

Starting a Food Business in New Mexico

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Many people dream of owning their own food business and marketing a family recipe. How many times have you heard, “You should sell this stuff”? Many of the huge food businesses, such as Kraft, M&M/Mars, and Bueno Foods, started as small family enterprises. There are always opportunities for new food products in today’s marketplace. This publication outlines the necessary steps to start a food business in New Mexico and make that dream a reality.

WHO ARE FOOD BUSINESS ENTREPRENEURS?

Many food-processing businesses start as a family business that is vertically integrated from the family farm, or as an expansion of a restaurant. Most food business entrepreneurs are creative types, food artists who enjoy creating new foods and flavors. A food business adds to the family income, and can be anything from a hobby to a major enterprise employing hundreds of people.

WHAT TYPES OF FOOD PRODUCTS ARE MADE?

New Mexico is known for red and green chile peppers, and has spawned many fresh and canned salsa and chile products. There are many other products, such as barbecue sauces, pasta sauces, and salad dressings, that



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incorporate New Mexico's chile. Breads, cookies, and tortillas are mostly sold in local markets, including farmers' markets. Several types of cheese, including flavored goat cheese, are also produced in New Mexico. Most New Mexico meat products are custom orders; however, the state has a thriving beef jerky industry. With a good supply of local pecans, pistachios, and peanuts, chocolate confections and other candy are well known outside of the state. Natural and organic teas and herbs are widely available throughout the state. Because of the success of current New Mexico food products, there are many more opportunities for new innovations.

HOW CAN A HOME RECIPE BE COMMERCIALIZED?

So how do you make grandma's recipe into a commercial success? Success of a food business is gained by hard work, good business management, imagination, and faith in your product.

The first step is to consider how the product might compete in the market. What does your product offer to the consumer compared to other products already on the market? Simply being a mom-and-pop company is not enough of a hook to engage a consumer to purchase a product, especially on a repeat basis. A food product must be wholesome and somewhat nutritious, and offer consumers an experience that will provide comfort or a change of pace—something exciting. Repeat purchases and proper product placement on grocery shelves become critical to grow the business. Faulty food business management, including miscalculated marketing schemes and poor distribution, is more often the demise of a food company than the merits of the food product.

WHERE ARE FOOD PRODUCTS MADE?

To operate a food-processing business in New Mexico, you must have a permit and the product must be produced in a regulated food-processing facility as per New Mexico Environment Department (NMED) food service and food processing regulations (NMAC § 7.6.2).

Many food businesses start out in rented space during a restaurant's off-hours or in a small commercial facility on their residential property. Others may use an incubator kitchen that provides the needed equipment and can be rented by the hour. As a company grows and the actual production of the product becomes very time-consuming, the business owner may want or need to focus on marketing, promotion, or distribution of the product. A co-packer or contract processor that has a permitted commercial facility that can make large quantities of product is attractive to a smaller firm because it handles larger volumes of product and may reduce production costs compared to smaller batches.

HOME-BASED FOOD PROCESSING

The NMED review board approved changes to the regulations (NMAC § 7.6.2.16, Home-Based Food Processing) to allow processing of **non-potentially hazardous food** in a residential home kitchen. Home-based food processors must attend a department-approved food safety course in addition to an annual permit and inspection. These products can be sold only through farmers' markets, roadside stands, or festivals at which the processors sell directly to the consumer. Additionally, these products cannot be sold within the city limits of Albuquerque. A home-based food-processing permit must be displayed at the processing site and location where product is sold. Additionally, packaged product must have a label with the words "Home Processed" as well as the following:

- The name, street address, city, state, and zip code of the manufacturer;
- An accurate statement of the net amount of food in the package, in terms of weight measure, volume measure (listed in both "English" and metric units), or numerical count;
- The common or usual name of the food contained in the package and ingredients of the food, listed by their common names, in order of their predominance by weight; and
- Nutritional panel information is exempt for home-based food products unless a nutritional or health claim is made, such as "low fat" or "heart healthy."

Non-potentially hazardous food will not support the growth of pathogenic microorganisms at room temperature, will have a pH of 4.6 or less, and will have a water activity of 0.85 or less. Examples of these products are traditional baked goods (no cream filling or sour cream frosting), hard candy (non-chocolate), nuts, honey, dried beans, dried chile, herbs, and traditional high-sugar jams and jelly products. Other parts of the regulation control acidified and low-acid foods as well as jerky products. A process authority (who are available at New Mexico State University and other state universities) can evaluate products that are not clearly classified by this definition.

Regulations for home-based food processing do place limits on household operations. Family cooking, pets, children, and "nonemployees" are restricted during food-processing operations. Strict sanitation procedures of utensils, processing equipment, and food contact surfaces as well as the sink must be followed as outlined in a detailed plan submitted by the food processor to

NMED. Additionally, these procedures apply to vehicles transporting product.

Home-based food processors are not required to have the same equipment as commercial food processors. Equipment such as a blender does not need to be commercial grade or certified. A three-compartment sink is not required, nor are there specific requirements for flooring in the kitchen or self-closing doors for exterior entrances or toilets. Furthermore, there are no requirements to maintain refrigerated temperatures below 45°F.

More information related to these regulations can be found at http://www.nmenv.state.nm.us/fod/Food_Program/HomeBasedProcessing.htm.

COMMERCIALIZING A PRODUCT

Initial product development will consider how the product will be sold: fresh, frozen, or canned; at a farmers' market or grocery store; direct sales; or through food service. There are many steps to follow to commercialize a food product: safe process evaluation, packaging and labeling, business structure, product liability, facilities and equipment, permits and regulations, and food safety and security. Each of these factors needs a closer look.

SAFE PROCESS EVALUATION

Once the concept of the food product has been developed, the recipe must be evaluated to ensure that a safe process is followed. The product may be tested for pH, water activity, and microbial stability, especially in the case of acidified and canned foods, which are considered "ready-to-eat." Breads and tortilla products must have a water activity below 0.95 to be unrefrigerated. A "Process Authority" must be used to review the formulation and processing steps of an acidified or low-acid canned product. As defined in the Code of Federal Regulations, "Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process" (21 C.F.R. § 113.83). "Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made

by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health" (21 C.F.R. § 113.89).

PACKAGING AND LABELING

Packaging and labeling issues should be thought out early in product development because how the product will be sold—refrigerated or shelf-stable—affects the type of packaging container. The size of the label depends on the size and shape of the container. A gallon container needs more than a 2-inch label. The font or typeface used must be legible and large enough to read from a reasonable distance. The U.S. Food and Drug Administration (FDA) has requirements for the format or layout of the label for specific content as specified in Code of Federal Regulations (21 C.F.R. §§ 101.1—101.9). Although FDA does not require prior label approval, New Mexico Environment Department (NMED) and United States Department of Agriculture (USDA) regulations require prior approval of labels before printing. Specific labeling information can be found at:

- **Food label:** <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064866.htm>
- **Nutritional food labeling:** <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064894.htm>
- **Allergen statement:** <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm>
- **Gluten-free labeling:** <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362510.htm>
- **Universal product code UPC or UCC application:** <http://www.gs1.org/10-steps-to-barcode-your-product>

Questions concerning the labeling of food products may also be directed to:

Division of Programs and Enforcement Policy
(HFS-155)
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
Telephone: 202-205-5229

Table 1. Abbreviated Summary of Business Structure Advantages and Disadvantages

	Ease of organization	Control/management	Liability	Taxation	Initial capital creation	Continuity of life
Sole Proprietorship	+	+	-	+	-	
Partnership	+		-	+	+/-	
Corporation			+	-	+	+
Limited Liability Company			+	+	+	
Cooperative			+		+	+

BUSINESS PLANNING AND MANAGEMENT

Successful new businesses require careful planning and management. Because businesses that produce and sell food can have a direct effect on public health and safety, they face increased government and consumer scrutiny. Food businesses must comply with numerous government regulations, making their development, operation, and success even more difficult.

Individuals interested in starting a food-processing business must gain a general understanding of business management issues before beginning a food-processing business. Additional and more specific information should be gathered from qualified professionals noted in the references section of this guide.

Business Structure

One of the first decisions an entrepreneur must make when developing a new business is which legal structure will be used for the business. A number of business structures should be considered because each has advantages and disadvantages. Income tax advantages and/or limited liabilities are usually cited as a reason to prefer one form over another. The assistance of qualified tax and legal professionals can avoid many headaches and save some tax dollars. Some of the more common structures used in the food-processing industry include (U.S. Small Business Administration, n.d.):

- Sole proprietorships
- Partnerships
- Limited liability companies and partnerships
- Corporations
- Cooperatives

Specific advantages and disadvantages to each of these business structures are discussed at the U.S. Small Business Administration (SBA) website at www.sba.gov. In addition, the SBA site provides other important tips for beginning a new business. A summary of advantages and disadvantages of different business structures is shown in Table 1.

Sole proprietorships. Sole proprietorships are the most common form of business structure for small businesses. A sole proprietorship offers the owner (usually one individual who is responsible for routine operation of the business) complete control of the business. In reward for their efforts, the proprietor receives all business profits but assumes responsibility for all risks and liabilities. This responsibility extends to the owner's personal assets; that is, the owner has unlimited liability and is legally responsible for all business debts.

Both business and personal assets are at risk under the sole proprietorship form of business ownership and structure.

Partnerships. Partnerships, which include general (i.e., normal) partnerships, limited partnerships, and joint ventures, extend ownership from one individual to two or more individuals. Partnerships usually require shared management of the business, and should be created with specific agreements regarding the management of the business (e.g., how decisions will be made, how profits will be distributed, how disputes will be handled, and how future growth or termination will be handled). As with sole proprietorships, individual owners in a partnership are responsible for all company liabilities (relief from this personal liability is found in limited partnerships). In the case of a general partnership, individuals may also be responsible for the decisions and actions of other partners within the business as well.

Limited liability companies and partnerships.

Limited liability companies or partnerships are hybrid forms of business ownership combining the advantages of several different ownership structures. Specifically, they extend liability limitations (similar to those of a corporation) and maintain certain tax advantages of simpler structures (e.g., partnerships).

Corporations. A corporation is considered a separate entity from its owner(s). A corporation can be taxed or sued, it may enter into contractual agreements, and it has a perpetual life (its life is not affected by ownership). Shareholders of a corporation own the business, and management is generally performed by a shareholder-elected board of directors (who may elect a management team, e.g., president). Benefits of corporate structure include limited liability for owners (shareholders), perpetual life, ease of ownership transfer, and ease of capital acquisition. Disadvantages include possible higher taxes (taxes must be paid by the corporate entity and by shareholders from dividend distribution) and complexities of creation and maintenance.

Cooperatives. Often used by agricultural producers, cooperatives provide a unique business format that

allows individual producers or processors to cooperate. Most cooperatives are organized as a special type of corporation “subchapter T” and must be chartered within a state. Common guiding principles for cooperatives include open membership with democratic or proportional voting (cooperative control), patron-provided equity, and net income distribution on a cost basis through patronage refunds (Barton, 1989).

A relatively recent advancement in cooperative organization is the development of “new generation” cooperatives. New generation cooperatives have several unique characteristics that distinguish them from more traditional cooperatives: delivery rights and requirements tied to equity investment, closed or limited membership, higher initial investment requirements, and the ability to transfer appreciable (and depreciable) stock or delivery rights (Bielik, n.d.).

Business Planning

In addition to determining the appropriate business or legal structure, food entrepreneurs must consider a number of other issues and develop management strategies for each issue. Feasibility studies and business plans are tools used by food entrepreneurs to develop working strategies.

Feasibility study. A feasibility study is a companion to the business plan (in some cases, such as small business ventures, the feasibility study is included as a section within the business plan). It is a preliminary analysis of the product and business idea to determine if the idea is viable (Reilly and Millikin, 1996). Information gathered in the feasibility study can be used to develop a formal business plan. A well-executed feasibility study will help determine if the product, the market, and the entrepreneur’s management skills and financing will likely combine to create a success. Common elements contained in a feasibility study include an assessment of the market, the financial feasibility of the business, and potential pitfalls that may be encountered in the development of the business.

Business plan. A business plan helps lay the roadmap for a new (or existing) business. While plans for different business ventures will vary, all business plans should address:

- Business description and situation analysis
- Market analysis and planning
- Financing
- Management

The business description and situation analysis should provide both the entrepreneur and potential outside stakeholders (e.g., partners, financial resource holders, etc.) a concise but complete description of the business. Included in this section should be a description

and an analysis of the current business climate in which the new business will operate. Much of this information will have been obtained during the feasibility study.

The market analysis section of the business plan will continue with the work previously performed in the feasibility study. Specific considerations within this section will include a summary of market research, a detailed analysis of competitors (e.g., identification of competitors, their strengths and weaknesses, etc.), an analysis of the proposed business (e.g., identification and analysis of the proposed business’s strengths and weaknesses), projections of future sales, and proposed strategies relating to the business’s marketing mix (development of strategies relating to pricing, promotion, place, and positioning of the proposed product).

The financing segment of the business plan will provide a complete and detailed look at financial resources the business will require (based on the assumptions and analyses performed in other sections of the business plan and the feasibility study), including owner-supplied funds and borrowing needs. This section should include pro forma financial statements, including income statements, cash flow (budget or forecast), and balance sheets.

The management section will help outline management structure and strategy as it relates to the business. Specific strengths and weaknesses of potential management should be identified with plans developed to help ensure that adequate management skills are provided for the successful launch of the business.

LIABILITY PROTECTION

Grocery stores and distribution companies require all food processors to carry product liability insurance. Product liability insurance can be an attached rider under a homeowner’s policy. Check with your insurance agent or even online for the best policy coverage (minimum \$6 million) and premium payment. Other types of liability protection to be considered are life insurance, general business liability insurance, property loss, equipment warranties, auto insurance to cover vehicles used for business purposes, and disability insurance for employees. The type of insurance needed may also depend upon the structure of business ownership.

FACILITIES AND EQUIPMENT

Building a certified kitchen requires considerable capital outlay and time investment to ensure that all local, state, and federal building codes are followed to create a safe food-processing facility. Most commercial food products cannot be made in a residential kitchen. A separate room or facility must be built.

Table 2. Food Business Incubators		
Name	Address	Contact information
Northern New Mexico Community College Sostenga! Commercial Kitchen	921 N. Paseo De Oñate Española, NM 87532	505-753-8952 Jan Matteson, janmatteson@nnmc.edu http://nnmc.edu
NMSU Extension Food Lab	Tejada Building, Lab Room 105 P.O. Box 30003, MSC 3AE Las Cruces, NM 88003	575-646-1179 Nancy Flores, naflores@nmsu.edu http://efcs.nmsu.edu/food-technology.html
Socorro County Commercial Kitchen	407 Center St. Socorro, NM 87801	505-507-0991 Al Smoake, aandjfamilyfarm@yahoo.com
South Valley Economic Development Center	318 Isleta Blvd. Albuquerque, NM 87105	505-877-0373 timn@rgcdc.org http://www.svedc.org/
Taos County Economic Development Corporation Food Center	P.O. Box 1389 1021 Salazar Rd. Taos, NM 87571	575-758-8731 tcedc@tcedc.org https://www.facebook.com/realTCEDC/

Wants and needs must be clearly defined when considering a private food-processing kitchen. That pretty Mexican tile is beautiful, but it may be inappropriate for wet floors and difficult to clean. A state-of-the-art mixer with a 100-gallon bowl may be nice, but a 20-quart bowl might suffice for the first year or two of production. Consider purchasing equipment with pieces that can be adapted and changed as the company's needs increase. Before embarking on a huge expense, consider all the options available to you, especially for a new venture.

Certified commercial facilities or incubator kitchens are available throughout New Mexico (Table 2) that provide major mid-sized equipment and can be rented by the hour. Some of these facilities have support personnel that can help with recipe development, safe food-processing procedures, and marketing and business plan development. Renting a certified, permitted church kitchen or restaurant during off hours is also an option. Many businesses start in rented facilities and then move into a private commercial food-processing facility once the business is established. Avoiding a large investment in facilities and equipment—and thus the fixed debt payments that follow—is a major step in managing risks and rewards during the startup phase of a small business.

PERMITS AND REGULATIONS

In addition to obtaining a permit to operate a food-processing facility, each business must have a tax identification number from the New Mexico Taxation and Revenue Department. A business license may also be needed depending on the town and county location of the processing facility. Other permits and regulations depend upon the product. The City of Albuquerque Environmental Health Department inspects food businesses within the city limits. Table 3 shows examples of commodities and regulatory agencies and required permits. It is important to establish a good working

relationship with state and federal regulatory agents and inspectors early in business and product development. New Mexico Environment Department has an environmentalist in every county who is responsible for inspecting restaurants and food-processing facilities. These inspectors have many years of experience and can offer assistance in meeting building codes and issues with food safety and process control. If there are issues with your product or commodity, the regulators can be helpful in bringing things under control quickly. A list of NMED district field offices is available at <https://www.env.nm.gov/district-field-offices/>.

FOOD SAFETY, FOOD DEFENSE, AND BIOSECURITY

There are various systems that are mandated by state and federal law to improve food safety and security. All of these systems require careful consideration of the process, facility, personnel, and protection of the final product. All personnel must be trained on and understand the principles of the food safety plans and must follow these procedures. Additionally, these systems require complete documentation and a recall procedure in case of contamination, mislabeling, or misuse of the product. One or more food safety systems that may apply to your food product include:

Hazard Analysis and Critical Control Point (HACCP, pronounced hassip). This is a preventive system rather than the typical reactive system (such as sampling and inspection of food products after manufacturing). Many HACCP principles are already in place in the FDA-regulated low-acid canned food industry and the seafood and juice industries. More information can be found at <http://www.fda.gov/Food/GuidanceRegulation/HACCP/>.

Good Manufacturing Practices (GMPs). GMPs are operational sanitation procedures for personnel, facilities, and grounds and proper maintenance of

Table 3. Commodity Food Products and Regulating Agencies			
Commodity	Regulating agency*	Permit issued?	Comments
All food-processing facilities	FDA	Registration	http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm Required for all domestic and foreign facilities.
Food importers	FDA	Registration, notification of import	Registration: http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ Information: http://www.fda.gov/ForIndustry/ImportProgram/
Acidified, low-acid (e.g., salsa, green beans, meat canned under pressure)	FDA	No	Attend Better Process Control School; file FDA form 2541 and 2541a to agency w/PA** review.
	USDA	Yes	Registration: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm Information: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm
Acidified, low-acid (e.g., salsa, green beans) formulated foods	NMED	Yes	File application: http://www.nmenv.state.nm.us/fod/Food_Program/applications.html Regulation: http://www.nmenv.state.nm.us/fod/Food_Program/regulations.html
Beef jerky	USDA, NMED	Yes	Product distribution determines regulating agency.
Baked goods	NMED	Yes	File application. May need to refrigerate depending on water activity level.
Raw commodity, consumed raw; food producer (fresh fruit, produce, honey, dried chile, unprocessed nuts)	NMED	No	***Follow Good Manufacturing Practices (GMP): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110&showFR=1
	FDA	Registration	https://www.fda.gov/Food/GuidanceRegulation/CGMP/default.htm Weights and measures: http://www.nmcpr.state.nm.us/nmac/parts/title21/21.016.0005.htm Labeling regulations: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064880.htm
Fresh/frozen meat	NMDA, USDA	Yes	File application; inspection during processing.
Fresh/frozen seafood	FDA	Yes	File application: HACCP: http://www.fda.gov/Food/GuidanceRegulation/HACCP/default.htm
Restaurant/mobile unit	NMED	Yes	File application: http://www.nmenv.state.nm.us/fod/Food_Program/applications.html
Water/ice plant	NMED	Yes	File application: http://www.nmenv.state.nm.us/dwb/forms/
Dairy, milk, cheese	NMDA	Yes	Information: http://www.nmda.nmsu.edu/dairy/
Eggs	NMED	Yes	Information: http://www.nmda.nmsu.edu/scs/egg-inspections/
Organic processed foods	NMCOC, NMED	Yes	3-year certification process, file application.
<p>* Regulating agencies: FDA = U.S. Food and Drug Administration, USDA = U.S. Department of Agriculture, NMED = New Mexico Environment Department, NMDA = New Mexico Department of Agriculture, NMCOC = New Mexico Certified Organic Commission.</p> <p>** PA = process authority; FDA form 2541 is "Food Canning Establishment Registration"; FDA form 2541a is "Food Process Filling for All Methods Except Low-Acid Aseptic."</p> <p>*** All food-processing facilities must follow GMP, weights and measures, and labeling regulations.</p>			

equipment. These practices are basic to any food-processing operation and are required by law (21 C.F.R. § 110.3). These regulations are currently under review by the FDA. Complete details can be found at <http://www.fda.gov/Food/GuidanceRegulation/CGMP/default.htm>.

Good Agricultural Practices (GAPs). The goal of the GAP project is to reduce microbial risks in fruits and vegetables by providing educational material for a food safety plan to food producers and educational professionals associated with agriculture. This is not a mandated program; however, brokers and distributors are asking food producers and processors to pass third-party inspections based on GAP requirements. Information can be found at <http://www.ams.usda.gov/AMSV1.0/GAPGHP>.

Public Health Security and Bioterrorism Preparedness and Response Act

The events of September 11, 2001, reinforced the need to enhance the security of the United States. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was signed into law June 12, 2002 (the entire document can be found at <http://www.gpo.gov/fdsys/pkg/PLAW-107publ188/html/PLAW-107publ188.htm>). The Bioterrorism Act, section 305, added section 415 to the Federal Food, Drug, and Cosmetic Act to include Registration, Administrative Detention, Record Keeping, and Prior Notice to provide FDA with information on the origin and distribution of food and feed products and thereby aid in the detection and quick response to actual or potential threats to the U.S. food supply.

Registration of Food-Processing Facilities

The Bioterrorism Act requires domestic and foreign facilities to register with FDA as of December 12, 2003, if they manufacture, process, pack, or hold food for human or animal consumption in the United States. The purpose of registration is to provide FDA with sufficient and reliable information about food and feed facilities. Registration information will also help FDA to notify facilities that may be affected by actual or potential threats. Facilities can register online at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.

A copy of this registration form can also be obtained by writing to

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville, MD 20857

or by requesting the form by phone at 800-216-7331 or 301-575-0156. Complete the form legibly and mail it to the address above, or fax it to 301-210-0247.

Food Defense Plan

A Food Defense Plan is a security plan that will reduce the likelihood of someone intentionally contaminating or damaging your food product in order to kill or hurt people, disrupt the food supply and damage the local economy, or ruin your business. This plan includes having security measures for the facility, incoming and outgoing shipments, chemical storage, mail, and employees, and limiting access to visitors. The plan may also include policies for record storage and disposal and information kept on computers and online. Additionally, an emergency response plan should be included in case of an incident, with contact information for local law enforcement and medical response teams. A template plan can be downloaded at <http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>.

Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) amended section 415 of the Federal Food, Drug, and Cosmetics Act (FD&C Act; 21 U.S.C. § 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to comply with specific preventive measures to ensure food safety. Comprehensive, science-based preventive controls will be required of all food producers and food processors.

FDA will establish minimum standards for the safe production and harvesting of fruits and vegetables, addressing procedures such as soil amendments, packaging, temperature controls, water, and other issues, including worker health and hygiene. Food producers must have a written plan that implements minimal practices to ensure food safety. The plan must indicate control measures, monitoring procedures, and corrective actions taken with defective product or deficient procedures. Food-processing facilities operating with a HACCP plan and following GMPs are already in compliance with FSMA. This law allows for inspection of food producers and processors based on risk level.

These laws are also applied to imported food producers, requiring them to have adequate preventive controls in place to ensure safety. FDA will be able to accredit qualified third-party auditors to certify that foreign food facilities are complying with U.S. food safety standards. FDA now has the authority to recall food products that do not meet standards. The legislation strengthens existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, Tribal, and foreign—to achieve a safe food supply. Some small operations and certain conditions are exempt from

Table 4. Exemptions and Modified Requirements for Preventive Controls for Human Food Required by FSMA (reproduced from FDA, 2013)

Type of facility or operation	Hazard and risk-based preventive control requirements	Current Good Manufacturing Practices (CGMP)
Certain low-risk manufacturing/processing activities, and packing or holding activities that are conducted by small or very small businesses on farms for specific foods. Examples: jams and jellies, honey, and maple syrup.	Exempt	Must comply
Foods subject to the low-acid canned food (LACF) regulation. Applies only to those microbiological hazards addressed by the LACF regulation.	Exempt	Must comply
Foods subject to HACCP regulations (seafood and juice)	Exempt	Must comply
Dietary supplements	Exempt	Dietary supplement CGMPs
Alcoholic beverages at certain alcohol-related facilities, and certain prepackaged food sold in limited quantities along with alcoholic beverages at the same facilities.	Exempt	Must comply
A facility that has food sales averaging less than \$500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end user is either a consumer (in any location) or a restaurant or retail food establishment purchasing the food for sale directly to consumers that is located in the same state or not more than 275 miles away.	Modified preventive control requirements apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
A very small business. Three options are being proposed by FDA to define a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation.	Modified preventive control requirements apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
Activities within the definition of “farm”	Exempt	Exempt
Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment.	If refrigeration is not required for safety, the facility is exempt. If refrigeration is required for safety, modified preventive control requirements apply: Requirements concerning temperature controls, including monitoring, verification, and records.	Must comply
Facilities, such as grain elevators, that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.	Exempt (provided they are solely engaged in such storage)	Exempt
Facilities, such as warehouses, that store raw agricultural commodities that are fruits and vegetables intended for further distribution or processing.	Must comply	Exempt
This table does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm256826.htm .		

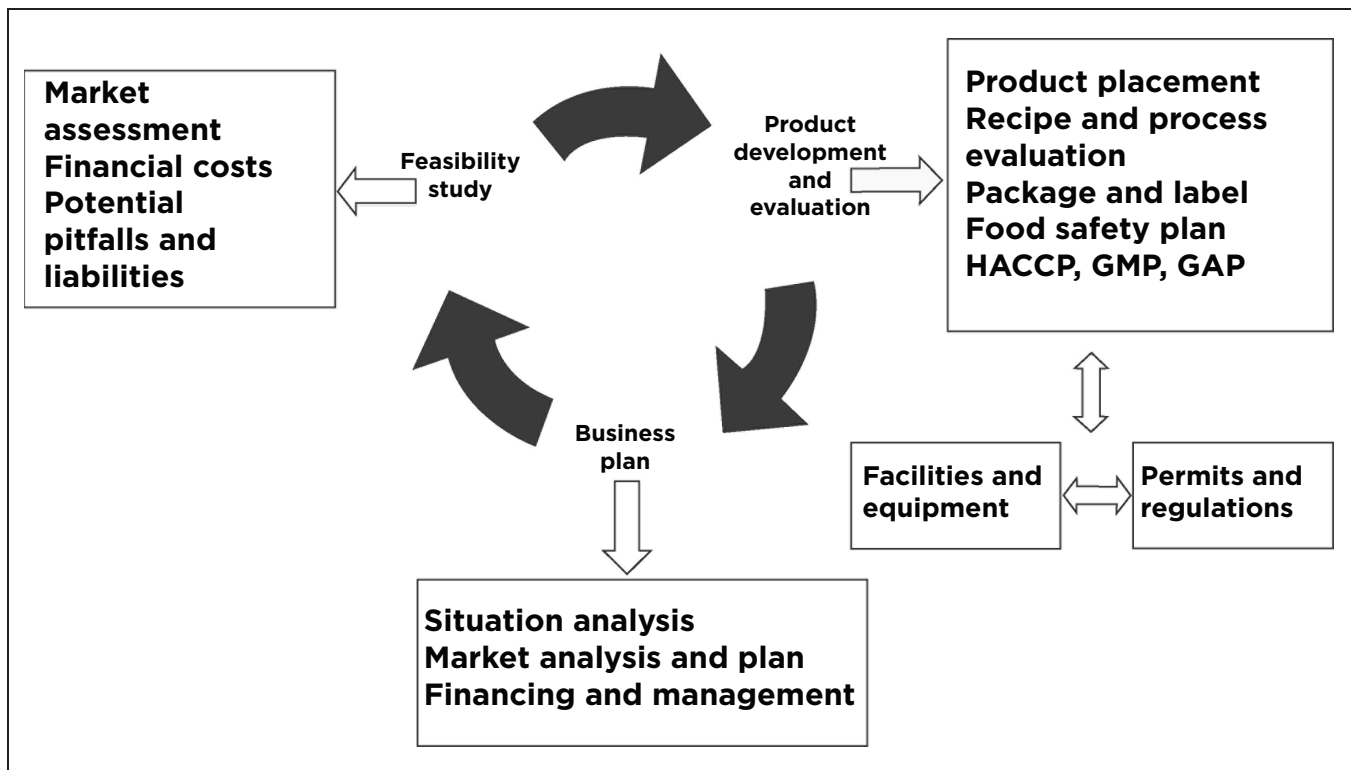


Figure 1. Diagram of planning and development processes of starting a food-processing business.

compliance with these regulations; these are noted in Table 4, but you must review the full context of law at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

STARTING A FOOD BUSINESS CHECKLIST

The following checklist can help you keep track of various requirements as you plan your food business. Figure 1 provides a visual diagram of the planning and development process.

Business planning and management

- Feasibility study
- Business plan
 - Situation analysis
 - Market analysis and plan
 - Financing and management

Product evaluation

- Product placement in market: refrigerated, frozen, or shelf-stable
- Recipe or formulation evaluation
- Process evaluation
- Packaging and labeling
- Food safety plan: HACCP, GMP, GAP, FSMA
- Food defense

Liability insurance protection

- Product liability insurance
- Business liability insurance
- Employee disability insurance
- Life insurance

Facilities and equipment: private, contract packager, or kitchen incubator

- Permitted facility
- Local, state, federal building codes followed
- Equipment maintained and working

Permits and regulations

- Local, state, federal applications
- Bioterrorism Act: registration, recordkeeping, prior notice
- Food processing permit: operational plan, label approval
- Tax identification number

WHERE TO GO FOR ADDITIONAL HELP

FDA — How to Start a Food Business

The primary focus of FDA as a regulatory agency is food safety, so it does not offer financing or business tips for starting and maintaining a business. However, FDA

offers information on food safety guidelines and regulations it has established that are required for informative labeling and the safe preparation, manufacture, and distribution of food products. This information can be found on their How to Start a Food Business website at <http://www.fda.gov/Food/ResourcesForYou/Industry/ucm322302.htm>.

The Food Technology Program at New Mexico State University

New Mexico State University responded to a grassroots stakeholder initiative by developing and implementing a Food Technology program. Since 1993, the Extension Food Technology program has assisted food producers in the state by providing information on food regulations and services such as process review of acidified foods and analysis for nutritional labeling. Food processors receive direct technical assistance for product development, labeling, and marketing of new food products. Please see <http://aces.nmsu.edu/ces/foodtech/>.

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