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FOOD SAFETY MODERNIZATION ACT

# GOOD MANUFACTURING PRACTICES



for Making Low-Risk Foods



**NC STATE**  
EXTENSION

A Guide for Small-Scale Farms and Food Businesses



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## CHAPTER 1

# INTRODUCTION

Proper food preservation begins by knowing how food is grown, packed and/or manufactured and by identifying and understanding which microbiological, chemical and physical hazards are associated with different foods and food handling activities during food preparation. Spoilage of foods can lead to different conditions conducive to food safety hazards and potentially foodborne illnesses. Other lapses in the manufacture and packaging of foods can create risks for injury and poisoning. Current **Good Manufacturing Practices (cGMPs)** are the foundation for a food manufacturer to successfully minimize these risks to consumers.

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# 1.1 FSMA PREVENTATIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS AND EXEMPTIONS

This manual was developed to be a resource for small and medium-scale processors of certain types of foods that are regulated by the US Food and Drug Administration (FDA) under the Food, Drug and Cosmetic Act (FDCA). FDA requires entities making food for human consumption to register with the agency as food ‘facilities’ and to properly apply cGMPs in producing their foods. In 2011 the Food Safety Modernization Act (FSMA) became law, and FDA made significant changes to its food processing regulations as a result, including some important revisions to the cGMP requirements, which now apply to virtually all processed foods under FDA jurisdiction<sup>1</sup>.

Additionally, FDA’s FSMA regulations create requirements for many food businesses to implement Hazard Analysis and Risk-Based Preventive Controls (HARPC) and Supply Chain (SC) programs. These are complex rules that add further layers of food safety management on top of the cGMPs. However, there are exemptions to the HARPC and SC requirements that are important for small businesses to understand.

## Exemptions from HARPC and SC

- **Qualified Facilities** This applies to establishments with less than \$1 million in average annual sales (2) of human food, adjusted for inflation (The average 3 Year Value for 2020 – 2022 is \$1,220,364). Qualified facilities must give notice to FDA that they fall under this sales threshold and annually verify whether their sales remain below that level. They also must warrant to FDA at least every two years that they have identified potential hazards in their production processes and are taking all necessary steps to control those hazards.
- **Low-Risk Food/Activity Combination Exemption** This applies to establishments with fewer than 500 full-time equivalent employees that are located on farms and that only pack, hold or manufacture foods that the FDA has determined to be ‘low-risk’. For the full FDA list of these low-risk foods, see Appendix 1.

Producers that fall under these two exemptions are not required to implement HARPC and SC programs; all exempt businesses have had to comply with cGMPs since 2018.

Importantly, food businesses with less than 500 employees *that are not located on farms* still need to know about the Low Risk Activity/Food Combination (LRAFC) exemption if they only pack, hold or manufacture foods on FDA’s low-risk list (see

Appendix 1). While these businesses are not exempt from HARPC and SC, they can take advantage of the fact that FDA has determined the foods they produce are low-risk to dramatically reduce the paperwork and effort they invest in HARPC and SC programs. That’s because by complying with cGMPs they are addressing the most significant food safety risks that a HARPC and SC program would need to address in the case of low-risk foods; a business making low-risk foods that is in compliance with cGMPs therefore achieves the purpose of the HARPC and SC regulations, and only requires a little extra documentation to meet rule requirements.

Any business that is making low-risk foods can benefit from this manual, including Qualified Facilities. In the following pages we will explain the essentials of GMPs and allow you to understand the FDA food safety regulations that are relevant to your operation. We will also help you understand and identify the hazards that your food safety program should address, and provide basic information about necessary steps for successful food manufacturing and preservation. And we will explain FDA’s rules on labeling foods that may contain allergens, and help you ensure you don’t cause illness or injury to people with food allergies.

This manual does not address FSMA’s rules for farms growing produce, nor for packing, holding and processing animal food. We will not cover state or local rules that may govern food safety practices in addition to the FDCA. We will not cover state or county ‘cottage food laws’ that may cover food safety at home-based businesses as an alternative to the FDCA. (We do include a resource guide that will help you find answers to those questions elsewhere.) But if your farm or business is making any of the low-risk foods included in Appendix 1, this guide will help you understand how to ensure you follow the cGMPs that apply to those foods, and meet FDA’s food safety regulations for food manufacturing of low-risk foods.

Taking every reasonable step to minimize foreseeable food safety risks in the foods you make is more than just a legal requirement. It’s a responsibility to, and covenant with, your customers and the people who will eat your products. And it’s just plain good business. You want the public to trust that your food will not cause them physical injury or illness. The collaborators behind this manual, Carolina Farm Stewardship Association, North Carolina State University and Oklahoma State University, congratulate you for taking on the challenge of making good food, and for making the commitment to protect your customers through good food safety practices.

<sup>1</sup> Businesses that pack, hold or manufacture food that make the majority of their sales directly to consumers are not covered by the Food, Drug and Cosmetic Act or FSMA, and are not required to register with FDA. Making foods at these businesses – such as restaurants, grocery stores, CSAs, farm stands, and caterers – is usually subject to regulation by local public health agencies. Some states may also have ‘cottage food laws’ that cover these establishments.

<sup>2</sup> A business determines its average annual sales using the three previous years’ sales. The dollar threshold for the Qualified Exemption is to be adjusted for inflation, with 2011 as the base year for calculating that adjustment. FDA FSMA Inflation Adjusted Cutoffs can be found here: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>.



## 1.2 DEFINITIONS & ACRONYMS

The following terms and acronyms will be used throughout this manual.

**Allergen** A food ingredient that contains protein derived from a classified allergen to include the top nine as identified by the FDA (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, sesame, wheat and soy).

**Acid food** Food that has a natural equilibrium pH of 4.6 or below.

**Allergen cross-contact** The unintentional incorporation of a food allergen into food.

**Cross-contamination** The unintentional transfer of a foodborne pathogen from a food or insanitary object to another food.

**Facility** Any establishment, structure or structures under one ownership at one general physical location or, in the case of a mobile facility, traveling to multiple locations, that manufactures / processes, packs or holds food for consumption in the United States. It may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility, and Retail Food Establishments (see below) are not facilities. Facilities are required to register with FDA.

**Food Spoilage** A process mediated by microorganisms (bacteria, molds, yeast and fungi), enzymes (substances naturally present in food or introduced into a food by microorganisms that accelerate degradation) and chemicals present or formed inside the food. They all lead to food deterioration to a point at which it is not edible to humans. Spoilage is controlled by maintaining proper storage temperatures, managing oxygen or carbon dioxide levels in the storage atmosphere, controlling relative humidity, as well as by ensuring the cleanliness of the raw agricultural commodities used to make the food. Spoilage occurs over time, gradually making the food less desirable, and can lead to a foodborne illness if pathogens have been able to grow or if existing microorganisms produced toxins that cause human illness. Spoilage results in changes in the appearance, smell, flavor and texture of a food. These parameters could also indicate that favorable conditions could have occurred for foodborne illness microorganisms to grow and/or produce toxins, although some of these toxins can be produced without detectable spoilage.

**Foodborne Illness** A physical illness that occurs when we consume foods that are contaminated with a microorganism (pathogenic bacteria, viruses, parasites) or a chemical (toxin) produced by microorganisms (mainly bacterial pathogens or fungi) that is capable of producing illness. Foodborne illnesses can range in intensity from mild intestinal disorders to death.

**Foodborne Infection** Pathogenic microorganisms located in food that invade the human body after consumption of contaminated food. Growth of the microorganisms in the food will not be necessary to cause illness. Examples: pathogenic *E. coli*, *Salmonella*, *Listeria monocytogenes* and all parasites and viruses.

**Foodborne Intoxication** Pathogenic microorganisms that grow in the food and produce a toxin that causes illness when the food is consumed cooked or raw. Growth of the microorganism in the food is necessary to produce the toxin. If the pathogen doesn't grow in the food, it will not produce toxin and so will not produce intoxication. Examples: *Staphylococcus aureus*, *Bacillus cereus* and *Clostridium botulinum*.

**Food-contact surface** Any surface that will come into contact with human food, including utensils and food-contact surfaces of equipment.

**GMPs (Good Manufacturing Practices)** Also referred to as Current Good Manufacturing Practices (cGMPs), the FDA regulations under the Food, Drug and Cosmetic Act that outline the conditions and practices that facilities must follow for

sanitary food processing. The details of the GMPs and what they require in terms of personnel, sanitation, facility maintenance, equipment and utensils, warehousing and distribution, and responses to contamination incidents are covered in Chapter 3 of this manual.

**Hazard** Any biological, chemical, or physical agent that has the potential to cause illness or injury. See Chapter 2 for a detailed discussion.

**Hazard Requiring a Preventive Control** A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would establish one or more preventive controls to significantly minimize or prevent the hazard (biological, chemical or physical) in food. Conducting an assessment evaluating the severity and probability of the illness or injury if the hazards were to occur in absence of the preventive control may be necessary. Management of the preventive controls must be addressed in the Food Safety Plan after determining the control's role in the food safety system as appropriate to the food, facility and the nature of the preventive control. This may include monitoring, corrections or corrective actions, verification and recordkeeping.

**Hazard Analysis and Risk-based Preventive Controls (HARPC)** A system of food processing, packing and handling controls that food manufacturers, processors, packers, and storage facilities are required to follow under FSMA, unless covered by an exemption. Also known as Preventive Controls For Human Food. Facilities that are not exempt from HARPC must:

- Identify food safety and adulteration hazards associated with their foods and processes
- Implement controls to minimize the hazards
- Verify that the controls are working
- Design and implement corrective actions to address any deviations from the controls

**Harvesting** Harvesting means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised, and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food (see definition for manufacturing/processing). Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

**Holding** The storage of food, including activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage), and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating grapes into raisins). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food

(see definition for manufacturing/processing). Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

**Manufacturing/Processing** Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing or holding.

**Microorganisms** Yeast, molds, bacteria, viruses, protozoa, and microscopic parasites, including species that are pathogens.

**Packing** Placing food into a container other than packaging the food, including activities performed incidental to packing a food (examples: activities performed for the safe or effective packing or re-packing of that food including sorting, culling, grading, and weighing or conveying incidental to packing or re-packing). Packing does not include activities that transform a raw agricultural commodity into a processed food. *Note: Packaging means placing food into a container that directly contacts the food and that the consumer receives.*

**Preventive Controls** Risk-based, reasonably appropriate procedures, practices, and processes consistent with the current scientific understanding of the safe manufacturing, processing, packing, or holding of food employed to significantly minimize or prevent the hazards identified under a hazard analysis. A **hazard analysis** refers to the process of collecting and evaluating information on hazards (microbiological, chemical or physical) and the conditions leading to their presence to determine whether they must be addressed in the Food Safety Plan. The Food Safety Plan for operations manufacturing low-risk foods is based on the establishment and implementation of Good Manufacturing Practices (GMPs) and any other process controls that minimize potential food safety risks.

**Preventive Controls Qualified Individual (PCQI)** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

**Pathogen** A microorganism of public health concern because it is likely to cause foodborne illness, intoxication or injury.

**pH** A measure of acidity or alkalinity of water soluble substances (pH stands for 'potential of Hydrogen'). A pH value is a number from 1 to 14, with 7 as the middle (neutral) point. Values below 7 indicate acidity, which increases as the number decreases, 1 being the most acidic.

**Prerequisite program** Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to address risks in food processing activities.

**Process controls** Procedures, practices and processes to ensure the control of parameters during operations such as heat processing and refrigerating foods.

**Qualified Individual** A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

**Raw agricultural commodity** Any food in its raw or natural state, including but not limited to all fruits and vegetables that are washed, colored or otherwise treated in their intact natural form prior to marketing.

**Retail Food Establishment** A business that manufactures foods and *sells more than half those products directly to consumers*, including through on-premises sales, farmers markets, community-supported agriculture, roadside stands, online, mail-order and other direct marketing platforms. Depending on state law and the kind of foods made, a retail food establishment may be regulated by the local health department.

**SAHCO Hazard** A hazard that has a high risk of causing Serious Adverse Health Consequences or Death.

**Supply Chain (SC) Program** A system for assessing the risks for hazards in food ingredients and materials provided by upstream suppliers that FSMA requires food manufacturers, processors, packers, and storage facilities to implement unless they are covered by an exemption. A facility subject to HARPC must implement a risk-based SC program if its hazard analysis identifies a hazard that requires a preventive control that should be applied by an upstream supplier. A facility does not need to have a supply-chain program if it takes action to control the hazard, or if a subsequent entity (such as another processor) will control the hazard, and the facility follows applicable cGMP requirements.

**Water activity ( $a_w$ )** A measure of the free moisture (available water) in a food.

## CHAPTER 2

# HAZARDS IN FOOD PROCESSING

The starting place for a small business's food safety program is understanding the food safety hazards that are relevant to its products. A hazard is any biological, chemical (including radiological), or physical attribute that can cause illness or physical injury and is known to be, or has the potential to be, associated with a food or with the facility where a food is made. This chapter discusses these terms and other important factors impacting food spoilage and food safety.

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Any particular hazard may be introduced into a food at any time during the journey from field to fork, including during harvesting, processing/manufacturing, transportation, or storage. There are five key sources of contamination to address in your food safety plan.

### Key Potential Sources of Contamination to Address

- Workers
- Ingredients or materials
- Equipment
- Manufacturing processes
- Building structures

**Table 1** correlates these potential contamination routes to the relevant likely biological, chemical and physical hazards.

FSMA further defines a **hazard requiring a preventive control** as known or reasonably foreseeable biological, chemical or physical hazards for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would establish one or more preventive controls to significantly minimize or prevent the hazards in food.

To determine if there are such reasonably foreseeable hazards in packing, holding or manufacturing a food, a food producer would conduct an assessment of the risk of such hazards and the severity and probability of any illness or injury if those hazards were to occur. This **hazard analysis** would involve collecting and evaluating information on microbiological, chemical or physical hazards and the conditions leading to their presence to determine their significance for food safety. Management would then need to identify the actions necessary to prevent those hazards, i.e. preventive controls.

**Preventive controls** means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Fortunately for manufacturers of low-risk foods, FDA already analyzed the relevant reasonably foreseeable hazards in these foods and determined the controls necessary to prevent them. In its FSMA regulations, FDA specifically identifies these types of low-risk foods, and comes to the conclusion that establishments that only make the foods on this list will adequately address all hazards requiring preventive controls if they implement GMPs. FDA's list of low-risk foods can be found in Appendix 1.

For Qualified Facilities making only low-risk foods, this means that having a compliant GMP program satisfies FDA's requirement that you identify potential hazards in your production processes and take all necessary steps to control those hazards. Beginning in 2020, FDA's documentation requirements for this exemption require you to file a written statement with the agency every two years that you have conducted this review of your hazards and your controls, which must be submitted during the period Oct. 1 and Dec. 31. You can confidently make that assurance by verifying that you are still only making foods on the low-risk list and that you are compliant with GMPs.

Farm-based Low Risk Activity/Food Combination producers that are not Qualified Exempt, but that have fewer than 500 employees, don't have to file such a written statement at any interval. Implementing GMPs will control all hazards requiring preventive controls.

Producers of low Risk Activity/Food Combination products (LRAFCs) only that aren't based on a farm, that aren't Qualified Exempt, and that have fewer than 500 employees also benefit from FSMA's low-risk determinations. You are required by FSMA to have a written food safety plan and a written hazard analysis, and to implement preventive controls as part of a HARPC program. But because FDA has already done the hazard analysis with respect to these low-risk foods, your written food safety plan will discuss your GMP program, and your hazard analysis simply needs to state that you are producing only foods that are deemed low-risk by FDA and that therefore your GMP program is sufficient to address all hazards. And because adhering to GMPs in low-risk foods sufficiently controls known or foreseeable hazards that might be present in raw materials that you bring in from other suppliers, you can also cite your GMP program as your basis for a decision not to implement a Supply Chain Program.

The following sections discuss the key biological, chemical and physical hazards that are of concern in food production and that GMPs are designed to address.

**Table 1.** Examples of biological, chemical and physical hazard sources.

SOURCE	BIOLOGICAL HAZARD	CHEMICAL HAZARD	PHYSICAL HAZARD
Workers	Worker illness and injury, human pathogens	Soaps, greases, pest control substances, or other chemicals used inside or outside the manufacturing area	Jewelry, clothing, pens, gum, paper
Ingredients or Materials	Microorganisms associated with each ingredient or cross-contamination within processing areas	Allergens, lubricants or other chemicals used in manufacturing	Foreign materials
Equipment	Poor sanitation practices and procedures and problems with airflow	Lubricants, cleaning agents and exhaust contamination on food contact surfaces	Metal fittings/shavings and parts
Processes	Cross contamination, inadequate heat treatments and storage conditions including inappropriate temperature	Boiler chemicals in steam generation or from residues	Foreign materials
Building Structures	Floors, condensation of water, pests, traffic or product flow and walls/ceilings	Ventilation effluents from different rooms and chemicals during in storage	Metal, wood, glass, plastic, and paper

## 2.1 MICROBIOLOGICAL HAZARDS

The CDC estimates 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year in the United States. Foodborne microbial pathogens linked to produce, meat and poultry contamination at field, packing or processing environments include bacterial, fungal, viral, and protozoa organisms. These pathogens may become a hazard under certain conditions including inadequate cleaning and sanitation, unsanitary equipment or facilities, temperature abuse, poor storage conditions (overcrowding), excessive moisture exposure, inadequate heat treatments and lack of training. These aspects form part of the basic establishment of a GMP program to manufacture food.

To control microbiological hazards we need to think like a microbe and understand where they come from, what they need to grow and survive, and where they live within our food growing and manufacturing environments. In general, when we think of bacterial pathogens we first need to consider their growing conditions and how they are built. It is also important to note that only bacteria, molds and yeast grow in foods, while viruses and parasites only grown within their host, not in food, and cause illness through cross-contamination.

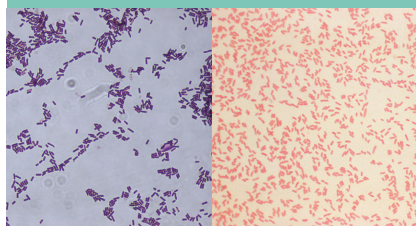
Because of the large number and diversity of low-risk foods, it is not possible to cover all processes and GMPs relevant for controlling microbiological hazards for every low-risk food category, but the following information will provide the basic concepts needed to guide you in safe food manufacturing.

### BACTERIA

Understanding the origin, basic structural characteristics, and potential routes of contamination of microbiological hazards will allow food manufacturers to address and control these hazards before they become a problem in food manufacturing environments. In the case of bacteria, the structural characteristics of these organisms impact the potential efficacy of sanitizers, including their ability to penetrate bacterial membranes and inactivate or oxidize those membranes.

In general, bacteria are classified as either Gram-positive or Gram-negative (Figure 1). This is important because some sanitizers available in the food industry are less effective on Gram-negative bacteria, and others are less effective on Gram-positive ones. Knowing whether the bacteria that are likely hazards in the specific foods you make are Gram-positive or Gram-negative helps you determine the correct sanitizer to use. In general, Gram-negative bacteria that are human pathogens live in the intestinal and respiratory tracts of many animals or insects and are accustomed to warm, moist conditions, favorable pH and a constant food supply. Examples include: *Pathogenic E. coli*, *Salmonella spp.*, *Shigella*, *Campylobacter jejuni*, *Vibrio cholerae*, *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, *Brucella spp.*

Figure 1. Gram-negative (left); Gram-positive (right)



Gram-positive bacteria that are human pathogens live in natural environments including soil, water, plants, air and the skin of humans where constant fluctuations in moisture, temperature

#### Conditions Influencing Bacteria, Mold and Yeast Growth

Remember the acronym FATTOM+

- Food (nutrient source)
- Acidity (pH factors)
- Time
- Temperature
- Oxidation Reduction Potential (reduced/no oxygen)
- Moisture (water activity)
- + Microbial Competition

and food sources occur. Those fluctuations in resources are considered detrimental to Gram-negative bacteria because they are accustomed to living in very favorable conditions. Gram-positive microorganisms in contrast tend to adapt, survive and grow under many different environments, resist different environmental stresses and utilize and source a wide range of environmental nutrients. Examples include: *Staphylococcus aureus*, *Clostridium botulinum* (proteolytic and non-proteolytic), *Streptococcus*, *Listeria monocytogenes*, *Bacillus cereus*.

Irrespective of whether bacteria are Gram-negative or Gram-positive, one of the most important factors impacting microbial loads (concentrations) in food and food environments is the generation time of these microorganisms. Generation time is the amount of time it takes for bacteria to double in numbers (Figure 2), and can

be manipulated by controlling and/or modifying the following components of a food or food ingredients.

#### Factors that Affect Bacterial Growth

- Water Activity (available free water in food)
- Acidity
- Oxygen
- Nutrients
- Temperature

Bacteria can multiply in environments outside of a host organism as well as inside a host. Most can multiply very quickly, reaching high numbers in a short period of time if they are in the right environment. It is unlikely that only a single bacterial cell will be present on a food or food contact surface, or in an environment; where there is one, there are usually many others and sometimes millions. Some pathogens, such as *E. coli* O157:H7, can cause illness with just 10 cells ingested. Other pathogens require a much higher dose: *Listeria monocytogenes* needs around 1,000 cells to cause illness.

Figure 2. Generation time of some bacteria under ideal temperature, nutrient, oxygen, acidity and water conditions.

TIME	# OF BACTERIA
20 min	2
40 min	4
1 hour	8
80 min	16
100 min	32
2 hours	64
4 hours	4096
6 hours	262,144

Under favorable conditions, some bacteria can multiply (double) once every 20 minutes and it is unlikely that in food or on food contact surfaces the initial microbial load is determined by only one bacterium. Consequently, higher initial microbial loads will lead to rapid microbial accumulation under certain growing conditions. Under the ideal growing conditions, one bacteria could multiply into hundreds of thousands organisms within a matter of 6 hours. Such conditions can occur in food or food environments. Making sure that adequate processes and that all cGMPs are in place will reduce or eliminate these microorganisms and the likelihood of pathogen contamination that carries over into the finished product. Foods that are allowed to be processed as low-risk activity food/combinations under FSMA are those that do not necessarily provide growth conditions that will favor pathogen growth due to being high in acidity, salt or sugar, or because producing them requires that they undergo manufacturing processes that eliminate microbiological hazards.

Another important aspect in microbial growth is related to how microorganisms grow in different environments. In general bacteria grow following an exponential growth curve with four distinct phases (see Figure 3).

### Phases of Bacteria Growth

- 1 Lag
- 2 Log or Growth
- 3 Stationary
- 4 Death

Temperature, water activity, salt or sugar content, preservatives, acidity, fermentation, ethanol concentrations and oil content will impact each phase differently, delaying or accelerating each phase depending on the conditions needed by any particular microorganism.

**Lag phase** At this stage bacteria adapt themselves to their surrounding conditions. They are not yet able to divide. During this phase synthesis of RNA, enzymes and other molecules occurs.

**Log (Growth) phase** This period is characterized by cell doubling and the number of new bacteria appearing per unit time is proportional to the present population. The actual rate of this growth depends upon the growing conditions in the food or food environment, which affect the frequency of cell division.

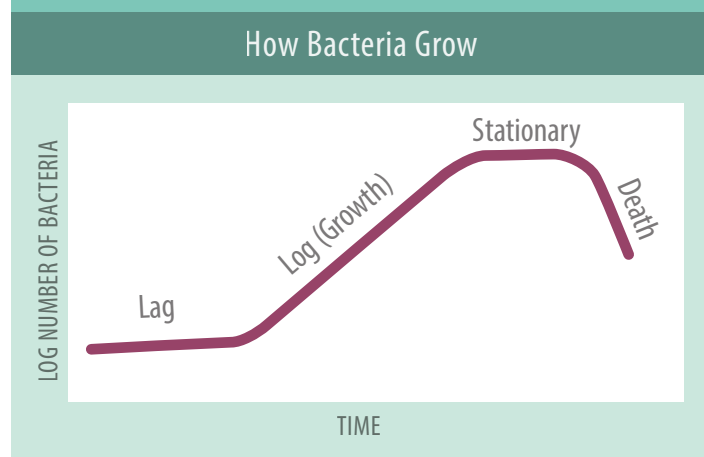
**Stationary phase** During this period bacterial growth is stopped by factors such as the depletion of an essential nutrient, or the formation of an inhibitory product such as an organic acid. Stationary phase results from a state in which growth rate and death rate are equal.

**Death phase** In this period bacteria die due to lack of nutrients and environmental conditions, including stressful temperatures and toxic chemicals produced by the bacteria that injure cells and cause cell death.

The goal in manufacturing food is to provide the necessary hurdles within the manufacturing process that will prevent bacteria from entering food or from entering the Log growth phase if they are present, since under ideal conditions bacterial numbers could reach millions of organisms in a matter of hours depending on the characteristics of the organism.

Bacteria can exist as active vegetative cells or dormant spores. Vegetative cells form spores under adverse conditions as a mean of survival. When conditions become favorable, the spores germinate, with each spore becoming a vegetative cell with the ability to reproduce. Some bacterial pathogens cause disease when humans directly consume the vegetative cells in food, while others cause disease indirectly through

Figure 3. Generation time of some bacteria under ideal temperature, nutrient, oxygen, acidity and water conditions.



toxin-producing spores resulting in food intoxication. The toxin is produced after the spore has germinated into a new vegetative cell as part of the reproduction process.

Vegetative cells are destroyed by heat in food processing, but spores are very resistant to heat: it takes temperatures above 100° C to destroy them. Spore-forming bacteria become a concern under anaerobic conditions found in different foods even if these foods use preservatives, dehydration or other hurdles to reduce the ability of bacteria to grow. In many instances, thermal processes are designed to inactivate spores that would otherwise germinate under storage conditions once the food has been prepared, packaged and shipped.

Bacteria and spores are both inhibited from growing in high acid environments (pH below 4.6). In foods with high acidity and low water activity, germination of spores from *Clostridium botulinum*, *Clostridium perfringens* and *Bacillus cereus* is unlikely. However, during the dehydration and blanching processes applied in preparing vegetables and spices for further low-risk processing, these pathogens could produce spores or spores may germinate, producing toxin, if germination conditions are not controlled. If this happens, the toxin will remain in food even after thermal processing, potentially causing severe intoxication to those consuming these products.

Food ingredients associated with different biological hazards are illustrated in Table 2. Because some of the ingredients can be used in making low risk foods, it's important to consider potential microbial hazards relevant to those ingredients so you can properly control those hazards during food manufacturing.

Other strategies that could be used to control and potentially remove pathogens include the removal of available water from food through dehydration and/or the use of preservatives followed by storing the food under aerobic conditions to prevent spore germination. The most common vegetative and spore forming human pathogens associated with food, food environments or sick humans are listed in Table 3, while Table 4 describes FDA's current understanding of LRAFCs, their associated human pathogens and key cGMPs. Understanding the source of each microorganism within the food chain is important in identifying hazards and the GMP practices needed to prevent contamination from these microorganisms.



**Table 2. Food ingredients associated with biological hazards**

INGREDIENT SOURCE	POTENTIAL BIOLOGICAL HAZARD
Raw milk and raw milk products	<i>Campylobacter</i> , <i>Salmonella</i> , <i>Brucella</i> , <i>Mycobacterium spp.</i> , <i>Strep group A</i>
Soft cheese and refrigerated ready-to-eat foods	<i>Listeria monocytogenes</i>
Eggs	<i>Salmonella</i>
Meat and poultry	<i>Salmonella</i> , <i>EHEC</i> , <i>C. perfringens</i> , <i>Campylobacter</i> (poultry), <i>L. monocytogenes</i> , <i>Yersinia enterocolitica</i> (pork)
Grains and cereal products	<i>Salmonella</i> , <i>EHEC</i> , <i>Bacillus cereus</i> (rice)
Fruits and vegetables(fresh)	<i>Salmonella</i> , <i>EHEC</i> , <i>L. monocytogenes</i> , viruses, <i>Clostridium botulinum</i> (vegetables), parasites
Tree nuts/peanuts	<i>Salmonella</i> , <i>EHEC</i>
Spices	<i>Salmonella</i> , <i>EHEC</i> , <i>C. perfringens</i>
Non-potable water/ice	<i>Salmonella</i> , <i>EHEC</i> , viruses, parasites

EHEC is Enterohemorrhagic *E. coli*, one of the most important *E. coli* groups within the genus *Escherichia*.

**Table 3. Common vegetative and spore forming bacteria**

VEGETATIVE BACTERIA	SPORE FORMERS
<ul style="list-style-type: none"> <li>• <i>Brucella spp.</i></li> <li>• <i>Campylobacter</i></li> <li>• <i>Pathogenic E. Coli (EHEC)</i></li> <li>• <i>Listeria monocytogenes</i></li> <li>• <i>Mycobacterium bovis</i></li> <li>• <i>Salmonella spp.</i></li> <li>• <i>Shigella spp.</i></li> <li>• <i>Staphylococcus aureus</i> (capable of producing a heat stable toxin)</li> <li>• <i>Streptococcus group A</i></li> <li>• <i>Vibrio spp.</i></li> <li>• <i>Yersinia enterocolitica</i></li> </ul>	<ul style="list-style-type: none"> <li>• Produce a spore that allows them to survive harsh conditions.</li> <li>• Once harsh conditions pass, spore opens and a new vegetative cell grows and is able to produce toxins.</li> </ul> <p>Examples</p> <ul style="list-style-type: none"> <li>• <i>Bacillus cereus</i></li> <li>• <i>Clostridium botulinum</i></li> <li>• <i>Clostridium perfringens</i></li> </ul>

**Table 4. LRAFC, associated pathogens and key cGMPs in food.**

LOW-RISK ACTIVITY FOOD COMBINATION	EXAMPLES OF FINISHED PRODUCT	ASSOCIATED PATHOGEN	KEY CGMPs SUPPLY CHAIN BEST PRACTICES
Baked grain products	Bread, Cookies	<i>Clostridium botulinum</i> , <i>Clostridium perfringens</i> , <i>Bacillus cereus</i> , <i>Staphylococcus aureus</i>	Control of water activity, prevention of hydration during packaging, storage and transport
Chopping, coring, cutting, peeling, pitting, shredding, and slicing of foods.	Acid fruit and vegetable products that have a pH less than 4.2, Sliced baked goods, Shredded dried cereals, Dried herbs or spices, Gums, Resins, Game meat jerky	<i>Bacillus cereus</i> , <i>Clostridium perfringens</i> , <i>Staphylococcus aureus</i> , <i>Pathogenic E. coli</i>	Sanitation procedures, equipment use, maintenance and design of equipment, sourcing of food (supply chain best practices), water quality, sanitizer concentrations
Boiling	Gums, Latexes and resins	<i>Salmonella</i> , <i>Mycotoxins</i> , <i>Staphylococcus aureus</i>	Sanitation of boiling equipment, avoidance of cross contamination after boiling, bottling conditions
Dried Foods	Rice/pasta, Pulses/grains, Herbs/spices, Dried game meat, Chips, Cereals	<i>Salmonella</i> , <i>Pathogenic E. coli</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>C. Perfringens</i> , <i>Aflatoxins</i>	Control of water activity, prevention of hydration during packaging, storage and transport, application of preservatives including sulfites
Freezing	Acid fruits and vegetables with a pH below 4.2	<i>Salmonella</i> , <i>Pathogenic E. coli</i> , <i>Listeria monocytogenes</i>	Sanitation of trays and freezing equipment, water quality, sourcing of ingredients (supply chain best practices)
Extracting (through pressing, distilling, or with solvents) dehydrated herbs, fresh herbs, fruits and vegetables, grains and spices	Oils, Herbal extracts	<i>Salmonella</i> , <i>Pathogenic E. coli</i> , <i>Staphylococcus aureus</i> , <i>C. Perfringens</i>	Sanitation of pressing unit, concentration of solvent (generally ethanol concentrations), sanitation of distillation equipment
Coating	Dried or dehydrated fruits and vegetables, Nuts, Grains, Popcorn	<i>Salmonella</i> , <i>Pathogenic E. coli</i> , <i>Staphylococcus aureus</i> , <i>C. Perfringens</i>	Water quality, sanitation of utensils and equipment including trays/other vessels

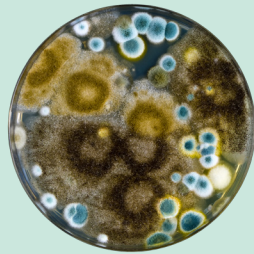
## FUNGI

This group of single cell or multicellular organisms can occur as yeasts, molds, and mushrooms. The cell is larger than a bacterial cell, and the organism reproduces by releasing spores, which can produce mycotoxins during germination that cause food intoxication. Fungal spores are able to survive the high temperatures and pH extremes often used in food preservation. Freezing also does not kill fungal spores. Thus control of vegetative cells of fungi during food storage, dehydration, extraction, baking and coating before they enter the spore-forming stage is essential to reduce the risk of human disease. This can be achieved through sanitation practices that reduce microbial loads, by sourcing ingredients that meet USDA grade standards, and by maintaining a pest and debris free environment.

## MOLDS

Molds are important in the food industry and are often used to add flavor or color to cheese and sauces. They are long branching thread-like filaments, referred to as hyphae. Some molds and yeasts can cause disease or food spoilage. Others have an important role in food production including beverages, biodegradation or in the production of antibiotics and enzymes. Molds are also used in the making of food additives such as lactic or citric acid. Molds require moisture to be able to develop, thus the water activity in food determines their ability to grow on certain foods. During reproduction, molds release spores into the air which can contaminate enclosed environments and the respiratory tract of humans if they are not controlled before they reach reproductive stage. Most molds have little heat resistance and cannot survive thermal processes.

Mold in a petri dish



### General Characteristics of Molds

- Tolerate a lower pH and water activity than bacteria
- Produce mycotoxins (chemical hazard)
- Raise the pH of food by metabolizing organic acids

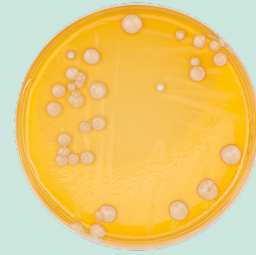
### Control Methods for Mold in Food Manufacturing

- Thermal processing
- Use of preservatives (mold inhibitors)
- Low water activity

## YEASTS

Yeasts are important microorganisms in food preservation or spoilage. This group of single cell microscopic organisms reproduces by budding. Some may form filaments (pseudohyphae, or false hyphae) similar to those formed by molds. There are over 1,500 species of yeast, many of them with food manufacturing implications. In general they are capable of converting sugar into alcohol and carbon dioxide, and they are normally found in fruits and berries rich both in sugars and organic acids that allow yeast to grow and reproduce. Heating foods to 171°F destroys most yeast forms, and therefore yeasts are unlikely to present a food safety risk in processed foods. Yeasts can be found in soil, insects, the guts of mammals, deep-sea environments and in and on human bodies. Those associated with humans generally live on the skin and could potentially cause disease. Examples of yeast found in humans that are known to cause disease include *Candida albicans* and *Rhodotorula rubra*, which can become a source of cross contamination.

Yeast in a petri dish



Control methods for yeast within cGMPs are linked to good personal hygiene and proper hand washing practices.

### Uses for Yeast During Low Risk Food Production

- Baking
- Extraction
- Dehydration

## VIRUSES

Viruses are microscopic and the smallest of all the microbiological associated hazards. They can survive outside their host for over 3 weeks. Viruses are unique because they can only grow and reproduce inside the cells of their host, meaning they cannot reproduce in or on food products and the environment, but can be transmitted by food that is contaminated with these organisms. There are millions of viruses in the environment; twenty-six virus families are known to infect humans. Only a few virus cells are needed to cause disease in humans, and they are easily spread through the environment or from person to person. Enteric viruses are viruses that can be passed to humans through food via the gastrointestinal tract, and according to the CDC are the number one cause of human foodborne illness; however, fatality rates are low when compared to bacterial pathogens like *Listeria monocytogenes* and *Salmonella enterica*. In most cases, humans infected with enteric viruses shed those viruses in feces, and this can happen when an individual is showing disease symptoms or if the virus remains present in the host after infection. Viruses are spread to food through cross contamination from human feces by food handlers who have not washed their hands properly before touching food or food contact surfaces. Examples of viruses associated with food include Norovirus and Hepatitis A. Prevention is key to reducing the spread of viruses, including basic handwashing, proper restroom use, and immediate illness reporting prior to handling food.

**Human Norovirus (NoV)** typically produces the following symptoms: nausea, vomiting, abdominal pain or cramps, watery or loose diarrhea, malaise, low-grade fever and muscle pain. It has a very low infectious dose (1–10 viral particles) with an incubation period between 24–48 hours, and symptoms may persist for up to 3 days in individuals that are not immunocompromised. Infected individuals can pass disease to others after symptoms have subsided and for up to 3 weeks after. Elderly, children and immunocompromised individuals tend to be the most affected by this virus.

The use of sanitizers can help reduce or eliminate NoV contamination. However not all sanitizers are able to inactivate this microorganism, and some others need very high concentrations to effectively inactivate NoV. In the case of chlorine solutions, concentrations of up to 1000 ppm may be needed to inactivate NoV.

**Hepatitis A (HAV)** is associated with liver disease and gastrointestinal symptoms including nausea, fever, anorexia, diarrhea, and jaundice. Disease symptoms last up to 2 weeks in humans that are not immunocompromised and greater than 5 years old. It can be controlled through vaccination, but in general is associated with poor hygiene practices, contamination by direct contact with infected individuals and by ingestion of contaminated food and water. It has a very low infectious dose of 10 or fewer viral particles, and disease symptoms can occur up to 50 days post contamination; progressive disease has been reported in 1–1.5% of cases, lasting up to 6 months.

### Control Methods for Viruses in Food Processing

- Vaccination (for HAV)
- Good personal hygiene and proper hand washing
- Thermal processing
- Sanitizers (to reduce the survival and persistence of viruses in food environments)

## PARASITES

Parasites are single or multicellular organisms that live in the environment and on or within a host (human or animal). They source their energy and food from the environment or their host, and parasites of public health concern are transmitted through water, soil or fecal/oral transmission. Parasites can remain viable in the environment for long periods of time and are often transmitted through water contaminated with fecal matter. Infection from these organisms causes a tremendous burden of disease around the world, especially in tropical and subtropical latitudes. Not all parasites can multiply in food, and some are not heat resistant.

**Protozoa** are single-celled organisms that can live in nature and multiply in humans, contributing to their survival and persistence under multiple natural and anthropogenic environments. Transmission from environmental sources to humans is typically through ingestion of contaminated water or food, although human-to-human trans-

mission through a fecal-oral route is possible. Protozoa that live in blood or tissue are transmitted to humans by an arthropod vector such as mosquito or sand fly bites.

Three specific parasites that are considered foodborne protozoan parasites are *Giardia lamblia*, *Cryptosporidium parvum* and *Cyclospora cayetanensis*; for all of them the common mode of transmission is contaminated water, and all are highly tolerant to chlorine disinfection. They most commonly cause diarrhea and other gastrointestinal symptoms, and they most often contaminate food due to food handlers not following good hygiene practices.

### Classifications of Human-Infecting Protozoa, Based on their Mode of Movement

- **Sarcodina** – the amoeba, e.g., Entamoeba
- **Mastigophora** – the flagellates, e.g., Giardia, Leishmania
- **Ciliophora** – the ciliates, e.g., Balantidium
- **Sporozoa** – organisms whose adult stage is not motile (moving spontaneously), e.g., Plasmodium, Cryptosporidium

Irrespective of the type and movement of protozoa, their importance in food contamination can't be underestimated. Many food ingredients including herbs, spices, fruits and vegetables and game meats may carry these microorganisms. Their presence is mainly impacted by growing, handling and processing conditions. For example *Giardia lamblia* is an infective protozoan with reservoirs in infected humans and domesticated and companion animal species, and its outer shell makes it tolerant to UV light and chlorine levels. It's mainly associated with water, soil and fecal contamination of foods prior to harvest and during other food processing. Infected food handlers normally shed Giardia cysts in feces, leading to contamination of food or food contact surfaces if handlers do not wash their hands adequately.

*Cryptosporidium parvum* is a protozoa associated with consumption of contaminated water and infected wild and domestic animals. Like Giardia, it's outer shell allows it to survive outside the host for prolonged periods of time and makes it very tolerant to chlorine disinfection and desiccation.

*Cyclospora cayetanensis* is a protozoa associated with consumption of contaminated water, herbs, fresh fruits and vegetables due to contaminated feces or irrigation water. It needs days to weeks after being passed in a bowel movement to become infectious for other individuals. Berries and some species of leafy greens are among the produce items most commonly associated with this disease.

### Control Methods for Protozoa in Food Processing

- Freezing
- Thermal processing



## 2.2 CHEMICAL HAZARDS

Chemical hazards found in food and food environments are substances that can cause health problems when ingested or inhaled, including toxins, chemicals and chemical residues. Chemical hazards can be naturally occurring (mycotoxins), intentionally added (nitrates, sulfites, preservatives, color additives, and synthetic substances approved for use in food), or unintentionally added (chemical residues from sanitizers, pesticides or environmental pollutants) in foods. Food allergens are also classified as a chemical hazard.

Chemical hazards can produce acute foodborne illness, or chemical poisoning through consumption of toxic or hazardous chemicals in food. The risk level depends on the duration of exposure and toxicity of the substance. The most effective control of contamination from these hazards is prevention through the establishment of food safety controls, including making sure chemicals are applied solely for their intended use, and following all instructions on chemical labels.

All chemicals used in making food or used in a food facility should have a letter of guarantee from the manufacturer, which specifies in writing that controls, treatments and analyses have been performed to reduce or eliminate hazards from the use of those substances.

### PESTICIDES

Pesticides are substances that are designed to control pests, weeds and diseases, and eliminate or reduce pathogens, particularly in the production of food. They include insecticides, fungicides, herbicides, rodenticides, sanitizers and molluscicides. Pesticides must be registered with the US Environmental Protection Agency (EPA) and must be used according to label instructions. Use and application of these chemical substances is regulated, and applicator licenses are needed to apply certain types of pesticides.

The U.S. Department of Agriculture (USDA) and EPA regulate and monitor the use and residues of these substances to ensure any contamination is within safe limits. The limits apply both to food produced in the USA and imported from elsewhere. Monitoring of pesticide residues on foods and food-contact surfaces may be a requirement for certain ingredients, and pesticide analysis in finished food products could be an appropriate verification activity that demonstrates that pesticides have been used according to their labels and relevant federal regulations.

### HEAVY METALS

Heavy metals are metals with high atomic mass including mercury, cadmium, arsenic and lead. Toxic in low amounts, heavy metals are recognized as a health hazard for humans linked to contamination of food from the environment. Once in the food, these metals cannot be removed. In fresh produce, lead and cadmium are the most common heavy metals of concern for consumers, while lead and mercury are the most common metal contamination sources in fish. In order for contamination to occur, the growing environment must have high concentrations of these metals. Federal regulations establish maximum acceptable levels for each heavy metal contaminant, which are specific to metal-food type combinations. Control of raw materials is the only mechanism for ensuring that levels do not become unsafe.

#### Sources of Chemical Hazards in Food Processing

- **Ingredients, including additives**
- **Allergens**
- **Food contact surfaces**
- **Employees**
- **Chemicals, such as pesticides**

In food processing, it is possible for heavy metals to leach from unsuitable materials being used as food contact equipment, including acidic food being fed through copper and lead pipes. The implementation of GMPs, requiring that food contact surfaces be made of suitable, nonporous, nontoxic material, will reduce the risk of heavy metal contamination in a food production process.

### INDUSTRIAL CHEMICALS

Contamination of food with these toxic chemicals may occur unintentionally during food manufacturing activities. It is important to consider these potential hazards in your cGMP program. These chemicals are associated with high risk and low risk food combinations, and the examples provided below highlight situations where they may be present in low risk foods.

**Acrylamide** is a known carcinogen that is formed in food through high-temperature cooking methods such as baking, frying and roasting, and is a particular concern with starchy foods. Examples of foods most at risk are potato products such as crisps and chips, coffee, crackers, bread and other cereal products. The European Union was the first to study issues with acrylamide formation, which resulted in the development of industry guidelines for minimizing contamination risks, which are summarized below.

#### Industrial Guidelines for Minimizing Acrylamide Risk

- Avoiding sources of asparagine
- Avoiding long cooking times and high cooking temperatures where possible
- Replacing ammonium bicarbonate as a processing aid in bread

**Chloropropanols** are a group of chemical contaminants, the most notable of which is 3-monochloropropane-1,2-diol (3-MCPD), that can occur in foods and food ingredients at low levels as a result of processing, migration from packaging materials during storage, or cooking by the end-user of the food. It has been found in a variety of foods including malt extracts, baked products, dehydrated leaves including tea-bags, and fried foods. Control of processing conditions and selection of ingredients and packaging materials is the main strategy to control levels of Chloropropanols.

**Furans** are colorless and volatile liquids used in some chemical manufacturing industries and found in foods. It is believed that Furans form in food during heat treatment techniques such as cooking, bottling, and canning. Furan has been found in bottled foods, beans, pasta meals, herb extracts, and oils.

**Dioxins/Polychlorinated biphenyls (PCBs)** These are persistent manmade toxic chemicals used in multiple industries, and they have been found in soil, water, sediment, plants and animal tissue in all parts of the world. Their release into the environment generally occurs as a byproduct of fires and by certain manufacturing processes. Their widespread environmental occurrence means that they may be present in any foods, and food is the most common route of human exposure. The highest concentrations are found in fatty foods, oil infusions, and dehydrated fruits. The only control to ensure safe levels of these chemicals in processed food is to prohibit their use in the production of foods and food ingredients.

**Polycyclic aromatic hydrocarbons (PAHs)** are a group of compounds that are considered to be carcinogenic and genotoxic. They are mainly found in petroleum and coal, and can be formed by the incomplete combustion of these fuels or other organic materials. PAHs have been detected in air, water, soil and foods. Foods may become contaminated through direct environmental exposure, migration from packaging material, or during high-temperature processing such as baking and frying. The occurrence of PAHs in fruit, vegetables and cereals is primarily due to soil and air exposure. Other foods of concern are fish, fats and oils including cocoa butter, and smoked foods.

Figure 4. Top 9 Food Allergies in the US



## FOOD ALLERGENS (naturally occurring chemicals)

Food allergens are chemical contaminants that can result in serious health consequences in humans. A food allergy refers to an immune system reaction that occurs from consuming certain foods. This reaction can occur almost immediately after consuming food or just by being exposed to small quantities of the allergen. Symptoms associated with allergen exposure can range from digestive problems, hives or swollen airways, to anaphylaxis in severe cases. In general the best approach to eliminate any issues associated with allergens is through avoidance of the allergens. In the United States there are 9 main sources of allergens responsible for over 90% of food allergic reactions (Figure 4).

When allergens are present in a food handling area, it is important to be sure proper controls are in place to reduce the risk of cross-contact of non-allergenic foods with allergen-containing foods. This is especially important when using a shared-use kitchen where others may be processing foods containing allergens. A robust cleaning routine can assist in the removal of allergens, but the use of sanitizers alone is not effective for removing allergens.

One of the most common mistakes in food manufacturing is improper labeling of foods, especially the failure to disclose potential allergens in a food product. Undeclared allergens are a leading cause of food recalls, accounting for 43.5 percent of all recalls of FDA regulated foods in 2022. The National Institutes of Health estimates that 4 percent of adults and 5 percent of children have food allergies.

Those situations can be significantly reduced by the implementation of an allergen control plan that includes labeling guidelines and controls coupled with prevention of cross-contact by scheduling, using different equipment and utensils to handle allergens, and implementing a sanitation program that eliminates allergen residues from food contact surfaces. Because of the significant health hazards that food allergens cause in susceptible individuals, it is important to understand and follow FDA's allergen labeling rules for the good of your customers and your business. See Chapter 4.3 for a detailed discussion of federal allergen labeling requirements.

## FUNGAL TOXINS (chemical toxins)

We mentioned previously that molds, a biological hazard, are capable of producing a chemical hazard called mycotoxins. There are several foodborne mycotoxins found in a wide variety of agricultural products worldwide. Food processing techniques such as milling and heat treatments at specific time/temperature controls can reduce

levels of mycotoxin contamination. Some examples of the most relevant mycotoxins found in food are the following: Aflatoxins, Ochratoxins, Fumonisin, Patulin, Trichothecenes, and Zearalenone (Table 5 and Table 6).

**Table 5.** Most common mycotoxins found in foods, their health impacts and production conditions.

FUNGAL TOXIN	COMMON FOOD CROPS AFFECTED	HEALTH EFFECTS	OPTIMAL GROWING CONDITIONS
<b>Aflatoxins</b> <i>Aspergillus flavus, Aspergillus parasiticus</i>	Peanuts, corn and grains, milk and cheese, meat (contamination from livestock feed), nuts, grains, soybeans, figs, dried spices and cocoa beans	Carcinogenic effects, immunosuppression, jaundice, liver failure and other symptoms	10-48 °C, water activity (a <sub>w</sub> ) as low as 0.82 and pH in the range of 2.0-11.0
<b>Ochratoxin A (OTA)</b> <i>Aspergillus ochraceus, Aspergillus carbonarius, Penicillium verrucosum</i>	Cereal grains, coffee, pork products, wine, beer and dried grapes	Carcinogenic effects, kidney damage	Temperatures ranging from 5-40 °C, optimal growth at temperatures 25-30°C
<b>Fumonisin</b> <i>Fusarium verticillioides, Fusarium proliferatum, Fusarium spp., Aspergillus niger</i>	Corn, sorghum and other cereal grains	Carcinogenic effects (humans), brain disease (livestock)	Moisture content at or above 14%
<b>Patulin</b> <i>Aspergillus, Penicillium patulinum</i>	Damaged and rotting fruits, fruit juices and vegetables (Apples most common)	Carcinogenic effects	10-48 °C, water activity (a <sub>w</sub> ) as low as 0.82 and pH in the range of 2.0-11.0

**Table 6.** Common chemical hazards associated with food and food environments.

CATEGORY	CHEMICAL HAZARD	POTENTIAL SOURCES
Plant toxins	Toxins, Cucurbitacins, Cyanogenic glycosides, Glycoalkaloids, Lectins	Naturally occurring in different plant cultivars
Biogenic amines	Known histamine sources	By products of bacterial growth produced during food spoilage before or after packaging of game meats, dehydrated foods
Contaminants from Food Contact Materials	Bisphenol A, Phthalates, Semicarbazide	Can be found in packaging, water, food contact surfaces
Radiological	Strontium-96, iodine-131 and cesium-137	Sources include water, produce, soil, air, packaging materials and ingredients with radionuclides



## 2.3 PHYSICAL HAZARDS

Physical hazards are either foreign materials unintentionally introduced to food products or naturally occurring objects that are hazardous to the consumers and that can contaminate food at any stage of production. In [Table 1](#), we mentioned several sources of physical hazards often found in food.

Potential risks associated with physical hazards are determined by the physical characteristics of the object (shape, size, sharpness), the type of product, and the individual consuming the product. All of them pose risks to consumers including cuts to the mouth or throat, damage to the intestines, damage to teeth or gums, and choking.

Choking hazards for adults are considered when items are 7 to 25mm. For children, physical hazards smaller than 7mm could pose a significant choking risk. The physical characteristics (shape, hardness, sharpness) and material of the physical hazard, impact the severity of the choking risk to consumers. ([Table 7](#)).

Several methods are available to detect foreign materials in food processing lines.

### Physical Hazard Detection Methods

- Magnets to attract or remove metals
- Metal detectors to detect metal
- X-Ray machines to identify hazards
- Visual Inspection

Visual inspection is the most common method used in small-scale food processing.

**Economically motivated hazards** These are hazards that result from the addition of any substance to food that could cause injury or illness to consumers and provide an economic advantage to the company. Examples include adding soy or almond oil to another oil not containing any allergens, or adding melamine to milk products.

**Table 7.** Materials of concern as physical hazards and their common sources

CATEGORY	INJURY POTENTIAL	SOURCES
Glass	Cuts, bleeding; may require surgery to remove	Bottles, jars, light fixtures, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones	Choking, broken teeth	Fields, buildings
Bullet/BB Shot/Needles	Cuts, infection; may require surgery to remove	Animals shot in fields, hypodermic needles used for infections
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employee
Jewelry	Cuts, infection; may require surgery to remove	Careless employee practices
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insects and other filth	Illness, trauma, choking	Fields, plant post-process entry
Insulation	Choking; long-term if asbestos	Building materials
Plastic	Choking, cuts, infection; may require surgery to remove	Sources include water, produce, soil, air, packaging materials.

## CHAPTER 3

# BASIC CONCEPTS FOR PROPER FOOD PRESERVATION

The goal of food preservations is to prevent the growth of microorganisms in food and to inhibit or inactivate enzymes and chemical reactions that will accelerate food spoilage during storage. This can be achieved by multiple approaches including the control of temperature, oxygen, acidity, and water activity, and the addition of food preservatives to prevent the growth of bacteria, fungi and other microorganisms. Food preservation ensures that food remains in a state where it maintains its optimal qualities of color, texture and flavor while keeping it safe to eat.

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## 3.1 BASIC FOOD CHARACTERISTICS

The internal or external characteristics of food can serve as a hurdle to delay or prevent microbial growth. In general, **Internal (Intrinsic Factors)** are specific to the commodity. Examples include the following: available nutrients, available water, pH (acidity or alkalinity) and physical structure. **External (Extrinsic)** refers to parameters that are manipulated in foods via formulation, processing, packaging or storage to modify the characteristics of foods. These modifications could also serve to extend shelf life and reduce or control microbial growth. Some examples of external factors include the modification of temperature, atmosphere (presence or absence of oxygen), packaging, water activity, and the use of preservatives like Nisin, Potassium sorbate, Sulfur dioxide, Nitrate, Nitrite, Sodium propionate and Benzoic acid.

### FOOD PROTECTION VS. FOOD SAFETY

**Food protection** refers to having controls within growing and processing environments where it is necessary to prevent contamination of food by a potential health hazard. Control can be achieved through planning and implementation of GMPs and other food safety programs including HACCP (Hazard Analysis and Critical Control Points) or HARPC (Hazard Analysis and Risk-Based Preventive Controls, also known

as Preventive Controls For Human Food). **Food Safety** refers to the implementation of food growing, handling, preparation, and storage practices in ways that prevent foodborne illness. It can only be achieved by safe handling of foods at all points within the food chain and by establishing a food safety program based on successful implementation of GMPs.

**Table 8.** Food preservation methods impacting microbial growth and safety of low risk foods

PRESERVATION METHOD	LIMITING FACTOR IN FOODS	IMPACT ON FOOD SAFETY AND MICROBIAL GROWTH
Use of Preservatives	pH of the food limits type of preservative. They can be synthetic, or of bacterial origin like Nisin	Inhibition of specific groups of micro-organisms
Drying (Dehydration and salt curing)	Final moisture content, case hardening, and length of the process and salt concentration. The type of food, fat content, time of exposure, piece size and temperature impact curing and drying time	Controls water activity in food. Low water availability prevents or controls microbial growth. Salt binds with water molecules and thus acts as a dehydrating agent in foods.
Pasteurization of honey	The final moisture content and time/temperature of the technique to inactivate some vegetative cells. Time/temperature combinations vary with pasteurization technique (avoiding crystallization). Will not inactivate environmental chemical contaminants.	Heat inactivation of microorganisms (yeast, molds and some vegetative bacteria, including <i>Clostridium</i> spp). Reduces water activity to retard the fermentation, oxidation and other spoilage reactions.
Refrigeration	Won't eliminate human pathogens but it reduces metabolic activities from foods and microorganisms. May introduce or reduce moisture content depending on the type of food	Low refrigeration temperatures will delay microbial growth before foods or food ingredients are processed.
Freezing	Composition and size of the food. Bulkier foods require longer freezing times that could impact the size of ice crystals in food. Larger crystal will rupture food tissue and when thawing will increase water leakage due to ruptured tissues (quality issue)	This methods slows or inactivates enzymatic reactions and oxidation processes, it also reduces water activity and inactivates some pathogens. It won't inactivate toxins or other chemical contaminants.
Vacuum/low oxygen packaging (No time/temperature controls)	Anaerobic conditions may lead to off flavors and growth of <i>Clostridium</i> and <i>Bacillus</i> pathogenic species	Low oxygen inhibits strict aerobes and delays growth of facultative anaerobes.
Sugar preservation	Not all foods are suited for high sugar concentrations.	High sugar concentrations reduce water activity. A high sugar concentration creates high osmotic pressure, which impacts survival and growth of most microorganisms.
Preserves	pH, brix and packaging temperature	Acidity at a pH of 3 to 3.5 used for the pectin to produce a gel, coupled with brix vales of 63 to 68% (high solutes) and cooking times, control, prevent or inactivate microbial growth.

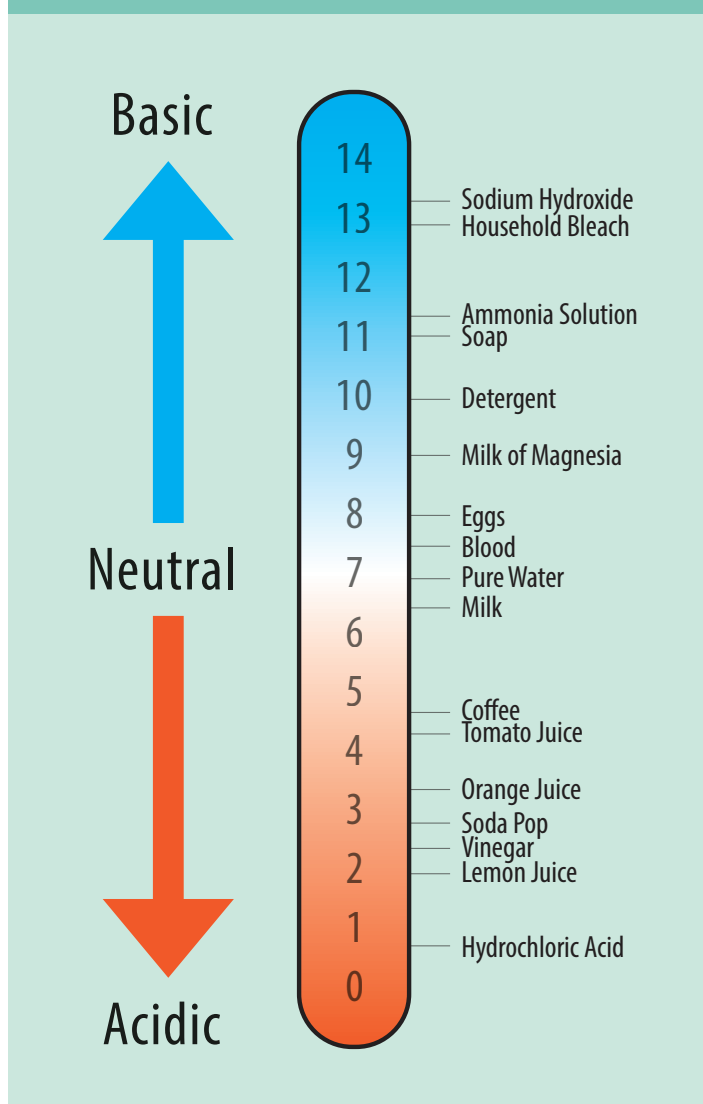
Depending on the type of food and manufacturing conditions, different preservation methods can be used to extend the shelf life of food. This cGMP manual explains those manufacturing conditions that are of importance in manufacturing low risk activity/food combinations as described by FDA (Appendix 1). Low risk foods as

defined by FDA are foods that will present little risk to consumers when consumed because of their intrinsic characteristics and preservation and packaging methods. **Table 8** illustrates some of the most common food preservation methods impacting the safety of food.

## 3.2 PH (ACIDITY & ALKALINITY)

A pH of 6.0–7.5 is considered optimal for bacterial growth. Most food products fall within the slightly acidic to neutral range. In general, having sufficiently high acidity/low pH controls/reduces microbial growth in foods. Every microorganism has an optimum, maximum and minimum pH for growth, and by altering the acidity in foods we can alter the growth rate (generation time), lag period, survival rates, and spore germination of a microorganism.

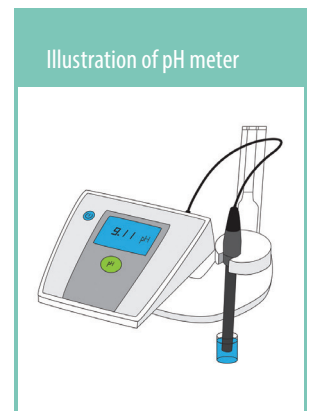
Figure 5. pH range of different chemicals and foods.



Foods with a pH of 4.6 or less are classified as acid foods. An equilibrium pH of 4.6 or below reduces the capacity of bacteria, fungi and yeast to grow, and will stop spore germination from *Clostridium botulinum*. Food producers can use milder thermal treatments for products with a pH of 4.6 or below, since the acidity coupled with formulation and environmental conditions will combine to inactivate vegetative cells and spores.

There are some other microorganisms that are capable of growing or surviving at low pH, including many pathogenic *E. coli* strains, *Salmonella* and other microorganisms (Table 9). For this reason it is imperative to reduce the potential for any foodborne illness by preventing cross contamination of foods with these pathogens since high acidity alone may not prevent growth or survival in different high acid foods.

**Acidity** is measured using a pH meter. This instrument measures the hydrogen-ion activity in water-based solutions, indicating its acidity or alkalinity expressed as pH. It measures the difference in electrical (potential of hydrogen) between an instrument and a reference electrode. The difference in electrical potential is linked to the acidity or pH of the solution. In foods it is imperative to measure the equilibrium pH. This is normally achieved over time and may require several measurements before the pH has finally stabilized.



Microorganism	Acidity (pH) limits for microbial growth of concern
<i>Salmonella spp</i>	4.2-5.0
<i>Staphylococcus</i> (toxin)	4.0 (4.5)
<i>Vibrio parahaemolyticus</i>	4.8
<i>C. botulinum</i> (toxin)	4.6-5.0 (4.6)
Enterohemorrhagic <i>E.coli</i>	4.4
<i>Aspergillus niger</i>	1.4



### 3.3 WATER ACTIVITY

Water activity ( $a_w$ ) is a measure of the free moisture, or available water, in a product. It represents the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. When all of the water is available,  $a_w = 1$ , and when none is available,  $a_w = 0$ . Water activity values below 0.86 prevent bacterial growth and germination of bacterial spores. Low  $a_w$  values aid in thermal processing: low water activity foods may require milder heat treatments to inactivate human pathogens (see Figure 6).

#### INSTRUMENTS FOR MEASURING WATER ACTIVITY

**Capacitive Hygrometer** Water activity is easily and accurately determined from the equilibrium relative humidity, a measure of the relative humidity of air in equilibrium with the sample food that is referred to as equilibrium relative humidity (ERH). A capacitive hygrometer is used to measure ERH. This instrument uses resistance or capacitance sensors to measure relative humidity. Any alteration in relative humidity triggers a very rapid proportional change in capacitance. A single measurement takes approximately 30 to 90 minutes.

**Dew Point Hygrometer** This instrument measures the temperature at which condensation occurs on a cooled mirror in the headspace of its sample chamber. The  $a_w$  is computed by converting temperatures of the food sample and the mirror to vapor pressures and calculating the ratio between them. It's usually much faster than a capacitive hygrometer, generally taking only 5 minutes for a single measurement. However, this instrument should not be used to measure products that are below 0.20  $a_w$ . This instrument is delicate, and the condensation of water on the mirror may trap airborne contaminants, hindering the instrument's accuracy.



A Figure 7 summarizes a range of water activity, food and pathogen combinations. This list is not exhaustive and will change based on the characteristics of the product. Many low risk foods will have different water activity levels and manufacturers of these foods should determine the water activity of the product to help them in the establishment of controls to reduce microbial hazards.

Figure 6. Impact of water activity on microbial growth. Lower water availability will slow down or even prevent microbial growth

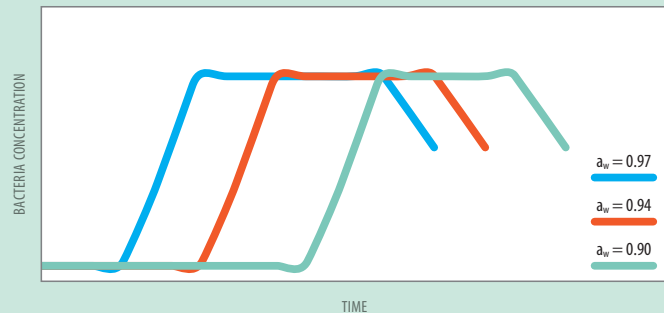


Figure 7. Range in water activity of foods and human pathogens of concern.

#### WATER ACTIVITY ( $a_w$ ) LIMITS FOR MICROBIAL GROWTH

0.98	<i>Campylobacter</i>
0.97	<i>Clostridium botulinum</i> type E (non-proteolytic)
0.95	<i>E. coli</i>
0.95	<i>Clostridium perfringens</i>
0.94	<i>Clostridium botulinum</i> types A & B (proteolytic)
0.92	<i>Listeria monocytogenes</i>
0.83	<i>Staphylococcus aureus</i> (an $a_w$ of 0.86 for toxin production)
0.88	Many yeasts
0.75	Many molds

#### WATER ACTIVITY ( $a_w$ ) OF SOME FOODS

0.97–1.00	Fresh Fruits
0.95–1.00	Cheese
0.95–1.00	Fresh Meat
0.60–0.90	Cured Meat
0.75–0.80	Jam
0.35	Peanut Butter
0.50–0.65	Honey
0.60–0.65	Dried Fruit
0.30–0.50	Chocolate
0.10–0.20	Cereal
0.10	Crackers

## 3.4 TEMPERATURE CONTROLS IN FOOD PROCESSING

There are two basic forms of thermal treatments to preserve food: subjecting the food to very low temperatures, or subjecting the food to very high temperatures. In either case, the food must be held at the desired temperature for a predetermined period of time in order to assure microbial inactivation of spoilage and pathogenic organisms.

### Factors that Affect Thermal Processing

- The container (heat penetration properties)
- Type of food
- Target microorganism
- pH of the food
- Fill weight vs. drained weight distribution

### LOW TEMPERATURE TREATMENTS

Low temperature food preservation is based on the principle that less energy is available at lower temperatures for microorganisms and chemical reactions to carry out their normal functions. This reduction in metabolic power reduces enzyme activity and metabolic activities of microorganisms.

**Refrigeration (<4C/39.2F)** Refrigeration slows down the chemical and biological processes in foods and the accompanying deterioration and the loss of quality. The storage life of fresh perishable foods such as meats, fish, fruits, and vegetables can be extended by several days following this process. The process involves cooling only without any phase change. Fresh fruits and vegetables are alive and thus they continue giving off heat that adds to the refrigeration load of the cold storage room. Removing the field heat and cooling as soon as possible after harvesting can extend the storage life of produce. The optimum storage temperature for most fruits and vegetables is about 0.5 to 1 °C above their freezing point.

**Freezing (< -20°C/4F)** This process involves three stages: (1) cooling to the freezing point, (2) freezing, and (3) further cooling to the desired subfreezing temperature. Considerations in freezing foods include the type of food to be frozen and the freezing method. Typically there are four methods used for frozen foods, and all of them are used to create small ice crystals as fast as possible to prevent quality issues during long-term storage and during thawing.

### Four Freezing Methods

- 1 **Air-blast Freezing** High-velocity air at about -30°C is blown over the food products.
- 2 **Contact Freezing** Packaged or unpackaged food is placed on or between cold metal plates.
- 3 **Immersion Freezing** Food is immersed in low temperature brine.
- 4 **Cryogenic Freezing** Food is placed in a medium cooled by a cryogenic fluid such as liquid nitrogen or liquid/solid carbon dioxide.

### HIGH TEMPERATURE TREATMENTS

There are two main temperature categories in thermal processing: pasteurization and commercial sterilization. The basic purpose for thermal processing is to reduce or eliminate microbial activity, to reduce or eliminate enzyme activity, and to produce physical or chemical changes to make the food meet a certain quality standard. This will provide the necessary level of quality and food safety under the desired storage conditions of the food receiving the thermal process.

**Pasteurization** This technique is a relatively mild heat treatment, in which food is heated to less than (100°C/212°F). It is mainly used for destroying enzymes, yeast, vegetative pathogens and other microorganisms that are relatively heat-sensitive. The severity of treatment that is needed in a low risk food like honey, jam, jelly, and herbal extracts, and the impact of the treatment on the shelf life of the processed food, is determined by the pH of the food and its water activity. In low acid foods (pH greater than 4.6), the main purpose is to eliminate pathogenic bacteria, while in acid foods with a pH below 4.6 pasteurization is intended to destroy spoilage microorganisms and enzymes.

### Three Pasteurization Methods

- 1 **Batch Method** The food is held in a container, heated to at least 63°C, and held for at least 30 minutes before being packaged.
- 2 **High Temperature Short Time (HTST) or Flash Pasteurization** The food is passed through a system of heat exchangers and tubes that heat the food to at least 72°C and hold it at that temperature for at least 15 seconds.
- 3 **Package Pasteurization** This method is used in some liquid foods. The thermal treatment occurs after filling the containers with the liquid and immersing these containers in hot water. This process is normally used when packaging into glass.

Two groups of microorganisms survive pasteurization temperatures. Thermoduric organisms can survive exposure to relatively high temperatures. Thermophilic organisms not only survive relatively high temperatures, but require high temperatures for their growth

**Commercial Sterilization** The aim of this process is to eliminate all pathogenic bacteria, including their spores. Heat treatment of such products must be severe enough to inactivate/ kill the most heat resistant bacterial microorganisms, which are the spores of *Bacillus* and *Clostridium*. Foods are placed in sealed containers and they are heated to temperatures above 100°C and normally range between 110°C and 121°C, depending on the type of product, and for a specific time that will allow the food to reach commercial sterilization (CS). CS is defined as a decrease in the amount of the microorganisms to 1 trillionth of the amount that was present before the thermal treatment, also referred to as a 12 Logarithm (12D) reduction of microorganisms. CS

implies less than absolute destruction of all microorganisms and spores, but any that remain would be incapable of growth in the food under normal storage conditions. These sterilization temperatures are needed for short periods of time (within a few seconds) to inactivate spores from *Bacillus* or *Clostridium*. These spores can also be killed at lower temperatures, but longer heat treatment periods must be applied.

### Sterilization methods

- **Ultra-Heat Treatment (UHT)** This is generally performed at high temperatures with a short treatment duration (1s at 135°C).
- **Canning** The product is stored in containers that are hermetically sealed and then sterilized through heating at temperatures over 100°C; treatment duration will depend on the food.
- **Aseptic Processing** The product and the package are sterilized separately and then the package is filled with the sterile product and sealed under aseptic conditions.

## THERMAL TREATMENTS & LOW RISK FOODS

Although some low-risk foods require the application of time/temperature controls, low-risk foods generally do not need to be refrigerated (until opened) and are usually high in sugar, salt or acid and, in most cases, low in water content. A combination of these food characteristics are needed to classify foods as low-risk. The thermal process (commercial sterilization) of low-acid canning, for example, is implemented to destroy the spores of the bacterium *C. botulinum*. Sterilization requires heating to temperatures greater than 100°C, which would be necessary in the sterilization of low-acid foods (pH greater than 4.6), but this is not the case for acidic foods that have a pH less than 4.6 where *C. botulinum* cannot survive. When canning in glass jars, sterilization of the jars is needed, not of the product, and this is accomplished by filling the jars with the hot liquid, for example in making jams and jellies.

For similar reasons, the pasteurization of honey is considered low-risk. Honey is low in water content and high in acidity, which means bacteria cannot survive in it. Unlike juice and milk that are pasteurized for food safety purposes, honey is pasteurized for quality purposes, reducing the chance of fermentation and delaying granulation. Honey is pasteurized by heating it to 71°C and quickly cooling it.

## 3.5 OXYGEN & ATMOSPHERE MANAGEMENT DURING PACKAGING

Removal of oxygen from packaging is an important factor for preserving low risk foods including chips, nuts crackers, dehydrated foods, spices, cocoa beans, and coffee. Several methods are available and include: commercial canning; boiling water canning for jams, jellies and preserves; and vacuum or modified atmosphere packing for foods that do not require time/temperature controls for safety. Removal of oxygen from foods can inhibit growth and persistence of microorganisms; however, spore formers including *Clostridium botulinum*, *Bacillus cereus* and *Clostridium perfringens* can survive in anaerobic conditions and can become a food safety problem for food manufacturers and consumers. Therefore GMPs and the control of other factors (temperature, acidity or water activity) must be employed to reduce hazards associated with spore formers.

### MODIFIED ATMOSPHERE PACKING (MAP)

MAP is a packaging practice that changes the composition of the internal atmosphere of a package, with the goal of improving the shelf life of the product. The modification process lowers the amount of oxygen in the package from 21% to 0.5%, to slow down the growth of aerobic organisms and prevent oxidation reactions, by replacing oxygen with nitrogen or carbon dioxide, both of which can lower the pH or inhibit the growth of bacteria. This technique is used in packaging of baked goods, dehydrated foods, pasta, and other dried foods.

### PACKAGING MATERIALS

When selecting packaging films the main characteristics to consider are gas permeability, water vapor transmission rate, mechanical properties, transparency, type of package and sealing reliability.

#### Films Used for MAP

- LDPE (low-density polyethylene)
- PVC (polyvinyl chloride)
- EVA (ethylene-vinyl acetate)
- OPP (oriented polypropylene)

The choice of which film to use will depend on the level of respiration from the food product. Films designed to allow gases to escape the package are called permeable films. Other films, called barrier films, used in vacuum packing, are designed to prevent the exchange of gases and are mainly used with non-respiring products like snacks and game meat products.

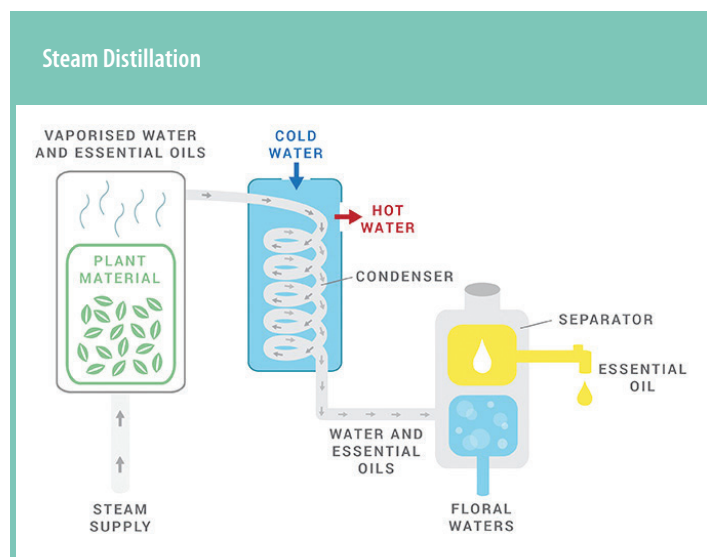
## 3.6 OTHER FACTORS

### SALTING OF LOW RISK FOODS

In the case of low risk foods, salting is not used as a preservation technique and instead is mainly used for flavoring purposes. For these foods, all chemical, physical and microbiological hazards have to be controlled using other methods; the addition of salt will not introduce hazards in low risk grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption. When processing these types of products, cleaning and sanitation of equipment before mixing with salt, and the storage conditions and source of the salt, are the factors that will impact quality and safety of these products.

### EXTRACTION THROUGH PRESSING, DISTILLING & SOLVENTS

Low risk foods produced through extraction rely on a thermal process to evaporate the desired substance from within foods, such as essential oils. Steam distillation is the most popular method used to extract and isolate essential oils from plants.



This process vaporizes the plant material's volatile compounds, which then go through a condensation and collection process into a large container or finished package. Essential oils from mint, herbs, spices, avocado, olives, seeds, and ethanol extractions are typical products that fall under this category of low risk foods where sanitation practices within the condenser and packaging materials influence the safety and quality of each product. During the separation stage where extracts are separated from the water vapor, cross contamination may occur if sanitation, employee hygienic practices and pest controls are not in place.

These products may be further infused with other herbs and aromatics, but in order to be considered low risk these infusion processes must occur with food ingredients that have undergone a treatment to eliminate chemical, physical and microbiological hazards. Some high value food ingredients like edible flowers and fruit blossoms can be processed through water distillation, and using only potable water for the process, along with good sanitation practices while maintaining the cleanliness of equipment, will be the determining factors impacting quality and safety of these essential oils.

**Solvent extraction** This method employs food grade solvents, such as hexane or ethanol, to isolate essential oils from plant material. It is best suited for plant materials that yield low amounts of essential oil, that are largely resinous, or that are delicate aromatics unable to withstand the pressure and distress of steam distillation. Through this process, the non-volatile plant materials such as waxes and pigment are also extracted and in some instances removed through filtration, refrigeration or other processes. After the plant material has been exposed to the solvent, a waxy compound is formed that is later mixed with alcohol to release the oils. Under these processing conditions the most critical factors within your cGMP program include the sourcing of solvents and the sanitation and hygienic practices followed during extraction and packaging.

**Maceration extraction** Maceration processes are normally used for the extraction of oils from seeds, and are used to extract essential oils with the strong flavors or aromas of the seed or grain being used. However, these oils also tend to oxidize faster due to the presence of enzymes found in seeds. Under these processing conditions, any macerated plant materials first needs to be dried to reduce any microbial hazards and to reduce excessive quantities of the enzymes that may expedite rancidity of the essential oils. Antioxidants used in the extraction process to reduce rancidity include vitamin E oil and wheat germ oil.



## CHAPTER 4

# GOOD MANUFACTURING PRACTICES

The federal current GMP regulation (21 CFR 117 Subpart B) applies to all food products regulated by the FDA, and requires food manufacturers to ensure that ingredients, products and packaging materials are handled safely and that food products are processed in a suitable environment. Designed to provide flexibility, the GMP regulation is general in nature to assist each operation in developing and implementing appropriate practices. GMPs are the basis of a food safety system meeting minimum food safety requirements. In the case of low risk activity/food combinations produced at facilities with fewer than 500 employees, no further preventive controls are necessary in addition to cGMPs for compliance with FDA's food manufacturing regulations.

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The current Good Manufacturing Practices address the nine aspects of food manufacturing identified to the right (with references to the specific section of the cGMP regulation that covers each).

It is management's responsibility to take all reasonable measures and precautions to maintain the basic operational and environmental conditions required to produce safe foods. Communicating the GMP rules with employees through training can minimize food safety risks significantly. **Table 12** illustrates the most common documentation and procedures used by the industry to demonstrate compliance with cGMPs. This table should be used as a guide rather than a comprehensive list of documents needed to develop and implement cGMPs.

## Nine Aspects of Good Manufacturing Practices

- 1 Personnel (§117.10)
- 2 Plant & Grounds (§117.20)
- 3 Sanitary Operations (§117.35)
- 4 Sanitary Facilities and Controls (§117.37)
- 5 Equipment and Utensils (§117.40)
- 6 Processes and Controls (§117.80)
- 7 Warehousing and Distribution (§117.93)
- 8 Holding and distribution of Human Food Byproducts for use as Animal Food (§117.95)
- 9 Defect Action Levels (§117.110)

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## 4.1 PERSONNEL

### DISEASE CONTROL

Any person who has an illness, open lesions, infected wounds, or any other potential source of pathogenic microbial contamination that could result in contamination of the food, food-contact surfaces, or food packaging materials must not work in a food processing area. Employees must be instructed to report health conditions to their supervisors.

### CLEANLINESS

People who work in direct contact with food, food ingredients or food contact surfaces of equipment or utensils must wear clean outer garments, maintain a high degree of personal cleanliness and conform to hygienic practices while at work. They must wash their hands thoroughly before starting work, after each absence from the workstation, and at any other time when the hands have become soiled or contaminated. Jewelry must be removed or covered if it cannot be removed, and if personnel are handling food, they should remove any jewelry that cannot be properly sanitized and covered from their hands. In some instances hand sanitizing may be necessary to protect against microbial contamination.

Additionally, the effective use of hair restraints and/or beard covers is necessary to avoid potential sources of cross-contamination of food. Operators must not store clothing or other personal belongings in food processing areas. Personnel are not allowed to eat, drink beverages, or use gum or use tobacco in any form in food processing areas, and they may not have or bring cosmetics, chemicals or medications into food processing areas.

### EDUCATION & TRAINING

Personnel must be trained in food safety, food hygiene, and in the operation they are performing at the facility. They should also receive training in the identification of hazards that could lead to food contamination, including poor personal hygiene employee illness and unsanitary work habits. Management is responsible for implementing training for personnel.

## 4.2 PLANT & GROUNDS

Grounds around a food processing facility must be free from improperly stored equipment, litter, waste, and uncut weeds and grass around the building; and maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. All drains and areas that can harbor contamination and pests must be adequately drained and free of any waste.

### PLANT CONSTRUCTION & DESIGN

Plant construction and design should provide enough space for sanitary arrangement of equipment and storage of materials. All floors, walls and ceilings must be constructed so that they are cleanable and must be kept clean and in good repair. Any activities that may cross contaminate food need to be separated by partition, location, time or other means to prevent undesirable microorganisms, chemicals, filth or other material from entering the processing environment.

Construction of the food facility should prevent birds, animals, vermin and rodents from entering or sheltering in the facility. Conditions within the facility should prevent contamination of foods with odors; noxious fumes or vapors; and glass from light bulbs, skylights or any other glass source.

#### Properly Designed Facilities

- Provide adequate space for equipment and storage of materials needed for maintenance and sanitation.
- Allow access to areas over and around food processing vessels as necessary to eliminate harborages for pests.

- Provide shatter resistant light bulbs/fixtures/skylights/glass if such objects are suspended over exposed food.
- Allow proper separation of operations to prevent cross-contamination and allergen cross-contact.
- Prevent drip or condensate from contaminating food products.
- Facilitate removal of debris and unused equipment without contaminating food products.
- Provide adequate ventilation and minimize allergen cross contact or food contamination potential from the operation of fans.
- Permit employees to perform their duties without contaminating food/surfaces/packaging, aisles and workspaces.
- Provide adequate lighting in hand-washing areas, dressing and locker rooms, toilet rooms, and in areas where food is examined, manufactured, processed or packaged.

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## 4.3 SANITARY OPERATIONS (General maintenance)

The plant and all fixtures must be kept in good repair and be maintained in a sanitary condition. Cleaning operations must be conducted in a manner that will minimize the possibility of contaminating foods or equipment surfaces that contact food.

### PEST CONTROL

No animals or birds are allowed anywhere in the plant, and programs must be in place to prevent contamination by animals, birds and pests. Pesticides may be used as part of a pest control program so long as the facility has precautions and restrictions in place that will protect food against contamination from these chemicals.

Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

Cleaned and sanitized portable equipment and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

### SANITATION OF FOOD CONTACT SURFACES

All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. Equipment surfaces that are not in contact with food should be cleaned as necessary to minimize accumulation of dust, dirt, food particles and other debris. When utensils or equipment are used in a continuous production operation, they must be cleaned and sanitized as necessary.

## CHEMICAL CONTROL PROGRAMS

Cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

### Key Chemical Hazard Controls

- Training employees on how to handle and apply chemicals used in sanitation, maintenance, or pest control.
- Only using chemicals approved for food contact surfaces, or that have been deemed “Generally Recognized as Safe” (GRAS) by FDA. (See Appendix 2 for further information on FDA’s GRAS list.)
- Storing chemicals in designated areas away from food, food ingredients, packaging, and food contact surfaces.
- Training maintenance personnel to properly clean and remove all chemical residues from food contact surfaces.
- Avoiding excessive application of food grade grease or lubricants on equipment.
- Ensuring chemical containers and measuring tools are clearly labeled and that they are used only for chemicals.
- Sourcing ingredients from reputable suppliers that effectively control chemical hazards.
- Vetting new suppliers of ingredients to ensure they have chemical hazard controls.

## ALLERGEN CONTROLS

Implementing controls for allergen cross-contact is an important component of general maintenance operations.

### Facilities Must

- Develop a master list of allergenic ingredients used in the facility.
- Prevent allergen cross-contact, such as physical barriers to separate processing lines, monitoring and reducing dust levels, and minimizing use of air compressors.
- Clean shared equipment that may come into contact with allergens prior to processing non-allergen foods.
- Avoid in-process or post-process allergen cross-contact, including scheduling processing of allergen-containing foods after non-allergen containing foods.
- Train employees in understanding allergens and recognizing allergen risks in food manufacturing.

The minimum requirement when inspecting surfaces and food manufacturing areas as part of an allergen control program is a visual inspection of cleanliness to assure there are no cross-contact issues associated with allergens.

In addition, the allergen control program must ensure all products containing allergens are accurately labeled, and including monitoring to verify that any labels used on finished products are correct and prepared and applied as intended.

**Allergen Labeling Requirements** The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was enacted in 2004. FALCPA amended the Food Drug and Cosmetic Act to establish labeling requirements for all FDA regulated packaged foods that contain, or are made with ingredients that contain protein derived

from one or more of the 9 major classes of food allergens: milk, egg, fish, crustacean shellfish, wheat, peanuts, soybeans, sesame, and tree nuts. (For FDA’s list of Common Tree Nut Allergens, see [Table 10](#)). Although more than 160 foods have been identified to cause food allergies in sensitive individuals, these 9 “major food allergens” account for 90 percent of all food allergies in the U.S. Allergens other than the major food allergens are not subject to FALCPA labeling requirements.

The law requires specific label declarations for those major food allergens in all packaged foods under FDA’s jurisdiction, except for raw agricultural commodities such as fruits and vegetables, and highly refined oils made from the 9 major allergens.

Products with labels that do not comply with FALCPA requirements may not be legally introduced into interstate commerce in the U.S. because such products would be considered misbranded under the Food, Drug and Cosmetic Act.

Table 10. Common Tree Nut Allergens

COMMON OR USUAL NAME	SCIENTIFIC NAME
Almond	<i>Prunus dulcis</i> (Rosaceae)
Beech nut	<i>Fagus spp.</i> (Fagaceae)
Brazil nut	<i>Bertholletia excelsa</i> (Lecythidaceae)
Butternut	<i>Juglans cinerea</i> (Juglandaceae)
Cashew	<i>Anacardium occidentale</i> (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	<i>Castanea spp.</i> (Fagaceae)
Chinquapin	<i>Castanea pumila</i> (Fagaceae)
Coconut	<i>Cocos nucifera</i> L. (Arecaceae (alt. Palmae))
Filbert/hazelnut	<i>Corylus spp.</i> (Betulaceae)
Ginkgo nut	<i>Ginkgo biloba</i> L. (Ginkgoaceae)
Hickory nut	<i>Carya spp.</i> (Juglandaceae)
Lichee nut	<i>Litchi chinensis</i> Sonn. (Sapindaceae)
Macadamia nut/Bush nut	<i>Macadamia spp.</i> (Proteaceae)
Pecan	<i>Carya illinoensis</i> (Juglandaceae)
Pine nut/Pinon nut	<i>Pinus spp.</i> (Pineaceae)
Pistachio	<i>Pistacia vera</i> L. (Anacardiaceae)
Sheanut	<i>Vitellaria paradoxa</i> C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California)	<i>Juglans spp.</i> (Juglandaceae)



## When Do FALCPA Labeling Requirements Apply?

- 1 When the common or usual name of an ingredient that is a major food allergen does not already identify its food source name.
- 2 When that major food allergen's food source name is not already identified elsewhere in the list of ingredients for another "allergenic" ingredient.

FALCPA requires that the presence of each major food allergen used as an ingredient be disclosed at least once on the label in plain English terms.

Some manufacturers are voluntarily labeling their products with statement such as "may contain (insert name of allergenic ingredient)", but this precautionary labeling should NOT be used in lieu of adherence to FALCPA requirements. While FDA allows such "may contain" statements, these statements do not satisfy FALCPA's requirement to have a "contains" listing on the label.

## Labeling Options of Major Food Allergens

The law provides a choice of two ways to label a food that contains a major food allergen as an ingredient.

- 1 **Ingredient List** The label must identify the presence of major food allergens within the ingredient list. If an ingredient that is made from a major food allergen has a name that does not identify its source, that ingredient name must be immediately followed in parentheses by that name of the source food. For example, if "whey", which is derived from milk and contains milk protein, is listed on a food label, it would have to be accompanied by the term "milk" in parentheses immediately after the term "whey", unless milk is disclosed as an ingredient elsewhere in the ingredient list.

### Ingredients:

ENRICHED WHEAT FLOUR [FLOUR, MALTED BARLEY FLOUR, REDUCED IRON, NIACIN, THIAMIN MONONITRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN B2), FOLIC ACID], WATER, YEAST, SALT, SUGAR, CALCIUM PROPIONATE AND SORBIC ACID (TO PRESERVE FRESHNESS), SOYBEAN OIL, WHEAT GLUTEN, GRAIN VINEGAR, **SOY LECITHIN**, SOY, **WHEY (MILK)**.

- 2 **"Contains" Statement** Alternatively, manufacturers can use a summary "Contains" statement, placed on the label immediately following or adjacent to the list of ingredients in a print size no smaller than that used for the ingredient list. The word "Contains" must be followed by a complete list of the food source names for all major food allergens used as ingredients in the packaged food, whether or not some of those food source names were already disclosed within the ingredient list (e.g., "Contains milk, egg, peanuts").

**INGREDIENTS:** bananas, chocolates (sugar, chocolate liquor, cocoa butter, whole milk, soy lecithin [emulsifier], vanilla), **peanut** oil.

**CONTAINS:** Milk and Soy

**MAY CONTAIN TRACE:** Egg, Peanut, Tree Nut or Wheat Products.

**Ingredients Subject to Specific FALCPA Labeling Requirements** FALCPA labeling requirements apply to foods that are made with any ingredient, including flavorings, colorings, or incidental additives (e.g., processing aids), that is or contains a major food allergen. Spices are not mentioned in the legislative language for FALCPA because no spice is derived from one of the food sources of a major allergen. However, if a seasoning mix or blend of spices contains a major food allergen as an ingredient or processing aid (such a wheat flour used as a flow agent), then its presence would have to be declared on both:

- 1 The label for the seasoning mix or blend if sold as such
- 2 The label of any other food that includes the seasoning mix or blend as an ingredient

Additional food labeling requirements specific to each allergen.

### TREE NUTS

FALCPA requires that in the case of tree nuts (Table 10), the specific type of nut must be declared (e.g., almonds, pecans, or walnuts).

### FISH AND CRUSTACEAN SHELLFISH

A declaration of the "species" of fish or crustacean shellfish is required using the acceptable market name provided in FDA's Seafood List. For example, any food made with salmon will either include "fish (salmon)" in the ingredient list, or state "Contains salmon" in any "Contains" statement.

### WHEAT (GLUTEN)

FALCPA labeling requirements apply to all grains that belong to the plant genus Triticum, the crossbred hybrid of wheat and rye called "triticale," and ingredients that contain proteins of any of these grains. Thus, wheat would include grains such as common wheat (*Triticum aestivum* L.), durum wheat (*Triticum durum* Desf.), club wheat (*Triticum compactum* Host.), spelt (*Triticum spelta* L.), semolina (*Triticum durum* Desf.), Einkorn (*Triticum monococcum* L. subsp. *Monococcum*), emmer (*Triticum turgidum* L. subsp. *dicoccon* (Schränk) Thell.), kamut (*Triticum polonicum* L.), and triticale (*x Triticosecale* ssp. Wittm.).

The term "flour" alone (unqualified) should only be used as a synonym for "wheat flour." If "flour" is stated in an ingredient list without the parenthetical declaration of wheat afterwards, either the term "wheat" must appear elsewhere within the ingredient list for another allergenic ingredient or in a separate "Contains" statement.

### PEANUTS AND SOYBEANS

FDA believes that the singular terms "peanut," and "soybean," as well as the singular terms (e.g., almond, pecan, or walnut) for the different types of tree nuts (Table 10) are acceptable substitutes for the plural terms for these major food allergens for the purpose of satisfying the FALCPA labeling requirements. Also, the terms "soybean," "soy," and "soya" are reasonable synonyms for the common or usual name "soybeans," and any one of these terms may be used to identify the food source of the major food allergen "soybeans." However, packaged foods that are made using "soybeans" as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should use the word "soybeans" as the appropriate common or usual name for this ingredient (e.g., "soy sauce (water, wheat, soybeans, salt)").

**Single Ingredient Labeling** Single ingredient foods must comply with the FALPCA allergen declaration. A single ingredient food that is or contains protein derived from sesame, milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans may identify the food source in the name of the food (e.g., “all-purpose wheat flour”) or use the “Contains” statement format. FDA recommends that if a “Contains” statement format is used, the statement be placed immediately above the manufacturer, packer, or distributor statement. For single ingredient foods intended for further manufacturing where the “Contains” statement format is used, the statement should be placed on the principal display panel (PDP) of the food package.

**Consequences of Non-Compliance with Allergen Labeling** In the event that a packaged food does not comply with the FALPCA labeling requirements, the company and its management may be subject to civil sanctions, criminal penalties, or both. The FDA may also request seizure of the food products where the label of the product does not conform to FALPCA’s requirements. In addition, FDA is likely to request that a food product containing an undeclared allergen be recalled by the manufacturer or distributor.

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## 4.4 SANITARY FACILITIES & CONTROLS

Any water that comes into contact with food, food contact surfaces, or processing equipment must be safe and of adequate sanitary quality: using only water that meets drinking water standards for these types of activities is a must.

### PLUMBING & WASTE WATER DISPOSAL

The plumbing system must be of adequate size and design to be able to supply enough water to all areas in the facility and properly convey sewage and disposable liquid waste away from the facility. Plumbing systems must be maintained in a manner that will not create a source of contamination or unsanitary conditions, and sewage must flow into an adequate sewage system or be disposed of through other adequate means.

Provide adequate floor drainage in areas where water or liquid waste is discharged onto the floor, including water from cleaning and sanitizing operations. Backflow and cross-connection between piping systems that discharge waste water or sewage must be prevented, and waste water separated from those systems that provide water for food manufacturing.

### TOILET & HAND-WASHING FACILITIES

Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

Hand-washing facilities must be designed to ensure that an employee’s hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Rubbish and offal disposal must be handled in such a manner that they won’t attract or harbor pests or create sources of contamination.

## 4.5 EQUIPMENT & UTENSILS

In general, equipment and utensils must be designed and constructed so that they are adequately cleanable, and do not adulterate food with lubricants, fuel, metal fragments, contaminated water, or other debris. They should be installed so that both the equipment and the areas around them can be cleaned easily. Food contact surfaces must be manufactured from nontoxic materials and must be corrosion-resistant, and seams on food contact surfaces must be smoothly bonded and maintained to minimize the accumulation of debris or food residues. See **Table 11** for a list of recommended materials for equipment and utensils.

**Table 11.** Recommended materials for food production

MATERIALS USED IN FOOD PROCESSING ENVIRONMENTS	PLASTICS USED IN EQUIPMENT	RUBBER ELASTOMERS USED IN EQUIPMENT
<ul style="list-style-type: none"> <li>Stainless Steel (ANSI: 304, 303, 316, 316L, 321, 316TI)</li> <li>Aluminum (poor corrosion properties, avoid in food contact surfaces)</li> <li>Titanium</li> <li>Copper (avoid in food contact surfaces)</li> <li>Galvanized iron (avoid in food contact surfaces)</li> </ul>	<p>Plastics should be assessed for chemical compatibility with the foods they will contact, taking into account the acidity of the food and potential exposure of the plastic to UV radiation.</p> <ul style="list-style-type: none"> <li>Polypropylene</li> <li>Polyvinyl chloride (unplasticized)</li> <li>Acetal copolymer</li> <li>Polycarbonate</li> <li>High density polyethylene</li> <li>Polyethylene tetrphalate</li> <li>Polytetrafluoroethylene (Teflon)</li> </ul>	<p>Elastomers are normally found on pumps and valves, and each material has unique elastic, swelling and shrinkage properties.</p> <ul style="list-style-type: none"> <li>Nitrile rubber</li> <li>Nitrile/butyl rubber (NBR)</li> <li>Ethylene propylene diene monomer (EPDM)</li> <li>Silicone rubber</li> </ul>

All equipment used in manufacturing, processing, packing, or holding food, including conveying and manufacturing equipment such as gravimetric, pneumatic, closed and automated systems, must be maintained in a sanitary condition. Equipment must be designed to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and cross contamination. Food-contact surfaces must be corrosion-resistant and be made of nontoxic materials capable to withstand the environment of their intended use.

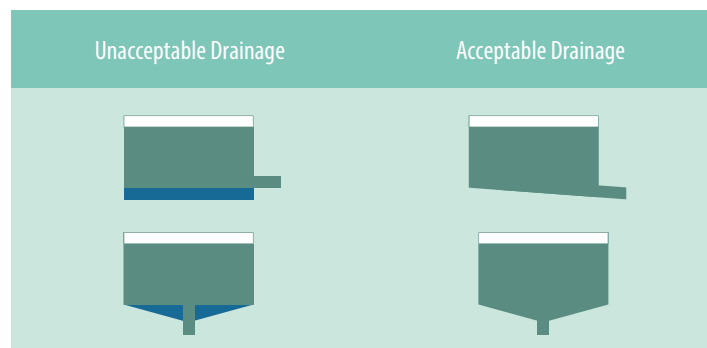
Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in a way that food is not contaminated with unlawful indirect food additives.

## MEASUREMENT INSTRUMENTS

Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses. Each freezer and cold storage compartment must have an indicating thermometer, temperature measuring or recording device installed to show the accurate temperature inside the equipment.

## DRAINAGE OF VESSELS

Vessels used to hold food during storage or manufacturing processes should be self-emptying, and built to prevent dead spaces that would allow proliferation of microbial growth from accumulation of product in those locations. These vessels should avoid having sharp corners and metal-to-metal contact points and should be easy to clean.



## LUBRICANTS

Much equipment and some utensils in food processing require lubrication to prevent contact between moving and static surfaces, and so prevent excessive wear, potential overheating and addition of physical hazards (fragments from equipment surfaces) to food. Leakage from open lube points and bearings must be avoided to prevent food contamination.

### USDA H1 Lubricants

- Bearing greases
- Chain lubricants
- Gearbox fluids (enclosed and open)
- Assembly and anti-seize compounds
- Hydraulic and compressor fluids
- Penetrating fluids
- Can seamer lubricants
- Sugar dissolving solutions
- Release agents
- General purpose sprays and lubricants

## 4.6 PROCESSES & CONTROLS

There must be a competent individual who is responsible for supervising the overall sanitation of the plant.

### RAW MATERIALS & INGREDIENTS

Raw materials must be inspected and sorted to ensure they are clean, wholesome and fit for processing into human food, and must be stored under conditions that will protect against cross-contamination, cross-contact with food allergens and product deterioration. They must be washed or cleaned as necessary to remove soil and other contamination using water of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

Containers and carriers that convey raw materials and ingredients should be inspected to assure that they are not a source of contamination for raw ingredients, and raw materials must not contain levels of microorganisms that may cause food-borne illness or disease. If pathogen contamination is found in raw ingredients, they must be pasteurized or treated during food manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

Frozen ingredients must be kept frozen until use, and if thawing is required prior to use, thawing must be done in a manner that prevents contamination.

### MANUFACTURING OPERATIONS

Food processing equipment must be kept in sanitary condition through frequent cleaning and sanitation, when appropriate and equipment must be taken apart for thorough cleaning when necessary. Food must be processed, packaged and stored under conditions that will minimize the potential for undesirable microbiological growth, toxin formation, deterioration, or contamination by other hazards, and a facility must have instruments and procedures to monitor critical factors in controlling those hazards. Food must be held under conditions that prevent growth of undesirable microorganisms.

Work-in-process—i.e. food when it is undergoing a manufacturing process— must be protected against contamination, and so must finished food, food containers and food packaging materials. Food or materials that are adulterated must be disposed of in a manner that prevents other food from being contaminated. Measures such as sieves, traps, or metal detectors must be used to protect against the inclusion of metal or other foreign materials in food. Steps such as washing, peeling, trimming, etc. must be performed in a way that protects food against contamination and allergen cross-contact, including protection against contaminants that may drip, drain, or be drawn into the food. If ice is used in the facility and comes in contact with food, it must be made from potable water and be maintained in a sanitary condition.

**Blanching** Heat-blanching, when required, must be carried out by heating the food to the required temperature, holding for a required time, then rapid cooling or passing the food to subsequent manufacturing, without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing.

**Water Activity** Foods that rely on control of available water for preventing growth of undesirable microorganisms, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, must be processed to and maintained at a safe moisture level.

#### Controlling Water Activity

- Monitor the  $a_w$  of food
- Control the soluble solids/water ratio in finished food
- Protect finished food from moisture pickup, by use of a moisture barriers or other means to avoid increases in the  $a_w$  of the food

**Acid Foods** In manufacturing acid foods that rely principally on the control of pH for preventing the growth of undesirable microorganisms, the pH of the food must be monitored and maintained at 4.6 or below during the manufacturing process.



## 4.7 WAREHOUSING & DISTRIBUTION

Storage and transportation of food must be under conditions that will protect against allergen cross-contact, prevent deterioration of the food and the container, and protect against biological, chemical (including radiological), and physical contamination of food.

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## 4.8 HUMAN FOOD BYPRODUCTS FOR USE AS ANIMAL FOOD

Human food byproducts held for distribution as animal food without additional manufacturing or processing by the human food processor must be held and handled under conditions that will protect against contamination.

### Handling requirements

- Containers and equipment used to convey or hold human food byproducts for use as animal food before distribution must be constructed of appropriate material and cleaned as necessary.
  - Human food byproducts for use as animal food must be held for distribution in a way that protects against contamination from sources such as waste, trash, and debris.
  - Human food byproducts for use as animal food must have labeling that accurately identifies the by-product by its common or usual name that is affixed to or accompanies the products when distributed.
  - If your facility is responsible for transporting the human food byproducts, or if it arranges a third party to transport them, you must ensure shipping containers and bulk vehicles used to distribute the products are examined prior to use to protect against contamination coming from the container or vehicle.
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## 4.9 DEFECT ACTION LEVELS

The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. The mixing of food containing defects at levels that render that food adulterated with another lot of food is not permitted, and renders the mixed lot of food adulterated.

The Food Defect Levels Handbook can be found at: <https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook>.

## GMP DOCUMENTS

**Table 12.** List of recommended documentation needed to demonstrate proper implementation of Good Manufacturing Practices

GENERAL FOOD FACILITY ACTIVITIES	FOOD MANUFACTURING OPERATIONS	PERSONNEL RELATED ACTIVITIES	RECORDS
<ul style="list-style-type: none"> <li>Ingredient specifications</li> <li>Supplier quality assurance and purchase contracts</li> <li>Quality assurance and quality control procedures</li> <li>Laboratory protocols and reporting systems</li> <li>Specifications for finished product</li> <li>Pest control and housekeeping procedures</li> <li>Customer and official complaint records</li> <li>Regulatory requirements for each food product</li> <li>Second and third party audit evaluations and results</li> <li>Recall procedures</li> </ul>	<ul style="list-style-type: none"> <li>Manufacturing procedures including scheduling, when relevant for food allergens</li> <li>Sanitation procedures</li> <li>Health and safety procedures</li> <li>Plant layout and traffic zones including hygienic zoning requirements</li> <li>Plant maintenance procedures</li> <li>Storage procedures for materials, ingredients and finished product</li> <li>Transportation procedures</li> <li>Allergen controls when applicable</li> <li>Management of chemicals and uses within the facility</li> <li>Labeling control procedures</li> </ul>	<ul style="list-style-type: none"> <li>Organizational chart including responsibilities and main tasks</li> <li>Training programs including topics related to food safety, food hygiene and the specific activity of the employee</li> </ul>	<ul style="list-style-type: none"> <li>General employee records</li> <li>Employee training records</li> <li>Process control records</li> <li>Sanitation records</li> <li>Allergen control records</li> <li>Supply chain records</li> <li>Pest control records</li> <li>Personnel health records</li> <li>Use and management of raw materials</li> <li>Control of rework when applicable</li> <li>Labeling records</li> <li>Laboratory analysis records for raw and finished products</li> <li>Environmental monitoring records</li> <li>Test and hold records of finished products</li> <li>Mock recall records</li> </ul>

## APPENDIX 1

# FDA'S LIST OF LOW RISK ACTIVITY/ FOOD COMBINATIONS

Manufacturing/processing foods using the methods described below has been deemed low-risk by the FDA in its FSMA regulations on Current Good Manufacturing Practices and Risk-Based Preventive Controls.

- Boiling gums, latexes, and resins
- Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/ latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts)
- Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens)
- Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea)
- Extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh min chopped dried mint)
- Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables)
- Grinding/cracking/crushing/ milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts)
- Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/jellies/ preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single ingredient peanut or tree nut flours), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)
- Making baked goods from milled grain products (e.g., breads and cookies)
- Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream)
- Making cocoa products from roasted cocoa beans
- Making dried pasta from grains
- Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below
- Making molasses and treacle from sugar beets and sugarcane
- Making oat flakes from grains
- Making popcorn from grains
- Making snack chips from fruits and vegetables (e.g., making plantain and potato chips)
- Making soft drinks and carbonated water from sugar, syrups, and water
- Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice,

sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane

- Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens
- Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt)
- Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)
- Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)
- Pasteurizing honey
- Roasting and toasting baked goods (e.g., toasting bread for croutons)
- Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption
- Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour)

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## APPENDIX 2

# ADDITIONAL RESOURCES

Food safety is just one aspect of the federal regulatory system for manufacturing food. In this appendix you will find web links to key additional documents that explain other aspects of FSMA that may be relevant to your business, as well as resources covering other important food regulations.

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### Food Safety Modernization Act

Carolina Farm Stewardship Association (CFSA) has a series of “Frequently Asked Questions” explainers regarding who is covered by FSMA, and the basic requirements for those who are covered.

<https://www.carolinafarmstewards.org/fsma-frequently-asked-questions-is-your-farm-covered-by-the-produce-rule/>

The National Sustainable Agriculture Coalition (NSAC) worked with the FDA to develop a flow chart to help farms and businesses determine if they are subject to the FSMA Produce Rule, which establishes requirements for farms growing fruits, vegetables and other produce, and the FSMA Current Good Manufacturing and Preventive Controls for Human Food Rule.

[https://sustainableagriculture.net/wp-content/uploads/2016/02/2016\\_2-FSMA-Final-Rule-Flowchart-V3.pdf](https://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf)

NSAC has a detailed explainer on FDA’s Current Good Manufacturing and Preventive Controls for Human Food Rule, including discussions of who is covered, and an overview of the requirements of the regulation.

<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>

NSAC also has a short discussion of how to calculate the sales volume thresholds for farms and food facilities to meet the qualified exemptions from the Produce Safety Rule and the Current Good Manufacturing and Preventive Controls for Human Food Rule.

<http://sustainableagriculture.net/blog/new-fda-fsma-website/>

And NSAC has an explainer on the types of food businesses that are exempt from the requirement to register as food facilities with FDA, such as restaurants and other retail food establishments, Community Supported Agriculture enterprises, and others.

<http://sustainableagriculture.net/blog/fsma-registration-rule-clarified/>

The Northeast Center to Advance Food Safety at the University of Vermont maintains an extensive searchable clearinghouse of FSMA training materials and information.

<http://www.uvm.edu/extension/necafs/clearinghouse>

The text of FDA's FSMA Produce Safety Rule and Current Good Manufacturing and Preventive Controls for Human Food Rule are available from the Federal Register.

**Produce Safety Rule** <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112>

**Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food** <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117>

FDA has a general resource page for the Produce Rule, with links to guidance documents and other interpretations from the agency.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

FDA also has a general resource page for Current Good Manufacturing and Preventive Controls for Human Food Rule, with links to guidance documents and other interpretations from the agency.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

The Food Safety Preventive Controls Alliance is an industry-and-academic collaboration that develops nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying FSMA.

<https://www.ifsh.iit.edu/fspca>

## General Food Regulations

For farms and food businesses in North and South Carolina.

**North Carolina** <https://www.ncagr.gov/fooddrug/food/>

**South Carolina** <https://agriculture.sc.gov/divisions/consumer-protection/food-safety-compliance/>

## Food Labeling

The FDA's official Food Labeling Guide is a non-binding guidance document explaining FDA's interpretation of the rules on labeling foods, including nutrition labeling, allergen labeling, ingredient lists, and health claims.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

FDA maintains a Question and Answer document on the Food Allergen Labeling and Consumer Protection Act (FALCPA).

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5>

FDA provides a model form for small businesses to use in claiming an exemption from nutrition labeling requirements.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053857.htm>

For businesses that are not exempt from nutrition labeling requirements, FDA has published guidance on how to calculate serving sizes for purposes of nutrition labeling.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535368.htm>

FDA publishes a list of acceptable market names to use in labeling of foods containing fish and crustacean shellfish.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list>

To determine if a chemical for use as a food ingredient has been deemed 'Generally Recognized as Safe' (GRAS), visit the FDA's GRAS resource center.

<https://www.fda.gov/food/ingredientpackaginglabeling/gras/>

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All links are current as of October 30, 2023.