



FRAME

fundamental resources for
agricultural micro-entrepreneurs



Module 2: Food Regulations

Extension
UtahStateUniversity.



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Module 2: Food Regulations

- Part 1: Regulatory agencies
- Part 2: FDA requirements for packaged foods





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Part 1: Regulatory agencies

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Why Is Regulation Necessary?

- CDC estimates 48M foodborne illness cases annually
 - 1 in 6 people
 - 128K hospitalizations, 3K deaths
- Regulations and trainings are designed to address specific types of food
- Training requirements depend on your inspection category and food products
 - Kitchen Manager Certification, HACCP, Preventive Controls, etc.

This module gives an overview, but cannot cover the specifics for all states and regions!



Who Regulates Food Production?

At the Federal Level:

- U.S. Food and Drug Administration (FDA)
- U.S. Department of Agriculture (USDA)

At the State or Local Level:

- State Department of Agriculture
- Local and regional health departments

For Utah:

- Utah Department of Agriculture and Food
- 13 local/regional health districts



Federal Level - USDA

- Voluntary grading (related to quality, not safety)
 - Meats, fruits & vegetables, eggs
- Organic production and labeling
- Bioengineered labeling
- Safe and humane slaughter and processing (9 CFR)
 - Amenable species (includes most major food animals)
 - Standards of identity for processed meats



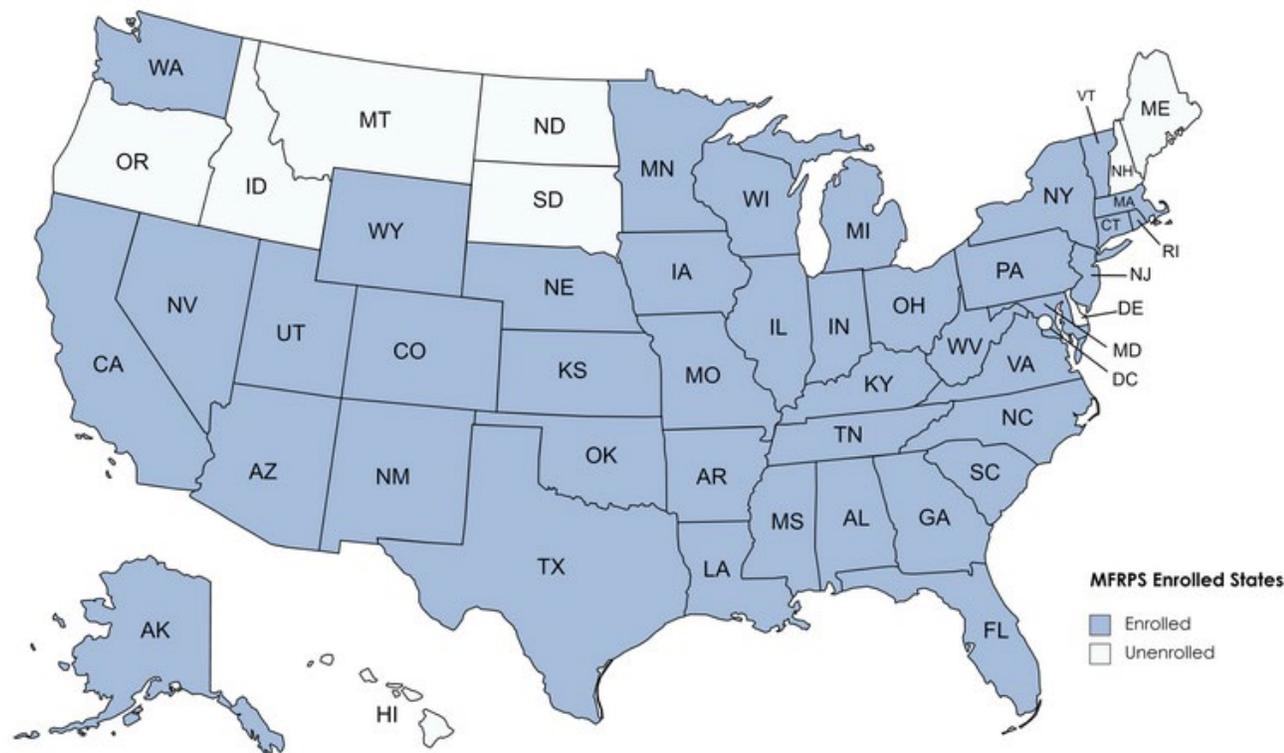
Federal Level - FDA

- All other food processing and labeling (21 CFR)
 - Nutrition facts and allergen labeling
- Additive review and approval
- Voluntary guidelines for restaurants and retail food establishments
 - FDA Food Code
- Food Safety Modernization Act
 - Safe food production, transport, warehousing



State Level – Food Processing

- Most states have cooperative agreement with FDA for inspection of Manufactured Food Establishments (MFP)

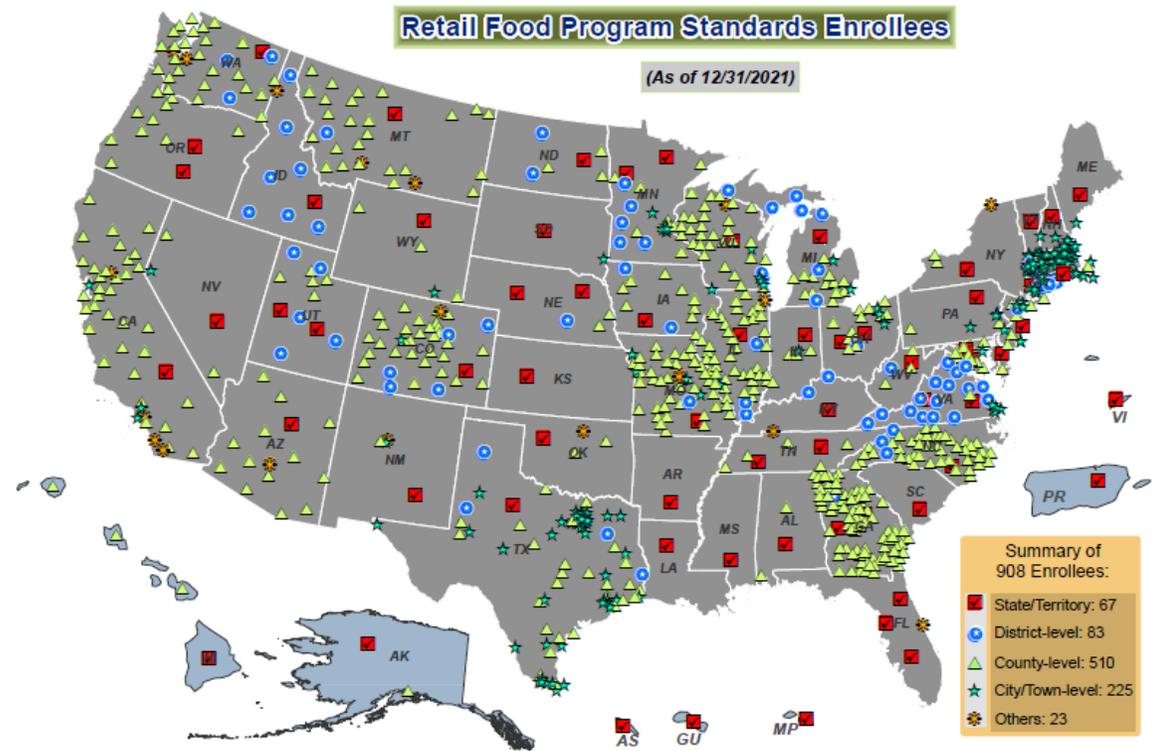


See Module 2 resource page for more information

State level – Retail Food Program

- All states have state or local agencies that participate in FDA's Voluntary National Retail Food Regulatory Program (RFP)

See Module 2 resource page for more information



Example of State Level Regulation

Utah Department of Agriculture and Food

- Cooperative agreement with USDA (meat inspection)
- Cooperative agreements with FDA (Retail and Manufactured Food programs)
- Administer special state-level programs (foods that can only be sold within Utah)
 - e.g. Cottage Food, State Meat Inspection Program, Raw Milk

Optional Module 6 covers Utah
Home Food Processing options



Selling Processed Foods

- Inspection and registration with Local, State and/or Federal Agencies
 - 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
- Must have FDA-compliant labels (this will be covered in Module 4)





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Module 2

Part 2: FDA requirements for packaged foods

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FDA Requirements for Specific Foods

- Foods must be evaluated to determine if they require temperature control or pose a safety risk
- Safety/microbial concerns associated with ingredients and finished product
 - Nature of processing – does it include obvious kill step(s)?
 - Packaging considerations – hermetic seal, aseptic packaging, or possible recontamination?
 - Frozen, refrigerated, or shelf-stable product?

Inspectors may require you to work with a Process Authority

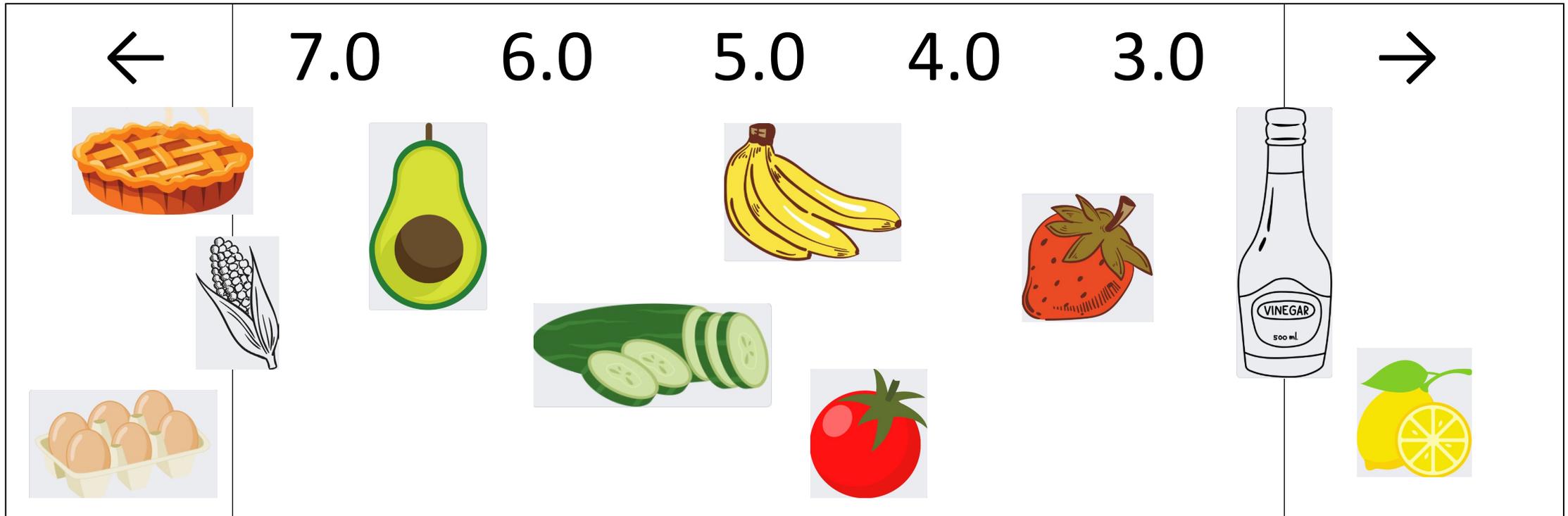


Information Needed by Process Authorities

- Type of business
- Classification under [RFP](#) or [MFP](#) or where you plan to sell
 - Farm stand, farmer's market, grocery stores, restaurant, online
- Description of the product
 - Complete ingredient list
 - Detailed processing steps, including cooking/bottling temps
 - Any pH, Aw, or moisture measurements already taken
 - Packaging used (or preferred packaging)
- Inspector contact information (e-mail) is also helpful!



pH ranges of common foods



| 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

- 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

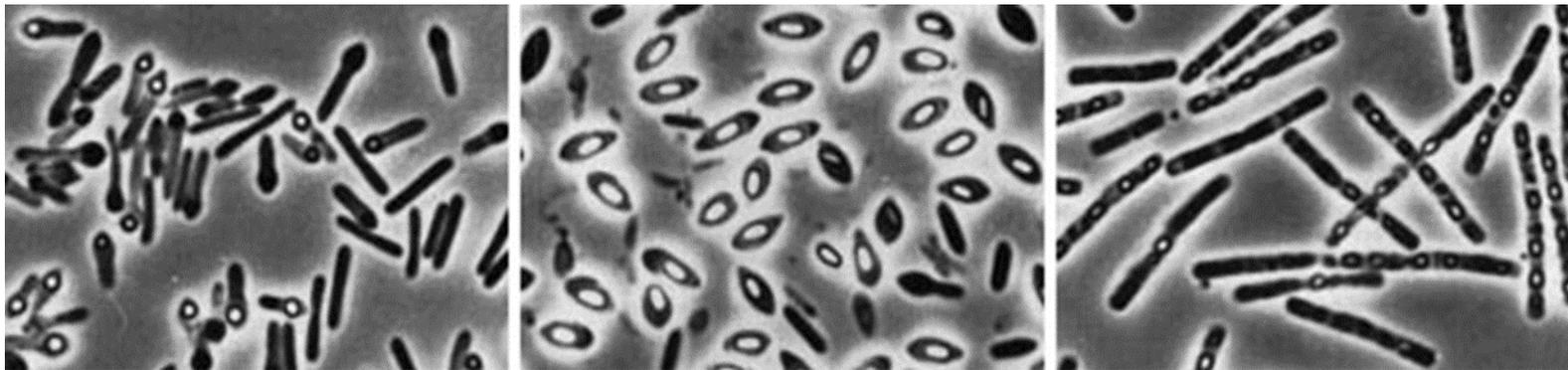


Photo source: CDC



Bottled Foods – Exempt Products

- Exempt products have a water activity < 0.85
- No special registrations or trainings are required



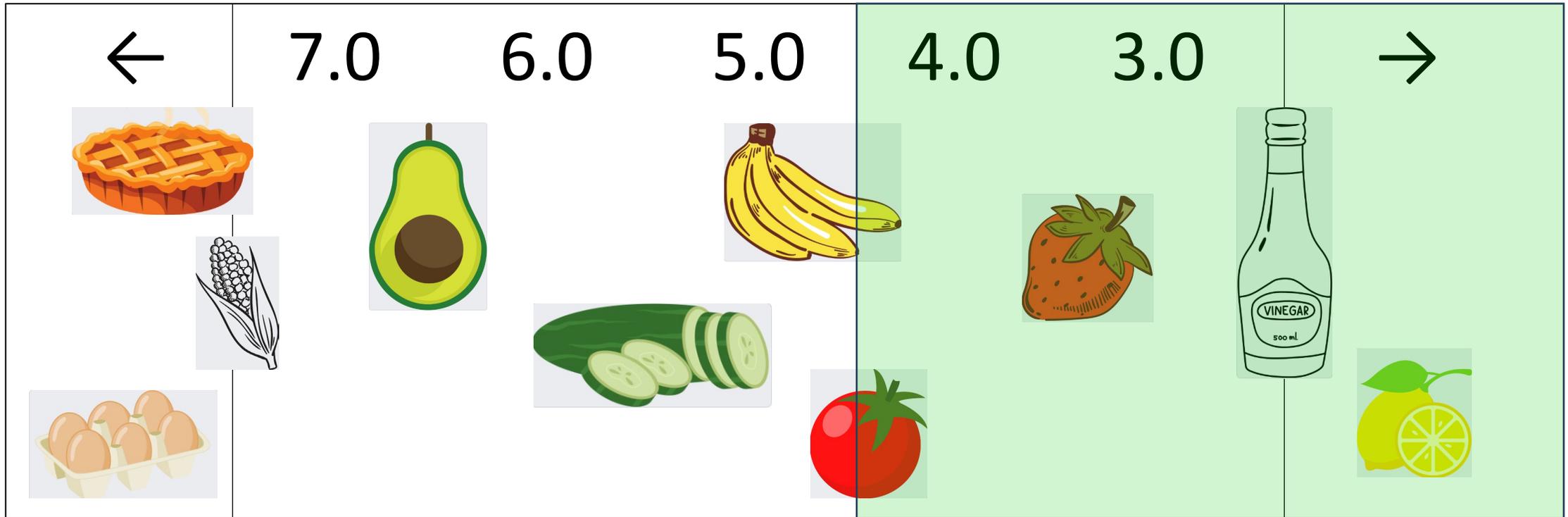
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Bottled Foods – Acid or Predominantly Acid

- Acid products have a natural pH < 4.6 and no added low-acid ingredients
- Predominantly acid products have a finished pH < 4.6 and a small amount of added low-acid ingredients
- No special registrations or trainings are required, but Acidified Food training is recommended



pH ranges of common foods



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
- Acidified Processors must attend Acidified Foods training
- 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
- Low-Acid Processors must attend Low Acid Canned Foods training
- Must register with FDA as low-acid processor and submit quarterly process filings



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 < 4.2 or Aw < 0.92
- No special registrations or trainings are required



Low Moisture Foods

- The bacteria *Salmonella* can live in very dry foods
- The FDA requires that you follow current Good Manufacturing Practices (cGMP) to reduce the risk of *Salmonella* contamination
- No special registrations or trainings are required



cGMP course is available online through USU Extension

