



Food Entrepreneurship Series

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Regulations for Indiana Food Processing

The purpose of food-processing regulations is to maintain a safe and wholesome food supply. These regulations can be confusing because several governmental agencies could be involved. The type of food, how it is prepared or produced, and where it is to be sold will determine which regulatory agency or agencies are involved.

It is best to consult knowledgeable sources before investing in a food-processing venture. Regulatory agencies require notification and inspection before food production can commence. It is necessary to know and understand which food regulations apply before starting a food business.

Inspection and Regulatory Requirements for Selling Locations

Retail Foods in Indiana

Retail foods are those produced and/or sold directly to the consumer. **Retail food establishments** include restaurants, supermarkets, camps, schools, caterers, bakeries, internet sales, and some temporary food stands. Indiana's Retail Food Establishment Sanitation Requirements (Title 410 IAC 7-24) provide specific details on facility, personnel, manufacturing, and sanitation requirements that must be followed for retail food sales. These types of facilities are regulated by the Indiana State Department of Health if on state property. Otherwise they are regulated by local



Department of
Food Science

In 2009, the Indiana General Assembly established a new food-manufacturing category known as a **home-based vendor** (HBV) through House Enrolled Act 1309. A HBV is a food manufacturer who is exempt from current health department rules (e.g., kitchen inspections, registration, licensing, etc.). This exemption allows individuals to produce non-potentially hazardous foods in a primary residence, such as a home kitchen. HBV products can **only** be sold at farmer's markets and roadside stands. HBV foods may not be sold at other venues, including retail food establishments, festivals, fairs, carnivals, or any other special events. For more information on this topic, please refer to *Using a Home Kitchen to Prepare Food for Sale*, Purdue Extension publication FS-18-W.



Kalista Johnston
Entrepreneur from Garrett, Ind., developed cheese crisps and founded Grace Island Specialty Foods. (<http://www.graceislandfoods.com/>)

county health departments (www.in.gov/isdh/24822.htm). A use permit, a plan review, and a pre-opening inspection are required before food production can begin at a food establishment. Specific registration requirements are found on the Indiana State Department of Health website (www.in.gov/isdh/21363.htm).

Wholesale Foods in Indiana

Wholesale foods are those sold to another entity for the purpose of reselling or redistributing the product. In general, these food products are produced and packaged at one location and sold at another location by another person or business. Indiana's Wholesale Food Establishment Sanitation Requirements (Title 410 IAC 7-21) provide specific details on facility, personnel, manufacturing, and sanitation requirements that must be followed. These requirements are regulated by the Indiana State Department of Health (ISDH) Food Protection Program. Wholesale foods may be sold in intrastate or interstate commerce. All new wholesale establishments must notify the ISDH of their intent to operate at least 30 days before beginning operations. Also, the owner must register any location and/or ownership changes with the state. Specific registration requirements are outlined in detail on the ISDH website (<http://www.in.gov/isdh/20640.htm>).

Additional Requirements

Certified Food Handler

As of Jan. 1, 2005, most Indiana food establishments—both retail and wholesale—must have at least one **certified food handler** in their employment. This person is responsible for and oversees the storage, preparation, display, and serving of food to the public. Training and other requirements for a certified food handler can be found at <http://www.state.in.us/isdh/21059.htm>.

Numerous exemptions exist for the certified food handler requirement based on menu items or business classification (e.g., nonprofit). For more information, please see the frequently asked questions found here: http://www.state.in.us/isdh/files/FAQ_November_2010.pdf.

U.S. Bioterrorism Act

The United States Food and Drug Administration (FDA) requires that all food manufacturers be registered under the Bioterrorism Act. More information can be found at <http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>.

Interstate Commerce

Processed and packaged foods sold across state lines may be regulated and inspected by the FDA. However, the Indiana State Department of Health conducts most of the inspections. Both federal and state regulations cover labeling and good manufacturing practices.

Hazard Analysis and Critical Control Points (HACCP) Program

For certain food products such as seafood, juices, and meat products, a Hazard Analysis and Critical Control Points (HACCP) program must be implemented (www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm). The FDA inspects seafood and juice facilities, while the U.S. Department of Agriculture Food Safety and Inspection Service inspects meat and poultry operations.

Other food industries may voluntarily use the HACCP principles to minimize food safety risks. This program has seven principles, which include determining critical control points from production and receipt of ingredients through processing and packaging of the food product, and setting limits at each of these control points. Other principles are monitoring of these control points, establishing corrective actions when limits are not met, and keeping effective records.

Requirements for Specific Food Types

Most all food products have specific requirements outlined in the Code of Federal Regulations (CFR), including standards of identity, processing conditions, and food safety. Title 21 of the CFR is the portion that governs food and drugs in the United States. This is enforced by the U.S. Food and Drug Administration (FDA). Title 9 of the CFR addresses sanitary requirements for processing meat and poultry products with enforcement provided by the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). A few specific requirements for high-risk products are outlined below.

Canned Foods

Acidified and low-acid foods that are canned—such as salsa and canned green beans, respectively—have special requirements that are covered in the Code of Federal Regulations under Title 21, part 113.3 and 114.3, and Title 9, part 318.300. The requirements for these foods include filing a **scheduled process**, which is a detailed processing plan. The plan must be prepared by a **process authority**,

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Regulatory Agencies by Food Type

	State Regulatory Agency	Federal Regulatory Agency
Meat/Poultry	Indiana State Board of Animal Health	USDA
Milk/Dairy	Indiana State Board of Animal Health	USDA
Eggs	Indiana State Egg Board	FDA (shell egg) USDA (egg product)
Fresh Fruits/Vegetables	Indiana State Department of Health	FDA

which is an individual or group of professionals recognized by the U.S. Food and Drug Administration to have specific expertise in the methods used for food preservation. And an individual that has completed certification through Better Process Control School (BPCS) must oversee canning operations. If an entrepreneur works with a **co-packer**—a company that manufactures and packages foods for clients, under contract—with a certified employee on staff, then the entrepreneur is not required to get the certification.

Organic Foods

The National Organic Program (NOP) is administered by the USDA Agricultural Marketing Service (www.ams.usda.gov/nop/). In order to be sold, labeled, or represented as **organic**, an agricultural product—including raw, fresh, or processed products—must be produced and processed according to the National Organic Program standards.

For more information about organic foods, see Organic Products, Purdue Extension publication FS-14-W.

Meat and Poultry

Meat and poultry products sold across state lines are regulated by the Food Safety and Inspection Service of the U.S. Department of Agriculture (www.fsis.usda.gov/). Meat and poultry products sold only in Indiana are regulated by the Indiana State Board of Animal Health (www.in.gov/boah/2332.htm). Inspected meats are beef, pork, poultry, lamb, goat, farm-raised deer and elk, and ratites (ostrich, rhea, emu, etc.). Specific standards and operational requirements must be met at slaughtering and processing facilities, including specific labeling rules, animal health inspection, and implementation of a Hazard Analysis and Critical Control Points (HACCP) program. Prior approval is required before slaughter and production can begin. In some situations, on-site inspectors are required. Contact the Indiana State Board of Animal Health before starting operations.

Milk and Dairy

The milk and dairy industry has many organizations involved in regulating products. All states follow the federal Grade A Pasteurized Milk Ordinance (PMO). In 1946, the National Conference on Interstate Milk Shipments (NCIMS) was created to develop a plan for the certification of interstate milk shippers. Today the NCIMS continues to exist as an organization of dairy farmers, processing personnel, and regulatory agencies working together to achieve the safest possible milk supply.

The USDA Agricultural Marketing Service (www.ams.usda.gov/) is responsible for developing quality grade standards for agricultural commodities such as milk. These federal rules and standards are enforced by the Indiana State Board of Animal Health through the Indiana Dairy Inspection Program, which monitors the safety of Indiana milk from farm to processing plant.

With increased public interest in raw milk and raw milk products, it is important to note that the sale of raw milk for human consumption is illegal in the state of Indiana. For human consumption, raw milk must be sold only to processors that hold the proper permits for pasteurization prior to selling to consumers.

Similar to retail and wholesale food establishments all producers, processors, and handlers of milk must register with the state and obtain proper permits before operating. Specific details can be found in the regulations on the Indiana State Board of Animal Health website (www.in.gov/boah/2333.htm).

Eggs

Fresh shell eggs are regulated by the Indiana State Egg Board (ISEB) located at Purdue University. Information on selling eggs and applications for both retail and wholesale certificates of registration are available at the ISEB website (www.ansc.purdue.edu/ISEB/). Grading standards for shell eggs are established by the USDA Agricultural Marketing Service (www.ams.usda.gov/).



All milk sold to the consumer must be pasteurized.

Fresh Fruits and Vegetables

Wholesale fresh fruits and vegetables are regulated by the Indiana State Department of Health Food Protection Program. Wholesalers must register with this program before beginning operations. For more information, contact the Food Protection Program (<http://www.in.gov/isdh/20640.htm>)

In recent years, there has been growing concern over foodborne illnesses caused by microbial contamination of fresh produce. The FDA has issued several guidance documents containing Good Agriculture Practices (GAPs) designed to minimize contamination and potential food-safety risks. Although these GAPs are not mandated by the government, they represent the current recommendations by the FDA, so many growers are implementing these practices to reduce possible produce contamination and associated liability risks. Other producers are complying with these GAPs to meet buyer requirements for this type of production. Plant product and produce guidance documents can be found at www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm.

Similar to milk, the USDA Agricultural Marketing Service (www.ams.usda.gov/) is responsible for developing quality grade standards for fresh fruits and vegetables. At this time, grading is not required for fresh fruits and vegetables grown in Indiana, but some buyers may still require producers to grade produce according to USDA standards before purchase. Grade standards are available at www.ams.usda.gov/AMSV1.0/Standards.

Additional information is offered by the Purdue University Department of Horticulture and Landscape Architecture through its Produce Quality and Safety Information for Growers website (http://www.hort.purdue.edu/prod_quality/) and Purdue Fruit and Vegetable Connection website (<http://www.hort.purdue.edu/fruitveg/default.shtml>).

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Frequently Asked Questions

- Can I use my home kitchen for my food business?**

In 2009, Indiana legislative changes made some home food operations legal under a home-based vendor exemption. Those that do not qualify for this exemption are classified as a wholesale or retail food establishment and are subject to inspection and regulations found in the state's Wholesale Food Establishment Sanitation Requirements or Retail Food Establishment Sanitation Requirements. To learn more about the qualifications for the home-based vendor exemption, please refer to *Using a Home Kitchen to Prepare Food for Sale*, Purdue Extension publication FS-18-W.

- Do I need to contact my local health department in Indiana if I want to sell a food product in the state?**

According to the Indiana State Department of Health website:

Indiana state law requires all food establishments to register through the state or county health department.

Retail food establishments that are NOT on state property should contact the local county health department (www.in.gov/isdh/24822.htm) for more information on registration and obtaining permits. Retail food establishments that are on state property need to contact the Indiana State Department of Health (ISDH). All operations must submit a plan review questionnaire and application along with a registration application to the ISDH. These three forms and the Retail Food Establishment Sanitation Requirements are available at the ISDH website (www.in.gov/isdh/21363.htm), or call 317-233-7360 to request copies.

Prior to beginning a wholesale food business, it is necessary to contact the office of the Food Protection Program with the Indiana State Department of Health (ISDH) (<http://www.in.gov/isdh/21643.htm>). This office will provide the business owner with the proper registration forms. The ISDH Food Protection Program must be notified of intent to operate a minimum of 30 days prior to start of food-processing operations.

Meat, poultry, and dairy products sold in Indiana are regulated by the Indiana State Board of Animal Health. Prior approval is required before slaughter and/or production can begin. Contact the Indiana

State Board of Animal Health (www.in.gov/boah/2332.htm) for more information.

Egg producers should contact the Indiana State Egg Board (www.ansc.purdue.edu/ISEB/) before starting a business.

Before beginning a produce operation, fruit and vegetable wholesalers must register with the Indiana State Department of Health Food Protection Program (<http://www.in.gov/isdh/20640.htm>). For more information, fruit and vegetable growers should visit the Purdue University Department of Horticulture and Landscape Architecture Produce Quality and Safety Information for Growers website (http://www.hort.purdue.edu/prod_quality/) and Purdue Fruit and Vegetable Connection website (<http://www.hort.purdue.edu/fruitveg/default.shtml>).

- ***Is there a fee associated with registering my food business?***

While there is no fee to register a food business, some local health departments require permits to operate retail facilities in their counties, which may include a fee. Please contact your local county health department for more information.

- ***What if food is being sold for a nonprofit organization?***

Indiana law excludes charitable organizations that are legal entities and are tax exempt (IRS 501 status). If food is made and labeled by the organization's members, Indiana law allows such organizations to sell food to the final consumer at an event or celebration for no more than 15 days in a calendar year without registering with the state or county health departments. This does not exempt food prepared by a for-profit entity or food provided in a restaurant or cafeteria with an extensive menu. Review the Indiana State Department of Health guidance document (http://www.in.gov/isdh/files/SEA190_FinalGuidance.pdf) to ensure that the organization meets the requirements specified in the law. Organizations are not exempt from other applicable laws. Any questions should be directed to the ISDH (<http://www.in.gov/isdh/21363.htm>).

- ***My product is a sauce that contains some meat. How is this regulated?***

Foods containing 3 percent or more raw meat or poultry ingredients or 2 percent or more cooked meat by weight are regulated and inspected as meat products. Contact the Indiana State Board of Animal Health (www.in.gov/boah/2332.htm) for more information.

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References

Indiana State Board of Animal Health

Dairy and Milk, www.in.gov/boah/2333.htm
 Meat and Poultry Inspection, www.in.gov/boah/2332.htm

Indiana State Department of Health

Certification of Food Handler Requirements, www.in.gov/isdh/files/FoodHandler-Final.pdf
 Local Health Department Information, www.in.gov/isdh/24822.htm

Starting a Wholesale Food Business in Indiana (Food Protection Program), <http://www.in.gov/isdh/20640.htm>

U.S. Department of Agriculture

Food Safety and Inspection Service, www.fsis.usda.gov/
 National Organic Program, www.ams.usda.gov/nop/indexE.htm

U.S. Food and Drug Administration

Bioterrorism information and registration, www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm

Food facility online registration, www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm

Grade A Pasteurized Milk Ordinance, www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSModelDocuments/PasteurizedMilkOrdinance2007/default.htm

Good Manufacturing Practices (GMPs), Code of Federal Regulations Title 21, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=110

Hazard Analysis and Critical Control Points (HACCP), www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm

Additional Resources

National Conference on Interstate Milk Shipments, www.ncims.org/

"Who Will Regulate My Food Business?" (Extension publication FSE 99-21), North Carolina State University Department of Food Science, www.ces.ncsu.edu/depts/foodsci/ext/pubs/regulatemyfoodbus.htm

For more information, please refer to other publications in the Food Entrepreneurship Series:

FS-14-W, Organic Foods

FS-15-W, Food Preservation Methods

FS-17-W, Using an Approved Kitchen to Prepare Food for Sale

FS-18-W, Using a Home Kitchen to Prepare Food for Sale

All of these publications are available at the
Purdue Extension Education Store,
www.the-education-store.com.