Food Processing:
Licensing
Requirements

Scott Plati – Food Safety Specialist
Iowa Department of Inspections &
Appeals.
Food & Consumer Safety Bureau

OBJECTIVES / OVERVIEW

- Discuss licensing
- Identify governing regulations
- Identify specific licensing requirements
- Identify resources for interested parties
Licensing Process

- Determine if a license is needed
  - Direct consumer sales of raw unprocessed produce, jams, jellies, & other non-potentially hazardous type foods
  - Wholesales of either non-hazardous & potentially hazardous foods

  What license type is needed?
  - Food Processing License

---

Licensing Process

- How is license obtained?
  - Obtain license application from DIA, Food & Consumer Safety Bureau
  - Submit application and fees, along with floor plan of proposed processing area.
  - Iowa administrative rules require application and fees to be submitted 30 days prior to opening.
  - Inspection of premises, process, and labels prior to opening business.
Governing Regulations

- Rules for operation of Food Processing Plants adopted in-accordance-with IA code – Chapter 31, 481- 31.2(137F)
  - 21 CFR, Part 113 – Low Acid Canned Foods
  - 21 CFR, Part 114 – Acidified Foods
  - Note that 21 CFR Parts 113 or 114 only apply if products are either canned or acidified.

Governing Regulations

- 21 CFR, Part 129 – Bottled Drinking Water
- 21 CFR, Part 165 – Beverages
Governing Regulations

- Other Things You Need to Know
  - IA code requires a separate processing facility
  - Kitchens in a private residence may not be used
  - Other areas in a private residence may qualify for licensing if approved by DIA.

Governing Regulations

- Other Things You Need to Know
  - Other Federal Regulations may apply, especially if finished products are wholesaled or distributed in interstate commerce.
  - Bioterrorism Act of 2002 - Facility Registration
  - FDA Food Defense Guidelines to encourage protection of raw materials and finished goods.
Licensing Requirements

- Basis for requirements
  - 21 CFR, Part 110 – Good Manufacturing Practices
  **Note: other CFR parts may be applicable in addition to part 110 (i.e. Part 113, 114, 129, and etc.)

Facility Requirements

- Plant & Grounds
  -- Floors, walls, ceilings constructed so that they can be adequately cleaned & kept in good repair.
  -- Lighting
    * Adequate number and intensity to ensure good cleaning practices.
    * Shielded, covered, or shatter resistant in areas with exposed foods, ingredients, or packaging materials.
Facility Requirements

-- Ventilation
  * Adequate to minimize odors
  * Adequate to ventilate excessive heat
  * Adequate to reduce or eliminate excessive moisture and/or condensation.

-- Doors, Outer Openings, & Windows
  * Tight Fitting – no gaps under doors
  * Adequate screening provided

Facility Requirements

-- Grounds
  * Free from litter
  * Vegetation control – no excessive weeds or tall grass
  * Free from pooling water

-- Roads, Yards, & Parking Lot
  * Maintained so that food is not contaminated.
Facility Requirements

- Water Safety
  - Municipal or private well water source?
  - Private well water sources must be tested annually for presence of bacteria (Coliforms & E. coli)
  - Municipal sources not required to be tested
    - May want to consider optional testing within plant to determine safety/quality of plumbing systems.
  - Some private well sources may need to be permitted as public water sources in accordance with IA DNR requirements.

Facility Requirements

- Equipment & Food Contact Surfaces
  - What is a Food Contact Surface?
    - Any surface which contacts human food & surfaces from which drainage onto food or onto surfaces that contact food ordinarily occurs during normal operations.
  - Designed & constructed of safe materials
    - Food grade materials
Facility Requirements

Equipment & Food Contact Surfaces

- Designed & constructed for cleanability
  - Smooth, non-porous, constructed from materials which can withstand multiple cleaning and exposure to cleaning compounds.
  - Free from rough edges and seams
  - Free from chips, pits, cracks, and other similar imperfections that would make cleaning difficult.

Suitable for their intended use.

**Note:** Gloves may be considered food contact surfaces, dependant upon application of use.

---

Facility Requirements

- Hand Sinks & Toilets
  - Hand washing stations
    - Adequate number provided
    - Conveniently located so as to promote & facilitate frequent hand washing.
    - Must have a supply of hot and cold water.
  - Toilet Facilities
    - Adequate number provided
    - Easily accessible
    - Equipped with self-closing doors
Facility Requirements

* Sanitation
  - Capable of demonstrating adequate methods/procedures for washing and sanitizing equipment and utensils.
  - Programs/procedures for cleaning facilities
  - Manual or mechanical washing machine/sinks provided.
  - Domestic or home style dishwashing machines do not meet requirements.

Facility Requirements

* Sanitation continued
  - Sanitizers
    * Must be approved for use on food contact surfaces
    * Personnel trained to mix and test concentrations
    * Method to validate that sanitizer is mixed at appropriate concentration
    * Criteria for sanitizers specified in 40 CFR 180.940
  - Master cleaning schedule recommended
  - Standard Operating Procedures for cleaning & sanitizing equipment recommended.
Other Requirements

- Processes and Process Controls
  - Must be adequate to ensure foods are free from contamination, filth, foreign material, and other forms of adulteration.
  - Each process must be evaluated independently

Other Requirements

- Processes and Process Controls cont.
  - Process approval based upon multiple variables
    - Product produced
    - Method(s) of production
    - Preservation and shelf life
    - Specific rules governing special processes (canning or acidification)?
Other Requirements

--- Pest Control

- Program to ensure exclusions of insects, pests, birds, animals, and etc.
- Pesticides used are approved and applied in safe manner.

--- Sewage and Waste

- Disposed of in accordance with state and/or local laws.
- Disposed of via an approved system.

--- Scales & other process control instruments

- Maintain accuracy
- Calibrated at frequencies to maintain accuracy
- Documentation of verifications/calibrations maintained on file.

--- Compressed Gases or Air

- If used in direct contact with food, equipment, or utensils - meet requirements for food grade applications
Other Requirements

-- Lubricants
  * Food grade if incidental contact with food, equipment, utensils, or food contact surfaces.

-- Use & Storage of Toxic items
  * Product is labeled as approved for use in food processing facility.
  * Product is used in accordance with manufacturer’s labeling instructions.
  * Product is stored so as to prevent contamination of foods, equipment, packaging materials, etc.
  * Recommend a secured separate storage area, with controlled access to area and authorized personnel only.

Other Requirements

-- Recalls / Consumer Complaints
  * Recommend written procedures for how instances are handled and resolved
  * Recall procedures/plan required under Parts 113 & 114
  * Distribution of finished goods
    - Adequate records maintained to determine location of finished product
Other Requirements

-- Personnel
  - Training programs developed and implemented to adequately train personnel with regards to GMPs
  - Good personal hygienic practices
  - Responsibility to report forms of communicable diseases to supervisors
  - Documentation maintained to demonstrate that training is done.
  - Provide adequate areas for storage of personal belongings.
  - Provide adequate areas for breaks, consumption of beverages and food.

Resources

- Iowa Department of Inspection & Appeals
  - Food & Consumer Safety Bureau
- Code of Federal Regulations
  - 21 CFR – Food & Drugs
- FDA
  - FDA Home Page
    - http://www.fda.gov
  - Food Labeling Guidance Document
Resources

- FDA cont.
  - Guide to Minimizing Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables
    - [http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064458](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064458)
  - Food Defense Guidance Document

- FDA cont.
  - Bioterrorism Act & Facility Registration
Resources

- FDA Small Business Representative – SW Region Office
  David Arvelo
  Phone: 214-253-4952
  E-mail: david.arvelo@fda.hhs.gov