What Can Be Sold Where?

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OBJECTIVES / OVERVIEW

• Discuss licensing
• Identify governing regulations
• Identify specific licensing requirements
• Farmer’s Markets
• Identify resources for interested parties
COMPUTER LITERATE CLERK NEEDED
Licensing Process

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

What license type is needed and suitable?
Licensing Process

- License types vary based upon how products are to be sold.
  - RS or Food Service – Prepared on site and sold to the consumer for consumption on premises.
  - FE or Retail Food Service – purchased on site but consumed off premises.
  - FP or Food Processing – manufacture and/or storage of foods for wholesale to other retail business (generally not direct to household consumer).
Licensing Process

- MF or Mobile Unit – Preparation and service direct to consumer. More limited than RS.
- HF or Home Food – Limited to bakery items as defined in IA administrative rules.
- FM or Farmer’s Market – preparation and/or sales of potentially hazardous foods at Farmer’s Market events, as defined in IA admin rules.
- TF or Temporary – preparation and sales of foods to consumers at events. Less restrictions than RS & FE licenses but similar requirements
Licensing Process

• How is license obtained?
  – Obtain license application from DIA, Food & Consumer Safety Bureau or representative Contracting Agency
  – 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.
X ↑ ↑ ↑ 6:30am TO 9:30pm
X X X ↑ 3:30pm TO 7:00pm
X X ↑ ↑ ALL OTHER TIMES
Governing Regulations

• Retail Establishments – 2005 Food Code and/or Iowa Administrative Rules

• Food Processing - 21 Code of Federal Regulations (CFRs)
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
– 21 CFR, Part 136 – Bakery Products
– 21 CFR, Part 137 – Cereal Flours & Related Products
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.
  • Must be segregated from individual’s private living areas and quarters.
Governing Regulations

• Other Things You Need to Know
  – Other Federal Regulations may apply, especially if interstate commerce is involved (finished product and/or materials).
  • Bioterrorism Act of 2002 – Facility Registration
  • FDA Food Defense Guidelines to encourage protection of raw materials and finished goods.
  • Reportable Food Registry
  • Food Safety Modernization Act – Jan 4, 2011
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, 165 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, dependent 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

• Some may require evaluation by a Process Control Authority

• Some require Hazard Analysis Critical Control Point (HACCP) Plans.
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, acidification, seafood, and/or juice)?
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.
  – State and/or local jurisdictions
Other Requirements

– 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
  • Traceability of both finished goods and ingredients from suppliers is strongly encouraged.
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.
Farmer’s Markets

• Farmer’s Markets as defined in IA Code 481-30.2(10A)
  – “A marketplace which operates seasonally as a common market for fresh fruits and vegetables on a retail basis for consumption elsewhere.”
  – A person selling potentially hazardous foods at a farmer’s market must obtain a license for each county in which the person operates.
Farmer’s Markets

• Considerations:
  – Farmer’s Markets may be registered with IDALS.
  – Non-hazardous foods are exempt from licensure. Source is generally exempt as well.
  – Jams and Jellies must meet standards of identity as defined in 21 CFR, Part 150
    • Pepper jams and jellies do not meet this standard of identity.
Farmer’s Markets

• Considerations:
  – Manufactured foods that are rendered shelf-stable due to acidification or canning must be made in a licensed facility.
  • Farmer’s market license not required once shelf-stable.
  – Exemptions for licensure at farmer’s markets may not apply elsewhere.
Farmer’s Markets

• Foods with potential considerations
  – Hermetically sealed foods
  – Fermented foods (Kombucha tea, ginger ale, some varieties of pickles)
  – Salsa
  – Pepper jams and jellies
  – Artificially sweetened jams and jellies
Farmer’s Markets

– Mushrooms (Morels and cultivated mushrooms)
– Juices (fruit and/or vegetable)
  • Wheat grass juice?
– BBQ sauces
– Sprouts
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
  – Food Defense Guidance Document
    • http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm
Resources

• FDA cont.
  – Bioterrorism Act & Facility Registration
  – Food Safety Modernization Act
    • http://www.fda.gov/Food/FoodSafety/FSMA/default.htm
Resources

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