


# Food Processing: Licensing Requirements

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## OBJECTIVES / OVERVIEW

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



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## 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



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## 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.



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## Governing Regulations

- Rules for operation of Food Processing Plants adopted in accordance with IA code – Chapter 31, 481- 31.2(137F)
    - 21 CFR (Code of Federal Regulations), Part 110 – Good Manufacturing Practices
    - 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.



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## Governing Regulations

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



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## 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.



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## 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.



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## 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.)



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## 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.



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## 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



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## 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.



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## 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.



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## 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



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## 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.



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## 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



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## 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.



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## 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.



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## 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



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## 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)?



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## 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.



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## 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



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## 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.



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## 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



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## 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.



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## Resources

- Iowa Department of Inspection & Appeals
  - Food & Consumer Safety Bureau
    - <http://dia.iowa.gov/page3.html>
- Code of Federal Regulations
  - 21 CFR – Food & Drugs
    - <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
- FDA
  - FDA Home Page
    - <http://www.fda.gov>
  - Food Labeling Guidance Document
    - <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>



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## Resources

- FDA cont.

- Guide to Minimizing Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables

- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/UCM064458>



- Food Defense Guidance Document

- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm>

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## Resources

- FDA cont.

- Bioterrorism Act & Facility Registration

- <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/UCM113877.pdf>



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## Resources

- FDA Small Business Representative – SW  
Region Office

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