Local Food Processing White Papers

FOOD SAFETY REGULATION

AN INTRODUCTION FOR ENTREPRENEURS

January 2018

Farm to Institution
NEW ENGLAND

THE EQUIPMENT QUESTION

FARM to INSTITUTION NEW ENGLAND

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FARM TO INSTITUTION NEW ENGLAND

Farm to Institution New England (FINE) is a six-state network of nonprofit, public and private entities working together to mobilize the power of New England institutions to transform our food system.

Since its inception, FINE has focused on developing cross-sector connections between K-12 schools, colleges and universities, hospitals, and other institutions. Today, FINE serves those at the forefront of the farm to institution movement in the region, providing a forum to connect and share ideas, models, resources, and support.

FINE leads projects related to key issues identified by farm to institution leaders and acts as the backbone organization for farm to institution work in the region: we strengthen the network, convene stakeholders, conduct research, develop tools and resources, and communicate with key audiences.

NEW ENGLAND FOOD PROCESSORS COMMUNITY OF PRACTICE

The New England Food Processors' Community of Practice has provided a forum for processors of local food to share information, visit each other's facilities, and develop collaborative solutions to common problems. The group has helped representatives from seven New England food processing facilities become better equipped to meet and overcome their challenges, and share what they are learning with other processors in New England and beyond.

The major goals of the group were to help existing processing facilities become more efficient at processing local produce and meat for institutions and share best practices with new facilities. Participants have learned valuable information about topics like processing equipment, plant design, and food safety.

This publication is part of a series of four white papers, which complements our suite of seven case studies featuring members of the New England Food Processors' Community of Practice.

Download these publications and watch an introductory video about the group:
www.farmtoinstitution.org/processors

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INTRODUCTION

The regulation governing food manufacturing is complex, with overlapping jurisdiction, distributed enforcement, and significant variation by location. This confusion is compounded by ongoing changes at the federal level following the 2011 passage of the Food Safety Modernization Act (FSMA). This brief introduction is intended for entrepreneurs either exploring or starting a food manufacturing business. Because state and local regulation varies, the focus will be on understanding the interlocking structure of food safety regulation, particularly at the federal level, and identifying resources for interested readers to learn more. Alcoholic products are subject to separate regulation and are not covered by this introduction.[1]

The single most important thing for new entrepreneurs to understand about food safety regulation is that there are multiple, overlapping jurisdictions. Depending on the food products produced and the manufacturing location, a producer may be subject to local regulation, state regulation, and both Food and Drug Administration (FDA) and US Department of Agriculture (USDA) oversight.

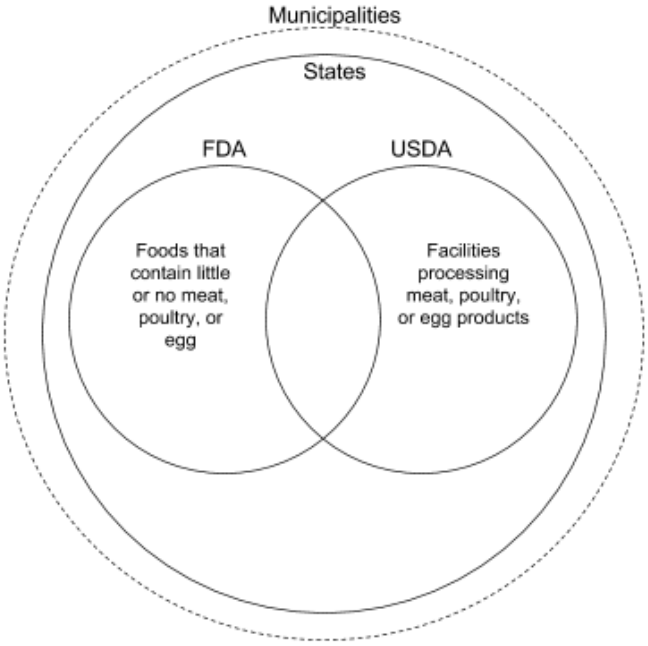


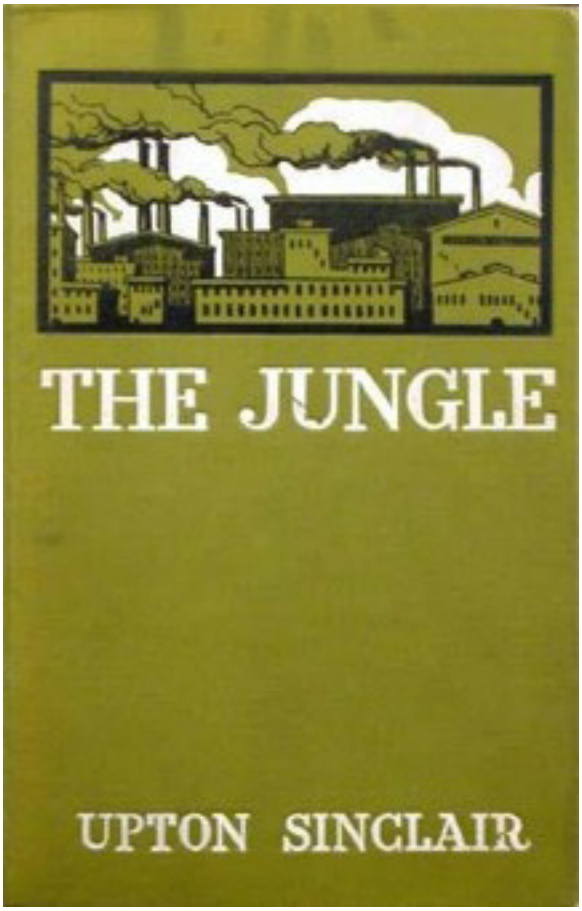
Figure 1. The Interlocking layers of food safety regulation

1 Alcohol is subject to federal, state, and local regulation. The federal authority is the US Department of the Treasury Alcohol and Tobacco Trade Bureau (TTB). To learn more visit www.ttb.gov.

Vermont Food Venture Center, Hardwick VT

FEDERAL FOOD SAFETY REGULATION

The origins of federal food safety efforts date back roughly to the beginning of the 20th century. The USDA had been organized in 1862 by president Abraham Lincoln, but it wasn't until the arrival of Harvey Washington Wiley as chief of the chemistry division in 1883 that consumer safety began to be a major focus. It was Wiley's work on food adulterants, including "a series of 'poison squad' experiments, in which able-bodied volunteers consumed varying amounts of questionable food additives to determine their impact on health" (Swann), along with the expose of Chicago's meatpacking businesses by "muckracking" journalists such as Upton Sinclair, that spurred federal action on food safety. In 1906, the landmark passage of the Federal Meat Inspection act and the Pure Food and Drug Act laid the groundwork for the federal food safety system that endures today.



Upton Sinclair's The Jungle. *Wikimedia Commons.*

Following the division of authority established by the 1887 Interstate Commerce Act, federal regulation of manufactured products takes effect only when they are offered for sale across state lines: prior to that point, states are responsible for enforcement. This allows new food manufacturers the ability to undertake different levels of regulatory approval in sequence, first obtaining state approval, selling products locally as recordkeeping systems are refined and validated, then seeking federal approval.

USDA

Within the USDA, the Food Safety and Inspection Service (FSIS) is in charge of ensuring the safety of the following foods ("Investigations Operations Manual" p104):

- Meat (cattle, sheep, goats, equines, and swine), poultry (chickens, turkeys, ducks, geese, guinea fowl, and ratites), and egg products (not shell eggs).
- Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination.
- Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat and poultry meat in any combination.

Any manufacturing establishment producing foods subject to FSIS oversight must obtain a grant of inspection, receive a registered plant number, and have labels approved prior to beginning production. The exception to this rule is an establishment that does not conduct slaughter and uses meat or poultry from USDA-inspected facilities to produce products solely for sale in-state. Such an establishment is subject to regulation by state authorities until the time at which products will be sold across state lines.

Brief History of USDA & FSIS

- **1862** USDA established by president Abraham Lincoln
- **1906** Federal Meat Inspection Act passed by president Theodore Roosevelt, requiring continuous inspection of slaughterhouses and meat processing plants whose products are intended for interstate commerce.
- **1957** Poultry Products Inspection Act passed, requiring poultry products shipped in interstate commerce to be continuously inspected, as well as establishing plant sanitation and labeling requirements.
- **1965** USDA federal meat and poultry inspection merged into a single program under USDA Agricultural Research Service's Consumer and Marketing Service
- **1970** Egg Products Inspection Act (EPIA) passed, mandating continuous inspection of all liquid, frozen, and dried egg products
- **1981** Following a decade of reorganizations, USDA meat and poultry inspection functions are consolidated into the newly-created Food Safety Inspection Service (FSIS)
- **1995** Responsibility for egg product inspection is transferred to FSIS
- **1996** FSIS issues Pathogen Reduction / HACCP systems rule, requiring the use of Hazard Analysis and Critical Control Point (HACCP) system in any facility processing meat products

FDA

Within the FDA, the Center For Food Safety and Applied Nutrition (CFSAN) is responsible for ensuring the safety of all domestic and imported food products not inspected by USDA FSIS, including all seafood, fish, and shellfish products. CFSAN maintains the Reportable Food Registry (RFR), an "electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences" ("RFR") as well as a national registry of food manufacturers. Field staff, from the FDA's Office of Regulatory Affairs, carry out inspections of regulated products and manufacturers and analyze product samples.

Brief History of FDA & CFSAN

- **1906** The Pure Food and Drug Act is passed by president Theodore Roosevelt. The Act prohibits, under penalty of seizure of goods, the marketing or interstate transport of food or drugs that had been "adulterated." Responsibility for enforcement is given to the USDA Bureau of Chemistry, headed by Harvey Washington Wiley.
- **1927** The USDA Bureau of Chemistry's regulatory powers are reorganized under a new USDA body, the Food, Drug, and Insecticide organization.
- **1930** The Food, Drug, and Insecticide Organization is renamed the Food and Drug Administration (FDA).
- **1938** After more than 100 people die

President Franklin Delano Roosevelt signing the 1938 Federal Food, Drug, and Cosmetic Act.

from a toxic solvent used in sulfanilamide medication congress passes the Federal Food, Drug, and Cosmetic Act (FDCA), giving the FDA power to oversee the safety of food, drugs, and cosmetics.

- **1940** The FDA is moved from being part of the USDA to being a part of the new Federal Security Agency
- **1953** The FDA is moved again, to the Department of Health, Education, and Welfare
- **1958** The Food Additives Amendment (to the 1938 FDCA) gives the FDA much tighter control over the amendments allowed in food
- **1980** A new Department of Education was created, and the former Department of Health, Education, and Welfare became the Department of Health and Human Services, which continues to house the FDA
- **2002** The Public Health Security and Bioterrorism Preparedness and Response Act requires all food manufacturers to register with the FDA and grants FDA power to review records and mandate detention of suspect food
- **2011** The Food Safety Modernization Act (FSMA) grants the FDA additional regulatory powers, including mandatory recall authority

Table 1. Comparing USDA and FDA Regulatory Enforcment

	USDA	FDA
Products	Meat, egg products, products containing more than 3% raw meat; 2% or more cooked meat or poultry	All food products not inspected by USDA FSIS, including shell eggs, products containing less than 3% raw or 2% cooked meat or poultry, and all seafood, fish, and shellfish products
Inspected Entity	Facility	Business (if operating out of a shared facility, each business inspected separately
Frequency of Inspection	Continuous for slaughterhouses, ongoing for food manufacturers (varies from daily check / records to review to continuous, depending on scale of production, past food safety record)	Periodic (annually to more frequent)
Label Approval	Required prior to sale	Inspected and non-compliant products subject to enforcement

Joint Jurisdiction

When a manufacturer produces products subject to oversight by both the USDA FSIS and the FDA, a situation of joint jurisdiction exists. A simple example might be a facility that makes a line of pizzas: if the proportion of cooked meat in the pepperoni pizza exceeds 2% of the total product weight, that product falls under USDA jurisdiction. This would mean the facility would need to obtain a grant of inspection from the USDA, the label would need to be pre-approved by the USDA, and a USDA inspector would visit the facility any time the pepperoni pizza was being produced to monitor production practices and check records for compliance with the product's HACCP plan. A vegetarian pizza made in the same facility would fall under FDA jurisdiction, and monitoring would take place only periodically. The result is that the pepperoni on the pepperoni pizza would be inspected three times (at the slaughterhouse, when the meat was made into pepperoni, and in the pizza-manufacturing plant)

while the vegetarian pizza would most likely not be inspected at all. Surprising, but true. For some products, especially those that involve both meat and additives the determination can be even more complex. Sausages, for example, may be subject to joint jurisdiction because the meat is overseen by the USDA, while the nitrates, seasonings, and casing material are overseen by the FDA. See the FSIS and FDA memorandum of understanding on information sharing and determination of jurisdiction in the resources section for more information.

President Obama signing FSMA into law on January 4th, 2011. Pete Souza https://www.flickr.com/photos/obamawhitehouse/5325468392/

Changes Under the Food Safety Modernization Act

With the advent of the Food Safety Modernization Act (FSMA), the FDA was charged with creating new science-based regulations to improve food safety. The major shift has been towards a prevention-based approach, emphasizing risk analysis and mitigation. The final rule with the most direct bearing on food manufacturers is "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (80 FR 55907, 2015) effective beginning November 16, 2015. This rule requires registered food facilities to create and maintain a documented food safety plan, perform a hazard analysis, and institute preventive controls for hazard mitigation. Facilities also need to monitor hazard controls, periodically verify the controls are effective, take appropriate corrective actions when noncompliance is found, and maintain records documenting the corrective actions taken.

Beyond updates to Good Manufacturing Practices and requiring a risk-based food safety management plan, FSMA contains a number of other provisions that impact food manufacturers:

- The FDA is mandated to establish produce safety standards, and farms are required to institute preventive food safety controls (impacting supply chain).
- The FDA is mandated to establish minimum inspection frequency for all food manufacturers, at higher-than-currently levels, and is granted the power to access all relevant records and the ability to require laboratory testing of certain foods.
- The FDA is given the ability to declare a mandatory recall of potentially harmful food products in the market, as well as expanded powers of administrative detention (to hold suspect food), and the ability to revoke food facility registrations.

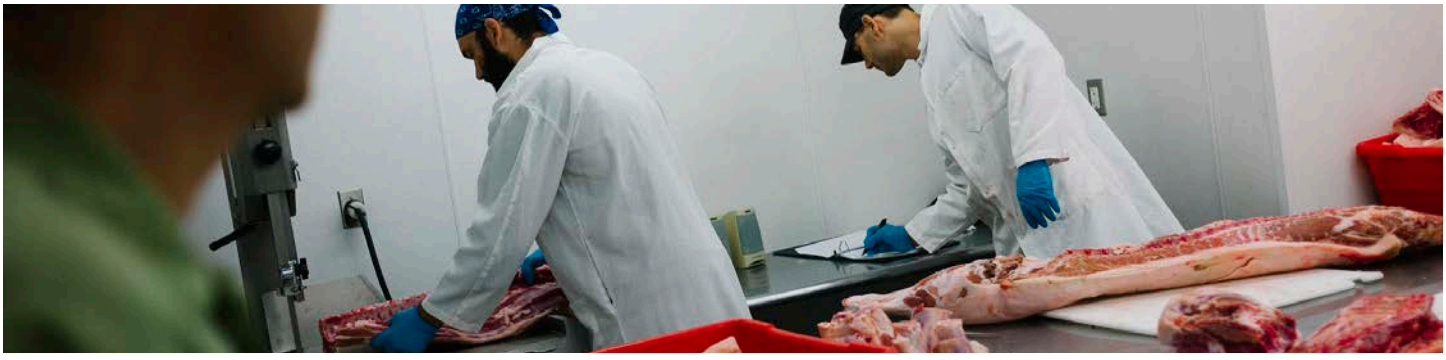
Implementation dates for the different rules are staggered based on business size, but even the smallest businesses (less than $1 million in annual revenues) will be required to comply with new regulations by 2018. See "FSMA Rules and Guidance for Industry" in the resources section.

STATE FOOD SAFETY REGULATION

The authority for regulating businesses rests with individual states, and different states manage food manufacturing businesses in different ways. The Federal Meat and Poultry Inspection Acts require "as good as" regulation by state officials; beyond this minimum requirement, the process of inspecting and licensing food manufacturers is left up to the states. To outline the requirements of even a few states would be beyond the scope of this brief introduction. Entrepreneurs interested in starting a food business should consult the relevant authority in their state (see table below) for specific guidance. Note that the regulatory authorities listed below handle licensing of food manufacturers in the six New England states. Particular products (e.g., dairy and meat) may be subject to additional oversight by different state agencies.

Table 2. State Regulatory Bodies Responsible for Licensing Food Processing Businesses

State	Office	Phone Number	Address
Connecticut	Department of Consumer Protection; Food and Standards Program	(860) 713-6160	450 Columbus Boulevard, Hartford, CT 06103
Massachusetts	Health & Human Services, Department of Public Health; Food Protection Program	(617) 983-6712	305 South Street, Jamaica Plain, MA 02130
Maine	Department of Agriculture, Conservation & Forestry; Division of Quality Assurance & Regulations	(207) 287-3841	22 State House Station, 18 Elkins Lane, Augusta, ME 04333
New Hampshire	Department of Health & Human Services; Division of Public Health Services, Food Protection Section	(603) 271-4589	29 Hazen Drive, Concord, NH 03301-4604
Rhode Island	Department of Health; Office of Food Protection	(401) 222-2750	3 Capitol Hill, Providence, RI 02908
Vermont	Department of Health; Food & Lodging Program	(802) 863-7220	108 Cherry Street, P.O. Box 70 - Drawer 30, Burlington, VT 05402-0070



Mad River Food Hub, Waitsfield, VT

LOCAL REGULATION

Most localities require new businesses to obtain a business license, a process which typically includes a check that the proposed business doesn't violate zoning ordinances for the proposed location. Some municipalities may also have regulations governing what types of food may be produced, restrictions on marketing, vending, or other specific rules. Boston, for example, banned the use of trans fats in food service establishments effective March 2009 ("Boston Trans Fat Ban"). Contact the city licensing bureau or town/county clerk's office to access the specific requirements for your planned business and location.

RESOURCES

History

- Johnson, Renee "The Federal Food Safety System: A Primer."
- FDA History
- USDA FSIS History

How-to

- USDA Regulatory Compliance Resources and Information: A general resources page for producers subject to USDA regulation.
- USDA AskFSIS: A question and answer portal regarding FSIS requirements and inspections.
- FDA How to Start a Food Business: Overview of the food safety regulatory requirements, including an introduction to Good Manufacturing Practices (GMPs) and Hazard Assessment and Critical Control Point (HACCP) plans.
- FSMA Rules & Guidance for Industry: A practical guide to understanding and complying with new FSMA regulations.

Other

- New England Food Entrepreneurs: A collective effort of various New England extension agencies, this site includes state-by-state information on licensing, training, organic certification, business development support, distributors, and more.
- USDA FSIS and FDA MOU governing information sharing and jurisdiction: The official details of how USDA and FDA collaborate in cases of joint jurisdiction.

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