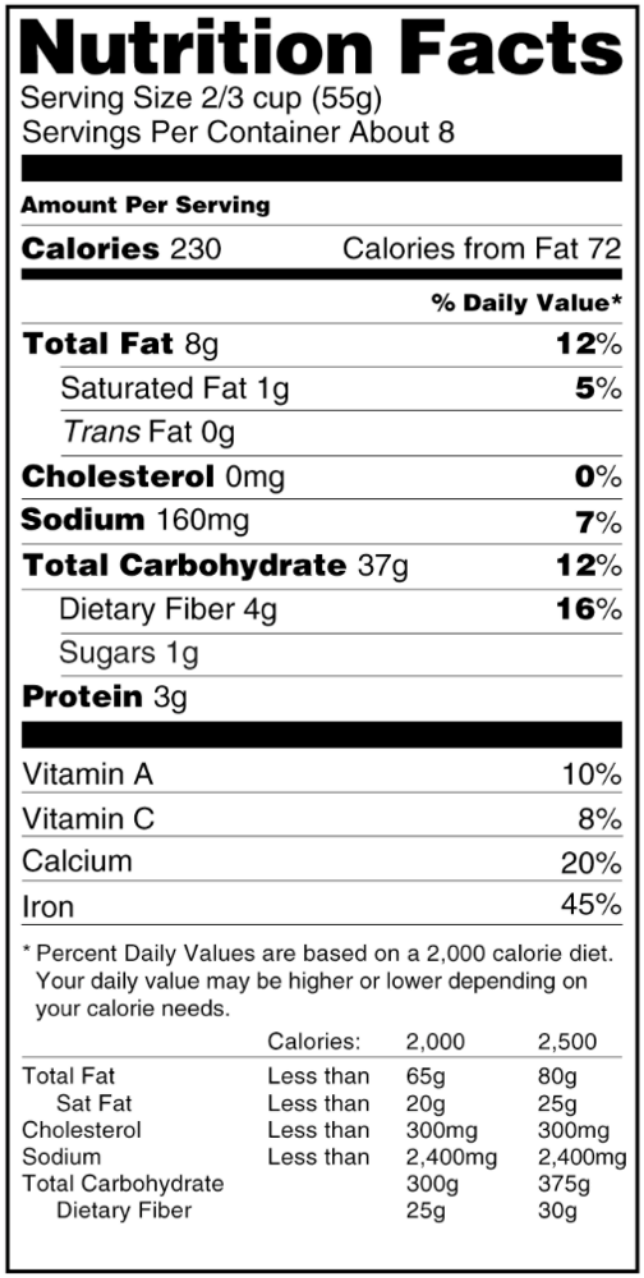
Must contain
•Product name (large, truthful and bold type)
•Net quantity of contents (U.S. and metric)
•If applicable:
- "Perishable Keep Refrigerated"
- "Made in a Home Kitchen"

Label Regulations

Information Panel

Must contain

- Nutrition facts
  - Small business exemption
- Ingredient list
  - Order by weight
- Name and address of responsible firm
- Allergens
  - Any of major 8
  - Gluten-free
    - new specific requirements



Nutrition Facts

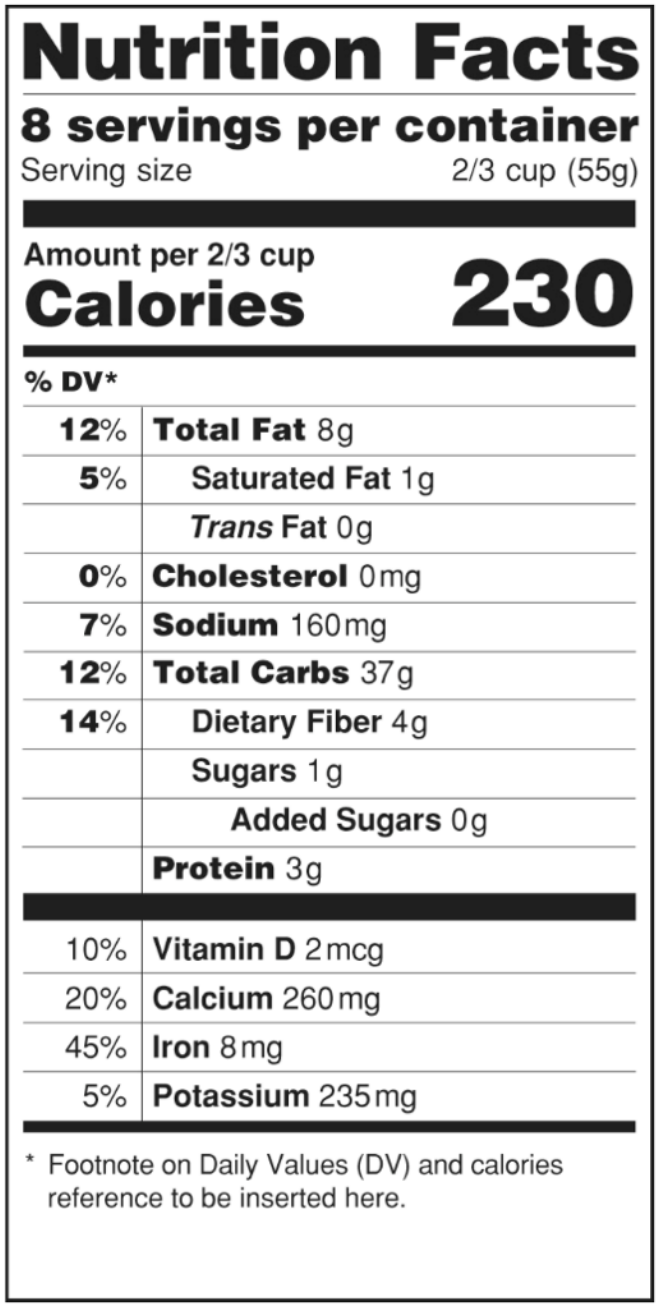
Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g



Nutrition Facts

8 servings per container
Serving size 2/3 cup (55g)

Amount per 2/3 cup
Calories 230

% DV*	
12%	**Total Fat** 8g
5%	**Saturated Fat** 1g
	***Trans* Fat** 0g
0%	**Cholesterol** 0mg
7%	**Sodium** 160mg
12%	**Total Carbs** 37g
14%	**Dietary Fiber** 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	**Vitamin D** 2mcg
20%	**Calcium** 260mg
45%	**Iron** 8mg
5%	**Potassium** 235mg

* Footnote on Daily Values (DV) and calories reference to be inserted here.

Nutrition Labels Changes Proposed August 2014

Not required but specific regulations/guidance

USDA Organic
Must meet USDA organic requirement

Nutrient Content Claims
That Have Specific Meaning

free, low,
reduced, fewer,
high, less, more,
lean, extra lean,
good source, and light

Not required no regulations

No FDA definition of “natural”, “*raw*”, “vegan”

Your story

Expiration dates, sell by, lot codes

- Very few required by law
- Dairy products (sell by)
- Infant formula (use by)
- Some type of dating or lot codes recommended
  - Consumer expectation
  - Retailer expectation
  - Assists in recall (should one be necessary)
- Determining shelf life
  - Some retailers will require for refrigerated foods

Dietary Supplement

- Structure/function claims
  - E.g., “calcium supports building strong bones”

“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.”

Shelf Stable Examples

REGISTERED FOOD PROCESSING FACILITY

RETAIL AND INTERSTATE SALES

Regulations
21 CFR 110 (GMPs)
21 CFR 150

21 CFR 150
Standard of Identity Fruit Butters,
Jellies, Preserves, and Related Products

pH 3.0
A_w 0.65

Red currants naturally acidic
Water activity <0.85

Regulations
21 CFR 110 (GMPs)
21 CFR 150

21 CFR 150
Standard of Identity Fruit Butters,
Jellies, Preserves, and Related Products

pH 3.6
A_w 0.93

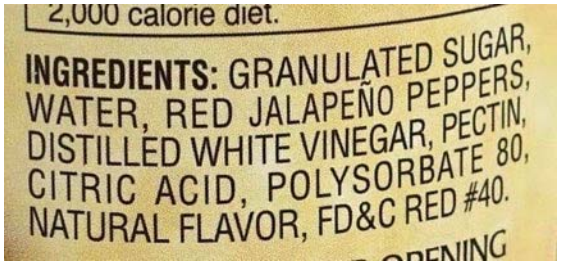
Apples naturally acidic
Water activity >0.85

Regulations
21 CFR 110 (GMPs)

pH 4.0
A_w 0.70

Exemption Status Depends:
- smooth or chunky
- pre acidified or fresh
- process control

Peppers not naturally acidic
Acidified using vinegar and citric acid
Exempt from pH control program
Water activity <u>≤0.85</u>


2,000 calorie diet.

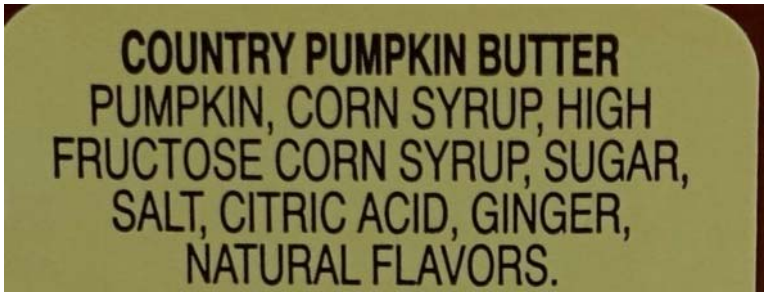
INGREDIENTS: GRANULATED SUGAR, WATER, RED JALAPEÑO PEPPERS, DISTILLED WHITE VINEGAR, PECTIN, CITRIC ACID, POLYSORBATE 80, NATURAL FLAVOR, FD&C RED #40.

Regulations
21 CFR 110 (GMPs)
21 CFR 114

pH 4.2
A_w 0.94

21 CFR 114
Acidified Low Acid Foods
California pH control program

Pumpkin not naturally acidic
Acidified using citric acid
Water activity >0.85



Regulations
21 CFR 110
21 CFR 114
9 CFR 304

pH 4.3
A_w 0.93

9 CFR 304
Pathogen Reduction;
Hazard Analysis and
Critical Control Point
(HACCP) Systems

Bacon not naturally acidic
Acidified using vinegar
Water activity >0.85
More than 2% meat

FOOD & DRINK

Maple Bacon Jam in Cronut Burgers Caused Food Poisoning Outbreak

The Cronut was innocent.

August 2013
Toronto, Ontario
Canadian National Exhibition

220 people
Staphylococcus aureus

Botulism 2014

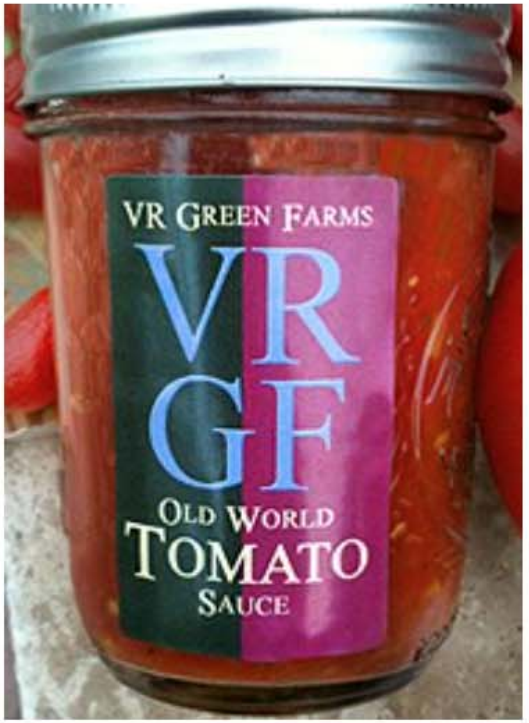
- Pesto sold farm stand "on and off for several years"
  - Father of bought 7 jars on a trip
  - Gave to friends in Colorado and daughter in Ohio
- 2 cases botulism in Ohio (daughter and friend in their 20s)
  - chicken pasta salad made with pesto sauce
  - Hospitalized and on ventilators
- Unlicensed California facility (Napa)
  - Inadequate process (pH 5.3 and water activity 0.965)
  - Inadequate label (incomplete ingredient statement, no lot code, best buy date, or a "Perishable Keep Refrigerated")
- CDPH FDB described the manufacturing process to be conducted under "insanitary conditions at a home residence".

http://www.marlerblog.com/legal-cases/a-botulism-tale-two-young-women-and-one-jar-of-pesto-sauce/#.VNUVOUKOXrM

California Food Recall

V R GREEN FARMS

Recalled Product Photos



Summary

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

Check your assumptions with regulators or experienced individual early on.

Processing Foods

www.ucfoodsafety.ucdavis.edu

Co-Packers

Co-packers are food processors that have extra manufacturing capacity and offer their services for a fee. This is often an attractive option for people starting in the food business. The product and its package must be matched to the co-packer and its available equipment. Co-packers often offer additional services such as product development (often critical to scaling up the volume of product produced), label review, and regulatory compliance.

- Choosing and Using a Co-Packer (NC State University) (PDF 26 KB)
- Co-Packers Database (UC Davis Food Safety). This database provides a partial list of co-packers with an emphasis on those located in California.
- A list of small Co-Packers in the northeastern US (Cornell University)
- Food Processing: Using a Co-Packer (Oklahoma Cooperative Extension) (PDF 43 KB)