Overview

• Which food products are considered “processed”
• Regulations that apply to processed and unprocessed food products at the state and federal level
• Proper food safety and sanitation procedures to apply during food processing
• Components required on FDA-compliant food labels and home-processed food labels (under Utah law)
Value-Added Foods

- Local, organic, vine-ripened, or specialty crops
- “Gourmet” or “Homemade” foods
  - Jams, jellies, preserves
  - Pickled vegetables
  - Hot sauces, salsas, tapenades
  - Herbed oils and vinegars
- Must consider the regulatory, safety, and labeling issues

Unprocessed Foods – Raw Produce, Nuts and Grains

- Do not need to register with UDAF
  - Only applies to grains sold as food
  - Seed grain sellers must register
- Must be sold by grower
- Produce must be whole and unprocessed
  - Can wash to remove dirt, dust
  - Cannot peel, cut, shred, tear, dehydrate
  - Must be displayed off of the ground
Unprocessed Foods – Eggs

- Small operations do not need to register with UDAF
  - Less than 3000 laying hens
- Must be sold by producer (owner of hens)
- Specific requirements (Utah Code 4-4-108, Admin Rule R70-410-4)
  - Clean cartons or containers
  - Name & address, “Keep Refrigerated”, handling instructions required on label
  - Restrictions on sales to restaurants

Unprocessed Foods – Raw Honey

- All hives must be registered with UDAF
  - Up to 20 hives is $10 annually
- Raw honey must meet definition (Utah Code 4-5-502, Admin Rule R70-520)
  - Extracted, settled, or strained but not pasteurized
- Honey bottling is considered processing
  - Can be bottled in a commercial kitchen or in a home kitchen (under Cottage Act or the Homemade Foods Act)
Processed Foods Include:

- Peeled or cut produce
- Produce washed in disinfectants (e.g. bleach water)
- Most dried or dehydrated produce

Produce Safety Information
www.producesafety.utah.gov

Resources Tab
- Personnel Training
- Standard Operating Procedure Development
- Recordkeeping

Training Tab
- Grower Training
- Ongoing education
What to expect

The trainers will spend approximately seven hours of instruction time covering content contained in these seven modules:

• Introduction to Produce Safety
• Worker Health, Hygiene, and Training
• Soil Amendments
• Wildlife, Domesticated Animals, and Land Use
• Agricultural Water (Part I: Production Water; Part II: Postharvest Water)
• Postharvest Handling and Sanitation
• How to Develop a Farm Food Safety Plan

Selling Processed Foods – Commercial Processing

• Inspection and registration with UDAF (Utah Wholesome Food Act)
• Two inspection programs, depends more on where you sell
  • Retail Food Program – mostly direct-to-consumer sales
  • Manufactured Food Program – wholesale sales UDAF inspector will assign you to an inspection program
  • May require additional trainings, product testing, FDA registrations
• No restriction on where foods can be sold
• Must have FDA-compliant labels

For more details: karin.allen@usu.edu
Selling Processed Foods – Co-Packers

• Certified food production facilities that package product on a contract basis
• Each co-packer has different requirements, capabilities & minimum runs
• You must license your business, but the co-packer will register with the FDA
  • Co-packer or inspector may require additional safety reviews or evaluations

Selling Processed Foods – Home Processing

• 2007 – HB 339, Regulation of Cottage Food Production Operations
  • Amended in 2017 Session by HB 58, Direct Food Sales Amendments
• 2018 – HB 181, Home Consumption and Homemade Food Act
  • Does not replace the Cottage Food Program
• Both have pros and cons
  • Which is best depends on your business
Overview of Cottage Program

- Allows non-potentially hazardous foods to be made in private home kitchens, products must be approved by UDAF
- Must have business license, food handler’s permit and pay annual registration fee
- Cannot sell to restaurants (to use as an ingredient) or for consumption on-premises
- Labels similar to FDA, must say “Home Produced”
- Apply on UDAF Cottage Food Program page

Utah Code 4-5-501 Admin Rule R70-560

Overview of Homemade Foods Act

- Allows all but a few specific foods to be made in private home kitchens
- Must have business license
- Specific labeling requirements
- Only direct to consumer sales from home, private property, or outdoor markets, no restaurants or stores
  - Specific signage requirements for outdoor markets

Utah Code 4-5-501 Admin Rule R70-560
Required Wording for Signage

FOOD ITEMS OFFERED FOR SALE IN THIS MARKET ARE HOMEMADE AND HAVE NOT BEEN CERTIFIED, LICENSED, REGULATED, OR INSPECTED BY STATE OR LOCAL AUTHORITIES

• 22 x 28” minimum
• White background
• Red print
• Capitalized text, at least 2” in height

Food Safety
Why Food Safety Matters

• Would you feel good about making even one customer sick?

Safety Issues to Consider

• How will you clean and sanitize?
• How will you prepare or cook your product to minimize safety risks?
• How will you package or protect your product?
• How will you store & display your product?
Cleaning vs Sanitizing

• Which comes first – sweeping or mopping?

• Clean: Free of visible dirt or debris
  • Whole, unprocessed foods

• Sanitary: Free of pathogenic bacteria
  • Applies to food contact surfaces and most processed foods

• Sterile: Free of all viable bacteria
  • Commercial sterility = 99.99% sterile

Cleaning and Sanitizing

• Clean surfaces and equipment first, then wipe with sanitizing solution

• Sanitize before starting and after finishing production, and once an hour during

• Cloths can be stored in sanitizing solution when not being used

• Check sanitizing solution once an hour and remix as needed
Using Sanitizers

- **Unscented** chlorine bleach
  - Minimum: 50 ppm (about 1 tsp per gallon water)
  - Maximum: 200 ppm (about 1 tbsp per gallon water)
  - Temperature about 70F, pH between 6.5 and 7.5
  - Leave on surfaces for at least 2 minutes
  - Stronger concentration can be used on surfaces, but they must be rinsed with fresh water before preparing food

- Quaternary Ammonium ("Quats") and Iodophores
  - Make and use according to manufacturer instructions

Chemical Contaminants
Physical Contaminants

Biological Contaminants

• **Viruses** – must infect a living host cell before reproducing, but can survive without a host
Biological Contaminants

• **Fungi** – multiply and grow without a host

Biological Contaminants

• **Bacteria** – multiply and grow without a host
Bacterial Growth & Survival

Food  
Acid  
Temperature  
Time  
Oxygen  
Moisture

FDA requirements for specific foods

• All food producers must have appropriate food safety training
• All food producers must show that they are addressing microbes that are typically associated with their products
  • *Salmonella* is becoming more common in low-moisture foods
• Additional requirements exist for:
  • Refrigerated foods
  • Canned or bottled foods
  • Bottled water, Juice, Seafood
Low moisture foods

- The bacteria *Salmonella* can live in very dry foods
- The FDA requires that you follow Good Manufacturing Practices to reduce the risk of *Salmonella* contamination
  - Use high-quality ingredients
  - Irradiated ingredients are the safest, but cannot be used in organic foods
  - Practice proper sanitation
- No additional registrations or trainings are required

Refrigerated foods

- The bacteria *Listeria monocytogenes* can grow at refrigeration temperatures
- FDA requires testing of refrigerated foods unless research shows that *Listeria* can’t grow
  - pH below 4.4
  - Water activity below 0.92
  - Bottled foods that are heat processed and sealed
- No additional registrations or trainings are required
Bottled foods

- The bacteria *Clostridium botulinum* can only grow when no oxygen is present
  - It produces a neurotoxin that can be fatal
- FDA has requirements designed to keep bottled food safe from *Clostridium botulinum*
  - Exempt, Acid, Acidified, and Low-Acid categories

Bottled foods – Exempt products

- Exempt products have a water activity < 0.85
- No additional registrations or trainings are required
| Water Activity ($A_w$) | Examples of foods in this range |
|-----------------------|---------------------------------
| 1.00 – 0.95           | Fresh produce & meat; canned produce & meat; milk; juice; bread |
| 0.95 – 0.91           | Cured meats (ham); semisoft & some hard cheeses (Swiss, young cheddar, provolone); moist cakes |
| 0.91 – 0.87           | Hard or aged cheese; sponge cakes; margarine; most fermented sausage |
| 0.87 – 0.80           | Syrup; flour; fruit juice concentrate; high-sugar cakes |
| 0.80 – 0.75           | Jam & marmalade; marshmallows; beef jerky |
| 0.75 – 0.65           | Soy sauce; molasses; jelly; nuts; oats; peanut butter; |
| 0.65 – 0.60           | Honey; caramels; dried fruit; toffee |
| 0.50 or below         | Spices; crackers; cookies; pasta; powdered milk |

**Bottled foods – Acid or Formulated Acid**

- Acid products have a natural pH < 4.6 and no added low-acid ingredients
- Formulated acid products have a finished pH < 4.6 and a small amount (<10%) of added low-acid ingredients
- No additional registrations or trainings are required
Bottled foods – Acidified products

- Acidified products have acid added so the final pH < 4.6
- Recipes and processing steps must be evaluated by a Process Authority
  - Testing is typically $70-$100/product
- Acidified Processors must attend Better Process Control School
  - $350-$500 for the course, online
- Must register with FDA as an acidified processor and submit quarterly process filings
Bottled foods – Low-Acid products

- Low-acid products have no acid added so the final pH > 4.6
- Recipes and processing steps must be evaluated by a Process Authority
  - Testing usually more expensive than acidified
  - No low-acid process authorities in Utah
- Low-Acid Processors must attend Better Process Control School
  - $350-$500 for the course, online
- Must register with FDA as low-acid processor and submit quarterly process filings

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Home Kitchen Decision Tree

- Your product can be made in a home kitchen, under either the Cottage Food Act or the Home Consumption and Homemade Food Act (HB 181).
- Your product might be approved under the Cottage Food Act, but more information is needed. You can make your product under the Home Consumption and Homemade Food Act (HB 181).
- Your product must be processed carefully to be safe from Clostridium botulinum, the bacteria responsible for botulism poisoning. Though it can be made under the Home Consumption and Homemade Food Act (HB 181), it is best to keep refrigerated or frozen and advise consumers to do the same.
- Your product cannot be made in a home kitchen. Commercial processors of meat and raw dairy must meet additional safety and inspection requirements.
Food Labeling

Value-Added Foods

• Local, organic, vine-ripened, or specialty crops
• “Gourmet” or “Homemade” foods
  • Jams, jellies, preserves
  • Pickled vegetables
  • Hot sauces, salsas, tapenades
  • Herbed oils and vinegars
• Must consider the regulatory, safety, and labeling issues
Required Label Components

Primary Display Panel

Statement of Identity

Net weight statement

Statement of Identity

- Many foods have a legally established name that must be used [CFR21 §101.3]
- All others must use “common or usual name”
- Other requirements include:
  - Form of food (e.g. sliced, cubed, crushed)
  - “___% Juice” for any drink showing fruit or vegetables on the label
Standards of Identity Exist for:

§ 131 Milk & cream
§ 133 Cheese
§ 135 Frozen desserts
§ 136 Bakery products
§ 137 Cereal flours
§ 139 Macaroni & noodles
§ 145 Canned fruit
§ 146 Canned fruit juice
§ 150 Jellies & preserves
§ 152 Fruit Pies
§ 155 Canned vegetables

§ 156 Vegetable juices
§ 158 Frozen vegetables
§ 160 Eggs & egg products
§ 161 Fish & shellfish
§ 163 Cacao products
§ 164 Tree nuts & peanuts
§ 165 Beverages
§ 166 Margarine
§ 168 Sweeteners & syrups
§ 169 Dressings & flavorings

Required Label Components

Information Panel

- Nutrition Facts panel
- Ingredient statement
- Producer name & address
Ingredient Statement

- Ingredients must be listed in order by weight
- Must list function of any preservatives
  - “Ascorbic Acid to promote color retention”
- “Spices”, “Natural Flavor” or “Artificial Flavor” can be grouped to save space
  - Except: onion/garlic/celery/vegetable items, salt, and MSG
- Certified colors must be specified
  - “Red 40” or “FD&C Red 40”

Allergen Statement

- Wheat
- Dairy
- Eggs
- Tree Nuts (by name)
- Peanuts
- Soy
- Molluscan Shellfish
- Finfish (by name)
- Sesame (as of Jan 1)
Nutrition Facts – New Format

- Nutrients
  - Added Sugars
  - Vitamins C & A no longer required
  - Potassium & Vitamin D are required
- Format – layout changes
  - Still recognizable
- Serving Sizes – “more realistic”
  - Some increased, some decreased, some new categories

Small Business Exemptions

- Retailer Exemptions: 21CFR§101.9(j)(1)

<table>
<thead>
<tr>
<th>Nutrition Labeling: Retailer Exemption</th>
<th>Annual Food Sales ONLY (Includes food resold and food manufactured)</th>
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<tbody>
<tr>
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<td>Up to $50,000</td>
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<tr>
<td>Total Annual Sales</td>
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<td>Nutrition labeling IS NOT required</td>
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<tr>
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<td></td>
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<tr>
<td>$500,001 or more</td>
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<tr>
<td></td>
<td>Nutrition labeling IS NOT required</td>
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</tbody>
</table>

* Does not apply if you make ANY health-related claims on your package (e.g. Low Fat, Healthy (or heart-shaped graphics), High in Iron, Sugar-Free).
Small Business Exemptions

- Manufacturer Exemptions: 21CFR§101.9(j)(18)

<table>
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<th>Nutrition Labeling: Low-Volume Exemption</th>
<th>Annual Units Produced and Full-Time Equivalent Employees (FTEs)</th>
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<tbody>
<tr>
<td></td>
<td>&lt;10,000 Units and &lt;10 FTEs</td>
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<tr>
<td>Products do not include imports</td>
<td><strong>EXEMPT</strong>&lt;br&gt;• Nutrition labeling IS NOT required&lt;br&gt;• Exemption notice IS NOT required</td>
</tr>
<tr>
<td>Products include imports</td>
<td><strong>EXEMPT</strong>&lt;br&gt;• Nutrition labeling IS NOT required&lt;br&gt;• Exemption notice IS required</td>
</tr>
</tbody>
</table>

* Does not apply if you make ANY health-related claims on your package (e.g. Low Fat, Healthy (or heart-shaped graphics), High in Iron, Sugar-Free).

Types of Health Claims

- Nutrient content claims
  - Specific guidelines for different types of food
- Approved health claims
  - General scientific consensus has been reached
  - Must put in context of whole diet
- Qualified health claims
  - No scientific consensus, but some evidence
  - Stricter wording requirements
Nutrient Content Claims

- Content Claims [21CFR§101.60-62]
  - “Free”, “Low”, “Reduced/Less”

- Relative Claims [21CFR§101.13(j)]
  - “Light”, “Reduced” or “Added”, “More” or “Less”

- Other Claims
  - “High”, “Rich In” or “Excellent Source of”
  - “Good Source”, “Contains” or “Provides”

Organic Labeling

- Crop, livestock, or food product certification
- USDA does not require certification for organic sales <$5000 / year
- Specific requirements for how it is stated on the label
“100% Organic”

- Must contain only organic ingredients (except water and salt)
- Must list certifying agency information
- Can use USDA and/or certifying agency seal

“Organic”

- Must contain 95% organic ingredients
- Cannot contain sulfites
- Must list certifying agency information
- Can use USDA and/or certifying agency seal
“Contains Organic ____________”

- Must contain 70% organic ingredients
- Cannot contain sulfites (except wine)
- Must list certifying agency information
- Can use certifying agency seal, but not USDA

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**Natural Labeling**

- No specific legal definition from FDA
  - Currently reviewing public comments on whether it should be more tightly regulated
  - USDA has stricter requirements for meat products
- Cannot contain artificial or synthetic ingredients
  - Colors
  - Flavors
  - Preservatives
Other Label Issues

• Many common claims are not regulated by FDA
  • “Handmade”, “Small Batch”, “Nothing Artificial”, “No Preservatives”
• These and others have been the focus of recent lawsuits
  • Label graphics imply that a food is “healthy”
  • “Greek Yogurt” not made in Greece
  • “Evaporated cane juice” instead of “Sugar”
  • “Made in USA” when some ingredients are foreign
• No way to predict what may trigger a lawsuit, but if it could be misleading someone will think it is!

Home Kitchen Labeling Requirements

Cottage Program
• FDA labeling requirements
• “Home Produced” by name
• Font size and placement requirements

Homemade Food Act
• Producer name & address
• Allergen listing
  – Ingredient statement not required
• “Not for Resale”
• “Processed and prepared without the benefit of state or local inspection”
• No font size or placement requirements
Example Labels for Home Kitchens

Cottage Program

Honey Caramels
Home Produced

Ingredients: Honey, cream, pecans
Allergens: contains milk, tree nuts (pecans)

Honey Candy Co.
123 Honeybee Lane
Salt Lake City, UT 84118
(801)123-4567

NET WT 24 OZ (1.5 LB) 680 g

Homemade Food Act

HONEY CARAMELS

NOT FOR RESALE
Processed without benefit of State or Local inspection

This food contains pecans and milk

Honey Candy Co.
123 Honeybee Lane, Salt Lake City, UT 84118

Questions?
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