Food and Drug Branch

Industry Assistance
Need to Know Information for Safer Food Process

The California Department of Public Health (CDPH), Food and Drug Branch (FDB) is a regulatory agency with a primary focus on food safety and security. Our main program objective is the protection of the public from unnecessary risk of illness, injury, and death from exposure to unsafe foods. FDB offers information on food safety laws, regulations and guidelines established for the safe preparation of food. FDB does not provide financing or business tips for starting up and maintaining a business. For general food safety information resource links are also provided.

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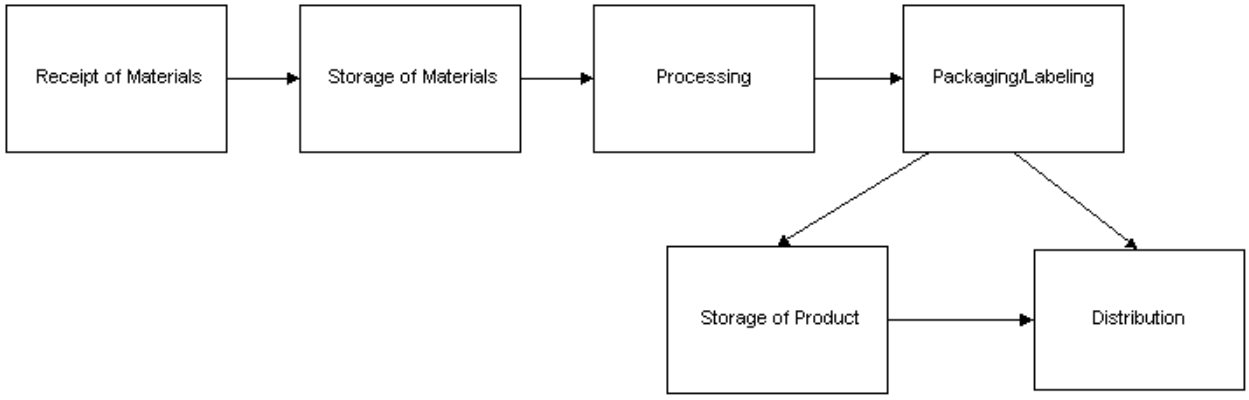
Introduction to Food Safety

So, you think you have a food recipe that the whole world wants and you are considering marketing it. If so, then this guide will provide you with essential information, laws, regulations, and guidelines for starting a food processing business. Starting a food processing business is not simple. It is time consuming, costly, and most of all, it requires careful planning, dedication and skilled management to be successful. The food business is unique as compared to other types of businesses. Your food products have a direct effect on your customer's health and safety. Foods that are improperly processed, or contaminated could have the potential to cause serious illness or even death. So, it is vital to establish strict safety rules and practices. Doing so not only enables your business to comply with laws and regulations, but it also adds to the reputation of your business for producing the most clean and safest food.

Food Safety

Beside drugs, food is the substance that we put directly into our bodies and it has the potential to cause great harm or even death if contaminated with food-borne pathogens, chemicals, radiological, or physical agents. The Center for Disease Control and Prevention (CDC) estimates that food-borne disease causes 76 million illnesses and 5,000 deaths in the United States annually. Food can be contaminated at any stage of production, from raw materials to finished products. Fresh meat, fish, eggs, and dairy products may be contaminated with food-borne pathogens; ingredients can support microbial growth; fresh fruit and vegetables may be surface contaminated with bacteria, parasites, viruses and/or mold. For this reason both the finished product as well as the ingredients must meet quality standards. They must be stored at proper temperatures to minimize the growth of microorganisms; processed to the recommended time and temperature to kill food-borne pathogens, and bacteria; packaged in clean containers and under conditions that minimize contamination and they must be properly stored until shipping to preserve product quality.

Basic Flow Diagram:



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Laws, Regulations, Voluntary Programs

Federal, state, and local agencies share responsibility for ensuring that food processors follow food safety laws. The goal of all of these laws is to protect the public by ensuring that food processors produce safe food. Laws and regulations are legal requirements that must be followed. "Prerequisite Programs" is the term used to describe a range of programs that enhance operational conditions and provide a foundation for food safety programs. Examples of such prerequisite programs are Good Manufacturing Practices (GMP), Standard Operating Procedures (SOP), and Sanitation Standard Operating Procedures (SSOP). Why are prerequisite programs important? Prerequisite programs, when properly followed, help keep small problems from becoming serious problems that could eventually have an impact on food safety. Voluntary programs are completely voluntary and in many cases are developed by the food industry associations to provide guidance for their members.

Local, state and federal public health agencies may inspect food-processing facilities. Federal agencies such as the FDA have jurisdiction over products in interstate commerce that is; products that move or have moved across state lines. State agencies have jurisdiction over food produced, distributed and consumed in the state. State regulators may adopt federal requirements as their own state laws. Some states may adopt requirements that must be met in addition to federal requirements. Food processing operations must comply with all existing state and federal laws and regulations that apply to food establishments.

To view the California Health and Safety Code, Division 104, Part 5, "Sherman Food, Drug, and Cosmetic Laws", click on the link below:

Sherman Food, Drug, and Cosmetic Law

"The Act"

The first of these laws is the Federal Food, Drug, and Cosmetic Act which is sometimes referred to as the "F D & C Act" or simply "The Act". The Act is one of the main legal authorities for food inspection in the United States. The Act was enacted to protect public health.

The Act prohibits the interstate shipment of adulterated food, which includes any food containing a pathogen (an organism that can cause disease) such as Salmonella, E. coli O157:H7, or any other harmful substance. Foods that are spoiled or that are prepared using spoiled food or foods that are contaminated by insects, rodents, or other types of filth are also considered to be adulterated. High quality food prepared or stored under insanitary conditions, such as in a dirty environment, or handled by workers with poor personal hygiene, is also adulterated. When food is adulterated, regulatory agencies have procedures that they follow. In some cases they may ask the firm to voluntarily correct the problem. Sometimes the agency may send a warning letter to the firm. In other cases the adulterated food may be removed from commerce through the courts. Finally, in serious cases the regulators may file an injunction to stop the firm from producing adulterated food or they may initiate a criminal prosecution of the responsible persons, typically the manager and owner of the firm.

To view the entire Federal Food, Drug, and Cosmetic Act, click on the following link:

http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

Good Manufacturing Practices (GMP)

GMP are regulations that describe how food processing plants should be designed and run to ensure food safety. GMP regulations for food production and storage facilities can be found in the Code of Federal Regulations, Title 21, Part 110 "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food". The GMP were designed to ensure that processed food is produced under conditions that meet minimum food safety standards. GMP are a system that you can incorporate into your daily operation to ensure the safety of your product from receiving of ingredients to distribution. The standards were developed with input from the public, including the food industry.

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (pdf)

Voluntary Programs

As mentioned previously, once GMP and Prerequisite Programs are in place, processors can develop additional food safety programs such as HACCP. HACCP (pronounced as "hassip.") H-A-C-C-P, is an acronym that stands for "Hazard Analysis and Critical Control Point". This concept is an important part of a food safety program because it builds upon the use of GMP and prerequisite programs and focuses on prevention of food safety problems. HACCP is a tool for managers and line workers to evaluate each of the firm's operations from receiving to distribution. In HACCP, the biological, chemical, and physical hazards that are associated with each operation are identified. After identifying the hazards, Critical Control Points (CCPs) are identified. CCPs are those points in the processing where controls can be applied and where loss of control would lead to a food safety problem. Therefore, a process is put in place for each CCP to make sure that food safety problems do not occur. The process is then monitored frequently to ensure that all aspects of the product process at the CCP are in control. HACCP programs are a mandatory part of juice, meat, poultry, and seafood production, but HACCP is not currently required for all processed food products. Just as one cannot sanitize without first cleaning, HACCP cannot be properly planned and implemented without a strong foundation of GMP and prerequisite programs.

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Employee Health and Hygiene

People can carry pathogens on their skin, in their hair, on their hands, and in their digestive system or respiratory tract. Infected food workers who handle food products and have poor personal hygiene are an important cause of food contamination and foodborne illness outbreaks. Under current GMP, everyone working in direct contact with food, food-contact surfaces, and food-packaging materials should use good hygienic practices to protect against contamination of the food.

Personal hygiene begins at home. This includes daily bathing, washing hair and wearing clean clothes. Personal hygiene continues at the plant by wearing clean smocks, hairnets, and clean gloves, where appropriate.

Hand Washing

Human hands are used for more than just handling food products. They are used to greet others, to comb hair, to eat, to scratch, and to handle unsanitary objects, and they are used when using the toilet. During these activities, hands may become contaminated with harmful microorganisms and in some cases harmful chemical substances. These microorganisms or chemicals can be transferred to food or food-contact surfaces if hands are not washed thoroughly.

Employees should know when and how to properly wash their hands. Fingernails should be trimmed, and maintained so that hand washing will effectively remove soil from under and around them. Polished or painted fingernails should be adequately cleaned and gloves should be worn.

Hands should always be washed:

- before food preparation,
- after touching human body parts,
- after using the toilet,
- after coughing, sneezing, using a handkerchief or tissue,
- after using tobacco, eating, or drinking,
- after engaging in any activity that may contaminate the hands such as taking out the garbage, handling cleaning chemicals, or picking up dropped items,
- after caring for or touching animals,
- before returning to the workstation, regardless of the reason for leaving the station.

Improper hand washing is as dangerous as not washing hands at all. Thorough hand washing is important in preventing illness. Employees should follow these steps to properly wash hands:

- wet hands with warm running water,
- apply a liberal amount of soap to the hands,
- scrub the surface of the hands, wrists, and forearms vigorously for at least 20 seconds (many microorganisms can be removed by friction alone)
- scrub the areas in between the fingers, under nails,

- wash the fingertips,
- rinse hands under clean, warm running water,
- dry with a clean, disposable towel.

Conveniently located and properly equipped hand washing facilities are one key to getting employees to wash their hands. Hand washing stations should be located in or adjacent to restrooms and should also be located in food processing areas. Hand washing stations should be clean and well maintained and should not be used for purposes other than hand washing. Hand washing stations should be equipped with hot and cold running water under pressure, a supply of soap, and disposable, single use towels. Warm water is recommended because cold water does not remove oils on the hands that may harbor microorganisms. Individual disposable towels are more sanitary than cloth towels for drying hands and are the preferred hand-drying devices. Adequate waste containers should be supplied for used towels.

Education and training programs should be designed to help employees involved in food processing understand what is expected of them and why it is important. Company expectations for proper hygiene and hand washing procedures should be clearly defined in pre-employment and periodic training programs. New employees should receive training prior to beginning employment, even if it takes considerable time and effort. Principles of personal hygiene and sanitation should be periodically reviewed with all employees. Prominently placed signs or posters are a good reminder.

Hygiene

Clothing worn by employees in food processing and production areas should be kept clean. Dirty and soiled clothes can be a source of contamination of food products. Clean uniforms, aprons, or other outer garments that are put on after the employee gets to work can help to minimize contamination from sources outside the processing facility. Clothing, food for meals or snacks, or other personal belongings should be stored in lockers or break room areas that are located away from processing areas or areas where equipment or utensils are washed.

Hair in food can be a source of both microbiological and physical contamination. Food workers should be encouraged to keep their hair clean and must wear appropriate hair and/or beard restraints at all times in food processing areas to prevent contamination of the finished products.

Under current GMP, rings, bracelets, necklaces, earrings, watches, and other body part ornaments should not be worn because they can harbor microorganisms that can cause foodborne illness. Jewelry can also fall into food causing a physical hazard. Jewelry should be removed prior to entering the processing facility.

Employees should eat food, chew gum, drink beverages, or use tobacco only in designated areas away from food or food-packaging materials or where equipment or utensils are washed. Healthy people can frequently harbor pathogens in their mouth and respiratory tract. Pathogens can move to employees' hands and then to the food products that they are processing when hand-to-mouth contact occurs. Hands should be washed every time an employee returns to work.

Perspiration may contaminate the food, food-contact surfaces, hands, and clothing. Wiping a sweaty brow with a cloth or hand introduces potential contamination. Ideally, the processing facility should be maintained at cool temperatures to minimize perspiration.

Diarrhea or open lesions are also a source of pathogens. Any employee with symptoms associated with acute gastrointestinal illness such as vomiting, diarrhea, fever, or jaundice should be prohibited from working with food. Company policy should encourage employees to report illnesses to their supervisor, so that the employee may be reassigned to a job that does not require contact with food.

Employees diagnosed with Salmonella Typhi, Shigella, E. coli O157:H7, or hepatitis A should not perform jobs that require contact with food or food-contact surfaces until a doctor determines that they are disease free. All of these diseases are easily transferred to foods and are considered severe health hazards.

Exposed areas of arms, wrists, and forearms that contain infected wounds should be completely covered by a dry, tight-fitting, impermeable bandage. Cuts or burns on the food worker's hands should be thoroughly bandaged, and covered with a clean glove. Food workers should minimize hand contact with processed food products. Use suitable utensils such as tongs, spatulas, or single-use gloves where possible. Single-use gloves are frequently used to avoid direct hand contact, but gloves may create a false sense of security for food processing workers.

Gloves and Dips

Dirty gloves, like dirty hands, can contaminate products. Single-use gloves should never be washed; they should always be thrown away when they need to be changed. An employee should put on fresh gloves only after thoroughly washing his/her hands. Employees should use sanitizer hand-dips frequently to reduce recontamination while on the processing line but not to replace handwashing.

Employees should understand the importance of maintaining clean gloves. Single-use gloves should be changed after any activity that may contaminate them. In other words, single-use gloves should be changed as often as needed and for the same reasons an employee would wash their bare hands.

If non-disposable gloves such as rubber gloves are used in the facility they should be washed as frequently as bare hands. Hands should be washed before and after putting on non-disposable gloves.

Hand or glove dips also may be considered. Sanitizers designed for this purpose can be obtained from sanitation supply companies and should be prepared according to the label instructions. The sanitizing solution should be monitored frequently to ensure the proper concentration is maintained. Hand or glove dips are only appropriate for use with clean hands or clean gloves. These dips are not a substitute for proper hand washing.

Boot dips are sometimes used to sanitize the bottom of boots or shoes when an employee moves from one part of the facility to another. When properly maintained, boot dips can reduce the spread of microorganisms throughout a facility. However, the sanitizing solution in boot dips can easily become depleted. The sanitizer concentrations should be tested frequently to ensure effectiveness.

Toilet Facilities

Toilet facilities are required for all employees. Employee restrooms should be conveniently located and accessible to employees during all hours of operation. Smocks and gloves should be left in the designated processing area and not worn into restrooms or breakrooms. Toilet facilities near work areas promote good personal hygiene, reduce lost productivity, and permit closer supervision of employees. Materials used in the construction of toilet rooms and toilet

fixtures should be durable and easily cleanable. The floors, walls and fixtures in toilet areas should be clean and well maintained. Toilet tissue and disposable paper towels should be supplied along with easy-to-clean containers for waste materials. Automatically actuated toilet flushing systems and sinks will reduce the frequency of touching and additional hand contact before leaving the facilities.

Poor sanitation in toilet areas can spread disease. Dirty toilet facilities also have a negative effect on the attitudes and work habits of the employees. These areas should be included in the routine cleaning program to assure they are kept clean and in good repair. Food or food packaging materials should never be stored in restroom areas.

Employee Training and Management's Role

Managers play a very important role in helping their employees prevent contamination of food products, such as providing health and hygiene training programs for employees. Managers should provide a clear understanding of the proper personal hygiene practices and company policies regarding illness and other health conditions, such as infected wounds that could contaminate products. Policies should provide reassurance that employees will not lose their jobs if they report an illness or a communicable disease.

Management should continually emphasize how important it is for employees to maintain a high level of cleanliness and good health and should serve as role models for good work habits and acceptable hygienic practices. They should also ensure that visitors are required to follow the same hygienic practices as employees, and have policies in place that prevent unauthorized personnel from being in food processing areas.

Adequate training is very important and should be documented. As part of the GMP, it is advisable to have a written training plan for employees that include procedures and documentation of training activities. It should cover topics on proper food handling, food protection, and concepts on how insanitary practices and poor personal hygiene can lead to consumer and employee illnesses. Once employees understand what is expected of them, effective supervision of employee practices in food processing areas should be used to ensure that employees follow proper procedures. Training should be reviewed whenever incorrect practices are observed.

Employees are more likely to follow good personal hygiene practices when facilities and supplies are adequate. Management is responsible for providing properly located and maintained facilities and supplies that will allow employees to adhere to personal hygiene requirements. Management should provide and maintain the following facilities:

- dressing and changing rooms that are adequate and properly maintained,
- laundry services and/or uniform services as necessary,
- designated employee areas for breaks, where eating and drinking are allowed,
- strategically placed and well-stocked hand-washing facilities throughout the production area,
- restrooms that are conveniently located, accessible to employees during all hours of operation, and are properly maintained.

In summary, processed food operations should be protected from contamination with microorganisms or foreign substances. Achieving this goal requires a healthy, clean, and properly trained workforce that understands the importance of proper hand washing techniques and other personal hygiene practices. Adequate training programs and management supervision are important elements in a program to ensure preparation of safe processed foods.

People

Employees come in contact with food products many times during processing and should be trained in safe food handling. This is because humans are often the vectors involved in the spread of disease, like the common cold or even food-borne illness.

Employees may transfer foodborne illness-causing microorganisms to processed food at various points in processing operations, such as:

- receiving ingredients,
- material warehousing and cold storage,
- unloading ingredients from delivery or storage containers,
- preparing product for machine processing,
- mixing, blending, or processing,
- packaging,
- weighing,
- boxing,
- warehousing finished products.

GMP also emphasize the need for adequate employee training in proper food handling, hand washing and food protection. Strict adherence to GMP is important, and employees should have the knowledge and understanding to carry out their responsibilities properly. Training should cover the dangers of insanitary practices and poor personal cleanliness, and how these practices can lead to consumer and employee illnesses. Adequate training of employees is everyone's responsibility and needs to be assigned to competent supervisory personnel.

GMP and good employee hygiene practices should be followed each step of the way by everyone including forklift operators, management, and visitors to the plant to reduce the chances of spreading food borne illnesses.

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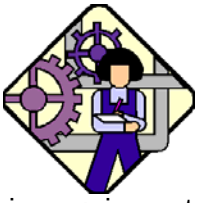
Equipment Cleaning, Maintenance, and Design

Processed food preparation areas and equipment are all potential sources of contamination from microbial, chemical or physical hazards.



Both visual and analytical evaluation of all processing equipment should be performed before processing begins to assure that proper cleaning, sanitation and maintenance has been performed. Traditional evaluation methods such as environmental swabs or contact plates are often used. Rapid test methods, such as the use of a bioluminometer before the start of processing, allow one to evaluate sanitation efficiency in real time. These real time measures also allow employees to take corrective action before processing begins. Some firms even provide financial incentives for sanitation crews meeting goals set by managers.

Most equipment for preparing, processing, and packaging food has food-contact surfaces. A food-contact surface is any surface that comes in direct contact with food, as well as any surface from which drippage, or condensation may contact food. An example of an item not typically thought of as a food-contact surface is a drip or condensation pan on refrigeration units. Food-contact surfaces must be kept clean and sanitary to prevent them from becoming a potential source of contamination.

All food-contact surfaces should be constructed so as to be durable, easily cleanable, non-absorbent and non toxic. This includes such items as:

- knives,
- conveyors, belts and chutes,
- product totes,
- gloves,
- tools such as shovels or racks,
- cutting boards,
- tables,
- packing scales.

All equipment or food-contact surfaces should be:

- constructed of suitable, non-corrosive materials,
- constructed with smooth, sanitary welds to prevent the build-up of food materials,
- easy to disassemble for cleaning and sanitizing.

Processing equipment can also be a potential source of chemical and physical hazards. Chemical hazards from processing equipment may include such things as:

- industrial lubricants from sprockets, bearings, and gear boxes, or
- hydraulic fluid from equipment, overhead lines, or gear boxes.

Physical hazards from processing equipment may include such things as:

- nuts, bolts and washers,
- small or large machinery parts, or metal fragments which may come loose from equipment.

Examples of acceptable equipment materials include some types of stainless steel, various plastics and laminates. Some types of stainless steel can corrode. Stainless steel that can corrode is not acceptable for food processing facilities. It is very important that equipment and utensils be constructed of food grade materials so as not to create a health hazard to consumers. Not all items found in general hardware stores or variety stores are recognized food-grade materials. If uncertain, contact the NSF International at 1(800) NSF-MARK (1 800 734-8010) to verify whether or not a material is considered food-grade.

Of course, it is always best to prevent contamination of foods during processing but one tool such as a metal detector is available to help detect physical contamination of food after processing. Metal detectors can determine if small pieces of metal are present within packaged products. This method is not fool proof however, as food processing equipment is typically constructed of stainless steel, and metal detectors are less sensitive to low iron content metals. Metal detectors are recommended to help screen packaged food products for gross metallic contamination such as broken knife blades or machinery nuts and bolts.

Once a metal detector is in place it should be:

- tested frequently to assure functionality,
- set up to eject packages from the normal product flow if a problem is detected.

Industrial Chemicals Associated with Food Processing

Food processing requires the use of many industrial chemicals, which when used and stored properly, pose little risk. However, if industrial chemicals such as cleaners, sanitizers, pesticides and lubricants are used or stored improperly, they may contaminate food products. Therefore:

- Processors should use only food grade chemicals to ensure the highest purity and minimize the dangers associated with inadvertent exposure to the product;
- Processors should always store hazardous chemicals in a locked storage space with access by authorized personnel only; and
- Processors should not leave hazardous chemicals such as cleaning or sanitizing agents in the processing area.

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All equipment, utensils and food-contact surfaces in the processing facility should be cleaned and sanitized on a daily basis, or more often if needed, to prevent the adulteration of food products. Most firms use Sanitation Standard Operating Procedures (SSOP), and Master Sanitation Schedule, which document specific details on how workers are to clean and sanitize, how sanitizers are to be used and mixed, and how and when tasks should be completed.

These documents should also describe how and where hoses, shovels and other utensils are to be used and stored. The SSOP and Master Sanitation Schedule should be reviewed by management periodically and be updated, if needed.

In order to properly clean and sanitize equipment, utensils and food-contact surfaces, it is important that they be adequately constructed so as to be easily cleanable and maintained. The materials used for equipment, utensils and food-contact surfaces should be non-toxic, durable and non-absorbent. In addition, equipment should be designed to be accessible for cleaning and sanitizing or be easily disassembled to allow for cleaning and sanitizing.

What is the difference between cleaning and sanitizing? Even though many people believe they are the same, they are really two completely separate steps in an effective operation. Cleaning is the removal of organic material and debris from surfaces in preparation for sanitizing. Cleaning involves washing and rinsing and is usually done with detergents and soaps, and physical scrubbing or agitation, followed by a clean water rinse. Sanitize means to treat clean food-contact surfaces by a process that destroys pathogens and reduces the number of other microbes without adversely affecting product safety.

To maximize the effectiveness of cleaning and sanitizing activities, there is an order of activities that should be followed. First, any equipment that needs to be disassembled prior to cleaning should be taken apart by the properly trained individuals. Then, all surfaces should receive a pre-rinse with potable water. Next, all surfaces and equipment should be effectively cleaned using hot water, detergent, high pressure or scrubbing, as necessary. Detergent type and strength will influence the effectiveness of any cleaning program. The type of detergent used is determined by the type of soil to be removed. The temperature of the detergent solution and the exposure time are also important, as is the amount of physical scrubbing required and how well the equipment is pre-rinsed. These factors should be specified in a written SSOP, and Master Sanitation Schedule to help ensure that they are adequately and consistently performed.
After cleaning, the detergent/soap should be completely rinsed off with potable water. Next, all surfaces should be sanitized with an approved anti-microbial agent. Commonly used sanitizers include chlorine, chlorine dioxide, or quaternary ammonium.

It is important that the level of sanitizer used be adequate to kill the targeted microbe, which could be Salmonella, Listeria monocytogenes or E. coli O157:H7 or any other pathogen. When using chlorine, a level of 100 to a maximum of 200 parts per million (PPM) Total Chlorine is considered acceptable. It is imperative to follow label instructions when mixing and applying the sanitizers used. All sanitizer levels should also be the development of pathogen resistance to that sanitizer.

There are also several factors to consider when choosing a sanitizer, such as the type of equipment or surface to be sanitized, the temperature and contact time required by the sanitizing solution, and the pH and the hardness of the water. Of these factors, the pH of the water is the most important. Consult with chemical suppliers for guidance in the choice and use of detergents and sanitizers. Also, it is important to read and follow all labels of all sanitizers and detergents.

All cleaning and sanitation activities should be documented in writing, and reviewed by a supervisor. This provides for uniformity in these activities and allows for changes should they be needed.

Another way to check on the effectiveness of all cleaning and sanitation activities is to conduct environmental monitoring of walls, floors, ceilings, drains, chiller and storage racks.

There are various types of environmental monitoring such as bacterial swabbing and the use of luminometers that use bioluminescence, or light from organic matter, to show whether a surface has been cleaned and sanitized properly. Luminometers measure the amount of organic matter that may be left on food-contact surfaces after cleaning and sanitizing. The amount of organic matter is read in the form of numbers. This type of monitoring provides for immediate feedback and can pinpoint problem areas.

Firms may conduct these monitoring activities "in house" or they may choose to hire an outside lab. In order to conduct monitoring activities, the proper authorities should certify outside labs. Check with local or state authorities, suppliers and technical magazines for acceptable laboratories in the area.

If a firm chooses to monitor in-house, proper procedures should be followed at all times and all monitoring should be documented and verifiable. It is always recommended that whatever methods are used, accurate results should be provided in as short a time as possible.

The proper use of all chemicals in a fresh-cut processing facility should be covered in the Sanitation Standard Operating Procedures and Sanitation Manual. The SSOP and Sanitation Manual should detail what chemicals are to be used for each job, how and when they are to be mixed and applied, as well as all precautions to be taken when using each chemical.

- All chemicals should only be used as labeled and when safe.
- All chemical containers should be labeled properly.
- All chemicals should be stored so as they do not contaminate food, ingredients or packaging.
- Chemicals should not be stored on food-contact surfaces and should not be stored in empty food or ingredient containers.
- The label instructions for all chemicals should be followed with no hesitation to contact the supplier if there are questions.

What Is the Importance Of Acceptable Equipment Construction And Proper Cleaning And Sanitizing Activities?

Acceptable equipment construction and proper cleaning and sanitizing activities play a key role in the control of biofilm

Have you heard your dentist talk about removing plaque from your teeth? Have you ever walked across a stream and slipped on slimy rocks? These are both common examples of biofilms.

Biofilm can be defined as a thin layer of bacterial cells that adhere to equipment and other surfaces and are more resistant to common sanitizers.

Various pathogens such as Listeria, Salmonella and E. coli O157:H7 have been shown to form biofilms that can contaminate food products during production. Biofilms can be found on the surfaces of product lines, cutting boards, stainless steel and plastic conveyor systems and any surface in constant contact with a product. Bacteria in biofilms are hard to find using normal monitoring techniques.

The control of biofilms is also very difficult. The bacteria in biofilm acquire extreme resistance to sanitizers, disinfectants and heat treatment. Because biofilms can build up over time, timely and proper cleaning and sanitizing is needed to ensure that bacteria are killed in the early stages of biofilm formation.

Sanitation workers should vigorously follow all cleaning steps, (pre-rinse, clean, post-rinse and sanitize), every time they clean. The cleaning crew should also strictly follow the directions for the concentration, temperatures and contact times for all cleaners and sanitizers and those cleaners and sanitizers should reach all food-contact surfaces. Supervisors, or a properly trained employee, should conduct visual sanitation inspections after all equipment and surfaces have been cleaned. Microbiological testing of equipment and surfaces should also be considered. A firm should replace or repair any rusty, pitted or deteriorated equipment and food-contact surfaces because rust and deteriorated equipment allows for the growth of bacteria. Such equipment becomes difficult to clean, which makes the formation of biofilms very easy.

Following the firm’s Sanitation Standard Operating Procedures and Sanitation Manual is imperative for controlling biofilm formation.

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Pest Control and Exclusion

Pests can and do contaminate foods and transmit disease. Safe and effective control and exclusion is a priority. Proper pest control and exclusion can be separated into two categories, physical controls and chemical controls. Exclusion is the practice of preventing the entrance of any vermin or pests into a facility.

Physical controls include items such as window screens, screen doors, proper weather-stripping of all doors, plastic curtains, and air fans at all doorways. Even the practice of keeping all doors closed serves as a physical control. Insects, rodents and birds, as well as domestic animals must be excluded from the facility at all time.

Other practices can serve as effective physical controls. Proper storage and removal of waste products from the facility, removal of old, unused equipment and maintaining the exterior grounds surrounding a facility all deter vermin. Keeping a sufficiently cleared space around the exterior perimeter of the buildings is also helpful.

Other practices in the day to day operation of a facility help control pests. Proper storage of ingredients, finished products and packaging, as well as the timely cleanup of spills and the proper lighting of the facility, all help in discouraging vermin infestations.

Chemical pest controls consist of the use of pesticides, traps and baits in and around the facility. It is suggested that food processors employ a licensed pest control operator or contract with an outside firm to conduct these activities. Any chemicals used in pest control applications must be acceptable for use in a food processing facility and their application must not contaminate foods, ingredients or food packaging. All pest control chemicals should be stored properly in designated areas, and not stored on food-contact surfaces or in any areas of the facility that could contaminate ingredients, finished products or packaging.

All pest control activities should be routinely monitored and recorded. Proper monitoring will show the effectiveness of those activities or it will point out areas that need more attention. Remember, chemical controls can only be effective when used in conjunction with well-established physical controls. The primary goal should be to exclude all pests.

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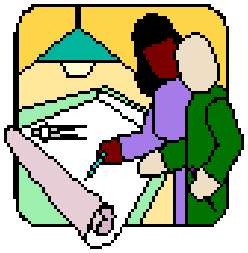

Processing, packaging, or packing of food takes place in diverse locations and physical structures and on many different scales. The overall design of the facility, from receiving area to shipping dock, is an important consideration in eliminating opportunities for chemical, physical, and microbial contamination. Both direct contamination and cross-contamination of product can be minimized with proper attention to physical design, construction material selection, and facility traffic flow.

The building should be designed so that incoming products never cross paths or co-mingle with finished products. This is a recommended practice for all processed food operations. Occasionally, the available space is limited, but physical separation of zones using walls or other barriers can achieve adequate separation. In addition, separate or segregated zones for chemical storage and mixing, and maintenance and fabrication shops are needed.

A properly designed facility is important because the additional mixing, processing, and packaging steps that may be part of food processing increase the opportunity for cross-contamination. Pallets and bins coming directly from a supplier may also be a source of contamination. Proper facility design can significantly reduce this potential hazard. Finally, processed, but unprotected, product should not be stored in the same room location with dirty containers and pallets. For example, the facility should have sufficient storage room space to keep processed product, which is being held for later mixing and packaging, separate from incoming and stored materials.

Like the overall facility design, the movement of processing water, waste streams, airflow, and employees should be planned with food safety in mind. To conserve water and minimize wastewater discharge, many facilities recirculate water.

In a similar manner, facilities may design and install an air-filtration system for central distribution and airflow counter to product flow. In these systems clean filtered air moves with a positive pressure from the cleanest areas--packaging and packing--back toward the receiving area. Positive pressure flow (backward airflow) helps reduce the chance of air-borne contamination along the linear facility design. In the same manner, there should be negative air pressure in the restrooms to keep air from flowing out of the restrooms. Additional airflow barriers, such as air-curtains, help to isolate receiving and shipping areas that may be open to the outside environment. Processors that use a bulk dump for incoming materials should consider installing a fixed wall with a pass-through to move product from outside to inside the facility. This point of separation will reduce the potential for water moisture or aerosol in air above or around the dump tank from contaminating the inside of the processing area during receipt of incoming materials.

Traffic flow from the outside environment and within the facility should also be carefully planned. Equipment and workers should not move between segregated areas. Cross-contamination can be avoided by preventing the movement of lift-trucks, bins, totes, tools, cleaning implements, clothing, and people from receiving or storage zones to processing and packaging areas. Color-coding bins, totes, clothing, cleaning tools, and other items can help achieve this separation of traffic.

Finally, proper facility design and selection of construction materials are major contributors to safe food processing operation. Floors should be designed for easy cleaning. A smooth, non-porous floor with coving at wall junctions prevents the entrapment of dirt and debris. Expert advice should be sought to select materials that facilitate cleaning and sanitation, and to design adequate floor slope for drainage. Flooring materials should be suitable for your facility and selected to be resistant to chemical damage and cracking from equipment movement. Cracks in flooring are difficult to clean and may easily become a site for plant residue accumulation and subsequent microbial growth.

Walls should be designed for and constructed of materials that are readily cleaned and will not serve as a home for pests. Sealing and screening must be used to exclude pest entry through windows and vents.

Any access doors leading directly from outside the facility to the processing and packaging area should be designed with food safety in mind. An effective design utilizes a double entry barrier, sometimes in combination with a "forced-air curtain" to help exclude insects. In this design, each person must enter self-closing doors, which open in opposing orientation, left to right then right to left. The doors leading directly to the outside must first close to allow the second door to open. Cautionary signs and boot dips alert the worker or maintenance person that they are entering a clean area. The use of such doors during operating hours should be strictly controlled. The areas outside the facility should be designed and maintained to minimize the potential for attracting or harboring rodents and other potential sources of human pathogens. Landscape design and weed control programs should be part of the overall food safety plan.

The location and design of drains, floor flumes, and pipelines can be made to greatly improve the ease of maintenance and effectiveness of clean-up procedures. Expert advice should be sought to design placement or protective aides to prevent pipe and wall condensation from becoming a source of contamination. Drains should be fitted with seals and grates capable of preventing rodent entry. The use of floor flumes should receive careful consideration because of the potential for water aerosol contamination of the room air or nearby equipment surfaces. This is especially true for floor flumes that carry water waste from one segregated area across another. The design of the collection area for wastewater should incorporate systems to prevent product or equipment contamination that might serve as an attractant for pests.

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Receiving/Storage/Packing/Transport

When purchasing food ingredients (both raw and processed), management should establish specifications for each of the items that are to be received. The specifications may be that the products meet management's standards in the areas of quality, temperature, size, and microbiological standards. Processors should evaluate whether the food product purchased was produced at sites that adhere to GMP and meet established specifications.

To ensure that the quality of freshly processed food is not compromised, all transportation equipment carrying these products should be cleaned and sanitized frequently.

At the time of receipt, processors should visually examine the incoming product for rot, decay, foreign objects, and damaged containers. All incoming ingredients must be inspected and be accepted or rejected. In case a traceback is required, processors will need to determine which incoming ingredients are components of which finished product. It is recommended that processors document the following information for traceback purposes, at the time of receipt of an ingredient: type of product; ingredient and product packaging; labeling; lot number; and pallet tag, quantity, size, and weight.

There are many ways a firm can document incoming product receipt and tie it to production for better traceback. Maintaining documents in case of a traceback may minimize the public health and economic impact of a recall.

Record keeping practices should be applied to all items that are added to processed food products and to packaging materials. Quality control review of all ingredients and packaging materials is the first step in producing the safest processed food at the facility. Workers involved in the loading and unloading of raw ingredients during transport should practice good personal hygiene and sanitation, as discussed previously.

To minimize potential microbial hazards when receiving product, the buildings, fixtures, other physical facilities, and surrounding grounds should be maintained in good sanitary condition. Pathogenic microorganisms may be found on floors, in drains of packing facilities and on the surfaces of sorting, grading, and packing equipment. Without use of good sanitary practices, surfaces that come into contact with raw ingredients could be a source of microbial contamination. Therefore, good sanitation practices should be used throughout the facility and staging areas to control contamination throughout the receiving, processing, and packing operations.
Packaging containers and other packing materials that are not used right away should be stored in a way that protects them from contamination by pests, dirt, and water condensing from overhead equipment and structures. Packaging materials should:

- be manufactured from food grade materials,
- be stored away from any industrial chemicals and other possible contaminants, and
- not be used to store hazardous chemicals to avoid cross-contamination.

To insure proper rotation of inventory all pallets should be dated upon receipt. Also, an appropriate detailed inventory system should be established in order to insure first-in-first-out

(FIFO) use and shipment of product. Similar commodities should be stored together in order to prevent cross-contamination.

All equipment should be maintained in a clean and sanitary condition. All remnants of food products on belts, tables, lines, and conveyors may serve as a source for microbial contamination and should be removed and the equipment cleaned. When knives and cutting equipment, boots, gloves, smocks, and aprons are used during the processing, they should be cleaned on a regular basis or replaced if they become damaged and/or cannot be kept in sanitary condition.

When preparing finished product for shipment to customers, processors are encouraged to examine all transportation vehicles before loading freight carriers or refrigerated trailers with product. Because transportation vehicles can be a potential source of microbial contamination, trailers should be inspected for general condition, obvious contaminants, and odors before loading. Only trailers with no obvious signs of contamination should be loaded. Drivers should be advised to properly clean, sanitize, and repair trailers prior to loading.

To view the FDA's booklet "Inspecting Incoming Food Materials" click on the following link: www.cfsan.fda.gov/~dms/insp-toc.html

This is only a brief outline of the GMP that are required for processed food. GMP can be useful in helping processors control their process and minimize microbial, chemical and physical hazards during all stages of the processing operation. In addition, some states, including California, have incorporated the GMP regulations into the State Health and Safety Codes making them requirements for all foods produced in the state.

To operate and maintain your business, you must meet the requirements in the GMP. The following documents are the GMP regulations and a checklist that you can use to check and make corrections to ensure all the conditions set forth in the GMP are met. Click on the documents below for a complete guide to GMP and an easy to follow GMP self inspection checklist.

To view a copy of the FDA's "Do Your Own Establishment Inspection", click on the following link: www.cfsan.fda.gov/~dms/selfinsp.html

A copy of the "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food" regulation can also be obtained by downloading from the FDA website at www.fda.gov.

GMP represent only one important prerequisite program. Other examples of prerequisite programs are Standard Operating Procedures (SOP), Sanitation Standard Operating Procedures (SSOP), operational actions such as raw material controls, product coding and labeling, product traceability and recall procedures, consumer complaint management and crisis management.

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Industry Assistance Standard Operating Procedures (SOP)

There are several areas of concern in a food production process where properly implemented and monitored GMP with appropriate Standard Operating Procedures (SOP) can effectively control contamination of food or food-contact surfaces. (Examples such as inadequate cleaning of food-contact surfaces, poor personnel practices, inadequate plant construction or design, and inadequate pest control.)
At a minimum, food processors should consider developing prerequisite programs for receiving and storage procedures, temperature control, microbiological controls, pest control, packaging procedures including methods and controls, storage, transportation, date coding and recall procedures.

If employees fail to follow SOP, reasons for the deviation should be clearly identified. For example, when a piece of equipment break downs, the specific location, time and reason for the equipment breakdown should be documented along with an explanation of what was done to correct the breakdown. Each employee should clearly understand every prerequisite program involving themselves and their work area. This can be achieved by implementing continuous training programs, another component of prerequisite programs.

Sanitary Standard Operating Procedures/ Master Sanitation (SSOP)

Important components of prerequisite programs are the SSOP and Master Sanitation Schedules. They are instructions or procedures for sanitary practices developed for each specific cleaning and sanitation operation. They identify what to clean, how to clean and sanitize, when to clean, and who should clean.

Why are they important? Proper sanitary controls and procedures identify problems, such as microbial contamination of fresh produce, and their sources, such as inadequately cleaned equipment, before they cause illnesses and injuries. Once problems are found, they can be corrected. Suitable cleaning and sanitizing prevents product contamination from unclean equipment, utensils, and facilities, thus reducing liability.

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Industry Assistance
Lot and Date Coding

Date coding is a system that enables you to do trace back from the buyer to the processing facility, or vice versa. The following are examples of two date coding systems:

Julian Date Code: (162 02B)

- 162 represents the day of the year. It is 162nd day from Jan 1st.
- 02 represents the year 2002
- B represents hour period or production batch. Established by the company.

Gregorian Date Code:

- July 15, 2002B or 7/15/02B
- Date is self-explanatory.

B represents hour period or product batch

Whichever system you decide to use, it is essential that you establish meaningful product coding and a record keeping system. All finished product packages, or cases should have the date code. You should also have the following record keeping log that include date codes which would with date codes which enable you to do a trace back, and help you run your company operation smoothly:

- Daily production log – records all products produced in a day or shift, identifies the product, total number of cases produced, and case sizes.
- Inventory log – amount of finished product or ingredients in storage, shipped dates and location description.
- Quality control log – identifies product tested, problems found, and solutions.
- Shipping form – identifies the products, their destinations.
- Sale invoices – identifies quantity sold and products involved.

Code dating should be on both logs and on all forms so that both the company and the customer can identify the products involved. If a recall is required, the product can be identified using the daily production log, inventory log, and shipping form. All affected products can be placed on hold, tracked to the store, and the customer until all products are accounted for, located, and takes back to the processing facility.

Finished products should be labeled or coded in such a way as to allow for the identification of a specific product lot or batch, based on raw ingredient supply or production date. Although good labeling and/or lot identification will not prevent the possibility of a foodborne illness outbreak, it may limit the liability if specific batches or lots can be traced to buyers and the product can be recalled.

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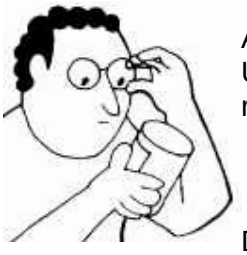
Product Labeling



All food packaged by your business must be properly labeled. The U.S. Food and Drug Administration (FDA) instituted laws and regulations pertaining to labeling.

The Department of Public Health, Food & Drug Branch (FDB) adopted all labeling regulations. It also has its own laws concerning additional labeling requirements. The law requires specific information such as Food Name, Responsible Firm, Net Quantity, Ingredient Listing, Product Dates, Nutritional Labeling, Nutrient Content Claims, and Health Claims. The information is to be listed and positioned in the proper display panel. Additional requirements are applied to juice products, refrigerated foods, confectionery products containing alcohol, and organic foods. If you are planning to do your own labeling, you must know all of the requirements. Consult with an expert whenever you are not sure, or contact any of the FDB offices.

Please click on the following for information on labeling.

Labeling Guide

The links that follow are for the FDA food labeling guide:

- http://vm.cfsan.fda.gov/~dms/flg-2.html
- http://vm.cfsan.fda.gov/~dms/flg-4.html
- http://vm.cfsan.fda.gov/~dms/flg-6c.html
- www.cfsan.fda.gov/~dms/nutrguid.html

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Industry Assistance
Product Recall Plan

It is important to plan ahead. Your food processing company may need to recall a product at some point. The recall may result from consumer complaints or your company has identified a problem. To recall a product, your company needs to be able to identify the product involved and determine the distribution of that product.

In the event of a foodborne illness outbreak, it is important to have traceback and recall procedures in place. We know that trace-backs cannot prevent foodborne illness from occurring. But being able to review good records and quickly trace a food back to its source can limit the public health and economic impacts of an outbreak. Food processors should develop and implement systems to facilitate tracebacks and recalls in the event of a problem. Food processors should test their systems regularly by conducting unannounced mock recalls. Traceback typically begins with the retail source of the food product thought to cause illness or injury and works back to a processing facility. Information from a traceback can often be used to aid in prevention of future illness outbreaks. Recall procedures are developed and used by processors to withdraw product that is already in the marketplace. A processor should be able to track all products. Records such as the supplier identification, production and distribution records for a specific lot of product should be orderly, properly maintained and easily retrievable in less than one hour. It is good procedure to periodically test the firm's ability to retrieve information from the records by conducting mock recalls. Lot coding packages by date code or other coding may facilitate recovery of the product, if a recall is needed. Production records and date codes help put the puzzle together to identify the source. What are the consequences of an outbreak that implicates a product? Without records, the whole product line is suspect. All of the production procedures are suspect. More questions are raised than can be answered. Is the problem limited to only one day, one week, or one month of production? Is the source of the problem incoming product or employee practices? Has dirty equipment contaminated the product? If a production facility has accurate records of effective cleaning and sanitation of equipment, has well-trained employees, and pays consistent attention to GMP, Prerequisite Programs and HACCP, the facility will greatly reduce the likelihood of it's products causing a foodborne illness outbreak.

A comprehensive guidelines, policies, and procedures for recalls can be found in the Code of Federal Regulations (CFR). Please click on document below.

21 CFR, Part 7.40

- To view the FDA's recall policies, click on the link: www.cfsan.fda.gov/~lrd/recall2.html.

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Industry Assistance
Food Processing License/ Permits

To operate a food processing business, you need to be approved and registered or licensed, with different local, state and federal agencies. Do not make any plans until you are satisfied that your business will comply with current law. You should do this during the initial planning stages. Do not wait! The following are agencies that you may need to contact at different levels:

State-Level Contacts:

Processed Food Registration: All California food processing businesses that manufacture, packing, or holding any processed food and businesses shipping food product intra or inter-state must register with the State of California, Department of Public Health, Food and Drug Branch (FDB). To request an application please contact:

Processed Food Manufacturer, Packer, Holder Registration

Department of Public Health
Food and Drug Branch
P.O Box 997413 MS-7602
Sacramento, Ca 95899-7413

(916) 650-6500

Or e-mail your request to: Jennie.Nunez@cdph.ca.gov

Please click on the documents below for information about Processed Food Registration:

Federal-level Contacts:

Two additional regulatory agencies that oversee processing food products at the federal level are:

U.S. Food and Drug Administration (FDA)
http:/www.fda.gov

United States Department of Agriculture (USDA):
http://www/usda.gov

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Industry Assistance Additional Resources

The Food and Drug Administration (FDA) has launched a Industry Portal on its website to make it easier for regulated companies to find information they need to comply with regulations.

The portal offers direct links to a wealth of useful industry-related information, including:

- guidance documents,
- inspection references,
- information on imports,
- warning letters and other FDA enforcement activities
- FDA-related parts of the Code of Federal Regulations

The portal also provides easy access to regulatory information from FDA's centers, streamlining the way companies can locate assistance specific to their products.

Companies can also use the portal to contact FDA with questions or comments. They can even submit comments online about proposed FDA regulations.

Links to FDA news items are also included on the portal, including Agency press releases, new Federal Register documents (before they are published in print), recent product approvals, as well as upcoming advisory committee meetings and other public meetings. The portal can even be used to sign up to attend meetings for which registration is required.

Finally, the portal enables visitors to sign up to receive (at no charge) any of the more than 20 electronic newsletters on various topics of interest to FDA-regulated industry.

The industry portal can be found at http://www.fda.gov/oc/industry. Or go to the FDA home page http://www.fda.gov and select the "Industry" link in the column on the right.

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