



Turning Out Your Product: From Food Safety to Marketing, There's a Lot You'll Need to Know

"Never be afraid to try something new. Remember, amateurs built the ark. Professionals built the Titanic." By John Taschek

Consumers are attracted to specialty foods because they see them as "homemade" from natural ingredients, uniquely packaged or specially prepared. Many specialty foods are not really "new" products but instead, are often variations or unique combinations of existing products. Your "Jammin' Jelly," for example, is an improvement on an existing product with a new name and perhaps, updated packaging.

Simply being a good cook with a better idea will not ensure good, safe products for commercial marketing. In Maryland, with the exception of certain products that can only be sold at farmers' markets or your on-farm stand, you cannot manufacture your product in your residential kitchen. Processed or value-added foods must be manufactured in a licensed commercial kitchen. You must comply with food preparation federal and state regulations, regardless of the size of your business. Food safety is a key issue in all food processing.

Prospective food processors are often discouraged by the food safety regulations that must be satisfied to establish a food processing business. In this report, we will break down the necessary steps to develop your product and bring it to market in accordance with Maryland

the Department of Health and Mental Hygiene's regulations and recommendations.

Unfortunately, many entrepreneurs have little, if any, training in food science, processing technology, large-batch recipe formulation, quality control/sanitation, packaging, regulations or equipment. A working knowledge of Good Manufacturing Practices and the Hazard Analysis Critical Control Point (HACCP) System is essential to meet the food processing regulations in Maryland. It is also recommended that you attend a Better Process Control class. You may need to submit a sample of your product to an accredited laboratory for pH, water activity and/or moisture testing. Creating your product under these controlled conditions helps not only ensure its safety, but can also add to product quality and flavor.

You may need the help of a food scientist to evaluate if there are any shelf life or safety problems with your product. Will light affect product quality? Is rancidity a problem? Will molds, bacteria, yeast, or other pathogens be a concern? Consulting a food scientist or other food consultant for assistance in scaling-up your recipe is strongly recommended.

Product development also includes packaging, labeling, Food and Drug Administration (FDA) regulations, UPC codes, and nutritive claims. Larger companies rely on development teams to handle the different aspects of product development. If your time and expertise in these various fields is limited, you might consider creating a virtual product development team from a network of experts and consultants. Many universities with food science and technology programs offer specialized testing and consultation services to small, private companies.

An additional option is to create your product with a co-packer rather than self-production. Co-packing is a contractual agreement between you and a certified food processor, where the co-packer manufactures the developed product according to your formula. Working with a co-packer can provide you with a safe and consistent product, allowing you more time for marketing, managing your business, and product development.

State Agency Assures Safety of Food in Maryland

The mission of the Office of Food Protection and Consumer Health Services is to review, license, and inspect food manufacturing facilities in the state (<http://phpa.dhmd.maryland.gov/OEHFP/OFPC/HS/SitePages/Home.aspx>). The Office also works with local health departments, other state agencies, and the federal government to assure the safety of the food supply and to respond to any potential or actual threats to the food supply.

The comprehensive food protection program includes: facility and process review; inspection of food establishments; licensing and certification of facilities; training and information sharing with local health departments and the

industry; statewide food safety initiatives; food sampling and analysis; product registration; consultation and complaint investigation; and enforcement of the laws and regulations.

Md. Code Annotated Health-General (Health-General), 21-305 requires “that a person may not operate a food establishment unless the person is licensed by the Department.” Operating a food establishment without a license is a misdemeanor punishable by a fine not to exceed \$1,000 and imprisonment not to exceed 90 days or both for each day of operation without a license. In addition the person is subject to a civil penalty of \$5,000 for each day without a license.

The State’s health regulations are comprised of three levels related to the size and location of production.

- The first applies to foods prepared in a residential kitchen for resale at a farmers’ market or bake sales. The relatively short list of foods allowed under State regulations include: non-potentially hazardous baked goods with fairly dry ingredients, have a low moisture level and a lower risk of pH problems. Hot-filled canned and fruit jellies, jams, preserves, and butters may also be prepared in a residential kitchen.

- Small and mid-sized specialty food processors must obtain a license to produce food in Maryland. These processors must complete the State Health Department’s facility and review process.

- Large-volume, corporate processors are subject to the Code of Maryland Regulations (COMAR) 10.15.04, the State’s broad food processing regulation. Because different foods have vastly different equipment and facility requirements, additional regulations pertain to the manufacture of specific foods, including:

- ◆ COMAR 10.15.01, Canning and Acidified Food Manufacturing;
- ◆ COMAR 10.15.02, Crab Meat;
- ◆ COMAR 10.15.07, Processing, Handling and Packing of Shellfish that are sold for human consumption; and
- ◆ COMAR 10.15.10, Procedures for the Safe Handling and Processing of Seafood.

Maryland Office of Food Protection and Consumer Health Services Food Processing Guide Addresses New Food Processors' Questions

Food safety laws and regulations apply to all commercial food businesses, including those conducted on a farm. If you are planning to operate a food processing plant, or prepare food for retail sale, there are several things you need to know:

- 1) Except as noted below, you need to obtain a license from the Maryland State Department of Health and Mental Hygiene or local health department.
- 2) You must operate in a food processing plant or food service facility approved by the licensing agency.
- 3) Terms used in the regulations are defined below:
 - ◆ **Food**-- Any item for human consumption, including any material made into or used as food or drink.
 - ◆ **Food processing plant**-- Any place used for, or in connection with, commercial food manufacturing, preparing, processing,

packaging, canning, freezing, storing, distributing, labeling, or holding. The following are considered food processing plants: bakery, cannery, confectionery plant, crab meat picking, food manufacturing, food warehouse, food distribution center, frozen-food processing, shellfish, soft drink manufacturing, or bottled water plants.

¹Md. Code Annotated Health-General (Health-General), 21-305 requires "that a person may not operate a food establishment unless the person is licensed by the Department." A person who operates a food establishment without a license is guilty of a misdemeanor and upon conviction is subject to a fine not exceeding \$1,000 and imprisonment not exceeding 90 days or both for each day the person operates without a license. In addition such a person is subject to a civil penalty of \$5,000 for each day the person operates without a license.

- ◆ **Food service facility**-- A restaurant, coffee shop, cafeteria, short-order café, luncheonette, tavern, sandwich stand, soda fountain, retail market, retail bakery outlet; food operation in an industry, institution, hospital, club, school, camp, church, catering kitchen, commissary, or similar place where food or drink is prepared for sale or service on the premises or elsewhere. The term also applies to any other operation where food is served or provided for the public with or without charge.

A food service facility does not include a kitchen in a private home where food is prepared at no charge for guests in the home or at a social gathering, or for service to unemployed, homeless, or any other disadvantaged populations; or food preparation or serving areas where only non-potentially hazardous food is prepared or served only by an excluded organization. An "excluded organization" is a volunteer fire company or bona fide nonprofit

fraternal, civic, or war veterans, religious, or charitable organization or corporation that does not serve food to the public more often than four days per week, except that an excluded organization may serve food to the public for up to 14 consecutive days.

You are not required to obtain a license for packaging raw agricultural products such as raw produce, grain, herbs, or honey.

Food processing may not be done in a home kitchen. Food processing must be done in a processing area dedicated to that operation, by a person licensed to operate at that location. If the food processing plant is attached to a dwelling, there may not be interconnecting openings between the food processing plant and any part of the living quarters. A person may be licensed to manufacture food in an existing food establishment such as a restaurant or church kitchen if that establishment complies with the regulations.

Getting a Food Processing License Allows You to Make, Store and Distribute Your Product

Food safety concerns and regulations controlling product stability and shelf life add to the complexity of how foods must be processed to guarantee their safety to the public.

In Maryland, a food processing license applies to both the person manufacturing the food and to the facility where the processing is done. If you lease space in a licensed commercial kitchen for processing your product, you still need to obtain a processor's license if you are the one actually doing the processing. A food processor's license in Maryland costs \$150 annually. Foods must be prepared under verifiable manufacturing processes that can be consistently duplicated. The process will dictate

the equipment and facility design needed for safe processing.

"Registered Sanitarians" at the Maryland Department of Health and Mental Hygiene, review and comment on proposed food and facility plans and can guide you through the licensing process. They are trained in facility and food processing design and can spot problems early in the review process that may save you time and money in building your business and help you avoid possible food contamination and safety issues.

Taking the Steps to Becoming Licensed to Process Foods

The first step on the path to a food processing license is to submit the following to the State Department of Health and Mental Hygiene, Division of Food Control (address listed at the end of this section):

- 1) A description of the food you want to manufacture;
- 2) The process steps to prepare, package, label, store, and transport the food;
- 3) A description of the building layout and equipment to be used.

The Division of Food Control is responsible for reviewing plans and manufacturing processes statewide. In addition, the Division of Food Control licenses and inspects facilities, except in Baltimore City, Charles and Prince George's counties. In those jurisdictions, the local health department handles these duties.

Construction of a food processing facility may require approval from other local and state agencies. Scheduled processes, laboratory analyses, or shelf life studies may be required to:

- Assess inherent hazards or risks associated with a food;

- Satisfy regulatory requirements;
- Incorporate previous scientific research results;
- Verify a food's shelf life; or
- Standardize a food process.

Certain foods, such as acidified foods and low-acid canned foods, require that a person receive specialized training in order to be approved to manufacture them.

For more information, please contact the State Division of Food Control at (410) 767-8400; toll-free at (877) 4MD-DHMH-TTY for the disabled, website at www.dhmf.state.md.us, or send a note to:

Division of Food Control, Facility and Process Review

6 St. Paul Street, Suite 1301
Baltimore, MD 21202-1608

The Maryland Department of Health and Mental Hygiene recommends that you follow the steps below to become a licensed food processor:

- 1) Fully develop the food item you want to process;**
- 2) Work with a Maryland Department of Health and Mental Hygiene sanitarian to make plan revisions or product changes to meet the specified requirements;**
- 3) Contact the Department to receive a Facility and Process Review Packet; and**
- 4) Decide where and how you will commercially process your specialty food produce.**

Each of these steps will be discussed in detail in the following sections.

1) 1). Fully Develop the Food Item that You Want to Produce

Create a prototype of your product: Try it out on family and friends. Do not offer it to strangers before you have a state-approved process for making your product. Collect and incorporate feedback on flavor, texture and overall quality. Determine what market and packaging style best suits your product, i.e., frozen, canned, jarred, refrigerated, or baked.

Develop large batch recipes: You must determine how to expand your “home-style” recipe for quantity production. It is suggested that you first quadruple your recipe. After making any necessary changes for taste, texture or appearance, this formulation becomes the base recipe from which larger batches will be prepared.

Determine the batch size you need for commercial processing. A good start for a liquid product (syrups and dressings) is 5-10 gallons. For solid product, consider a 15-25 pound batch.

The ingredients in your family recipe are expressed in volume measurements such as teaspoons or cups. For large batch recipes, you will need to convert these measurements to weights, pounds and ounces, for more precise measurement. This is especially critical for baked goods where slight inconsistencies in the small batch can be disastrous in the large batch formulation.

Brands of ingredients can make a difference too. Don't change ingredient brands without testing the results in a small batch first. You may want to experiment with your recipe to cut costs by testing the minimum amount of an ingredient that you can use without affecting the

quality of your product; but again, try it first in a smaller batch.

Understanding how to convert recipes to large batches can be more complicated than it seems, depending on your product. Most people can double or even quadruple a recipe and turn out a consistent product. However, going from producing 4 units to 400 units of a product is more challenging. A university food science department or food science specialist can assist you.

In addition to creating a large batch recipe, you also need to develop a standardized processing regimen. Arrange your equipment for the most efficient production and streamline your work methods. Repeat making the recipe until your results are the same every time.

The Virginia Department of Agriculture recommends that a processor's recipe include:

- ◆ An appropriate descriptive title;
- ◆ Size of servings in volume, weight, or pieces;
- ◆ Yield number of servings and/or volume or weight;
- ◆ Pan size needed, especially for baked or congealed items if important to the quality of the finished product or portion sizes;
- ◆ Number of pans needed, whether glass or metal;
- ◆ Ingredients in the order used and brand names;
- ◆ Type or form of ingredients, such as all-purpose flour, melted fats, finely

chopped onions, etc.;

- ◆ Quantity of ingredients in both weight and volume; and
- ◆ Clear, precise instructions for:
 1. Preparing and combining ingredients;
 2. Cooking method;
 3. Time and temperature;
 4. Size of portion and method of service; and
 5. Any possible substitutions, if desirable.



2) Work with a Maryland Department of Health and Mental Hygiene Sanitarian to Make Plan Revisions or Product Changes to Meet the Specified Requirements

Before submitting your processing and food plan to a sanitarian, you'll need to have your product reviewed and approved. This is done through a *Process Authority*. The *Authority* is an FDA approved process consultant or institution with the expert knowledge, experience, and adequate facilities to make determinations about the safety of a food process or formulation. Process consultants work closely with processors to assure their process practices meet Good Manufacturing Practices

and comply with the Hazard Analysis and Critical Control Point (HACCP) Program. A process consultant also can advise you on food labeling requirements, product storage, and transportation.

Process consultants can analyze your product for safety at their in-house laboratory. These tests help determine product safety and shelf life. A process consultant will use your test results to pinpoint potential problems in your processing procedures or recipe design.

Food analyses may include pH (acidity or alkalinity), water activity (moisture), shelf-life (product life under conditions of storage), microbial testing, and chemical composition. These tests will cost from \$15 for a pH test, \$10 for a moisture test, to over \$100 for a dietary fiber test.

Most laboratories also provide nutrient labeling information. This is important if you are required to provide a “Nutritional Facts” label on your product. The Nutritional Labeling NLEA 90 Package required by the FDA for several classifications of processed products requires testing for the product’s total contents of dietary fiber, iron, calcium, sodium, vitamin A, vitamin C, total sugar, and cholesterol and fat composition. A laboratory-certified, label-ready presentation of the Nutritional Facts Panel, with calculations of Percent Daily Values, usually costs at least \$600. Check with state and federal regulatory agencies to determine which tests are required for your products.

You should receive your test results back from the laboratory on a Certificate of Analysis. This may be a very simple form or a more elaborate report. This document verifies that certain microbiological, chemical, or physical analyses were conducted on the product, and that it performed within the established criteria.

3). Contact the Maryland Department of Health and Mental Hygiene to receive a Facility and Process Review Packet

A process consultant can assist you in designing a written program, known as a Scheduled Process, for your food manufacturing operation and processing. When followed, the Scheduled Process will help ensure safe and sanitary food processing. This document is issued by a Process Authority and provides a detailed procedure for a single product, including formulation, critical control points, processing steps, storage, distribution, selling conditions, and restrictions.

During the approval process, a Process Authority reviews your procedures and makes suggestions for improvement. The Scheduled Process also provides the required safety documentation.

A Scheduled Process is important because:

- ◆ It is required by the Maryland Department of Health and Mental Hygiene for the processing of most food products;
- ◆ It is required by FDA for Acidified (pickled) products that do not need refrigeration (shelf-safe);
- ◆ The development process forces a critical evaluation of your operation that may identify potential safety concerns, including:
 - Unmet regulatory regulations;
 - Changes in your recipe or production that could affect product safety;
 - Critical steps that are not verified or documented; and
 - Suggested improvements to your procedures.

Every Scheduled Process must include:

- ◆ A descriptive identification of the product, i.e. condiment, beverage, etc.;
- ◆ A list of the exact formulation of the product, including an itemized list with weights (grams, ounces, pounds, etc. NOT tablespoons, cups, etc.).
- ◆ Precise, step-by-step directions for the process. A flow chart is an effective way to outline the steps;
- ◆ Your name, address, phone numbers, fax, and e-mail address;
- ◆ The date on which the document was developed;
- ◆ Required laboratory analyses;
- ◆ The type and size of packaging container to be used; and
- ◆ A statement if the product is to be sold refrigerated, frozen or shelf-stable.

Every product must have a unique Scheduled Process. You must follow the approved schedule as written and maintain appropriate record of the critical points, such as pH and temperature, for every batch of product made.

Most Specialty Foods are Subject to Federal Regulations because Products Cross State Lines during Distribution

If your product is sold across state lines, it will be subject to regulations of the Federal Food, Drug and Cosmetic Act and Fair Packaging and Labeling Act. These include labeling, ingredients, preparation, and handling requirements. The federal agencies responsible for food safety are the FDA and the USDA.

There are three sets of regulations that food processors must comply with to operate in accordance with state and federal mandates:

- ◆ Good Manufacturing Practices (GMP)
- ◆ Hazard Analysis Critical Control Point System (HACCP)
- ◆ Better Process Control Training (where applicable)

GOOD MANUFACTURING PRACTICES (GMP)

A food processing operation should be designed and operated according to “Good Manufacturing Practice” regulations. A copy of these regulations is available from:

FDA Regional Office

Baltimore District (BLT-DO)
900 Madison Avenue
Baltimore, MD 21201
(410) 962-4012
Fax: (410) 962-0044

Working through the “Food Establishment Plan Review” process with the Maryland Department of Health and Mental Hygiene’s Bureau of Food Control will help guarantee you meet GMP requirements. All food plants, except meat and poultry, are subject to FDA inspection to ensure compliance with GMP regulations.

Specialty foods containing meat and poultry fall under USDA’s jurisdiction. For more information concerning food safety regulation for meat and poultry products, call the USDA Meat and Poultry Hotline, (888) 674-6854.

FDA publishes a compilation of “Current Good Manufacturing Practice (CGMP) Regulations” and any amendments to the current regulations in the *Federal Register*. The CGMP regulations

are printed in Title 21 Code of Federal Regulations, Part 110 (21 CFR 110).

You may subscribe to the Federal Register's online database by sending an e-mail to the GPO Access User Support Team at gpoaccess@gpo.gov. For more information, contact Electronic Information Dissemination Services, U.S. Government Printing Office at (202) 512-1530, or (888) 293-6498 (toll free).

Here is a general outline of GMP regulations.

OUTLINE OF AREAS COVERED BY GOOD MANUFACTURING PRACTICE REGULATIONS

Personnel

- A. disease control
- B. cleanliness
- C. education and training
- D. supervision

Plants and grounds

- A. grounds
- B. plant construction and design

Sanitary facilities and controls

- A. water supply
- B. sewage disposal
- C. plumbing
- D. toilet facilities

- E. hand-washing facilities
- F. rubbish and offal disposal

Sanitary operations

- A. general maintenance
- B. animal and vermin control
- C. sanitation of equipment and utensils
- D. storage and handling of cleaned, portable equipment and utensils

Equipment and procedures

- A. general
- B. use of polychlorinated biphenyls in food plants

Process and controls

- A. raw materials and ingredients
- B. raw ingredient containers and carriers
- C. ice
- D. food processing areas
- E. food processing equipment
- F. good processing conditions and controls
- G. testing procedures
- H. packaging processes and materials
- I. product codes
- J. storage and transportation of finished products

Natural or unavoidable defects in food for human use that present no health hazard.

Source: **Bulletin 1051/March, 1991**, The University of Georgia and Ft. Valley State College.

Compliance with Good Manufacturing Practices and Sanitation Requirements are the Foundation for Safe Food Production

The table that follows takes each of the six sanitation areas and relates them to specific citations in FDA's 21 CFR Part 110, Good Manufacturing Practice regulations and the Pasteurized Milk Ordinance (PMO). Additional

guidance on GMPs and requirements for the sanitary production and storage of food products can be found in FDA's "CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOODS" 21 CFR Part 110, and in the FDA "Pasteurized Milk Ordinance (PMO)".

Six Areas of Sanitation (Sanitation Standard Operating Procedures-SSOP's)	Corresponding Part 110 Requirements	Corresponding PMO Sections (Section 7 unless otherwise noted)
(1) Safety of process water	110.37(a); .110.80(a)(1)&(b)(16): Process water safe and of adequate sanitary quality; water used for washing; rinsing; or conveying of safe and adequate sanitary quality; water used for ice manufacture of safe and adequate sanitary quality 110.37(b)(5): No cross connections between sewer or wastewater and process water	7p (water supply), Appendix D (Standards for Water Sources)
(2) Condition and cleanliness of food contact surfaces	110.40(a)&(b): Food contact surfaces designed, fabricated, maintained, and installed to be environment of use and cleaning compounds; smoothly bonded seams. 110.35(d)(2); .80(b)(1) & (b)(10) & (b)13(ii): When cleaning is necessary to protect against introduction of microorganisms, clean and sanitize before use, after interruptions, and as necessary. 110.10(b)(1)&(5): Gloves should be impermeable, clean, and sanitary; outer garments suitable	10p (sanitary piping), 11p (Construction and repair of containers and equipment, 12p (Cleaning and sanitizing of containers and equipment)
(3) Prevention of cross contamination	110.10(b)&(b)(2)&(b)(3)&(b)(4)&(b)(7)& (b)(8) &(b)(9); 110.80(b)(6)& (b)(13)(v): Food handlers conform to hygienic practices to the extent necessary to prevent contamination; maintain adequate personal cleanliness; wash, and sanitize if necessary, hands before start work, after absence from work station, and when become contaminated; taking precautions as necessary to protect against contamination with microorganisms; effective measures to prevent finished product contamination by raw materials, other ingredients, refuse; remove jewelry that cannot be sanitized; abstaining from eating, chewing gum, drinking, or using tobacco near exposed food or equipment; storing clothing or personal items away from exposed food and equipment. 110.20(b)(1)&(2)&(4): Plant design must reduce potential for contamination of food, food contact surfaces, and packaging material and must permit employees to protect	15p(B) (cross connections)

	<p>against contamination of food from clothing or personal contact; separation of operations.</p> <p>110.37(e)&(e)(1) -(4): Hand washing and, where appropriate, hand sanitizing facilities should be at each location where good sanitary practice dictates their use; effective hand cleaning and sanitizing preparations; water at suitable temperature; sanitary towel service or suitable drying devices; designed to prevent recontamination.</p> <p>110.37(c)&(d): Adequate sewage disposal system; adequate, readily accessible toilet facilities; maintained in sanitary condition; self-closing doors; protect food from airborne contamination</p>	
<p>(4) Protection of food, food packaging material, and food contact surfaces from adulteration.</p>	<p>110.40(a);.110.80&(a)(5)&(a)(7)&(b)(5) &(b)(7)&(b)(10)&(b)(12)&(b) (13); 110.93: Design, construction, and use of equipment precludes adulteration of food with lubricants, fuel, metal fragments, contaminated water, or other contaminants; all reasonable measures to ensure that production methods do not contribute contamination; raw materials held to protect against contamination; work-in-progress handled to protect against contamination; equipment protects food from contamination; mechanical steps protect from contamination; batters, breadings, sauces, dressing, etc. protected from contamination; filling, assembly, packaging, and other operations protect food from contamination; storage and transportation protect the food from contamination-----</p> <p>110.20(b)(4);.80(b)(10)&(b)(12) (iv): Drip or condensate from fixtures, ducts and pipes does not contaminate food, food contact surfaces, or packaging material; Adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food should be provided-</p> <p>110.40(g): Compressed air or other gases mechanically introduced treated to prevent contamination of food.</p> <p>110.35(b)(2)&(c): Toxic cleaning compounds, sanitizing agents, and pesticides identified, held, and stored in a manner that protects food, food contact surfaces, and packaging material from contamination; all relevant regulations for their use followed; pesticides used only when food, food contact surfaces, and packaging material protected from contamination.</p>	<p>13p (storage of cleaned containers and equipment), 14p (storage of single service containers), 15p(A) (protection from contamination), 18p (bottling and packaging), 19p (capping), 21 (clean properly constructed vehicles)</p>
<p>(5) Control of employee health conditions and hygiene that could result in microbiological contamination of food, food packaging material, and food contact surfaces..</p>	<p>110.10(a): Food handler who has illness or open lesion, or other source of microbiological contamination that presents reasonable possibility of contamination of food, food contact surface, or packaging material excluded from such operations.</p>	<p>6p (toilet facilities), 8p (hand-washing facilities), 20p (personnel cleanliness) , Section 13 (Personnel Health), Section 14 (Procedure When Infection or High Risk of Infection is Discovered)</p>

(6) Exclusion of pests.	110.35(c): No pests shall be allowed in any area of a food plant.	3p (outer openings adequately protected against entrance of pests), 9p (no evidence of pests in milk plant), 22p (surroundings free of harborages)
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Hypertext updated by ces/cjm 2000-MAR-06 from the U.S. Food and Drug Administration web site

HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP) PROGRAM

Maryland requires food processors to have a HACCP program to obtain a food processor's license. HACCP plans are proactive in their approach to food safety. HACCP Systems control safety before and during the manufacturing process.

In the past, periodic plant inspections and sample inspections were used to check product quality and ensure safety. Inspection and sample testing provides information relevant only for the specific time the product was inspected or tested. What happened to the product before or after? This method offers the public little protection or assurance that the product is safe and stable.

HACCP was developed by the Pillsbury Company in the 1960's as a way to produce safe food for NASA. The HACCP system identifies potential problems before production begins and provides effective monitoring during production to make sure problems have not occurred.

Since then, the principles of HACCP have been adopted by a number of food industry segments. The use of HACCP principles are required by the U.S. government in the seafood

industry, juice operations, the meat and poultry inspection service, and in plants that produce meat and poultry products. Discussions are currently underway to include dairy and fresh and processed produce under these requirements.

HACCP consultants can help you set up a system. The Maryland Department of Health and Mental Hygiene has a fact sheet, "Guidelines for Submitting A Hazard Analysis Critical Control Point Plan" that includes detailed information on plan requirements and examples of completed plans. You can obtain the fact sheet by calling the Department at (410) 767-8440 or from the web site at <http://dhmh.maryland.gov>.

HACCP has worked well in the food industry. It will protect your business and customers and can be a selling point for your product. An understanding of HACCP concepts and principles should be incorporated into your product development plans.

HACCP is based on seven principles:

1. **Hazard analysis** of the product is done from delivery of the raw ingredients to the consumer's plate. There are three kinds of hazards in food preparation:
 - ◆ Biological hazards such as bacteria and viruses;

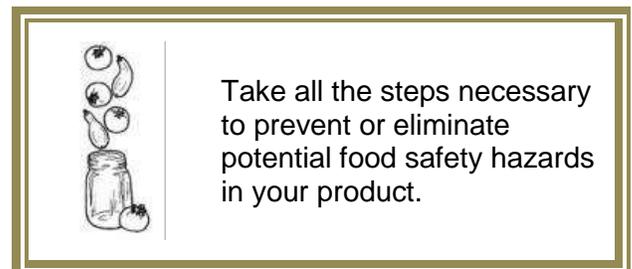
- ◆ Chemical hazards such as toxins, improperly used pesticides, or cleaning compounds; and
- ◆ Physical hazards such as foreign objects like glass, metal, plastic or wood.

You should develop a flow chart that indicates how your product is produced, the packaging involved, the temperature requirements for storage, distribution and display of your product and finally, your intended customer base. This chart will help you identify possible sites for the introduction of hazards into your production and distribution process. Your chart should also list the steps that will be taken to control the hazard.

- 2. Identification of critical control points (CCP's)** is a step in your process during which a safety hazard can be prevented or eliminated. Typical critical control points include cooking time/temperature parameters, proper acidity (pH) and/or drying steps in your food process.
- 3. Establish measureable critical limits** for preventive measures. The critical limits guarantee safe production of your product and are defined in your Certified Process. If the critical limit criteria are not met, the process is “out of control” and food safety hazards are not being prevented or eliminated. Examples of critical limits include checking processing temperature and time and maintaining proper pH.
- 4. Establish monitoring procedures** in a planned sequence of measurements or observations to ensure that processing is proceeding correctly and if not, to make adjustments before loss of control occurs. The monitoring interval must be adequate to

ensure reliable control of the process. Examples of monitoring include visual observations and checks on processing time and temperatures, and moisture levels.

- 5. Establish corrective actions** if the HACPP plan intended to prevent variations in your product or production process is not followed. Mistakes will happen. If they do, you must have a written plan for correcting the situation and disposing of the product. Examples of corrective actions are discarding the food, fixing the problem, and maintaining a written history of the actions taken.
- 6. Establish verification** procedures to review your HACCP system at least annually to make sure it is working properly. Additional audits should be done if you add new equipment or change your Authorized Process.
- 7. Establish recordkeeping** in order to meet the HACCP system requirements for preparation and maintenance of a written HACCP plan. This plan must include all records generated during the monitoring of each CCP and notations of corrective actions taken. Keep and review daily records to ensure that your system is operating within controls. Keep your recordkeeping system simple.



HACCP is only one tool in your food safety program and is not meant to be a stand-alone

program. It should be coupled with other food safety processing tools such as Good Manufacturing Practices and Sanitation Standard Operating Procedures. HACCP plans can and should change as your processing business changes. If changes occur in your process, your HACCP plan must be evaluated and revised by a recognized Process Authority to reflect those changes.

The specific requirements for each of the seven principles can be found in the Code of Federal Register, Part 417-Hazard Analysis and Critical Control Point (HACCP) Systems. For more information, contact:

USDA/FSIS, HACCP Small Plant Coordination Office at (202) 720-3219.

USDA Food Safety and Inspection Service Web site: www.fsis.usda.gov.

Food and Drug Administration, Foodborne Illness Education information Center, USDA/FDA HACCP Training Programs and Resources Database, Web site: http://fsrio.nal.usda.gov/nal_web/fsrio/fseddb/fseddbsearch.php

USDA Meat and Poultry Hotline
1-(888) 674-6854

Maryland Department of Health and Mental Hygiene, Office of Food Protection and Consumer Health Services. Web site: <http://phpa.dhmh.maryland.gov/OEHFP/OFPCHS/> ~ (410) 767-8400

States may have HACCP plan guidelines that vary in title from the seven principles listed, but not in content. Maryland Code Annotated, Health-General Article, and the Code of Maryland Regulations require that plans and specifications be submitted to the Maryland Department of Health and Mental Hygiene when a person proposes to construct, remodel

or alter a food establishment, or convert or remodel an existing building for use as a food establishment. This information is used to make a priority assessment of the facility. A HACCP plan is required for all high-or moderate-priority facilities.

For a copy of Maryland's "Guideline for Submitting A Hazard Analysis Critical Control Point (HACCP) Plan" that lists the necessary information for priority assessment and developing a HACCP plan, contact the Office of Food Protection and Consumer Health Services.

BETTER PROCESS CONTROL SCHOOL

The Food and Drug Administration and USDA Good Manufacturing Practices require companies that manufacture low-acid and acidified foods to operate with a certified supervisor on the premises when processing as specified in 21 CFR Part 108.25(f) and 108.35 (g) (FDA) or 9 CFR 318.00 and 281.300 (USDA).

Better Process Control Schools (BPCS) offer FDA-approved instruction and certification for operators, supervisors, managers, and technical staff in the canned food industry who work or control (1) food acidification procedures and practices, and (2) thermal processing systems and systems.

To become a certified supervisor, you must attend training and pass competency tests in the areas of:

- ◆ Food Microbiology of Canning
- ◆ Food Container Handling
- ◆ Food Plant Sanitation
- ◆ Records for Production Protections

- ◆ Principles of Thermal Processing
- ◆ Process Room Instrumentation, Equipment, and Operation
- ◆ Closures for Metal Containers
- ◆ Closures for Glass Containers

Most schools give separate exams for each section. Passing an examination will certify you as a supervisor for the operations covered by that particular exam, whether you are working in these areas or not. Expect to pay \$500-\$600 for the course, plus food and lodging expenses.

Better Process Schools are often offered through FDA-approved courses conducted by the Food Science Departments of many state universities. The Pennsylvania State University, University Park, PA conducts a Food Processors Institute, offering various food processing courses. For information on their next scheduled Better Process Control School visit their Web site at <http://foodscience.psu.edu/workshops/better-process-control>.

Other Midwest schools, such as Purdue University, the University of Tennessee, and Michigan State University also conduct FDA-approved processing schools.

Processors of Low-acid and Acidified Canned Foods Must Register with FDA and State Health Department

In addition to registering, low-acid canned food and acidified food processors must have their processes approved by a recognized processing authority. Full text of the low-acid canned foods and acidified food regulations is in the Code of Federal Regulations (CFR), Title 21 Parts 108, 113, and 114, available at:

Superintendent of Documents
Government Printing Office (GPO)
Attn: New Orders
P.O. Box 371954
Pittsburgh, PA 15250-7054

Regulations Cover Food Standards, Good Manufacturing Practices and Food Additives

There are nine volumes of Title 21, but only Chapters 1 through 3 will apply to you. They cover general regulations, food standards, Good Manufacturing Practices and food additives.

Food Standards, as published in the CFR Title 21, are regulations enforced by the FDA. These standards assure consumers that all labeled products are the same. Examples of standardized food are peanut butter, ketchup, and jams and jellies. Food Standards include:

- ◆ **Standards of Identity:** The name of a product and its ingredients.
- ◆ **Standards of Quality:** The minimum standards and established specifications for specified products.
- ◆ **Fill of Container:** Defines how full the container must be and how this is measured
- ◆ **Imitation Food:** A substitute that resembles another food but is nutritionally inferior. The product must bear the label "imitation."

4) Decide Where and How You Will Commercially Process Your Specialty Food Product

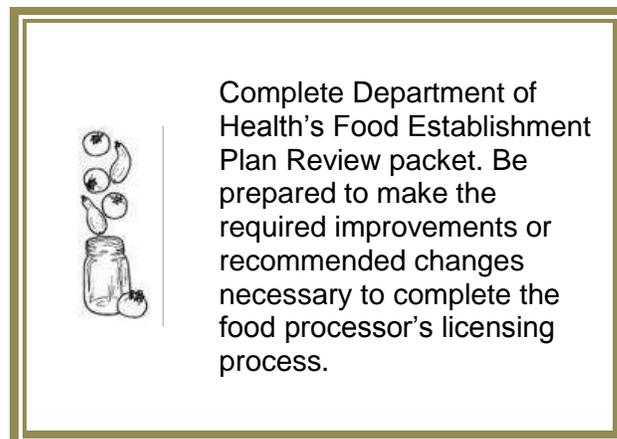
Once you have obtained your Scheduled Process documentation, you will have a better concept of the facility that will be required to process your product. When applying for a food

processing facility license, you will need to submit a detailed drawing of your plant design and a list of equipment to be used in handling and processing your product.

The Maryland Department of Health's Food Establishment Plan Review provides a step-through process to help you design and construct a facility that meets all of the state's food processing regulations and provides for the safest, and often most efficient, production of your product. A copy of the Department's "Processing Plant Plan Review General Notes" is contained in the Appendices section of this manual.

Once you have a general plan and a preliminary drawing of your facility's floor plan, contact the Department of Health and Mental Hygiene and request a "Food Establishment Plan Review" packet. The packet includes application forms and detailed requirements for construction materials, a written HACCP plan, plumbing and ventilation requirements, restrictions on sources of potable water, required food processing equipment, lighting, waste disposal requirements and more. Familiarization with the plan requirements will save you several steps in the review process. Make additions and corrections to your general plan and facility drawings based on this detailed information. A copy of this information is also available in the Appendices Section of this manual or on-line at www.dhmh.state.md.us.

Once your plan has been submitted, it will be given an initial review. You will be contacted to supply any missing information. This will prolong your review process, so make your initial submission as complete as possible.



FDA Regulations Ensure that Product Labels Meet Standards and are Not Misleading

The Food, Drug, and Cosmetic Law and the Fair Packaging and Labeling Act, were enacted to standardize product labeling. Amendments to these regulations are published annually on April 1 under Title 21 of the U.S. Code of Federal Regulations. It is the explicit responsibility of producers to stay current with any changes in product labeling policies.

Labels also serve two other functions. First, a label attracts customers to your product and persuades them to choose it over your competition. Secondly, it announces what your product is, how it is made, and its nutritional components.

The FDA offers an illustrated booklet that will answer most of the questions you might have about properly labeling your product. Contact the FDA and ask for a copy of the Food Labeling Guide at:

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, DC 20204
(202) 205-5229

or download a copy on line at
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>.

Food labeling is required for most prepared foods such as breads, cereals, canned and frozen foods, snacks, desserts, etc. Nutritional labeling for raw produce (fruits and vegetables) and fish is voluntary. The information on food labels is (1) mandatory on all processed food products; (2) provided voluntarily and worded according to regulation; or (3) can include optional information. Each of these categories is summarized in this table taken from the Virginia Cooperative Extension publication, "Starting a Food Processing Business in Virginia."

Food Labeling Requirements

MANDATORY	MANDATORY WORDING	OPTIONAL
Statement of liability	Nutritional labeling	Universal Product Code
Net quantity declaration	Grades	Open dating
Name/ address of manufacturer	Labeling for special dietary use	Registered trademarks/ symbols
Ingredient listing	Servings representations	
Manufacturing code		

Your Label Must Conform to FDA's Labeling Standards

Depending on the size of your business, your label may need to comply with federal labeling regulations and with nutritional labeling laws. To meet these standards, some statements on your label must be located in a specific location. The Principal Display Panel (PDP) is the portion of the label most prominently displayed to the customer. The Information Panel (IP) is the panel immediately to the right of the PDP. Depending on the configuration of your packaging, your IP may appear on the back of the package as well. All statements on your label must be written in English, prominently displayed, and in ordinary language that consumers can readily understand.



Certain required information must appear on the PDP or IP, as indicated below:

- ◆ The name, street address, city, state, and zip code of the manufacturer, packer, or distributor. You may also wish to list an (800) number, email address, and web page, if you have one. The street address may be omitted if the firm is currently listed in the telephone directory. If the food is not manufactured by the person or company whose name appears on the label, then the name must be qualified by "Manufactured for" or "Distributed by" or a similar statement.

- ◆ A statement of the accurate net weight of the product in the package, not including the container or any additional packaging. Net weight should include all the ingredients, including water, used in packaging the food. Net weights must be stated in both units of the U.S. Customary System (pounds) and Metric (grams) measure. The net weight must appear on the PDP in lines generally parallel to the base of the package when displayed. The type size of the net weight statement is determined as a percentage of the size of the PDP.
- ◆ The product name is the common or usual name of the food. The name should be printed at a minimum of one-half the type size of the largest print appearing on the PDP. If the product is subject to a standard of identity (such as mustard), it must meet the specific standard for those products. For example, if your product is defined as mustard on the label, it must contain mustard seeds in the ingredients.
- ◆ A list of all your ingredients in descending order by weight. Ingredients are defined as the individual foods that come together to make the final product. If an ingredient is the characterizing element of the food, such as in a fruit juice, the percent of that ingredient may be required to be part of the name of that food on the label.

While not required, many businesses also include preparation and serving instructions on their labels to better inform their customers on their products' uses. Your label can also provide additional marketing information such as how the product was made or an eye-catching slogan.

In addition, voluntary nutrition information is available for many raw foods including the 20

most frequently eaten raw fruits, vegetables, and fish, under FDA's voluntary point-of-purchase nutrition information program; and the 45 best-selling cuts of meat, under USDA's program.

Although voluntary, FDA's program for raw produce and fish carries a strong incentive for retailers to participate. The program will remain voluntary only if at least 60 percent of a nationwide sample of retailers continues to provide the necessary information. There are a number of online label services that offer fee-based nutritional analysis:

- ◆ Prime Label Consultants
<http://www.primelabel.com>
- ◆ NutriLABEL
<http://www.nutrilabel.com/>
- ◆ Nutrition and Diet Services,
<http://nutrition-dietservices.com>
- ◆ NutriCoster
<http://www.sweetware.com>

FDA Allows Certain Exemptions for Nutritional Labeling, Particularly for Products Made by Small Businesses

The following is taken from the guidance document for the Nutritional Labeling and Education Act (NLEA), and is available on the Web at:

<http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>

Under NLEA, some foods are exempt from nutrition labeling. These include:

- ◆ Food served for immediate consumption, such as in hospital cafeterias and airplanes, and products sold by foodservice vendors;

for example, mall cookie counters, sidewalk vendors, and vending machines;

- ◆ Ready-to-eat food that is not for immediate consumption but is prepared primarily on site; for example, bakery, deli, and candy store items;
- ◆ Food shipped in bulk, as long as it is not for sale in that form to consumers;
- ◆ Medical foods, such as those used to address the nutritional needs of patients with certain diseases; and
- ◆ Plain coffee and tea, some spices, and other foods that contain no significant amounts of any nutrients.

Food produced by small businesses also may be exempt, under 1993 amendments to the NLEA. Businesses with fewer than 100 full-time equivalent employees may claim an exemption for food products that have U.S. sales of fewer than 100,000 units annually. Almost all companies seeking an exemption will have to notify the FDA that they meet the criteria. Those that do not have to notify the FDA are U.S. companies with fewer than 10 employees making fewer than 10,000 units of product a year. Also exempt are retailers with annual U.S. gross sales of less than \$500,000 or with annual U.S. gross sales of food of less than \$50,000.

Although certain foods may be exempt, they are free to carry nutritional information, when appropriate, as long as it complies with regulations. Nutritional information about game meats—such as deer, bison, rabbit, quail, wild turkey, and ostrich—is not required on individual packages. Instead, it can be given on counter cards, signs, or other point-of-purchase materials. Because few nutrient data exist for these foods, the FDA believes that allowing this option will enable game meat producers to give

first priority to collecting appropriate data and will make it easier for them to update the information as it becomes available.

Even though your product may not need a nutritional label, many retail outlets require labeling. Moreover, labels can be a helpful marketing tool since they provide information about your product and make it appear more professional.

Three Claims Can be Used on Foods and Dietary Supplement Labels

The three categories are:

- ◆ Health claims
- ◆ Structure/function claims
- ◆ Nutrient content claims

The responsibility for ensuring the validity of these claims rests with the manufacturer, the FDA, or in the case of advertising, with the Federal Trade Commission. A detailed discussion of the “Claims that Can Be Made for Conventional Food and Dietary Supplements” is available on the Web at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

A food claim is often made by the manufacturer on the front of the package - for example, "low fat" or "no cholesterol." The FDA only allows claims on labels that are supported by scientific evidence. Claims may indicate lower cholesterol content, lower-sodium products, and low-fat or fat-free foods, but must meet specific FDA regulations. For example:

- ◆ **Reduced fat** has 25% less fat than the same regular brand;
- ◆ **Light** means the product has 50% less fat than the same regular product;

- ◆ **Low fat** means a product has 3 grams of fat per serving of 2 tablespoons.

Major Component of Quality Control System Should be a System for Coding Food Products

Your product should be identifiable by manufacturer, by the year and day it was packed, and by the batch number, if more than one batch is processed per day. If it is processed in more than one processing facility, that must also be identified in the product code.

It is imperative that these codes are recorded on distribution invoices so the product can be recalled promptly if there is a problem. All cases and individual containers must be coded. The coded lots should be small enough to enable easy identification during sales and distribution.

These codes are not specified or regulated. They should be recognizable by the processor and usually include a combination of the production date and batch number. Alphabetical letters are often used to identify the month a product was packed. Julian dates are used to indicate the manufacture date. An example of a code is "001F022," where "001" indicates the first day of the year; "F" is the month (February); "02" is the year packed; and 2 for the second batch run that day. Accurate records of these codes allow processors to trace the cause of consumer complaints, control distribution and inventory, ensure proper product rotation and conduct a recall if necessary.

Product coding provides a management tool for food manufacturers but does not indicate to the consumer any information about the freshness or quality of the product. To help consumers judge the freshness and quality of product,

manufacturers often print the "sell by" and "best if used by" dates clearly and prominently on their package.

According to the National Food Processors Association, the "**sell by**" date is the **last date** the product may be sold. After that date, the product **should not** be on store shelves. Most "sell by" dates are found on **short shelf-life products** such as bakery items, meat and poultry, and milk.

Products with a "sell by" date are likely to be safe for some time after that date. However, consumers **should not purchase** any products **AFTER** the "sell by" date. The same applies to products with phrases such as "expiration," "use by," and "use before."

The "**best if used by**," "**best before**" and "**best if used before**" are dates that tell consumers how long the product will retain its best flavor or quality. These dates are related to quality, not safety. **The product poses no health risks** if it is consumed after the "best if used by" date. The food is still safe to eat after the date, however, it may have become stale, changed in taste and appearance, or have a lesser vitamin content than declared on the label.

Products Sold Through Distributors, Retailers or Major Retail Stores Require UPC Codes

How does a barcode work?

A barcode essentially is a way to encode information in a visual pattern that a machine can read. The combination of black and white bars (elements) represents different text characters which follows a set algorithm for that barcode type. If you change the sequence of elements, you get different text. A barcode scanner reads this pattern of black and white

that is then turned into a line of text your computer can understand.

What is a UPC barcode?

You are probably familiar with the barcodes you see on most packaged products. These barcodes are in the UPC-A code format. It is 12 digits long and looks something like this:



Do I need a UPC number?

If you sell products to a distributor or a retailer, you typically will need a UPC barcode. If you are not sure, it is best to contact the company selling your product to find out their policy on UPC barcodes. When you obtain your UPC number, you will also get a certificate authenticating your number. Most retailers require proof of the certificate to verify that your number is unique and authorized.

Usage	UPC needed?
Tracking internal inventory	No
Selling products directly to customers	No
Selling products through a distributor or retailer	Most of the time (Contact your distributor or retailer to be sure)
Selling products through a major national store	Always

How Do I Get a UPS barcode?

- ◆ Getting a Universal Product Code (UPC) means first joining a group to get assigned a unique identification number.
- ◆ Membership can be pricey — an initial fee of least \$750 and at least \$150 annually.
- ◆ Save money by using a UPC code reseller, but if you're selling through major retailers, this isn't an option.

Source: <http://www.barcodesinc.com/faq/>

Packaging is Key to Attracting Customers

In his book *From Kitchen to Market*, Stephen F. Hall states, “Packaging is the single most important element in the consumer’s decision to purchase a new specialty food product.” (p.52). Other factors such as price, coupons, convenience, recipes included, and advertising also influence purchasing decisions, but packaging is the first thing consumers see of your product.

Components of a successful package are packaging materials, size, color and graphics. Visit gourmet shops, gifts shops and specialty food shows to see examples of great packaging. The International Fancy Food and Confection Show features a special display called “Focused Exhibits.” This display offers an excellent opportunity to compare packaging styles and to do some cost-comparison shopping for prices and suppliers.

The packaging you select will depend on your product. Containers come in a variety of shapes and sizes, but at least when just starting out, consider choosing from containers that are readily available. Then, if you change your mind later and change your packaging, you’re not stuck with an inventory of unusable containers. Odd-shaped containers can also be difficult for storeowners to stock on standard-sized store

shelves. If you plan to direct market your product at farmers' markets or through mail order where stacking is not an issue, then an odd-shaped container, such a bear shape for honey, can add to your product's appeal.

Containers that are both attractive and affordable are available in glass, metal, cellophane, plastic, and cardboard. The packaging you select will depend on your product. Be sure the container's food contact surface is "food grade" quality. It is best to purchase your containers from distributors specializing in approved food-grade materials. When choosing your container size, consider consumer demand and salable quantity.

Different types of packaging materials have different advantages. Glass containers are used because the product can be seen and there is no tin taste. Examples of products that are often sold in glass containers include condiments, sauces, dressings, jams and jellies, juices and confections.

Canned products include such items as syrup, soup, pate, loose tea, coffee, spices, and nuts. Consumers tend to prefer products in jars rather than cans. Cans are slowly being taken over by a new technology called "aseptic packaging." It is currently being used with fruit juices, coffee creams, puddings, and yogurt. Products in aseptic packaging require less shelf space and are cheaper to transport because they weigh less.

Whether You Produce 20 or 1000 Jars of Product, You Will Need Specialized Equipment to Meet Commercial Food Processor's Licensing Requirements

In the start-up phase of your business, your production process probably will be very labor intensive, but affordable for small volumes. As demand for your product increases, you will

need to gear up your production with equipment that improves your production efficiency, maintains product quality, and meets health and safety regulations.

When purchasing processing equipment, consider the production and sales goals you listed in your business plan. Low-volume production, less than 40 pounds/day (5 gallons), can be done manually. Food service volume, 50 to 150 pounds/day (10 to 25 gallons), requires restaurant and cafeteria-type equipment. Producing more than 200 pounds/day (25 gallons,) requires small-scale food processing equipment. This is specialized equipment and can be hard to locate. Expect to pay hundreds to thousands for this equipment.

Be Sure to Ask Questions When Purchasing Equipment

Your processing equipment is a major financial investment and is vital to the success of your food business. Invest some time determining your equipment needs, learning the standards used to rate different pieces of equipment, and researching the reputation of different manufacturers and dealers before you start making equipment purchases.

When contacting a company, specify the function and capacity a specific piece of equipment must serve. Discuss the power requirements for each piece in detail (electrical voltage and phase, gas flow needs, volume of air required, etc.) Be sure to ask:

- ◆ Is the equipment made from material rated USDA/FDA food grade?
- ◆ Who is responsible for shipping charges for the equipment?
- ◆ Who is responsible for insurance charges while in transit?

- ◆ What does the warranty on the equipment cover?
- ◆ Do you have the right of refusal upon delivery of unacceptable equipment?
- ◆ Is handling equipment, such as a forklift, necessary upon delivery?
- ◆ Who is responsible for unloading the equipment?

Equipment Needs are Based on Audited Process and the Product Being Produced

The following is a list of equipment often required by small-scale food processors.

Preparation Equipment:

Cutter, grinders, slicers - basically large food processors. Continuous feed is preferred, stainless steel or plastic food contact parts, FDA and/or USDA approved for food, at least ½ horsepower.

Mixers - dough mixers from 12 to 140 quarts.

Pulper/finisher - purees fruits or vegetables and separates seeds and skin.

Juice extractors - squeezing action

Peeler - typical potato peeler

◆ Heating/Cooking Equipment:

Kettles - steam kettles are available from 0.5 to 200+ gallons. Preferable options include 316 stainless steel, tilting, bottom discharge with valve, and

agitator.

Continuous pasteurizers - rated by flow = gallons per minute.

Ovens- for baking and roasting. Forced convection is faster.

Fryers - 10 to 40 gallon capacity is typical.

◆ Cooling Equipment:

Refrigerators - good temperature control is critical. Built-in temperature indicator preferred.

Freezer - blast freezer for quick chilling gives best quality, but is more expensive than a conventional unit.

◆ Filling/Packaging Equipment:

Dry products - usually filled by weight manually or with auger type fillers.

Wet products - filled by volume or weight with a variety of fillers based on product consistency. Capacity is given by the flow rate or containers per minute.

Bag sealers - different types are available including manual, form-fill-seal, gas flushed, and vacuum sealers.

Tray/cup sealers - lid or film is heat-sealed to container. Can be done manually or fully automated.

Steam or vacuum cappers - normally used for glass jars to decrease oxygen in headspace and to provide vacuum.

The Northeast Center for Food Entrepreneurship publication, "Small Scale Food Entrepreneurship: A Technical Guide for Food Ventures" (p.84) lists these points to consider before making your final decision to purchase any processing equipment:

- ◆ Your volume must justify the equipment.
- ◆ Determine the most important steps that limit your production.
- ◆ Determine capacity needed in volume per unit of time.
- ◆ New vs. used, warranty, condition, spare parts/service, lease option.
- ◆ Make sure equipment meets FDA and/or USDA requirements. Check materials and design.
- ◆ Make sure equipment is easy to clean and service.
- ◆ Consider renting space in an established kitchen and complement with your own equipment.
- ◆ Get at least three quotes for the same type of equipment.
- ◆ Stay alert for auctions.



Determine what equipment and supplies you will need and how much they will cost. Determine if you can save some money by buying secondhand equipment in the proper condition.

Co-packers Can Produce, Package, Store and Distribute Your Product According to Your Recipe and Specifications

Co-packers manufacture and package foods. They may process foods for other people and/or may be in business with their own lines. Utilizing a co-packer will allow you to devote more time to management and marketing, while eliminating the expense and responsibility of operating a production facility.

Contracting with a co-packer to produce your product can:

- ◆ Reduce start-up costs;
- ◆ Allow you to more accurately predict overhead costs due to manufacturing;
- ◆ Provide professional assistance in formulating your product;
- ◆ Provide you the opportunity to test produce and market your product before you launch into a full-scale production operation.

Remember that there is a labeling requirement on products that have been co-packed. When the food is not manufactured by the person whose name appears on the label, the name must be qualified by the phrase that reveals the connection the person has with the product: such as "Manufactured for" or "Distributed by," or any words that express the facts.

You Might Need a Co-packer to Help You Reach Income Goals

People don't really consider the number of employees or family members they'll need to run their business. New processors get so busy making their product that they have no time to market it. The orders start increasing and they start trying to make more than they and their

limited help are capable of doing. Then, the quality and consistency of their product starts to decline. No time to market and declining product quality is a combination that will soon put you out of business.

If you're reluctant to get a co-packer involved in your operation, take this test:

- Ask yourself how much money you want to take out of your business annually.
- Calculate your total cost of production, including marketing and distribution.
- Determine how many units of product you'll need to produce and sell to cover those costs and take out your target income.
- If you can't produce that much product on your own, then you'll need to (1) increase your prices; (2) lower your production costs; or (3) do both.

A co-packer can help you do both.

There are Advantages and Disadvantages of Working with a Co-packer

Your co-packer becomes your business partner. You are entrusting the co-packer with your good name, the quality of your product, and much of the success of your specialty food processing business. Look for a co-packer that has experience in processing your type of products. The processing skills necessary to safely process acidified foods, such as barbecue sauces, are different than the skills needed to process high-sugar-content products like jellies. While your co-packer becomes your business partner, he is not your banker. Most co-packers will request payment in advance of your product run.

Advantages of Working with a Co-packer

You can contract with a co-packer to produce, package, store and distribute your product according to your recipe and specifications.

1. Co-packers have extensive experience in the food processing business. They are familiar with county, state and federal food safety regulations and are well versed in HACCP requirements. They work with food safety regulators on a regular basis and understand their requirements and procedures. Co-packers are also familiar with current food safety testing requirements and can assist you with having your product tested at a certified foods testing laboratory.
2. Their knowledge of food science helps them evaluate your product and your production process to determine if your product is safe. They can make processing recommendations that can help safely stabilize your product, improve its appearance and texture, or extend its shelf life. Even when working with a co-packer, small foods processors should educate themselves about the chemical characteristics of their products, including pH, water activity, and acidity traits.
3. Working with a co-packer can significantly lower your per-unit production costs. Co-packers purchase all their inputs in bulk. For example, you may need to purchase 400 jars for your production run. Co-packers order the same jars in lots of 10,000 and can command a much better wholesale price than your small volume order. A co-packer also has a delivery dock and warehouse space for receiving and storing bulk quantities of glassware and ingredients.
4. Since co-packers operate large capacity cooking and pouring equipment, they can fill jars or bottles faster than most labor-intensive small processors. This eliminates differences in cooking times and

temperature fluctuations from the time pouring starts until the last container is filled. Faster filling helps produce better product consistency, texture, and quality.

5. Co-packers can guide your recipe expansion process. Based on their knowledge and working experience, they can make recommendations for both percentages of ingredients and any additions or deletions of stabilizers, emulsifiers, or preservatives that may be needed to expand your four-dozen batch recipe for the best homemade cookies ever, into a four hundred dozen batch recipe.
6. Many co-packers can assist you with marketing and distributing your product. They often attend specialty food trade shows and have established distribution channels that are beyond your current reach. Sharing booth space with your co-packer at a fancy food show can be a very cost-effective way to reach a large target audience for your product. A co-packer who is willing to store your product after production and then ship it directly to your buyers can help you lower your distribution costs significantly.

Disadvantages of Working with a Co-packer

1. Most co-packers will not do exactly what you want, the way you want it done. They will not stir your secret sauce for only x number of times or position the product in some unique fashion in the jar or bottle.
2. You are at the mercy of the co-packer's production schedule, fixed costs and methods of doing business. In some cases, the co-packer may be producing a competing product.
3. Using a co-packer may not be cost effective for your product if you want to produce less

than 400 pints of product total. In addition to the ingredients and containers, co-packers charge by the hour for production time. This charge includes set-up, production, filling, and tear-down time. While production and filling time are directly proportional to the number of units produced, set-up and tear-down time is the same for producing 400 or 40,000 units of product.

4. Disagreements between customers and co-packers are not easily resolved. Disputes and litigation can be expensive. Finding an alternative co-packer who can produce the same product can be difficult.
5. Finding a good co-packer to work with can be challenging. The best source of information about co-packers, their abilities, and how they work with specialty food entrepreneurs, is often other entrepreneurs. The National Association of Specialty Food Processors maintains a list of co-packers by geographical area. Specialized co-packers will often advertise in food trade periodicals and directories. State Directories of Manufacturers and State Departments of Public Health often have a list of local food co-packers.

Before Choosing a Co-packer, Do Your Homework

Your business and marketing plans should outline your product needs, including container size, the number of units needed in a given period, your wholesale and retail prices, and your product distribution plans. You should already have written specifications for ingredients, packaging materials, regulatory compliance, and finished product.

Conversely, there may be several questions that a co-packer will ask you to determine if he/she can manufacture your product safely and profitably.

Questions You Should Ask a Co-packer

1. Can your co-packer produce your product and produce it when you need it? The last quarter of the year is a very busy time for co-packers. If Christmas is your peak sales season, be sure your co-packer can meet your product demands. The first quarter of the year is traditionally a slower production time for many co-packers. Some co-packers even offer lower fees during these slack periods.
2. Can you watch at least the first batch being made? Some processors don't appreciate an audience. Others are happy to allow you to watch not only the first process run, but other runs as well.
3. What are your cost variants? What different prices do you charge for ingredients, types of bottles, type of closures, seasonal produce and does the number of runs you plan to make have any bearing on your costs?
4. Ask your co-packer to sign a confidentiality agreement with you before discussing your recipe. Reputable co-packers sign confidentiality agreements that will guarantee you retain ownership of your recipe. Next, send the co-packer a copy of your recipe to review. Then visit the facility and bring along enough ingredients to make a stove-top batch of your product there. Knowledgeable co-packers can advise you on what additional ingredients or additives you need in your recipe to aid in product homogenization, to extend its shelf life, or to improve its appearance.
5. Do you have product liability insurance? Co-packers usually carry product liability insurance at the rate of \$3 million dollars per incident. Many are now increasing their coverage to \$10 million per incident. Ask to see a copy of their insurance coverage. However, as the business owner selling the product, you will still need to have your own product liability coverage.
6. Ask to see the co-packer's county, state, and federal food processing licenses and proof of their facility's current inspection status.
7. Ask how long the co-packer has been in business and how much experience does he/she have in processing products similar to yours?
8. Will he/she keep your product proprietary?
9. How long can you leave product in the warehouse?
10. How will he/she pack your product; four or six cases to a pack?
11. Can you pull sample jars from the production run?
12. How much will the co-packer charge for a quote? Most co-packers don't like to give free quotes.



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Questions a Co-packer Might Ask You

1. Have you had your product tested? Product testing should be done in a certified testing laboratory. Depending on the analyses performed, expect to invest \$300 to \$4,300 in product testing.
2. Have you put this product on the market before and have you worked with a co-packer before?
3. What type of container do you want for your product?
4. Do you need product warehousing and what additional services, such as drop shipping, will you need?
5. Is your label legal? Co-packers can guide you through the process of designing a label that meets all federal and state requirements.
6. Will you need help with marketing and distributing your product?
7. Do you have product liability insurance? Co-packers carry liability insurance, but will also expect you to have your own coverage.
8. How much product will you need? Don't overestimate your production. Don't tell the co-packer you plan to process \$500,000 worth of product when you really will only need \$50,000 worth.
9. How much product do you want the co-packer to produce each run? Most co-

packers have a 400-pint minimum run requirement.

A Written Contract Will Help You Avoid Problems

Once you are satisfied that the co-packer will manufacture your product adequately in both the quantity and quality you want, develop a written contract for services to be rendered.

Be sure you understand the terms of the contract. Have an attorney examine the contract before you sign it.

Dr. John E. Rushing, North Carolina State University Department of Food Science, encourages processors to address the following concerns, at a minimum, when contracting with a co-packer:

- ◆ What are the services you are contracting for? Who will handle raw product testing? Where will records be kept? How will final product quality be checked?
- ◆ What ingredients and supplies are you responsible for purchasing or providing?
- ◆ How does the co-packer dispose of excess ingredients or supplies you purchase or furnish? Where will they be stored between processing runs?
- ◆ What processing manipulations will be required for ingredients, such as slicing, dicing, or blanching? Are piece sizes specified?
- ◆ Will there be samples furnished for your approval prior to the first production run? Will there be storage/stability or finished product tests?

- ◆ Will you be present and consulted during processing plant runs? If so, are you covered under insurance or Workmen's Compensation?
- ◆ Will you have any coverage under the manufacturer's product liability insurance? If so, what will it be? Note that it will be necessary for you to furnish your own liability insurance to sell your product to stores.
- ◆ What are the critical factors that must be met in processing, such as pH, packing temperatures, or heat processing? Are ingredient substitutions accepted?
- ◆ What are the limits? Are these covered in your ingredient specifications?
- ◆ The contract should note scheduled processes that must be filed and certifications that must be obtained.
- ◆ What is the delivery date of the finished product? Must it be immediately removed from the premises?
- ◆ What are the payment terms?
- ◆ What will render the product unacceptable? What are the appearance factors such as color, separation, piece size, and texture? Who will judge adequacy of flavor and taste?
- ◆ What are the appearance factors for the container, such as label placement, closure gasket materials and closure color, or neckband placement, size and color? How tight is the closure to be?
- ◆ Who is responsible for disposal and disposal costs or rework of unacceptable product?
- ◆ The entrepreneur should furnish labels.
- ◆ How much lead time is necessary for the production run to be delivered?
- ◆ Will the co-packer be required to furnish grade certifications, third party, or other certifications of lots and batches?
- ◆ The co-packer should certify that the label statements are accurate.
- ◆ What lot or batch coding is to be used?
- ◆ What is the manufacturer's recall plan? Be sure you have a copy.
- ◆ Is there a non-compete agreement with the co-packer?
- ◆ Are confidentiality and privacy issues covered?
- ◆ What finished product testing will be provided?

While there may be many other points to be covered in the contract, the above represents those points for which many disagreements.

Use this Checklist to Help Guide You through the Process of Turning Out Your Product

- Develop your product.
- Get assistance up-scaling your recipe and developing a certified process that complies with food safety regulations.
- Submit your processing plan and preliminary facility floor plan drawing to the

Maryland Department of Health and Mental Hygiene for review.

- Learn about food safety.
- Develop a logo for your product and other graphic promotional material.
- Determine the amount and size of processing equipment your operation will require.
- Consider contracting with a co-packer to make your product.

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