FOOD PRODUCTION AND PROCESSING REGULATIONS

Legal Considerations

Processed Food

- **Definition**
  - Any food product that is:
    - Washed
    - Cut
    - Packaged
    - Labeled
  - Examples of exceptions:
    - Shelling peas/beans and shucking corn would be an exception (unless corn is being cut off with a knife)
    - Packaging strawberries in a clamshell will not be considered processed unless washed, topped and/or cut

Regulations And Safety Practices

- Application for Home Processor Inspection
- Code of Federal Regulations (21 CFR)
  - Also know as Good Manufacturing Practices (GMP)
- N.C. Food, Drug and Cosmetic Act
- Zoning
- Water supply
- Bioterrorism Act
- Nutritional facts

Is Your Product Low-Risk Or High Risk?

- After completing the “Application for Home Processing Inspection”
  - NCDA&CS Food and Drug Protection Division inspector will determine if testing is required
  - N.C. State University's Food Science Department will analyze products for risk

Home Food Production

- Who should fill out the "Application for Home Processor Inspection"?
  - Vendors producing low-risk packaged foods, such as:
    - Baked goods
    - Jams and jellies
    - Candies
    - Dried mixes
    - Spices
    - Some sauces and liquids
    - Pickles and acidified foods
  - Products not processed or manufactured in any way do not require inspection

Non-Home Based Commercial Facility

- Who needs to produce their food in a non-home based commercial facility?
  - Vendors producing high-risk packaged food, such as:
    - Refrigerated or frozen products
    - Low-acid canned foods
    - Dairy products
    - Seafood products
    - Bottled water
  - Contact a Food Compliance Officer at 919-733-7366 for answers to any questions regarding production facilities
Better Processing School

- Qualifies individuals as commercial operators to process conventionally canned foods
- May only produce canned acidified foods in the home
- Good Manufacturing Practice (GMP)
- 21 CFR Part 114
  - Specific GMP for acidified foods

Pickles Or Pickled Products

- Code of Federal Regulations
  - 21 CFR 114: Acidified Foods
  - 21 CFR 108: Emergency Permit Control
- Acid foods: natural pH of 4.6 or below
  - Acidified foods: low-acid foods to which acid(s) or acid food(s) are added with a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below
  - Include:
    - Beans
    - Cucumbers
    - Cabbage
    - Artichokes
    - Cauliflower
    - Puddings
    - Peppers
    - Tropical Fruits
    - Fish

Jams, Jellies, Preserves

- Regulated under Good Manufacturing Practices (GMPs)
  - 21 CFR 150
- Jams, jellies and preserve products are characterized by low water activity and a low pH
- Fruit butters: five parts by weight of the fruit ingredient to each two parts by weight of the nutritive carbohydrate sweeteners (5:2). The finished soluble solids content of a fruit butter is not less than 65%
- Fruit jellies: 45 parts by weight of the fruit component to each 55 parts of the sweetener solids (45:55). The finished soluble solids content of a jelly is not less than 65%
- Fruit preserves and jams: are divided into two groups, generally the berries and the pomes. In both cases the finished product is not less than 65% solids
  - Berry group require 47 parts by weight of the fruit component to 55 parts of the sugar
  - Pomes are 45:55

Food Product Labels

- Product name
- Manufacturers name and address
- Net weight of the product in ounces/pounds and the gram weight equivalent
- Complete list of ingredients in order of predominance by weight

More information on labeling requirements is available at:
- www.fda.gov/
- ncsu.edu/foodscience/extension_program/nutrition_labeling.html

Cut Leafy Greens

- Definition
  - Fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn
  - Includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce, escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard
- To reduce the risk of pathogen growth, maintain cut leafy greens at 41 °F (5 °C) or less during storage and display
- Routinely monitor the temperature of the product and the equipment used to maintain product temperature

Resources

- NC State Food Science Department's Guide for Small Food Processors in North Carolina
- Business Link North Carolina by the NC Department of Commerce
- N.C. Department of Agriculture and Consumer Services’ Marketing Division Agribusiness Development Office
- FDA Good Manufacturing Practice Guidelines
- Blue Ridge Food Ventures - a full-scale commercial kitchen operation for value-added food production in western North Carolina.
Questions?
Selling Food In A Retail Market

FURTHER CONSIDERATIONS
Certifications And Insurance

GAPs Certification
- GAPs certification is voluntary (not mandatory)
- Growers of fresh produce need to decide whether to adopt GAPs and get certified
  - Economic decision
  - Weigh benefits vs. costs
  - Economic Risk Reduction
  - GAPs adoption and certification not 100 percent guarantee of food safety
  - Reduces risk/probably of outbreak
- Improved Market Access Opportunities
- Many markets require 3rd-party GAPs certification
- Credibility from having 3rd-party certifiers

Insurance coverage
- General farm liability insurance
- Commercial business liability insurance
- Product liability insurance
- Product recall insurance
- Accidental/product contamination insurance
- Malicious tampering insurance
- Combination policies
- Excess/umbrella/surplus lines of insurance
- Adjusted gross revenue (AGR) or adjusted gross revenue-lite (AGR-Lite) insurance

General Farm Liability Insurance
- Protects against liability claims for bodily injury and property damage arising out of one’s premises and/or operations
- Protects against lawsuits due to on-farm accidents
- Recommended for pick-your-own operations and with on-farm stands
- Covers lawsuits from activities considered “farming”

Product Liability Insurance
- Protects against claims of injury caused by a defective or hazardous product (e.g. contaminated fresh produce)
- Provides protection if fresh produce causes injury or illness
- Strictly covers claims of injured parties, not recall costs
- Premium estimate: $1,000 per year for $1 million of protection
**Product Recall Insurance**
- Covers actual or direct costs of a product recall
- Costs associated with getting contaminated product off the shelf and destroyed
- Cost of replacement
- Transport costs
- Does not cover indirect costs
- Intended for growers that were contaminated (source)

**Accidental Or Product Contamination Insurance**
- Covers both direct and indirect costs of product recall.
- Examples of indirect costs – third-party expenses, loss of profit due to recall (lost confidence), business interruption losses
- Intended for growers that were contaminated

**Malicious Tampering Insurance**
- Covers direct and indirect losses of product recall, but also covers losses from criminal actions of sabotage against grower
- Intended for growers that were contaminated

**Combination Policies**
- Combines several different policies.
- For example, you can combine general farm liability and homeowner’s insurance if the family operations are smaller
- Typically have lower premiums compared to the cost of purchasing separate policies

**Excess/Umbrella/Surplus Lines Of Insurance**
- To provide for coverage when underlying available insurance is “lacking” – hard-to-place risks.
- Not regulated under state laws - premium rates not regulated and no guarantee protection from Insurance Guaranty Association

**Adjusted Gross Revenue (AGR) or Adjusted Gross Revenue-Lite (AGR-Lite)**
- Whole-farm revenue insurance based on tax forms
- Covers revenue losses below a guarantee – if losses are from insured cause of loss
- Can cover part of revenue losses of non-contaminated growers if losses are due to market fluctuation (industry-wide drop in prices due to a product warning)