

Ensuring Food Safety in Specialty Foods Production

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Contents	
Glossary	2
Unique Characteristics of Specialty Foods.....	3
Food Safety Concerns in the Production of Specialty Foods	5
Food Safety Hazards	5
Food Safety Concerns in Specialty Foods Production	8
Possible Prevention and Controls for Ensuring Food Safety	9
Food and Other Functional Ingredients	10
Water as a Food	13
Sanitation.....	14
Workers Health and Hygiene	15
Prevention of Cross-contamination	16
Temperature Control during Storage and Distribution	16
Recall Contingency Plan	17
Examples of Implementing Specific Food Safety Controls.....	18
Acidified Foods	18
Mexican Cheeses	19
Specialty Fruit Juice.....	20
Dried Beef Jerky.....	20
Tahini (Sesame Paste).....	21
Appendix	22
For More Information	23
Important Food Safety Programs.....	23
Federal Agencies	23
State Resources	23
Other Organizations	24
References.....	24

This publication is prepared to assist processors of specialty food, distributors, vendors, and food regulators of backgrounds and experience in finding specific information on producing safe specialty food products. This publication discusses the unique characteristics of specialty foods, identifies food safety concerns in specialty foods production, and provides examples of specific control measures for ensuring food safety of specialty food products.

It is our hope that this publication can provide information and some basic procedural tools to specialty food processors, vendors, distributors and food inspectors for enhancing their knowledge of food safety for ensuring the safe production of specialty food products. A companion website, "Ensuring the Safety of Specialty Food Production in the U.S. Northwest Region," has also been developed (<http://specialtyfood.fst.oregonstate.edu>).

Note this publication does not provide specific information on regulatory agencies but rather gives information concerning jurisdiction overlap for commercial food products regulated by either or both the FDA and USDA (see Appendix). It is also not the intention of this publication to discuss food security and defense programs in detail. A web-based training module on food defense awareness, ALERT (<http://www.cfsan.fda.gov/alert>), offers guidance regarding food defense issues and preparedness.

Glossary

Acidified food. A low acid food to which acid(s) or acid food(s) are added to produce a product that has a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. Acidified food is regulated by FDA (21 CFR 114.3).

Approved sources. The sources that are approved and considered satisfactory by the local director of health based on a determination of conformity with principle, practices, and generally recognized standards that protect public health, and in compliance with applicable state and local laws and regulations.

Bacteria. Single-celled microorganisms that can exist either as independent (free-living) organisms or as parasites (dependent upon another organism for life).

Biofilm. Complex aggregation of microorganisms and other materials that enhance survival and growth of microorganisms; once formed they are very difficult to remove.

Coliform. A group of Gram-negative, facultative anaerobic rod-shaped bacteria that ferment lactose to produce acid and gas within 48 hours at 95°F (35°C).

Control. The act of preventing, eliminating, or reducing hazards to a safe level.

Critical control point. A point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

Deviation. Failure to meet a critical limit.

Ethnic/regional food. Food that can be identified in the public mind with a foreign source or an American minority group.

Fancy food. Food which is not plain or simple, but of particular excellence or highest grade.

FDA. United States Food and Drug Administration.

5-Log reduction. A 100,000-fold reduction in microbial load (colony forming units [CFU]/g or CFU/ml).

Food additive. Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (21 CFR 170-180).

Food allergy. An adverse immune response to a particular food protein(s), which may progress to anaphylactic shock.

Food contact surfaces. Surfaces that contact human food and surfaces from which drainage onto food or surfaces that contact food ordinarily occurs during the normal course of operations.

Food safety hazard. Any physical, chemical, or biological contaminations that may cause a food to be unsafe for human consumption.

Functional ingredients. A diverse group of compounds that are intended to produce a positive effect on the health of the consumer.

Good Manufacturing Practices (GMPs). Manufacturing procedures for sanitation, facilities, equipment, processes and controls. Current Good Manufacturing Practices

(cGMPs) are included in FDA regulations for the food industry (21 CFR 110).

Gourmet food. Food which is of the highest quality, perfectly prepared and artfully presented.

Hazard Analysis and Critical Control Points (HACCP).

A systematic approach to establish safety standards throughout the food industry. The program focuses on preventing hazards that could cause food-borne illnesses by applying science-based controls, from raw material to finished products.

Natural food. FDA's policy does not restrict the use of the term "natural" except for added color, synthetic substances and flavors, and use of "natural" means that nothing artificial or synthetic (including all color additives regardless of source) has been added. USDA's policy defines natural foods as product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative, or any other artificial or synthetic ingredients, and product and its ingredients are not more than minimally processed.

Parasite. An organism that lives on or in another usually larger host organism in a manner that harms or is of no advantage to the host.

Pasteurization. A thermal treatment of food that effectively reduces numbers of pathogenic microorganisms in food to a safe level.

Pathogen. A microorganism (bacterium, parasite, virus, or mold) that causes disease in humans.

Recall. Action taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

Sanitize. Adequately treat food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Specialty food. "Foods and beverages that exemplify quality and innovation, including artisanal, natural, and local products that are often made by small manufacturers, artisans and entrepreneurs from the U.S. and abroad" (National Association for the Specialty Food Trade definition).

Sanitation Standard Operating Procedures (SSOPs).

Specific step-by-step procedures related to sanitation and needed for processes in juice and seafood processing plants subject to HACCP (21 CFR 120.6).

Temperature recorder. A waterproof device to permanently record the temperature of the food content in a container.

USDA. United States Department of Agriculture.

Virus. A submicroscopic parasite consisting of nucleic acid (DNA or RNA) surrounded by a protein coat, and sometimes also encased in a lipid and glycoprotein envelope. Viruses are completely dependent on a living host cell to survive and multiply, and therefore cannot multiply in or on food.

Unique Characteristics of Specialty Foods

The term “specialty foods” has been used widely by food manufacturers, vendors, and distributors and has been used in product descriptions for quite some time at retail stores. However, how specialty foods are defined is vague. There is no universal and standard definition of specialty foods. Despite the unique characteristics of these products, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) do not regulate specialty foods differently from other conventional foods.

Several organizations have given their own definition of specialty foods. According to the National Association for the Specialty Food Trade (2011), specialty foods are “foods and beverages that exemplify quality and innovation, including artisanal, natural, and local products that are often made by small manufacturers, artisans and entrepreneurs from the U.S. and abroad.”

The Nibble (2011), a consumer magazine focusing on specialty foods, defines specialty foods as follows: “Specialty foods exist in every category. Most are foods you eat every day: jam, olive oil, vinegar, coffee, tea, meat and poultry, cookies, bread and even butter. Specialty just means better: made with better ingredients and/or artisan techniques. The majority of specialty foods are all natural, made without preservatives. Higher quality does not necessarily equate to high cost. Most specialty food items do not cost that much more than their mass-production counterparts.”

Specialty foods may have one or more of the following distinctions:

- Quality of ingredients, manufacturing process and/or finished product (natural, local, organic, eco-friendly, and sustainable are important characteristics for specialty food)
- Sensory appeal in flavor, aroma, texture, and/or appearance
- Unique presentation from the branding or packaging
- Origin of the products manufactured
- Distribution channel such as specialty food retail stores or designated sections within supermarkets and grocery stores

The use of the term “specialty foods” has been integrated or mingled with ethnic, natural, and gourmet foods. Alternatively, these terms can be included as subsets of specialty foods. In this publication, organic foods are not discussed as specialty foods since organic food manufacturing has a distinct set of criteria mandated by the USDA National Organic Program.

Subsets of Specialty Foods

Gourmet foods:

- “High quality, accurate preparation and artistic presentation” (Vogel 2005).
- “Defined by complexity and nuance, not by rarity and expense” (*The Nibble* 2011).
- “Food which is of the highest quality, perfectly prepared and artfully presented.” (Herbst 2001).

Ethnic/regional foods:

- Any food “that can be identified in the public mind with a foreign source or an American minority group.... However, it pertains only to food prepared or consumed by members of an ethnic group as a manifestation of its ethnicity” (Lockwood 2003).

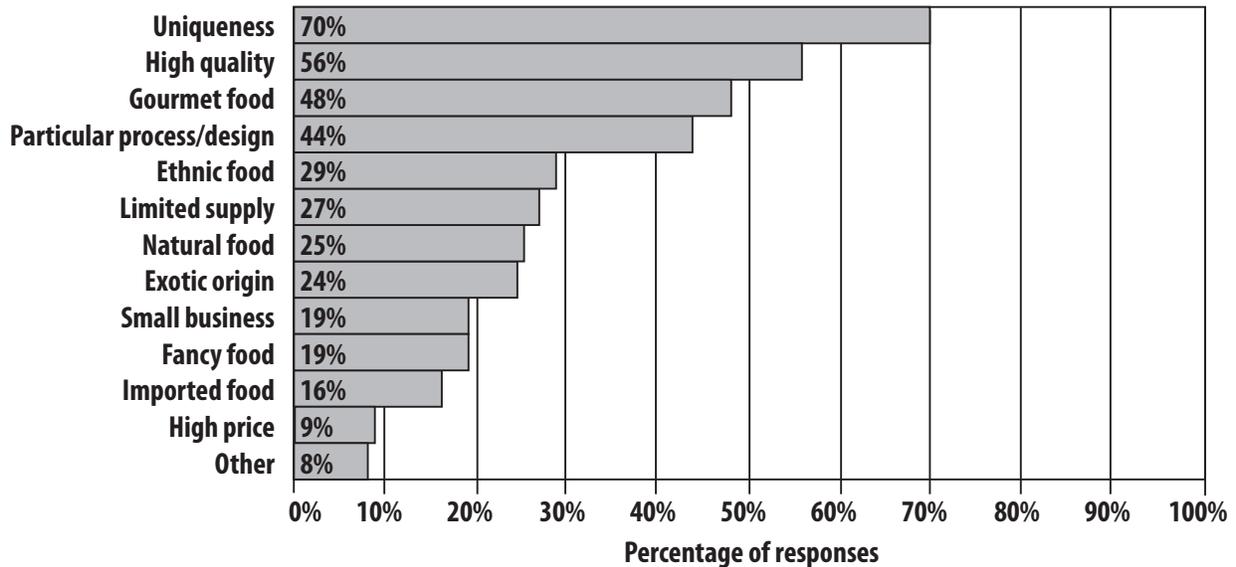
Natural foods:

- FDA defines *natural* as “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.”
- USDA defines natural foods as product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative, or any other artificial or synthetic ingredients, and product and its ingredients are not more than minimally processed. USDA also describes natural foods as “whole foods,” which have an emphasis on minimal processing.

According to two surveys of specialty food processors and food inspectors in Idaho, Oregon, and Washington states conducted in Fall 2009, the top four characteristics selected to describe specialty foods by the specialty food processors were “uniqueness” (70%), “high quality” (56%), “gourmet foods” (48%), and

“particular process/design” (44%) (figure 1a). Those selected by the food inspectors were “exotic origin” (70%), “particular process/design” (67%), “ethnic food” (63%), and “uniqueness” (61%) (figure 1b). The commonly selected characteristics were “uniqueness” and “particular process/design.”

(a) Specialty food characteristics selected by specialty food processors (462 participants)



(b) Specialty food characteristics selected by food inspectors (68 participants)

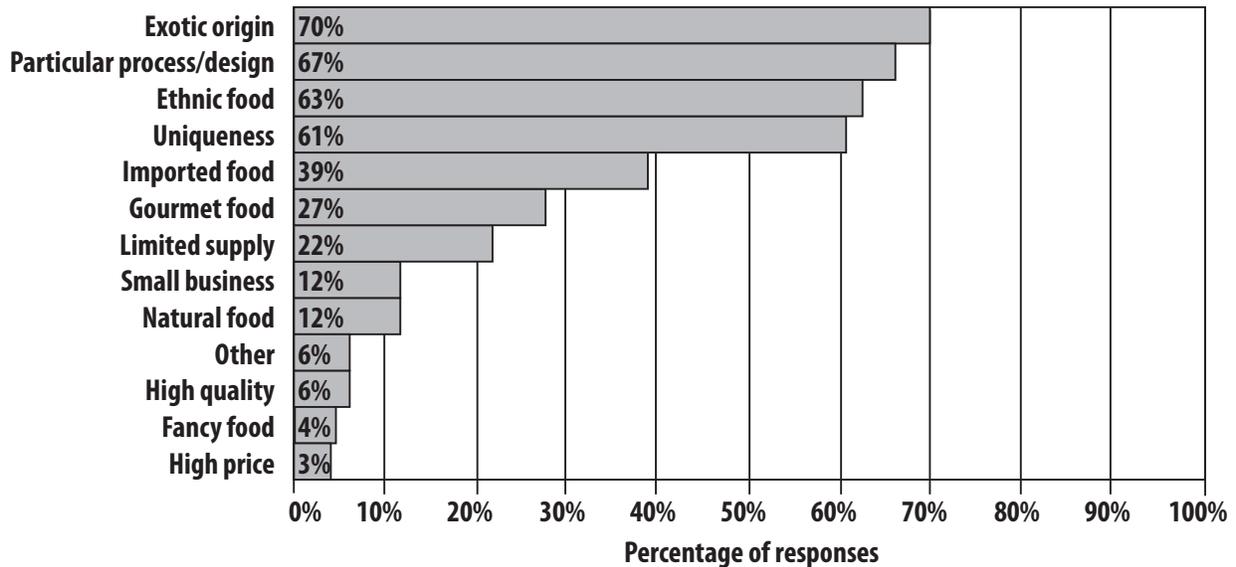


Figure 1. Characteristics describing specialty foods selected by (a) specialty food processors and (b) food inspectors in Idaho, Oregon, and Washington states. (More information: <http://specialtyfood.fst.oregonstate.edu/survey.htm>.)

Food Safety Concerns in the Production of Specialty Foods

Food Safety Hazards

A **food safety hazard** is any physical, chemical, or biological contamination that may cause a food to be unsafe for human consumption.

A **physical hazard** is any extraneous object or foreign matter in a food item that may cause illness or injury to the consumers. Sources for

such contaminants include raw materials, badly maintained facilities and equipment, improper production procedures, and poor employee practices (table 1). Processors must identify the sources and types of materials that can be physical hazards in foods and the regulations regarding physical hazards, and determine the types of controls to minimize the potential for physical hazards in food.

Table 1. Physical food safety hazards.

Materials	Potential injury	Sources
Wood	Cuts, infection, choking; may require surgery to remove	Toothpicks, wooden skewers, pieces of building material, twigs pallets
Plastic	Choking, cuts; may require surgery to remove	Packaging material, construction material, and gloves
Metal	Cuts, infection, choking; may require surgery to remove	Broken utensils; metal staples and nails from cardboard boxes; bolts, screws, and other equipment parts; metal shavings from cans caused by sharp can opener; bits of steel wool
Glass	Cuts, bleeding; may require surgery to find, remove, or repair	Bottles, glasses, light fixtures, glass bowls and covers, etc.
Bones of food origin	Lacerations in the mouth, choking, broken teeth, may take surgery to remove	Meat, fish, and poultry (improper processing)
Whole spices and herbs	Choking and trauma	Bay leaves, peppercorns, whole all-spice left in products after preparation
Insects and rodents, their parts and excreta	Illness, trauma, choking	Entrance of insects and rodents from surrounding environment or in packaging material; failure to keep facility clean
Personal items	Cuts, choking, broken teeth; may require surgery to remove	Stones or settings from jewelry; gloves; buttons, pins, safety pins; tie clips and tie tacks; gum, cigarettes and ashes; hair; bandages; artificial fingernails, contact lens; pens, pencils; threads of cloth

A **chemical hazard** is toxic substances and any other compounds that may render a food unsafe for consumption (table 2). Chemical hazards may lead to acute foodborne illness, chemical poisoning or food allergy. Successful chemical control programs include training employees to follow safe handling and application procedures for sanitation, maintenance or pesticides chemicals; making standard practices, after maintenance, for staff to properly clean and remove all chemical residues from food contact surfaces; storing chemicals in designated areas away from food, ingredients, packaging and food contact surfaces; receiving incoming materials and raw ingredients from reputable suppliers that effectively control chemical hazards; ensuring restricted ingredients and additives are correctly measured; and following good storage practice.

Each year, millions of Americans have allergic reactions to food. Although most allergic reactions are mild, some food allergies can cause severe reactions, and may even be life-threatening. Table 3 describes the eight food allergens that must be included on labels in plain language understood by the consumer.

Table 2. Chemical food safety hazards.

Poisonous substances
Cleaning chemicals, sanitizers
Lubricants, other plant chemicals
Pesticides, fungicides, insecticides
Fertilizers
Toxins, such as patulin (a mycotoxin produced by a variety of molds)
Intentional food additives (added in excess)
Unintentional additives
Heavy metals, such as lead and mercury
Antibiotic and other drug residues in meat, poultry, and dairy products
Adverse food reactions (food sensitivity)
Food allergies
Food intolerances
Metabolic disorder-based reactions
Pharmacological food reactions

Table 3. The “big 8” food allergens and controls to prevent food allergy.

Allergen	Description
Milk	Includes ice cream; powdered milk; evaporated milk; yogurt; butter; cheese; cream and sour cream; non-dairy products and any other food products containing lactose, caseinate, potassium caseinate, casein, lactalbumin, lactoglobulin, curds, whey, milk solids.
Egg	Egg is present in most processed food and is present if the label indicates any of the following additions: constituent egg proteins or their derivatives (e.g., albumen, ovalbumen, globulin, ovomucoid, vitelin, ovovitelin, silicoalbuminate).
Fish	Such as bass, founder, and cod. Any type of fin fish; any food product containing fish.
Crustacean shellfish	Such as crab, lobster, or shrimp. Also includes any food product containing these crustaceans.
Tree nuts	Such as almonds, pecans, or walnuts. Also includes any food containing tree nuts (e.g., salads, entrees, cookies, cakes, candies, pastries, or breads).
Wheat	All types of wheat flour; any baked products and any prepared products containing wheat flour, wheat gluten, or wheat starch.
Peanut	Also includes any food product containing peanuts.
Soybean	Also includes any food product containing soybeans.

Biological hazards include parasites, viruses and bacteria, which may lead to food spoilage or foodborne illness (table 4). The basic food safety principles include practicing good personal hygiene, controlling time and temperature to limit the amount of time that potentially hazardous foods are held in the temperature danger zone (41–145°F [5–63°C]) during preparation,

in another word, keep cold foods cold and hot foods hot, and preventing cross-contamination from food to food, from people to food and from environment to food.

To protect the customers and assure the products are the safest possible, the processors must take all the necessary steps to prevent or eliminate potential food safety hazards in their operation.

Table 4. Examples of biological hazards in food.

Hazard	Description
Parasites	
<i>Cyclospora cayetanensis</i>	A protozoan that causes a self-limiting diarrhea through the oral-fecal route.
<i>Cryptosporidium parvum</i>	Primary symptoms are acute, watery, and non-bloody diarrhea; of particular concern in immune compromised patients, leading to dehydration and, in severe cases, death.
<i>Giardia lamblia</i>	A flagellated protozoan that causes diarrhea, malaise, excessive gas, etc., through ingestion of dormant cysts in contaminated water, food, or by the fecal-oral route.
Viruses	
Hepatitis A virus	Causes an acute infectious disease of the liver through the oral-fecal route via contaminated food or drinking water; approximately 10 million people worldwide are infected with this virus every year.
Norovirus	Causes acute gastroenteritis in humans; increasingly being recognized as leading causes of foodborne disease in the U.S.
Rotavirus	The leading single cause of severe diarrhea among infants and young children; transmitted by the oral-fecal route.
Bacteria from animals (manure and manure, animal living spaces, carcasses)	
<i>Salmonella</i> spp.	Cause diarrheal illness in humans. Pass from the feces of people or animals to other people. Associated foods: raw and undercooked eggs, undercooked poultry, fruits, and vegetables. Serotype Typhimurium and Enteritidis are most common in the U.S.
<i>Escherichia coli</i> O157:H7	Can produce deadly toxins, leading to hemorrhagic diarrhea, and occasionally to kidney failure. Associated foods: raw and undercooked ground beef, unpasteurized milk and juice, contaminated water, fruits, and vegetables.
Bacteria from people (food handlers, pickers, packers, and consumers)	
<i>Shigella</i> spp.	Only naturally found in humans. Causes dysentery via ingestion (fecal-oral contamination). Some strains produce enterotoxin and Shiga toxin, causing hemolytic uremic syndrome. Associated foods: salads, raw vegetables, milk and dairy products, meat.
Bacteria from the environment (contaminated water, air, plants)	
<i>Listeria monocytogenes</i>	Widely distributed in nature. One of the most virulent foodborne pathogens; responsible for ~2,500 illnesses and 500 deaths in the U.S. annually. Its ability to grow at temperatures as low as 37.4°F (3°C) permits multiplication in refrigerated foods; the USDA retains a zero tolerance policy for ready-to-eat foods. Associated foods: raw and unpasteurized milk and cheeses, ice cream, raw vegetables, raw and undercooked meat and poultry, raw and smoked fish.

Food Safety Concerns in Specialty Foods Production

Increased production of specialty foods has also raised questions about food safety in this unique food category. In addition to the common food safety hazards associated with mainstream food processing due to mishandling, processing, and transportation, other potential hazards are noted below.

Potential hazards that lead to food safety concerns in the production of specialty foods may include the following:

- Many specialty foods are claimed to be “all natural” with “no added preservatives”. While this can be of great appeal to consumers, barriers preventing contamination by microorganisms, especially foodborne pathogens may be lacking.
- Most specialty foods are manufactured in small-scale operations and some processors are newly started family businesses, which may have limited training and experience in safe food production practices and may be unaware of licensing and inspection requirements. Thus, limited training and education in food safety may be an issue.
- Some uncommon and poorly characterized ingredients and processing procedures may be used in the production of certain specialty foods, which may lead to potential allergen and/or microbial safety problems.
- Many specialty food products are sold in farmers’ markets, which may lack regulatory oversight.

Hundreds of food recalls are reported each year in the United States, causing huge economic loss and the loss of consumer confidence. Many food recalls have been associated with specialty food products. For example, over ten specialty food recalls were reported during the period of January to March 2011, which included pumpkin chipotle roasting sauce recall due to undeclared wheat flour, wheat-free and gluten-free French bread pizza recall due to potential contamination with *Listeria monocytogenes*, and coconut water recall due to potential growth of mold. The recent food product recalls are provided on the FDA’s website (<http://www.fda.gov/Safety/Recalls/default.htm>).

The FDA categorizes all recalls into one of three classes according to the level of hazard involved:

- **Class I recall** is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall** is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall** is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

Possible Prevention and Controls for Ensuring Food Safety of Specialty Foods

FDA is implementing a food protection plan that addresses both food safety and food defense for ensuring the safety of the nation's food supply. Food safety seeks to prevent and control the unintentional threats that constantly exist to the food supply, while food defense addresses sporadic intentional threats and the associated vulnerabilities and consequences. The Food Protection Plan operates through a set of integrated strategies that provides three elements of protection: prevent foodborne contamination, intervene at critical points in the food supply chain, and respond rapidly to minimize harm (<http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/default.htm>).

The FDA's ALERT food defense awareness program is a web-based training module that provides guidance on food defense issues and preparedness (<http://www.cfsan.fda.gov/alert>).

To ensure the food safety of specialty foods, controls should be applied from the beginning to the end of all stages of food production, preparation and processing to reduce any potential hazards as a means of prevention rather than intervention of finished products.

The following programs are used most often to ensure food safety and quality of processed foods:

- Good Manufacturing Practices (GMPs)
- Sanitation Standard and Operation Procedures (SSOPs)
- Hazard Analysis and Critical Control Points (HACCP)

Good Manufacturing Practices (GMPs). The GMPs guidelines describe practices for the safe manufacture of foods. They are required by law (21 CFR 110), and apply to all food manufacturing companies. GMPs are prescribed for four main areas of food processing:

1. Personnel hygiene to prevent the spread of illness
2. Adequate buildings and facilities
3. Sanitary food contact surfaces (e.g., equipment and utensils)

4. Process controls to prevent cross-contamination

Sanitation Standard and Operation

Procedures (SSOPs). The SSOPs are mandatory for juice and seafood processing plants (21 CFR 120.6) subject to HACCP. Although specific protocols may vary from facility to facility, SSOPs provide specific step-by-step procedures to help ensure sanitary handling of foods. These documents describe procedures for eight sanitation conditions:

1. Safety of water
2. Cleanliness of utensils and equipment
3. Prevention of cross-contamination
4. Hand washing and toilet facilities
5. Protection of food from contaminants
6. Labeling and storage of toxic compounds
7. Monitoring employee health
8. Pest control

Hazard Analysis and Critical Control Points

(HACCP). The HACCP program is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. In the 40 years since its inception, HACCP systems have grown to become the universally recognized and accepted method for food safety assurance. The FDA and the USDA have issued regulations that make HACCP mandatory for seafood, juice and meat products as an effective approach to food safety and protecting public health. HACCP is not a stand-alone program. The success of HACCP depends largely on prerequisite programs including GMPs and SSOPs. A foundation of effective prerequisite programs is necessary for HACCP to be successfully implemented.

HACCP is a systematic and preventive approach to food safety focusing on preventing hazards that could cause food-borne illnesses by applying science-based controls, from raw

material to finished products. It is specifically applied for seafood and juice. HACCP involves seven principles:

1. Hazard analysis
2. Critical control points (CCP) identification
3. Establishment of critical limits
4. Monitoring procedures
5. Corrective actions
6. Record keeping
7. Verification procedures

In addition, other food safety programs that have been well recognized internationally may include Global Standard for Food Safety (www.brcglobalstandards.com), Safety Quality Food 2000 (www.sqfi.com), and Foundation for Food Safety Certification 22000 (www.22000-tools.com/fssc-22000).

Food and Other Functional Ingredients

Food ingredients directly impact the final product quality, safety and price. For specialty foods, the big consideration on food ingredients are natural, organic, locally produced (within 250 miles from production site), and sustainable. For ensuring final product quality and food safety (microbial and allergic safety), here are some basic considerations:

- Each ingredient should have a specification sheet from the supplier.
- A specification sheet should give details about the characteristics of the ingredient and quality attributes.
- There will be time when you will need to work with a supplier to establish a specification for an ingredient that you will receive.
- It will be your responsibility to monitor your incoming ingredients to assure that they meet the specification standards that you expect.
- It is not cost effective to test every ingredient that is used in your product each time you receive it.
- You will need to identify the critical or sensitive ingredients that will be monitored 100% of the time.
- The 80/20 rule is a useful rule to follow. It is a probability distribution law.
- 20% of your ingredients will cause 80% of your ingredient concerns. The remaining

ingredients should have a limited auditing schedule to assure quality.

- The ingredients and the quality of those ingredients will help define your product quality.
- If an ingredient does not meet your quality or food safety standard it should be returned to the supplier.

In addition to the food ingredients, there are many additional functional ingredients that may be employed in the processed foods for enhancing quality, food safety and/or extending shelf life of the specialty food products (table 5).

Appropriate quality control operations shall be employed to ensure that the ingredients to be incorporated into finished food are premium and consistent. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.

In addition, there may be issues relating to the potential allergenicity of an ingredient. If any "big 8" food allergens are used as ingredients in specialty foods production, effective control measures shall be carried out to prevent potential food allergies. Note that other countries may have additional labeling requirements for allergen disclosure. For example, in Canada sesame seeds and more recently mustard seeds are now considered food allergens. This is important if considering export to other countries.

Table 5. Examples of common functional food ingredients.

Types of ingredients	What they do	Examples of uses	Names found on product labels
Chemical preservatives	Prevent food spoilage from bacteria, molds, fungi, or yeast; slow or prevent changes in color, flavor, or texture and delay rancidity; maintain freshness	Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables	Ascorbic acid, citric acid, sodium benzoate, calcium propionate, sodium erythorbate, sodium nitrite, calcium sorbate, potassium sorbate, BHA, BHT, EDTA, Vitamin E
Sweeteners	Add sweetness with or without the extra calories	Beverages, baked goods, confections, table-top sugar, substitutes, many processed foods	Sucrose, glucose, fructose, sorbitol, mannitol, corn syrup, high fructose corn syrup, saccharin, aspartame, sucralose
Color additives	Offset color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correct natural variations in color; enhance colors that occur naturally; provide color to colorless and "fun" foods	Many processed foods, such as candies, snack foods, margarine, cheese, soft drinks, jams/jellies, gelatins, pudding and pie fillings	FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow Nos. 5 and 6, Orange B, Citrus Red No. 2, annatto extract, beta-carotene, grape skin extract, cochineal extract or carmine, paprika oleoresin, caramel color, fruit and vegetable juices
Flavors and spices	Add specific flavors (natural and synthetic)	Pudding and pie fillings, gelatin dessert mixes, cake mixes, salad dressings, candies, soft drinks, ice cream, BBQ sauce	Natural flavoring, artificial flavor, and spices
Flavor enhancers	Enhance flavors already present in foods (without providing their own separate flavor)	Many processed foods	Monosodium glutamate (MSG), hydrolyzed soy protein, autolyzed yeast extract, disodium guanylate or inosinate
Fat replacers (and components of formulations used to replace fats)	Provide expected texture and a creamy "mouth-feel" in reduced-fat foods	Baked goods, dressings, frozen desserts, confections, cake and dessert mixes, dairy products	Olestra, cellulose gel, carrageenan, polydextrose, modified food starch, micro-particulated egg white protein, guar gum, xanthan gum, whey protein concentrate
Nutrients	Replace vitamins and minerals lost in processing (enrichment), add nutrients that may be lacking in the diet (fortification)	Flour, breads, cereals, rice, macaroni, margarine, salt, milk, fruit beverages, energy bars, instant breakfast drinks	Vitamin B ₂ , niacin, niacinamide, folate or folic acid, beta carotene, potassium iodide, iron or ferrous sulfate, alpha tocopherols, ascorbic acid, Vitamin D, amino acids
Emulsifiers	Allow smooth mixing of ingredients, prevent separation; keep emulsified products stable, reduce stickiness, control crystallization, keep ingredients dispersed, and to help products dissolve more easily	Salad dressings, peanut butter, chocolate, margarine, frozen desserts	Soy lecithin, mono- and diglycerides, egg yolks, polysorbates, sorbitanmonostearate
Stabilizers and thickeners, binders, texturizers	Produce uniform texture, improve "mouth-feel"	Frozen desserts, dairy products, cakes, pudding and gelatin mixes, dressings, jams and jellies, sauces	Gelatin, pectin, guar gum, carrageenan, xanthan gum, whey
pH control agents and acidulants	Control acidity and alkalinity, prevent spoilage	Beverages, frozen desserts, chocolate, low acid canned foods, baking powder	Lactic acid, citric acid, acetic acid, ammonium hydroxide, sodium carbonate
Leavening agents	Promote rising of baked goods	Breads and other baked goods	Baking soda, monocalcium phosphate, calcium carbonate
Anti-caking agents	Keep powdered foods free-flowing, prevent moisture absorption	Salt, baking powder, confectioner's sugar	Calcium silicate, iron ammonium citrate, silicon dioxide
Humectants	Retain moisture	Shredded coconut, marshmallows, soft candies, confections	Glycerin, sorbitol
Yeast nutrients	Promote growth of yeast	Breads and other baked goods	Calcium sulfate, ammonium phosphate
Dough strengtheners and conditioners	Produce more stable dough	Breads and other baked goods	Ammonium sulfate, azodicarbonamide, L-cysteine
Firming agents	Maintain crispness and firmness	Processed fruits and vegetables	Calcium chloride, calcium lactate
Enzyme preparations	Modify proteins, polysaccharides and fats	Cheese, dairy products, meat	Enzymes, lactase, papain, rennet, chymosin
Gases	Serve as propellant, aerate, or create carbonation	Oil cooking spray, whipped cream, carbonated beverages	Carbon dioxide, nitrous oxide

Source: <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm094211.htm#introduction>.

CHECKLIST FOR SAFETY OF FOOD INGREDIENTS

- Have the ingredients been inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food?
- Are they stored under conditions that will protect against contamination and minimize deterioration?
- Do they not contain levels of microorganisms that may produce food poisoning or other disease in humans, or are they pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be contaminated? Compliance with this requirement may be verified by any effective means, including purchasing ingredients under a supplier's guarantee or certification.
- Are ingredients that are susceptible to contamination with aflatoxin or other natural toxins comply with current FDA regulations and action levels for poisonous or deleterious substances before they are incorporated into finished food?
- Are ingredients susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable FDA regulations and defect action levels for natural or unavoidable defects?
- Are they held in bulk, or in containers designed and constructed so as to protect against contamination and held at such temperature and relative humidity and in such a manner as to prevent the food from becoming contaminated?
- Are frozen ingredients kept frozen? If thawing is required prior to use, it shall be done in a manner that prevents them from becoming contaminated
- Are liquid or dry ingredients received and stored in bulk form held in a manner that protects against contamination?

CHECKLIST FOR INGREDIENT-RELATED ALLERGEN CONTROLS

- Is there an appropriate and proportionate policy for assessing the allergen status of ingredients?
- Is the allergen status of all ingredients checked with suppliers and reviewed regularly?
- Do suppliers notify the manufacturer of changes in the allergen status of the materials they supply?
- Are there procedures in place at reception of ingredients to verify that the correct material has been delivered?
- Are there procedures in place to check that ingredients, intermediate goods and finished product are clearly labeled so there is no risk for mistakes?
- Are allergenic ingredients and other ingredients kept separate from each other and from other foods so the risk of contamination is minimized?
- Are there protocols to ensure the handling of allergenic ingredients does not cause contamination of other ingredients?
- Are there procedures in place to ensure that the correct ingredients are always used?
- Are allergenic ingredients properly labeled as regulated by the Food Allergen Labeling and Consumer Protection Act of 2004?

Water as a Food

In the food industry, water plays a large number of roles, often at the same time. It can be a food ingredient, be used in food preparation and processing, as well as the more general use as utility water. Unsafe water, whether the result of direct contamination or improper treatment, may result in a contaminated food product. Specialty food processors should be fully aware of the various possible contaminants, their potential risk to human health and appropriate safety precautions. Typical water-borne contaminants include the following:

- Bacterial pathogens: *Salmonella*, *Shigella*, *Vibrio*, *Campylobacter*, and pathogenic *Escherichia coli*

- Viral pathogens: Noroviruses, Hepatitis A and E, Enteroviruses, and other human enteric viruses
- Parasites: *Entamoeba histolytica*, *Giardia lamblia*, *Cryptosporidium parvum*, and *Cyclospora*
- Chemical contaminants that could result from environmental contamination or from a chemical spill, incorrect use of pesticides or cross contamination of the water supply with sewage or industrial waste

When water is used as a food ingredient or used in food preparation and processing, a system should be in place to ensure that safe/potable water is continuously used in food production and processing.

CHECKLIST FOR ENSURING WATER SAFETY

- Are all water supplies in connection with any operation in the preparation of food potable (safely drinkable), having either been drawn from mains supply or suitably treated according to their source?
- Is ice that comes into contact with food produced from safe water supply, stored separately from ice used to refrigerate drink bottles or cans, and dispensed by food handlers using a scoop?
- Is the quality of water, steam or ice that comes into contact with food regularly monitored to ensure they present no risk to product safety?
- Have arrangements been made with local health officials to ensure immediate notification of the plant if the potability of the public water supply is compromised?

Sanitation

Sanitation is a multistep process that involves cleaning and sanitizing as two very important and separate steps. Effective cleaning and sanitation procedures, which include debris removal, use of detergent solutions, rinsing with water, disinfection where necessary and dry cleaning, are required to achieve the correct level of hygiene in food handling or production facilities. If these are not adhered to, there is a greater risk of food becoming contaminated by pathogenic or spoilage microorganisms. There is also a risk of biofilms forming on factory and food preparation surfaces if these programs are inadequate. It is important to avoid the use of phenolic and metal-ion based products as they may cause

product tainting and consumer safety issues. Table 6 describes the common chemicals used for sanitizing in food handling facilities. More information on sanitizers for food handling facilities can be found in the National Science Foundation White Book (<http://www.nsf.org/usda/Listings.asp>).

Cleaning and sanitation programs include four steps:

1. Routine procedures performed throughout and at the completion of food processing or preparation on a daily basis
2. Periodic procedures required less frequently
3. Monitoring to ensure the procedures are performed correctly
4. Verification to check effectiveness of the program

Table 6. Common chemicals used for sanitizing in food handling facilities.

Class	Other name or example	Optimum pH	Optimum use temperature	Advantage	Disadvantage
Chlorine releasing	Sodium hypochlorite	Neutral to slightly acidic	Room temperature	Effective against a wide variety of organisms; effective at low temperatures; generally inexpensive	Corrosive, irritating to the skin; effectiveness decreases with increasing pH of solution; short shelf life; organic matter reduces activity
Iodine based	Iodophor	Acidic	Room temperature (<95°F [$<35^{\circ}\text{C}$])	Stable; active against a wide range of non-spore-forming bacteria; long shelf life; less corrosive	Can stain; less effective against bacterial spores; bactericidal effectiveness decreases greatly with increase in pH
Quaternary ammonium compounds	Quat	Alkaline	Room temperature	Stable; long shelf life; less corrosive; odorless and colorless	Leaves residues; high foaming; slow destruction of coliform and psychrophilic organisms
Peroxyacetic acid	Peracetic acid	Acidic	Chilled to room temperature	Effective against a wide variety of organisms; environmentally friendly	Hazardous in concentrate form
Acid-anionic		Acidic	Room temperature to hot	Less corrosive; stable	Narrower spectrum of antimicrobial activity; relatively high cost
Alcohols	70% isopropyl	Neutral to slightly acidic	Room temperature	Fast acting	Not effective against spores; limited effectiveness against viruses; flammable
Ozone		Neutral	Chilled to room temperature	Effective against a wide variety of organisms; fast acting; environmentally friendly; no harmful chemical residual	Very short half-life when temperatures are about 104°F (40°C); must be generated on site due to its instability, and the equipment and operating costs can be quite high

Sources: National Science Foundation, White Book (<http://www.nsf.org/usda/Listings.asp>); Oregon Department of Agriculture Food Safety Division, Sanitizer Selection Guide (http://www.oregon.gov/ODA/FSD/docs/pdf/pub_sanitizer_select.pdf).

CHECKLIST FOR VERIFYING THE EFFECTIVENESS OF SANITATION PROGRAMS

- Are food preparation and storage areas well lit, clean and free of dirt, debris and pests?
- Is flooring nonabsorbent, easily cleanable, and in good repair? Are spills removed promptly and floors cleaned every day?
- Is garbage located away from food preparation and storage areas?
- Are garbage containers leak proof, vermin proof, and have tight-fitting lids?
- Is equipment in good working condition and repaired or replaced as necessary?
- Are proper procedures used to clean and sanitize all food contact surfaces, including, equipment, counters, dishes and utensils?
- Is all food preparation equipment (including cutting boards and utensils) properly cleaned and sanitized after each use?
- If heat sanitizing, are the utensils allowed to remain immersed in 171°F (77.2°C) water for 30 seconds?
- If using a chemical sanitizer, does it mixed correctly and a sanitizer test strip to determine chemical concentration?
- Are sanitized utensils and equipment air dried?
- Is equipment stored properly to prevent contamination?

Workers Health and Hygiene

Regardless of type of processing or food handling operation, the number one consideration in food sanitation is people. It is essential that the full meaning of sanitation and its wide economic scope be accepted by everyone concerned in the food system-including management. Injury and illness reporting is critical and specific training regarding personal hygiene and behaviors is essential.

CHECKLIST FOR ENSURING FOOD HANDLERS' HEALTH AND HYGIENE

- Are employees trained to follow good hygienic practices?
- Do employees appear in good health?
- Are employees familiar with typical signs and symptoms of infectious diseases?
- Do employees wear clean and proper uniform including shoes?
- Do employees wear appropriate hair restraints?
- Is eating, drinking, chewing gum, smoking, or using tobacco allowed only in designated areas away from preparation, service, storage, and ware washing areas?
- Are training programs established and directed towards health and hygiene, including basics such as proper hand washing techniques and the importance of using toilet facilities?
- Is protection offered to workers with cuts or lesions on parts of the body that may make contact with fresh produce?
- Are gloves properly used so hands will not become a vehicle for spreading pathogens?

Prevention of Cross-contamination

Cross-contamination is one of the main risks to food safety during processing. Cross-contamination can occur in three main ways:

1. **Food to food.** Food can become contaminated by bacteria from other foods. This type of cross-contamination is especially dangerous if raw foods come into contact with cooked foods.
2. **People to food.** People can be a source of cross-contamination to foods, when good hygienic practices are not performed by food handlers, such as handling foods after using the toilet without first properly washing hands, touching raw meats and then preparing foods without washing hands between tasks, using an apron to wipe hands between handling different foods, or wiping a counter with a towel and then using it to dry hands.
3. **Equipment to food.** Contamination can be passed from kitchen equipment and utensils to food. This type of contamination occurs because the equipment or utensils are not properly cleaned and sanitized between each use.

CHECKLIST TO PREVENT CROSS-CONTAMINATION AND REDUCE HAZARDS

- Are separate chopping boards, knives and other equipment used for raw and cooked foods?
- Are separate work surfaces provided and used for raw and high-risk foods?
- Is dirty equipment stacked away from clean equipment?
- Are surfaces used for high-risk foods sanitized before use?
- Are frozen raw meats thawed away from ready to eat foods?
- Are surfaces used for raw food sanitized after use?
- Are raw foods stored below cooked foods or physically segregated?
- Do food handlers use good hygienic practices?

Temperature Control during Storage and Distribution

Disease-causing pathogens can grow well in food when it is kept at temperature between 41°F (5°C) and 145°F (57°C), which is known as the temperature danger zone. If food is kept at these temperatures for more than 4 hours, pathogens can grow to levels high enough to cause serious food borne illnesses. Therefore, it is very important to keep hot food at 145°F or higher and cold food at 41°F or lower, and check the food's temperature at least every 4 hours during storage and distribution.

CHECKLIST TO PREVENT TEMPERATURE ABUSE DURING FOOD STORAGE AND DISTRIBUTION

- Are functional thermometers provided to all food storage equipment?
- Are refrigerators and freezers kept clean and organized?
- Is sufficient air circulation allowed for storage of foods in freezer and refrigerator?
- Are shipments inspected at the central warehouse before distribution to local stores?
- Is all transported food is covered and well insulated?
- Is food maintained and delivered at appropriate temperatures (hot foods at 145°F (57°C) or above, cold food at 41°F (5°C) or below, and frozen foods below 0°F (-18°C)?
- Do time-temperature monitors accompany food during the whole shipment?
- Is food put into cold storage within 15 minutes of delivery?
- Is the food's temperature checked at least every 4 hours during storage and distribution?

Recall Contingency Plan

Recall means a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (21 CFR 7.3 (g)). On December 21, 2010, Congress passed the FDA Food Safety Modernization Act of 2010. The President signed the bill into law on January 4, 2011. For the first time, FDA has the authority to order a recall of food products. FDA is immediately granted mandatory recall authority if a company refuses to voluntarily recall a product for which "there is a reasonable probability" that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause "serious adverse health consequences or death."

In the event a firm is involved in a product recall the following information may be necessary:

- Identity of the product involved
- Reason for the removal/correction of the product and date the deficiency was discovered
- Evaluation of the risk involved with the deficiency
- Total amount of products produced and time span of production
- Total amount of product estimated to be in distribution channels
- Distribution information
- Proposed communication for the firm during the recall
- Proposed strategy for conducting the recall
- Name and telephone number of the firm's contact information during the recall

A recall can be disruptive of a firm's operation and business, but there are several things that prudent business can do to facilitate a recall action (21 CFR 7.59):

- Prepare and maintain a current written contingency plan for use in initiating and implementing a recall.
- Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all lots in violation.
- Maintain product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning record retention.

Recent food product recalls can be found at the FDA's website (<http://www.fda.gov/Safety/Recalls/default.htm>).

Examples of Implementing Specific Food Safety Controls in Specialty Foods Processing

Acidified Foods

An “acidified food” is defined by FDA (21 CFR 114.3 (b)) as a low acid food to which acid(s) or acid food(s) are added to produce a product that has a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. Equilibrium pH means the final pH measured in the acidified food after all the components of the food have achieved the same acidity. The pH value of 4.6 is important because it is the limiting factor for the growth of *Clostridium botulinum*, a microorganism that is not destroyed by pasteurization or cooking temperatures below 212°F (100°C) and produces a potent toxin that causes the lethal disease botulism. Examples of acidified food may include acidified artichoke hearts, marinated beets or mushrooms and fresh-pack pickles. Acidified foods shall be manufactured, processed, and packaged to achieve a finished equilibrium pH value of 4.6 or lower within the time designated in the scheduled process and maintained in all finished foods (21 CFR 114.80 (a)). However, some barriers exist in the preparation of acidified foods, including inadequate acid in the cover brine to overcome buffering capacity of the food, the presence of alkaline compounds from peeling or other processing aids, and the peels, waxing, piece size or oil in the product causing a barrier to penetration of the acid. These barriers may cause the failure to achieve the final equilibrium pH of ≤ 4.6 and raise the concerns on the growth of pathogens and production of toxins in the final products.

All acidified foods must be heat processed to destroy microorganisms that cause spoilage and to inactivate enzymes that might affect color, flavor, or texture of the product. They can be heat processed in a boiling water canner or by low-temperature pasteurization. The processing time, temperature, and procedure necessary to safely preserve the acidified foods are determined by level of acidity (pH), size of food pieces (density) and percentage salt. An FDA recognized process authority must review the product and make the appropriate recommendations for time and

temperature requirements. Temperatures higher than 185°F (85°C) may break down the pectin and cause unnecessary softening of acidified foods.

CONTROL MEASURES FOR ENSURING FOOD SAFETY OF ACIDIFIED FOODS

- Acidified foods must be properly acidified to a pH below 4.6, but in practice this value is usually 4.2 or below for safety reasons.
- To assure quick and proper acidification, the food is normally cooked or heated with the acid before being filled into the final container.
- A thermal process or heating step is required to kill all the pathogens and any other non-health significant microorganisms that could grow during the shelf-life of the product, which must be done either by hot-filling the product or by the boiling water bath process. The heating temperature and time are critical factors that must be monitored, controlled and documented.
- The final equilibrium pH must be checked, controlled and documented after the product has received the heating step. A pH meter with two decimal places accuracy must be used to measure the pH if the final pH is 4.0 or above; other methods can be used such as pH paper or a pH meter with one decimal place, if the pH is below 4.0.
- Containers for acidified foods should be such that a hermetic seal is obtained. Vacuum is a good indicator of a hermetic seal and helps to keep the quality of the product.
- Final products should be protected from recontamination.

Mexican Cheeses

Mexican cheeses, including fresh cheeses (queso panela), soft cheeses (queso quesillo) and semi-soft cheeses (queso asadero), have a shorter shelf-life than firmer cheeses, due to their high moisture content and faster spoilage rate. Mexican cheeses, such as queso fresco and queso cotija molido, have been responsible for outbreaks of food poisoning by several types of bacteria. Mexican cheeses are often prepared from raw milk because pasteurization can decrease flavor and lengthen the ripening time of cheese. Due to the lack of pasteurization, Mexican cheese made from raw milk cannot be guaranteed to be free from pathogenic bacteria. During the cheese-making process, some pathogens are inactivated depending on the temperature and pH during production and ripening, yet many may survive this aging process and cause serious infectious diseases including listeriosis, brucellosis, salmonellosis and tuberculosis in consumers.

The USDA regulations require that cheeses made from unpasteurized milk must be aged for greater than 60 days at a temperature not less than 35°F (1.7°C). The aging process allows for a combination of factors, which include pH levels, salt content, and water activity to render cheeses microbiologically safe for consumption. The lactic acid formed during this aging process has been shown to inhibit the growth of pathogenic bacteria and to kill off any existing pathogens. Therefore, the storage conditions of each batch of aging cheese must be monitored by measuring room temperature and recording storage length to assure unpasteurized cheese is aged for minimum 60 days at $\geq 35^{\circ}\text{F}$. If temperature drops below 35°F, cheese makers must increase aging by 1 day for each day under 35°F. The FDA also has regulations on cheeses and related cheese products (21 CFR 133).

POSSIBLE CONTROL MEASURES FOR ENSURING SAFETY OF MEXICAN CHEESE

- The raw milk shall be obtained from approved sources, collected and maintained in good hygienic conditions.
- If the milk is held more than 2 hours between time of receipt and setting, it shall be cooled to 45°F (7.2°C) or lower until time of setting.
- Good conditions of hygiene, such as frequent cleaning of food contact surfaces, shall be maintained during production of the cheese to prevent contamination.
- The cheese must be aged for greater than 60 days at a temperature not less than 35°F (1.7°C).
- The cheese shall be refrigerated to minimize multiplication of bacteria.
- The labeling requirement for raw or unpasteurized milk products varies by the states. For example, in Washington State, warning labels are required on the products to establish a consumer advisory that discloses to consumers which items contain raw or unpasteurized milk and warns the consumer of the risk of consuming the product, especially by pregnant women and immune-compromised individuals. Therefore, the labeling of Mexican cheese products shall comply with the state's labeling laws or regulations.

Specialty Fruit Juice

Specialty fruit juices, such as pomegranate juice, mangosteen juice, and noni juice, are often claimed to contain high content of health-promoting phytochemicals, including antioxidants and bioflavonoids. When a health claim is made on the label of juice products, the labeling should follow the FDA's food labeling regulation on health claims (21 CFR 101.14).

If improperly handled, fruit juices can harbor pathogenic microorganisms and have been associated with food-borne illness outbreaks. The FDA has issued regulations that mandate the application of HACCP principles to the processing of fruit and vegetable juices (21 CFR 120). The HACCP plans shall include control measures that will consistently produce a minimum of 5 log reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism (21 CFR 120.24). For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice, e.g., *Escherichia coli* O157:H7.

Pasteurization is a critical control point in juice processing. The heat process used in pasteurization increases the shelf life of juice by inactivating microorganisms and certain enzymes. To better maintain the color and flavor, flash pasteurization, also called *high temperature short time* (HTST) processing, is widely used for fruit juices. It will provide a safe product for the public, yet keep to a minimum amount of flavor-degradation found in ultra-pasteurized product. In flash pasteurization, the minimum temperature used is 160°F (71.5°C) for a holding time between 15 and 30 seconds. To ensure the success of pasteurization, the temperature of juice needs to be continuously monitored by temperature recorder during pasteurizing process. When monitoring indicates a deviation from the established critical limit, juice producers must segregate and hold affected product for evaluation, destroy, or divert to nonfood use, and adjust pasteurizer (temperature or flow rate) to achieve the critical limit. The accuracy of the temperature recording device needs to be checked daily against a mercury and glass thermometer. The mercury and glass thermometer should be annually calibrated.

POSSIBLE CONTROL MEASURES FOR ENSURING SAFETY OF SPECIALTY FRUIT JUICES

- A supplier guarantee must exist to specify that the shipment includes only fruit harvested to exclude fallen fruit.
- The fruit must be rinsed and then brush washed with a sanitizer containing minimum of 200 ppm of available chlorine for 30 seconds of contact time.
- A pasteurization process with a minimum temperature of 160°F (71.5°C) for 15–30 seconds is required to provide a 5-log reduction of the pertinent pathogen. The heating temperature and time are critical factors that must be monitored, controlled and documented.

Dried Beef Jerky

Beef jerky is a ready-to-eat (RTE), protein-rich dried product that is enjoyed across the United States. It is generally considered to be shelf-stable (i.e., it does not require refrigeration after proper processing) due to the lack of moisture. However, multiple outbreaks of illness involving *Escherichia coli* O157:H7 or *Salmonella* have been linked to beef jerky, which raised the concerns on the lethality of jerky-making processes.

In 2007, the USDA Food Safety and Inspection Service (FSIS) published the "Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants" to provide updated information and guidance to small meat processors. Within this guideline, the lethality treatment and drying steps are required in all processes to ensure that a safe product is produced. To have sufficient lethality, a thermal treatment combined with the 90% humidity parameter (moist cooking) must be applied in a jerky-making process to achieve a 5.0-log reduction in *Escherichia coli* O157:H7 and *Salmonella*. After the lethality treatment, the product must be dried to meet a water activity level that will stabilize the finished product for food safety purposes. Achieving a water activity of 0.85 or less is critical for controlling the growth of all bacterial pathogens of concern.

CRITICAL CONTROL MEASURES FOR ENSURING FOOD SAFETY OF DRIED BEEF JERKY

- A heat treatment using the time-temperature combinations provided in the lethality compliance guidelines must be used in the jerky-making process to ensure sufficient lethality (http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/RTE_Poultry_Tables.pdf). The heating temperature and time are critical factors that must be monitored, controlled, and documented.
- The relative humidity must be maintained above 90 percent throughout the cooking or thermal heating process to meet the lethality performance standards. Humidity during heating is a critical factor that must be monitored, controlled and documented.
- After the lethality treatment, the product must be dried to achieve a water activity level of 0.85 or less to stabilize the finished product for food safety purposes. The water activity in the final product must be checked, controlled and documented.
- The final product must be protected from moist conditions by packaging. Gel desiccant pillows may be used to control moisture.

Tahini (Sesame Paste)

Tahini, a paste of ground sesame seeds, is a traditional food in Asia and North Africa. It is made by milling cleaned, dehulled and roasted sesame seeds and sold fresh or dehydrated. Tahini is mainly composed of oil and protein, and its pH value ranges between 5.65 and 6.0, with an average of 5.9, while the water activity (a_w) ranges between 0.12 and 0.18, with an average of 0.16. The low a_w in tahini would not support the growth of any known foodborne microorganisms. However, low water activity does not guarantee the safety of tahini. The outbreaks of *Salmonella* infection related with the consumption of imported tahini have been reported in Australia, New Zealand, and Canada. NSpired Natural Foods of San Leandro, California, voluntarily recalled all MaraNatha Sesame Tahini in 2007 due to the potential contamination with *Salmonella* spp. Therefore, safety controls, especially those relevant to cleanliness, personnel hygiene and pest control, must be implemented in tahini production.

CRITICAL CONTROL MEASURES FOR ENSURING FOOD SAFETY OF TAHINI

- Foreign objects must be removed from sesame seeds by using efficient sieves, magnets and dust suction machine.
- The water used for washing and soaking sesame seeds must be from a potable source. Total coliforms should not be detectable in 100-ml water samples. Frequent sanitation of tanks and filters should be maintained to prevent contamination.
- A proper heat treatment (roasting at 350°F [176.7°C] for 10–15 minutes) is required to eliminate disease-causing microorganisms. The heating temperature and time are critical factors that must be monitored, controlled and documented.

Appendix

This table summarizes information concerning jurisdiction overlap for commercial products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc. Products carrying the USDA shield are USDA jurisdiction.

Jurisdiction for products produced under the School Lunch Program, for military use, etc., is

determined via the same algorithm, although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200, and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

Jurisdiction overlap for commercial food products regulated by either or both the FDA and USDA.

FDA jurisdiction	USDA jurisdiction		
	Meat	Poultry	Eggs
21 USC 392(b): Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals, and all members of the deer family including elk [wapiti] and moose). FDA responsible for all non-specified birds including wild turkeys, wild ducks, wild geese, and emus.	The Meat Inspection Act specifies the species of animal covered and includes carcasses or parts of cattle, sheep, swine, goats, horses, mules, or other equines. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001.	The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include chickens, turkeys, domestic ducks, domestic geese, and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA.	The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose, or guinea. Grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs and egg products.)
Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow, or meat extract, alone or in combination.* Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2%) in any combination. Closed-face sandwiches.	Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination.* Open-face sandwiches.	Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat, and poultry meat in any combination.*	Egg processing plants (egg washing, sorting, egg breaking, and pasteurizing operations) are under USDA jurisdiction.
FDA is responsible for egg containing products and other egg processing not covered by USDA, e.g., restaurants, bakeries, cake mix plants, etc.			Products that are basically known for their egg content are under USDA jurisdiction such as egg rolls for slicing, heat 'n serve omelets, etc.
Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), spaghetti sauce with mushrooms and 2% meat, pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor.	Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie.	Chicken sandwich (open face), chicken noodle soup.	

Source: *FDA Investigations Operations Manual* (<http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127390.pdf>).

*These percentages are based on the amount of meat or poultry product used in the product at formulation.

For More Information

Important Food Safety Programs

British Retail Consortium Audit Info
<http://www.brc.org.uk>

British Retail Consortium Global Standards
<http://www.brcglobalstandards.com>

Center for Science in the Public Interest (food safety research for the public, policymakers, and regulators)
<http://www.cspinet.org/foodsafety/index.html>

Commercial On-Farm Food Safety Practices (information and tools to help you reduce chances of causing on-farm food contamination by biological or other means)
<http://gaps.nmsu.edu>

Foundation for Food Safety Certification
<http://www.22000-tools.com/fssc-22000.html>

Global Food Safety Initiative (independent non-profit foundation managed by Consumer Goods Forum)
<http://www.mygfsi.com>

GlobalGAP (sets voluntary standards for certification of agricultural products)
<http://www.globalgap.org>

Global Red Meat Standard (owned by Danish Agriculture and Food Council)
<http://www.grms.org>

HACCP Guidelines , FDA
<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm>

International Featured Standard
<http://www.ifs-certification.com>

National GAP Program, Cornell University
<http://www.gaps.cornell.edu/indexhighspeed.html>

Primus GFS (private scheme that establishes requirements for the certification of agricultural sector products in a voluntary manner worldwide)
<http://www.primusgfs.com>

Safe Quality Food Institute
<http://www.sqfi.com>

Synergy 22000 (set of two complementary standards allowing developing a reliable FSMS)
http://www.synergy-gss.com/ApprovedStandards/Synergy_22000

Federal Agencies

Agricultural Marketing Service, USDA
<http://www.ams.usda.gov/>

Agricultural Research Service, USDA
<http://www.ars.usda.gov/main/main.htm>

Bureau of Alcohol, Tobacco and Firearms
<http://www.atf.gov/>

Cooperative Program, Rural Development, USDA
<http://www.rurdev.usda.gov/rbs/coops/cswhat.htm>

Food and Drug Administration
<http://www.fda.gov>

Food and Nutrition Service, USDA
<http://www.fns.usda.gov/fns/>

Food Code, FDA
<http://www.cfsan.fda.gov/~dms/foodcode.html>

Food Labeling Guide, FDA
<http://www.cfsan.fda.gov/~dms/flg-toc.html>

Food Safety and Inspection Service, USDA
<http://www.fsis.usda.gov>

FoodSafety.gov (food safety information)
<http://foodsafety.gov>

Internal Revenue Service
<http://www.irs.gov/businesses/small/index.html>

Nutrient Data Laboratory, USDA
<http://www.ars.usda.gov/nutrientdata>

Nutrition.gov (access to food and nutrition information from across the federal government)
<http://www.nutrition.gov>

President's Food Safety Working Group (recommends a new, public health-focused approach to food safety based on three core principles: prioritizing prevention; strengthening surveillance and enforcement; and improving response and recovery)
<http://www.foodsafetyworkinggroup.gov>

Seafood Inspection Service, U.S. Department of Commerce/National Oceanic and Atmospheric Administration
<http://seafood.nmfs.noaa.gov>

Starting a Food Business, FDA
<http://www.cfsan.fda.gov/~comm/foodbiz.html>

U.S. Customs Service, U.S. Treasury Department
<http://www.customs.gov>

U.S. Small Business Administration (variety of programs through which small businesses can secure loans; loans are guaranteed by SBA but administered by lending institution)
<http://www.sba.gov>

State Resources

Oregon:

Food Handlers Manual
<http://www.oregon.gov/DHS/ph/foodsafety/manual.shtml>

Food Sanitation Rules
<http://egov.oregon.gov/DHS/ph/foodsafety/docs/foodsantiationrulesweb.pdf>

Oregon Department of Agriculture Food Safety Division
<http://www.oregon.gov/ODA/FSD/>

Oregon Specialty Markets
http://www.all-oregon.com/food/gourmet_stores.htm

Washington:

Washington Association for Food Protection
<http://www.waffp.org>

Washington State Department of Agriculture Food Safety and Consumer Services Division
http://agr.wa.gov/AboutWSDA/Divisions/FS-CS_Div.aspx

Washington State Department of Health Food Safety Program

<http://www.doh.wa.gov/ehp/food/>

Idaho:

Idaho Preferred Specialty Food Products

<http://www.idahopreferred.com/consumers/specialty-foods-and-products.htm>

Idaho Public Health Food Safety and Sanitation

<http://idahopublichealth.com/environment/food>

Idaho State Department of Agriculture Food Safety Program

<http://www.agri.state.id.us/Categories/InspectionsExams/FoodSafety/indexfoodSafetyHome.php>

Idaho State Department of Health and Welfare Food Protection Program

<http://www.healthandwelfare.idaho.gov/Health/FoodProtection/tabid/96/Default.aspx>

Tastes of Idaho

<http://www.tastesofidaho.com>

Other Organizations

Agricultural Marketing Resource Center

<http://www.agmrc.org>

American Food Safety Institute

<http://www.americanfoodsafety.com>

Center for Science in the Public Interest (outbreak alert database)

<http://www.cspinet.org/foodsafety/outbreak/pathogen.php>

Food Alliance

<http://foodalliance.org>

Food Marketing Institute (leadership and advocacy for the food distribution industry worldwide)

<http://www.fmi.org>

FoodReference.com (articles about foods, short facts and trivia, cooking tips, recipes, etc.)

<http://www.foodreference.com>

National Association for the Specialty Food Trade

<http://www.specialtyfood.com>

The Nibble (magazine about specialty foods)

<http://www.thenibble.com>

Northeast Center for Food Entrepreneurship (click on "Publications," then "Fact sheets")

<http://www.nysaes.cornell.edu/necfe/>

Northwest Specialty Foods Association

<http://www.nwspecialtyfoods.org/>

Service Corp of Retired Executives

<http://www.score.org>

Sustainable Agriculture Research and Education Program

<http://www.sare.org>

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