

PRINCIPLES OF RESEARCH AND DEVELOPMENT: A HANDBOOK FOR TEACHING
BASIC CONCEPTS IN NEW PRODUCT DEVELOPMENT

by

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Abstract

Food product development involves more than just creating the perfect recipe. Representatives from marketing, procurement, research and development, safety, and quality all work together to complete product development projects. This manuscript is aimed to serve food science students and professionals learning the basics of the product development process, food component functionality, basic units of food processing, regulatory considerations, food safety concepts, consumer testing, confidentiality/intellectual property issues, and essential pieces of marketing. Many other texts concentrate on food product development, but this text looks to create a more comprehensive guide. The breadth of knowledge needed for food product development are vast. Food science students and professionals can use this text to provide basic (not exhaustive) knowledge necessary to be a valuable part of a new product development team.

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Chapter 1 - Food Additives

The food industry uses food additives in products for many reasons—to improve the nutritional quality, improve the sensory characteristics, increase acceptability, enhance freshness and shelf-life, safety, or assist in processing. A food additive is defined as any substance, natural or artificial, that is added to a food product during any phase of production, including processing, packaging and storage. Currently, more than 2,800 different substances are intentionally added to the food supply, while as many as 10,000 other substances can incidentally be added to foods through environmental factors or other means.

Major Uses of Food Additives

Food additives must have a purpose to be added to a product. Food additives should not be used to deceive the customer of defect or alter the appearance of the product without reason. Major uses for food additives include preservation, enrichment, improvement in color and flavor, alteration of texture, and processing and/or preparation aid.

Preservation

A main function of food additives is to preserve. Without the addition of preservatives, natural spoilage of products would occur at a more accelerated rate than expected by the American consumer. Typically, consumers prefer fresh tasting products that have a relatively long shelf-life. In order to achieve freshness for a longer period of time, preservatives are included in products to ensure consumer satisfaction. Without preservatives, it would be more common to see baked goods with mold at the grocery store.

Because the nutrient content of food provides a supportive medium for microorganisms, preservatives are added to control microbial growth. organic acids and their salts, sulfites, nitrites, parabens, and a host of other compounds are examples of preservatives used to limit microbial growth, therefore increasing shelf-life and reduce the risk of foodborne illnesses.

The government regulates additives by limitations on substances, the product types in which they can be incorporated and the maximum amount allowed. Some ingredients that can act as antimicrobial agents also have other functions. For example, salt and sugar are common

ingredients in food but can assist in reducing microbial growth by decreasing the amount of water available. Acidulants that reduce the pH of the product can help reduce microbial growth because acidic environments less than 4.6 tend to harbor much less growth. Lysozymes, present in eggs and milk, are naturally present antimicrobial agents.

Preservative choice is an important part of a certain additive's effectiveness in the product. Food scientists should know the limiting factors of microorganisms (pH, water activity, heating) that could possibly thrive in the product. Ready to eat products should be treated with great care because recontamination can cause these foods to easily be unsafe.

Enrichment

Enrichment is yet another function food additives perform. Enrichment refers to the addition of certain nutrients in amounts that do not exceed those found in the food before processing. Foods with an "enriched" claim must contain at least 10 percent or more of the Recommended Daily Intake (RDI) for vitamins or minerals or of the Daily Recommended Value (DRV) for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference food similar in nature.

Vitamin degradation can occur in processes such as milling, canning, heating, freezing, and storage. Various cereal grain products are enriched to restore the original amount of nutrients prior to processing. A typical example of an enriched product is bread; without the addition of thiamine (B1), riboflavin (B2), and niacin (B3), bread would be deficient in these B-complex vitamins and iron. Flour (21 CFR 137.165) and bread (21 CFR 136.115) have specific regulations in order to use the claim "enriched."

Fortified foods are similar to enriched, but the vitamins and minerals were not present in the food prior to processing. Like enriched foods, fortified products should have 10 percent more vitamins or minerals (based on RDA) and dietary fiber, protein, and potassium (based on DRV) than a product without fortification. A common example of a fortified product is vitamin D milk. Fortified foods are generally represented as having vitamins and minerals given as a percentage of the RDA. Nutrition labels are required on products that make nutritive claims or have added nutrients.

Improvement in Color

Consumers rely on colors to identify flavors and determine acceptance of products. Just imagine you are in the grocery store looking for produce or meat—how do you determine which product to buy? Most shoppers look at the commodity, smell it, and choose the item that best fits their perception of “good.” Color is an important factor in food choice, and is therefore, utilized by the food industry to make foods more appealing. The motivations for adding colorants, natural or synthetic, are to: 1) create attractive appearance by restoring natural colors that are lost during processing or storage, 2) give color to foods with little color otherwise—such as ice creams, confections, and soda drinks, and 3) produce consistent color when raw materials may vary in color intensity. Color also pertains to consumer perception of safety.

Improvement of Flavor

Flavoring agents include both natural and synthetic compounds used to create a desired flavor. Synthetic flavor additives can be found in a wide variety of products. Methyl salicylate and benzaldehyde are two commonly used synthetic flavors that impart wintergreen and cherry flavoring, respectively. Artificial flavors (or artificial flavoring) are any substances that are used to impart flavor that are not derived from spices, fruit or fruit juices, vegetable or vegetable juices, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products. A statement of must be given when artificial flavorings are used. Naturally flavored products can be listed on the label as using naturally derived flavor ingredients, while artificially derived flavors must be declare that artificial flavors are used.

Plant extracts, essential oils, herbs, spices and other substances head the list of natural flavors used by industry. Natural flavorings are essential oils, oleoresins, essence or extractives, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from natural substances whose significant function in food is flavoring rather than nutritional value.

Spices, a form of natural flavoring, can be listed by their common names. Labels refer to common ingredients added for flavor as “spice.” Spices that are also used for coloring purposes, such as saffron, paprika and turmeric, can be listed as “spices and coloring.” Dehydrated aromatic vegetables, such as garlic, celery and onion powders, are recognized by consumers as food and should be listed by their common names.

Flavor enhancement technologies are readily used in the food industry. With the task of reducing sodium in process foods, bitter blocker technologies have been a source of experimentation in the food industry. Potassium chloride, a product with notable bitterness, is a common sodium chloride substitute with a bitter taste. Adenosine Monophosphate (AMP) is one of the compounds that has been found to block the bitter taste of foods that can lend to better tasting foods (such as naturally bitter grapefruit juice). Monosodium glutamate (MSG), a flavor enhancer used in food processing in the United States since the 1940s, is commonly used in broths, snacks, and Chinese food and heightens the umami taste. MSG is the salt form of glutamic acid, an amino acid. Although flavor enhancers are not new to food processing, developments are continually being made. Disodium guanylate (21 CFR 172.530) and disodium inosinate (21 CFR 172.535) are also added to foods as flavor enhancers.

Alteration of Texture

Recipe modification involves more than simply reducing or eliminating the amount of fat in a formulation. Gels, gums and water-based shortening substitutes are used to eliminate fat and caloric intake without sacrificing texture, mouthfeel, and other sensory characteristics of the food. Additives that fulfill the qualifications of texture manipulation contribute desirable characteristics to the food. The food manufacturer utilizes countless approved ingredients and chemicals to help modify texture in complex food systems.

A simple compound, such as sucrose or table sugar, can be used in varying concentrations to achieve a variety of results. Sugar affects texture differently depending upon its concentration. In a dilute solution, it adds body and mouthfeel to soft drinks, while in higher concentrations it crystallizes and adds brittleness to hard candies.

Processing Aids

The manufacturer for the ease of processing uses certain food additives. . FDA regulations (21 CFR Part 173) define secondary direct food additives as substances that are required during the manufacture or processing of a food and are ordinarily removed from the final food. Residuals carryover to the final food is likely, but no functional changes in the food are seen. Secondary direct food additives are consistent with FDA's definition of a processing aid and are not declared as an ingredient in food products due to the small quantity present. Processing aids, in theory, should not present any risk to human health.

Because secondary direct additives and processing aids do not directly affect product attributes, they do increase efficiency of producers. The United States Department of Agriculture (USDA) and the FDA classify additives as processing aids if they meet one the following criteria:

1. Substance is added, but then removed and not a significant ingredient in finished food
2. Substance is added to food, then changed into a component of food present in insignificant quantity that do not alter the structure of the food
3. Substances that are added during processing but are only present in insignificant quantity and do not alter the finished product's structure or function.

Common functions of processing aids include antimicrobial functions, clarifying agents, and substances to help remove skins on roots and tubers, and antifoaming products. Processing aid that are commonly used in the food industry include fruit and vegetable washes such as chlorine rinses, decolorization agents (dimethylamine epichlorohydrin copolymer, used for refined sugar) and ingredients for strengthening baked goods (sodium stearyl lactylate, used in frozen baked goods). Although processing aids are not listed as ingredients, they are regulated in the same manner as all other food additives. The USDA, who regulates meat, poultry, and egg products, has stated that food producers may not categorize an additive as a processing aid without prior consent from their organization.

The food industry uses food additives in products for many reasons—to improve the nutritional quality, improve the sensory characteristics, increase acceptability, enhance freshness and shelf-life, safety, or assist in processing. A food additive is defined as any substance, natural or artificial, that is added to a food product during any phase of production, including processing, packaging and storage. Currently, more than 2,800 different substances are intentionally added to the food supply, while as many as 10,000 other substances constitute the category of incidental food additives.

Categories of Common Food Additives

Food additives have been used to flavor, preserve, and perform various functions for thousands of years. However, additives can be the source of misinformation and confusion in consumers. Classification of additives is based on the function of the additive, but individual additives may serve more than one purpose. The following is a simple classification of food additives according to function.

Acidulants

Table 1.1 Common Acidulants Used in Foods

Acidulant	Common uses
Acetic Acid	Pickling applications, condiments, baked goods, chewing gum and dressings
Adipic Acid	Jellies, jams, for leavening, dairy products, frozen desserts.
Ascorbic Acid	Fruit drinks, soft drinks, bread dough
Citric Acid, anhydrous	Candy, gelatin, alcoholic beverages, fruit drinks
Citric Acid, monohydrate	Wide variety of foods and beverages
Fumaric Acid	Wine, confections, soft drinks, pie fillings, cakes mixes.
Lactic Acid	Salad dressings, biscuits, ready to eat meats, infant formulas
Malic Acid	Fruit juices, sauces, processed meat products, confections, ciders, soybean products
Phosphoric Acid	Sodas and other carbonated beverages, cheese and beer making
Succinic Acid	Bakery items, dry mixes, confections, dairy products, sauces
Tartaric Acid	Baking powder, chewing gum, cocoa powder

Acidulants are pH-adjusting/controlling chemicals that assist in enhancing flavors, controlling microorganism growth, and gelling and coagulation. Properties of food acidulants such as solubility in water, taste characteristics, and physical form, help the processor choose an acidulant to add to a product. Common food acidulants utilized in the food industry are acetic, adipic, ascorbic, citric, fumaric, lactic, malic, phosphoric, and tartaric acids. While many of these acidulants are derived from fruits and vegetables, fermentation and chemical synthesis are also methods of generating acidulants. Common acidulants are listed in Table 1.1.

Anti-Caking Compounds

Compounds added to dry mixes to prevent clumping and keep powders free flowing are called anti-caking agents. Excess water is adsorbed by these additives in order to create a more appealing and useful product for consumers. (Calcium silicate also adsorbs oil.) Anti-caking agents not only keep high fat foods (especially boxed mixes) from caking together, but also serve as a processing aid. These compounds are very fine powders that are used to separate crystals of substances which would otherwise adhere.

Anti-caking agents can be found in dry mixes (cakes, cheese sauce, etc.), shredded cheese, powdered sugar, instant soups, and table salt. Natural ingredients, such as potato starch, cellulose, and sugar beet fiber, have also been used for anti-caking purposes. Examples of commonly used anti-caking agents are listed in Table 1.2.

Table 1.2 Anti-Caking Compounds and their Regulations

Anti-Caking Compound	Regulations in 21 CFR	Limitations on Use
Calcium silicate	172.410, 182.2227	Up to 2% in foods, but up to 5% in baking powder
Iron ammonium Citrate	172.430	Cannot exceed 25 ppm in salt
Silicon Dioxide	172.480	Not to exceed amount needed to prevent caking, and cannot be used over 2% of final food
Yellow prussiate of soda	172.490	Can be used in salt in the amount needed for anti-caking effect, and not over 13 ppm
Aluminum calcium silicate	182.2122	Not to exceed 2% of salt
Magnesium silicate	182.2437	Not to exceed 2% of table salt
Sodium aluminosilicate	182.2727	Not to exceed 2% of finished food
Sodium calcium aluminosilicate, hydrated	182.2729	Not to exceed 2% of finished food
Tricalcium silicate	182.2906	Not to exceed 2% of table salt
Potassium acid tartrate	184.1077	Allowed for use in baked goods, confections and frostings, gelatins and puddings, hard candy, jams and jellies, soft candy.
Calcium Chloride	184.1193	0.2 percent for cheese, gravies and sauces, 0.32 percent for coffee and tea, 0.05 percent for food categories not specified in regulation*
Calcium sulfate	184.1230	0.5 percent for frozen dairy desserts and mixes , 0.4 percent for gelatins and puddings, 0.07 percent or less for all other food categories*
Magnesium carbonate	184.1425	Not to exceed amount needed to prevent caking
Magnesium oxide	184.1431	Not to exceed amount needed to prevent caking
Propylene Glycol	184.1666	97 percent for seasonings and flavorings, 5 percent for nuts and nut products, 24 percent for confections and frostings, 2.0 percent for other food categories*
Sorbitol	184.1835	75 percent in chewing gum, 98 percent in soft candy, 12 percent in all other foods
Carnauba Wax	184.1978	Can be used in baked goods and baking mixes, confections and frosting, chewing gum, gravies and sauces, and soft candy

*Only foods that may need anti-caking agent are listed. Other limits are found in the Code of Federal Regulations.

Antifoaming Agents

Foam, an accumulation of bubbles created when certain gases are released into a liquid, can be controlled by making processing changes, by using mechanical defoaming equipment, or by using chemical antifoam agents. Chemical antifoams have proven to be the most effective

and economical means of controlling this processing menace. Defoaming agents (21 CFR 173.340) can be used in the processing of foods as long as regulations are followed. Effective antifoaming agents have low surface tension, disperse easily, have low solubility, and have no odor. Antifoaming agents may be used in deep fat frying oil, cocoa, fermentation systems, jam and jelly making, and other processes.

Most antifoam agents are generally comprised of silicone and are mostly classified as secondary direct additives (processing aids), substances whose functionality is required during the manufacture that are ordinarily removed from the final food or found in small percentages. Products in which antifoams are specifically approved for use are: canned pineapple juice, yeast, sugar beets, sliced potatoes, fermentation processes and fruit butters, jellies, and preserves. Consulting with antifoam ingredient suppliers for the best antifoam in processing is recommended.

Antioxidants

Antioxidants, as the name implies, serve to prevent or minimize oxidation. Oxidation is the loss of electrons and gain of O₂, which can cause off odors and quality degradation. Common antioxidants naturally present in food include lecithin, vitamin E, tocopherols, and certain sulfur-containing amino acids. Lecithin is commonly found in soybeans and is obtained for commercial use by solvent extraction. Although antioxidants can be traced to natural sources, synthetic chemicals are much more effective. Synthetic antioxidants commonly used include butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), tertiary butylated hydroquinone (TBHQ), and propyl gallate (PG). Considerations when choosing an antioxidant include:

- Potency
- Solubility
- Discoloration
- pH
- Type of process
- Flavor and odor
- Legal and regulatory status

Antioxidants are usually added directly into fats and oils. Suppliers of fats and oils are skilled at using these additives. Food companies can have them added prior to receiving these ingredients. For nuts and cereals, antioxidants are dissolved in solvent before being sprayed onto the foods. Packaging materials can also deliver antioxidants. Antioxidants can be included in

Table 1.3 Antioxidants and their Regulations

Antioxidant	Regulation in 21 CFR	Limitations on use
Anoxomer	172.105	Not more than 5,000 ppm based on fat or oil content
BHA	172.110	50 ppm: Dehydrated Potatoes, potato flakes, sweet potato flakes, dry breakfast cereal* 2 ppm: Beverages and desserts prepared from dry mixes (or 90 ppm in dry mix) 32 ppm: Dry diced glazed fruit 200 ppm: Stabilizers for shortening* 1,000 ppm: Active dry yeast
BHT	172.115	50 ppm: Dehydrated Potatoes, potato flakes, sweet potato flakes, dry breakfast cereal* 200 ppm: Stabilizers for shortening* 10 ppm: Potato granules
Ethoxyquin	172.140	5 ppm: uncooked fat of meat from animals (excluding poultry) 3 ppm: uncooked liver and fat of poultry 0.5 ppm: uncooked muscle meat of animals, poultry eggs 100 ppm: chili powder, paprika, and ground chili
4-Hydroxymethyl-2,6-di-tert-butylphenol	172.150	Can be used alone or in combination with other antioxidants at a level that should not exceed 0.2% of the oil or fat content of the food
TBHQ	172.185	Can be used alone or with BHA and BHT, but should not exceed 0.2% of the oil and fat content of the food
THBP (2,4,5-trihydroxybutyrophenone)	172.190	Can be used alone or in combination with other antioxidants at a level that should not exceed 0.2% of the fat or oil in food
Isopropyl citrate	184.1386	Can be used in margarine, non alcoholic beverages, and fats & oils
Propyl gallate	184.1660	Should not exceed 0.2% of the oil or fat content of the food
Propylene glycol	184.1666	97 percent for seasonings and flavorings 5 percent for alcoholic beverages, nuts and nut products 2.5 percent of frozen dairy products 24 percent for confections and frostings 2.0 percent for other food categories
Sodium carbonate	184.1742	Should not be used at levels that exceed necessity
Stannous chloride	184.1845	Maximum level of 0.0015 percent or less
Stearyl citrate	184.1851	Can be used in margarine, non alcoholic beverages, and fats & oils
Tocopherols	182.3890	None.

paperboard, polyethylene, and wax paper materials. Food processors should keep in mind that antioxidants can be destroyed by processing steps, therefore timing of addition is important.

Fats degradation occurs from oxidation or hydrolysis. Hydrolysis is an effect of water reacting with the triglycerides in fat; this interaction generates glycerol, mono- and diglycerides, and free fatty acids. The processing of foods in high temperature environments, such as deep fat frying, is especially susceptible to hydrolysis. A solution for fat degradation by hydrolysis is to use ingredients of high quality. Antioxidants do not prevent hydrolysis. Without antioxidants, potato chips, breakfast cereals, salted nuts and many other fatty foods could not be stored without becoming rancid.

Antioxidant effectiveness is product dependent. Tocopherols are very effective on animal fats and oils, especially in frying processes. Vegetable oils are protected well from oxidation by TBHQ. Baking applications can benefit from a BHT, BHA, and tocopherol antioxidant cocktail. Nut products are well protected by a variety of antioxidants, but TBHQ is commonly used for nut oil and butters. Dry breakfast cereals commonly use BHA and BHT incorporated into packaging material to help protect flavor. Antioxidants, their regulations, and limitations of use are listed in Table 1.3.

Bases

Like acidulants, bases provide a means of adjusting or controlling pH. Certain processes incorporate adjusting the pH into the unit operation. The vegetable industry often submerges vegetables in a hot alkali solution to facilitate skin removal. An alternative can be the use of a 1 percent lye solution at elevated temperatures to loosen the skins. Because the cost of lye and of treating lye-containing waste waters can be appreciable, processors often use less expensive techniques such as hot water scalding, steaming or direct exposure to gases or flame.

Bases also play a key role in color development, alteration of texture, and removal of bitter compounds in certain products. Sodium hydroxide, a base commonly used in the food industry, is often added to ripe olives to assist in darker color development and removal of bitter compounds. When dipped in a 1.25 percent sodium hydroxide solution prior to baking, pretzels display a more desirable brown color and a smoother texture than without this treatment. The sodium hydroxide converts to sodium bicarbonate in the baking process through its reaction with carbon dioxide. ($\text{NaH} + \text{CO}_2 \rightarrow \text{NaHCO}_3$)

Dough Conditioners & Strengtheners

Dough conditioners help control the baking process and create the best crumb structure, volume, and shelf-life. Additives added to baking processes include dough strengtheners, leavening agents, yeast nutrients, antioxidants, sweeteners, thickeners, emulsifiers, enzymes, preservatives, and vitamins. In dough systems, the formation of a gluten network and retention of carbon dioxide are important.

Gluten networks can be improved through the use of oxidizing and reducing agents. Oxidants improve bread strength, while reducing agents improve dough extensibility and improve softness. Oxidizing agents are calcium peroxide, potassium iodate, azodicarbonamide (ADA), ascorbic acid, calcium iodate, potassium bromate, and calcium bromate. Under-oxidized products leads to soft, weak, sticky, and hard to work with dough, and bread with low volume, weak crust, and uneven grain and texture. Over-oxidized products lead to tight dough that tears easily. The bread from an over-oxidized dough will result in small volumes, large holes in the bread, and uneven grain. Reducing agents, which can cut down mixing time, are generally used alongside oxidants. Commonly used reducing agents include coated ascorbic acid, sodium metabisulfite, sorbic acid, and L-cysteine hydrochloride. Ascorbic acid acts as an oxidizing agent in the presence of oxygen, and a reducing agent in the absence. Coating the ascorbic acid can delay action to ensure the product acts as a reducing agent.

Bleaching Agents

Bleaching agents have an important use in the bakery industry, primarily in flour milling and bread making. Benzoyl peroxide is applied to wheat flour to remove plant pigments and produce a white product. Hydrogen peroxide is used in the dairy industry to create more desirable color characteristics, especially in milk. Hydrogen peroxide is removed before the milk is packaged and transported through the use of catalase, an enzyme.

Chelating Agents (Sequestrants)

Chelating agents are needed for form a complex with unwanted trace metals and render them inactive. The most problematic metal ions in foods are iron, copper, nickel and zinc because discoloration, turbidity and oxidation can occur in their presence. Because chelating agents are used to control the reactions of trace metals in food systems, they are often termed “metal scavengers.” Other specific applications of chelating agents are detailed in Table 1.4.

Table 1.4 Chelating Agents and Common Uses

Category	Food	Chelating Agent	Function
Beverages	Carbonated beverage (in can)	Calcium EDTA	Flavor retention
	Alcoholic Beverages – Distilled	Calcium EDTA	Flavor retention, color retention, product clarity
Dairy	Skim Milk	Disodium EDTA	Prevent fats from separating
Fats & Oils	Vegetable Oil	Potassium Citrate, Sodium Citrate	Preservative
	Lard	Potassium Citrate, Sodium Citrate	Preservative
	Mayonnaise	Calcium EDTA, Disodium EDTA	Preservative
	Salad Dressing	Calcium EDTA	Preservative
Fish	Frozen Fish	Potassium Citrate, Sodium Citrate	Color retention, Slows rancidity
	Clams (canned)	Calcium EDTA	Color retention
	Crabmeat (canned)	Calcium EDTA	Color retention, Prevents struvites
	Shrimp	Calcium EDTA	Color retention, Prevents struvites
Meat & Poultry	Beef, cooked	Disodium EDTA	Antibacterial
	Chicken, cooked	Disodium EDTA	Flavor improver
	Pork, fresh	Potassium Citrate, Sodium Citrate	Color retention, flavor retention
Fruit	Apple slices	Disodium EDTA, Potassium Citrate, Sodium Citrate	Prevents browning
	Bananas	Disodium EDTA	Inhibits discoloration
	Frozen fruit	Potassium Citrate, Sodium Citrate	Color retention, flavor retention
	Fruit spreads, artificially colored	Disodium EDTA	Color retention
Vegetables	Black eyed peas, canned	Disodium EDTA	Color retention
	Chickpeas, canned	Disodium EDTA	Color retention
	Kidney beans, canned	Disodium EDTA	Color retention
	Potatoes, canned	Calcium EDTA	Color retention
	Potatoes, frozen	Disodium EDTA	Color retention
	Mushrooms, canned	Calcium EDTA	Color retention
	Cabbage, pickled	Calcium EDTA	Color / flavor retention, improves final texture
	Cucumbers, pickled	Calcium EDTA	Preservative
Eggs	Egg Product	Calcium EDTA	Preservative

Without chelating agents, discoloration would occur in foods such as potatoes where the iron reacts with phenolic compounds in the presence of oxygen. Citric acid and polyphosphates are commonly used in the food industry to prevent discoloration, but the most effective sequestrant is ethylenediamine tetra acetic acid (EDTA), which can be used in food as disodium EDTA or calcium EDTA. Applications of chelating agents include adding phosphates in soft drinks to chelate heavy metal ions that interfere with carbonation and using EDTA in mayonnaise to protect flavor. Common chelating agents and their solubility are listed in Table 1.5.

Table 1.5 Chelating Agents, their Solubility, and Regulations

Product	Solubility (g/100 ml H₂O)	Regulation in 21 CFR Part:
EDTA—CaNa₂• 2H₂O	40	172.120
EDTA—Na₂H₂• 2H₂O	10	172.135
Citric Acid	160	184.1033 (GRAS)
Potassium citrate • 2H₂O	167	184.1625 (GRAS)
Sodium citrate • 2H₂O	71	184.1751 (GRAS)

Clarifying Agents

The beverage industry relies on clarifying agents to prevent cloudiness in the final product. Agents such as bentonite are used in processing juices, wines, vinegar and other liquids. This helps provide an attractive, clear liquid that appeals to consumers.

Emulsifiers

Emulsifiers are active in almost every stage of the baking process. Emulsifiers compensate for abuse from under and over-mixing (if not too extreme) as well as excessive fermentation time, therefore these additives are desirable in automated processes. Emulsifiers used in the baking industry include mono and di-glycerides, sodium stearoyl-2-lactylate, calcium stearoyl-2-lactylate, lecithin, and polysorbate 60. Selected emulsifiers and their uses are listed in Table 1.6.

Table 1.6 Emulsifiers Used in Baked Goods

Emulsifier	Typical Use Levels	Limit (by FDA)
Mono- and diglycerides	0.15-0.75%	No limit*
Sodium stearoyl-2-lactylate (SSL)	0.25 – 0.5%	0.5% based on flour basis
calcium stearoyl-2-lactylate (CSL)	0.25 – 0.5%	0.5% based on flour basis
Lecithins		No limit
Polysorbate 60	0.15 – 0.4%	0.5% in bread 0.46% in cakes

*Some types of Mono- and diglycerides may have more strict regulations. Refer to 21 CFR for more information.

Enzymes

Enzymes have specific functions based on the food system application being utilized due to the need for specific substrates. As biological catalysts, they lower the energy required in biochemical reactions and accelerate the rate of the reaction. Enzymes are utilized extensively in the food industry for a variety of applications. Groups of enzymes used in food processing are:

1. *Oxireductases*. Act as catalysts in oxidation or reductions.
2. *Transferases*. Catalyze the shift of one chemical group to another
3. *Hydrolases*. Aids by speeding the reaction of hydrolytic splitting of substrates.
4. *Lyases*. Removal or addition of groups to their substrates without hydrolysis.
5. *Isomerases*. Catalyze intramolecular rearrangement.
6. *Ligases*. Aid in the joining of two substrate molecules. Also called “synthetases”

The environment of an enzyme affects the catalytic activity. Factors that can affect this are: 1) temperature, 2) pH, 3) concentration of the enzyme and substrate, 4) the presence of inhibitors or activators and 5) the amount of time in the system (also referred to as residence time). Food scientists should be aware of the following characteristics in order to take advantage of the greatest enzymatic activity.

Temperature can be important when controlling enzymatic activity. Acceleration or retardation of the desired reactions can occur with increasing temperatures. If the temperature goes above the temperature of denaturation for that specific enzyme, the enzyme will no longer be active. The optimal pH also varies for an enzymatic reaction. Some enzymes need a very specific pH, while others catalyze in a wide range. During production, it is essential to add the enzyme in a range that is appropriate for the desired function.

Table 1.7 Enzymes Used in Food Processing

Category	Enzyme	Enzyme Group	Product usage	Function
Cereals	Amylases	Hydrolase	Bread, other baked goods	Increase fermentation to improve loaf volume. Also benefits crust color and crumb structure
	Proteases	Hydrolase	Biscuits	Reducing mixing time needed for baked goods through modification of gluten.
Alcoholic Beverages	Amylases	Hydrolase	Brewing	Decreases viscosity of mash in brewing, aids in conversion of starch to sugars
	Tannase	Hydrolase	Brewing	Removal of polyphenolics
	Glucanases	Hydrolase	Brewing	Assist in filtration, Act as extra sugar for fermentation
	Protease	Hydrolase	Brewing	Add nitrogen for growth of yeast, help in filtration process
	Pectinases	Hydrolase	Wine	Used to clarify. Increase the yields of extraction. Decreased press times.
Non-alcoholic Beverages	Cellulases	Hydrolase	Coffee, Tea	Used to break down cellulose.
	Pectinases	Hydrolase	Coffee	Eliminates gelatinous coating.
			Cocoa	Separation of pulp from beans
Dairy	Catalase	Oxidoreductase	Milk	To remove H ₂ O ₂ in milk.
	Proteases	Hydrolase	Cheese	Casein coagulation
			Evaporated Milk	Stabilizes.
	Lipase	Hydrolase	Cheese	Used to develop flavor.
Meat & Fish	Proteases	Hydrolase	Fresh meat and fish	Tenderizes, removes oil from tissue of fish
Eggs	Glucose oxidase	Oxidoreductase	Dried egg products	Removes glucose.
	Lipases	Hydrolase	Various egg applications	improves emulsification properties and stabilizes egg white foaming properties
Fruits & Vegetables	Amylases	Hydrolase	Juice	Remove starches to improve extraction
			Vegetables	Tenderizes.
	Naringinase	Hydrolase	Citrus juice	Reduces bitter taste.
Fats & Oils	Cellulase	Hydrolase	Vegetable Oils	Hydrolyses cell walls.

Enzymes are typically present in small concentrations, therefore acting as the limiting factor of the reaction. In food systems, the enzyme concentration is usually indicative of the rate of reactions. Although enzyme concentration can keep catalytic functions from occurring, compounds in the product may have an effect on enzymatic activity as well. Inhibitors are those chemical compounds in the system that deter enzymatic reactions from occurring. Metals, like copper, iron, or calcium, can affect enzymatic reactions by acting as inhibitors. Enzyme activators can also be present in the system by making the environment more stable or increasing its function as a catalyst. The catalytic reaction must also have enough time at the controlled environment to complete.

A common use of enzymes is in the bakery industry where amylase functions to accelerate the fermentation process. Yeast must have fermentable carbohydrates to produce carbon dioxide and leaven bread. Flour naturally contains α -amylase and β -amylase, but more α -amylase may be needed. This enzyme can be added by incorporating malt flour, fungal amylases (*Aspergillus*, usually added in a tablet or powder form), or bacterial amylases (*Bacillus* species). Other common uses of enzymes in applications can be found in Table 1.7.

When a food scientist is choosing an enzyme for a specific product, the following factors must be considered: cost, legal status, availability, and convenience. As with many additives, some enzymes have received GRAS status. Others have limitations to use.

Flavoring Agents

Flavoring agents can be broken down into food flavors and flavor enhancers. Food flavors include more than 1,200 different flavoring materials and constitute the single largest category of food additives. Natural flavoring substances include herbs, spices, essential oils and plant extracts. However, today there is more emphasis on the use of synthetic flavors because they are more economical compared to natural flavors. Flavor enhancers or potentiators are also considered flavoring agents. Unlike food flavors, which contribute flavor, flavor enhancers do not have flavor in themselves. Flavor enhancers serve to intensify the flavor of other compounds present in foods. Monosodium glutamate (MSG), the most commonly used potentiator in the food industry, is an example of a flavor enhancer. Baby food companies, however, discontinued use of this compound after an investigation by the National Academy of Sciences National Research Council revealed that MSG may be linked to brain damage.

Food Colors

Color is a strong visual tool used to evaluate food products. Food colors may be added to products for several reasons:

- To restore the original appearance of the food.
- To ensure uniformity of color due to natural variations in color intensity.
- To intensify colors to the level associated with a specific food type.
- To help protect flavor and light-sensitive vitamins during shelf storage.
- To give an attractive appearance to foods otherwise unattractive or unappetizing.
- To help preserve the identity or character by which a food is recognized.
- To serve as visual indication of quality.

Food products may attain their final color from several sources, including natural or artificial sources. Naturally occurring plant pigments, such as carotene, chlorophyll, and lycopene, help impart hues of orange, green, and red, respectively. Animal pigments, including myoglobin and heme, exist and serve to incorporate color in products such as meat. Certain red colors, such as kermes and lac, are derived from insects. Certain algae and fungi also produce color and can be incorporated into specific foods. Without the addition of vegetable dye, Cheddar cheese would lack its familiar orange color. Although these colorants come from natural sources, these are not categorized as “natural colorants” because a “natural” color can only be derived from the food itself.

Table 1.8 Colorants Certified by the FDA

Colorant Name	Hue	Regulation
Citrus Red No. 2 (<i>only used on citrus fruit</i>)	Red	74.302
FD&C Blue No. 1 (Brilliant Blue)	Greenish Blue	74.101
FD&C Blue No. 2 (Indigotine)	Deep Blue	74.102
FD&C Green No. 3 (Fast Green)	Bluish Green	74.203
FD&C Red No. 3 (Erythrosine)	Bluish Red	74.303
FD&C Red No. 40 (Allura Red)	Yellowish Red	74.340
FD&C Yellow No. 5 (Tartrazine)	Lemon Yellow	74.705
FD&C Yellow No. 6 (Sunset Yellow)	Reddish Yellow	74.706
FD&C Lakes (All except Red No. 3)		

Artificial colorants are synthetically manufactured and the primary source of commercial colorants. Artificial colorants must be approved by the FDA, and are named with the prefix

FD&C (food, drug, and cosmetic). In 2012, there were nine approved synthetic color additives. Artificial colors can be in lake form or as a pure colorant. Lakes are dyes that have been precipitated with an insoluble base to create a colorant that is insoluble in most solvents. Lakes can be prepared out of all approved FD&C colors except Red #3. Physical and chemical properties of certified food colors include hue range, compatibility with food components, and their stability to light, oxidation and pH change. FD&C Blue #1 (brilliant blue), FD&C Green #3 (fast green), FD&C Red #40 (erythrosine), and FD&C Yellow #6 (sunset yellow) are examples of synthetic colors used in the food industry. Synthetic colorants certified by the FDA are listed in Table 1.8.

Sources of naturally occurring colors are endless, but economics may influence whether to use a natural or synthetic food color. Although naturally occurring colors are often used in food products, artificial coloring is a viable alternative. The use of artificial colors can be more economical than natural colors, and synthetic colors generally excel in coloring power, color uniformity, and color stability. Naturally derived colorants exempt from certification are listed in Table 1.9.

Table 1.9 Colorants Exempt from Certification in Food Products

Colorant	Hues	Derived from	Regulation
Annatto	Reds, Yellows	Tropical Shrub	73.30
Beet juice concentrate	Red to Yellow	Beets	73.260
Beets (dehydrated)	Red to Yellow	Beets	73.40
Cabbage (red)	Red	Red cabbage	73.260
Caramel	Brown	Heating of sugar	73.85
Carmine	Red	Lake of cochineal	73.100
Carrot oil	Yellow	Carrots	73.300
Cochineal extract	Red	Female cochineal insects	73.100
Fruit juice concentrates	Various	From fruit	73.250
Grape color extract	Red to blue	Grapes	73.169
Grape skin extract	Red to blue	By-product of wine processing	73.170
Paprika	Red	Peppers	73.340
Saffron	Yellow	<i>Crocus sativus</i>	73.500
Turmeric	Yellow, green	Dried, ground herb	73.600
Vegetable juice	Various	Various vegetables	73.260

Food Irradiation

Food irradiation is an alternative to chemical substances for food preservation. Although food irradiation can be seen as a processing method, it falls under food additives in an FDA regulation found in the 1958 Food Additive Amendment to the Food, Drug, and Cosmetic Act. Applications for irradiation include sprout inhibition, insect disinfestations, sterilization, pasteurization, shelf-life extension and elimination of parasites. Although irradiation has been authorized for many processes, costs associated with the procedure can be high and acceptance from the general public has been low for most commodities.

Gases

Industrial gases have a variety of uses and functions in the food industry, with nitrogen and carbon dioxide being the two most widely used. The presence or absence of certain gases can directly influence shelf stability, color, texture and flavor of a product. By controlling the amount or level of gases in a food's environment, the processor can increase the product's longevity. The combination of gas flushing and food preservation methods (freezing, irradiation, dehydration) yields a high quality product. Gas flushing is commonly used in the packaging of potato chips and meat.

Freezing or chilling. Carbon dioxide and nitrogen are used in the freezing and chilling of foods because of their cryogenic traits. Cryogenic refers to very low temperatures. To freeze or chill foods, liquid nitrogen or carbon dioxide (in liquid or solid state) are allowed to come in contact with the food to be chilled and upon contact the cryogens will go through a change of state. Changing of state releases the heat from the product being chilled and the carbon dioxide or nitrogen is released as a gas. Special handling procedures are needed for both of these additives.

Controlled Gas Atmospheres. The controlling of a gaseous environment can help maintain product integrity during storage and shipping. There are two options when altering gases – modified atmosphere or modified atmosphere packaging (MAP). Modified atmosphere is the continuous control of storage conditions under particular atmospheric conditions. MAP means replacing the normal air in a package with specific gases, which are allowed to change

over time as a result of product changes, bacterial activity, and the penetration of gases through the packaging material.

Modified atmosphere storage is used to prolong the life of fruits and vegetables, meat, and nuts. After harvest, fruits and vegetables begin aerobic respiration in which they absorb oxygen and begin to degrade. Aerobic respiration can be slowed through the depletion of oxygen present during storage. The best conditions for storing fruits and vegetables is dependent on the type of product. Meat, poultry, and fish all utilized a modified atmosphere in order to extend their shelf-life. Poultry is best kept under an atmosphere of 30 to 60 percent carbon dioxide and 1-5 percent oxygen, while fish is better at 40 to 100 and 0 to 2 percent respectively. Red meats are best with a higher concentration of oxygen (30-50% carbon dioxide, 50 -80% oxygen). Higher oxygen helps preserve the bright red color of meats. Myoglobin reacts with oxygen creating oxymyoglobin, the bright red pigment that indicates freshness and quality to the consumer. Nuts and snack products with nuts are usually packed in nitrogen atmospheres, which prevents rancidity caused by deterioration of oil from occurring.

Other Uses. Carbon dioxide is a commonly used additive in the beverage industry to make soda and other carbonated beverages. Carbonated beverages are usually carbonated under pressure in order to allow for a higher rate of carbon dioxide incorporation. This process is responsible for the fizz in these products as well as some of the sharp flavor.

Ozone, a strong oxidizing agent, is another gas used in the food industry. Recycled poultry chill water is commonly treated with ozone to destroy objectionable odors, flavors, and to sterilize. Ozone is generally generated at the plant location using ozone generators.

Humectants

The primary purpose of humectants is to bind water that may be present in a food system to retain proper moisture, fresh flavor and texture. Humectants such as glycerol, propylene glycol and sorbitol are often added to products such as candies, shredded coconut and marshmallows. Sucrose (table sugar) and salt also fall into this classification as additives due to their ability to bind water.

Leavening Agents

Leavening agents, such as baking soda, baking powder and yeast, play an important role in the bakery industry. Leavening agents, which produce carbon dioxide, assist in providing the light

texture in baked goods such as cakes and breads. Chemical leavening agents work by a reaction of an acid and a soda, while biological forms (like yeast) work by fermenting carbohydrates in the system. In both cases, carbon dioxide is released into the baking system. Chemical leavening agents and some common applications are listed in Table 1.10

Table 1.10 Chemical Leavening Agents and Common Applications

Chemical Leavening Agent	Applications
Monocalcium phosphate monohydrate	Pancake, cookie, and angel food cake mixes; double acting baking powder
Sodium acid pyrophosphate	Doughnuts, refrigerated dough, baking powder, mixes
Sodium aluminum phosphate	Baking mixes
Dicalcium phosphate dihydrate	Cake mixes
Sodium aluminum sulphate	Used in combination with fast acting leavener

Source: Food additive user's handbook(1991). Smith, J. S.

Sweeteners

Sugar is a common word to describe fructose, sucrose, dextrose, levulose, invert sugar, molasses, brown sugar, and honey. Table sugar, or sucrose, is the most widely known sweetener. With increasing obesity, cutting out carbohydrates and sugar have been a great focus of the food industry. Sugar is also associated with incidence of dental caries. There are a wide variety of sweeteners used to replace table sugar. Sugar replacers can provide carbohydrates or be non-nutritive. Sugar is a great provider of bulk, as mentioned later in this chapter. Therefore, the use of intense sweeteners may require the addition of bulking agents like maltodextrin. Carbohydrate sweeteners and their descriptions are listed in Table 1.11.

Sugar substitutes that do not contribute calories are called non-nutritive. Approved non-nutritive sweeteners include aspartame, acesulfame potassium, saccharin, sucralose, and neotame. Aspartame is commonly used in snack foods such as gelatin desserts, diet soft drinks, and other snacks. Acesulfame potassium is approved for use in dry food products and is

relatively heat stable. Saccharin can be utilized in low-calorie products such as jams, beverages and desserts, but it can impart a bitter aftertaste and also must have a notice when used warning of heightened incidence of bladder cancer in rats after its consumption. Many of these sweeteners are used in combination with one another to create a taste as close to sucrose as possible.

Table 1.11 Carbohydrate Sweeteners and their Applications

Sweetener	Description and Applications
Brown sugar	Partially refined sucrose
Corn syrup	Sweet syrup of glucose and short polymers produced by hydrolysis of corn starch. Dextrose equivalent (de) above 20
Fructose	Monosaccharide used in place of sucrose, sweetness level at 175 (compared to sucrose at 100)
Glucose	A monosaccharide found in grains, fruits and blood, and produced commercially by hydrolyzing starch completely; less sweet than sugar (degree of sweetness:75)
Oligosaccharides	Sugar molecules containing two or more glucose units. Invert sugar: sweeteners produced by catalyzing an aqueous sucrose solution to produce equal quantities of glucose and fructose
Liquid sugar	Sucrose in enough water to keep product fluid
Maltodextrin	A blend of mixed sized sugars with a collective DE of less than 20
Maltose	A disaccharide of two glucose units produced commercially by partial hydrolysis of starch
Molasses	Sweetener produced as a byproduct of the refining of sucrose from sugarcane
Powdered sugar	Pulverized granulated sugar with cornstarch
Sucrose	A disaccharide produced by condensation of glucose and fructose
Table sugar	Refined sucrose

Polyols are sweeteners commonly referred to as sugar alcohols that have low to no cariogenicity. These sweet ingredients are also bulking agents. Xylitol, mannitol, and sorbitol are natural polyols, making their consumer appeal higher than other artificial sugar alcohols.

These ingredients are commonly used in sugarless chewing gums. Characteristics of common sweeteners and their sweetness levels are detailed in Table 1.12.

Table 1.12 Characteristics of Common Sweeteners

Sweetener	Sweetness*	Other Characteristics
Saccharin	300-400	Petroleum based with metallic aftertaste
Aspartame	200	4 calories per gram; not heat stable, sweet aftertaste
Acesulfame Potassium	200	Heat stable, slight bitter aftertaste
Cyclamate	130	Heat stable, distinct aftertaste
Maltitol	65	Non-cariogenic, used in sugar free chocolate and other confections, hygroscopic, inhibits crystallization
Mannitol	50	Slow absorption rate, does not promote tooth decay, may have laxative effect in large quantities
Sucralose	600-800	pH and heat stable, non-caloric
Sorbitol	50	Slow absorption rate, does not promote tooth decay, may have laxative effect in large quantities, humectant properties, high viscosity
Stevioside	300	Anise aftertaste, slow sweetness onset
Xylitol	100	Cooling effect, used commonly in chewing gum; laxative effect in large quantities

*Sweetness compared to sucrose

Fat Replacers

Reducing the fat of foods can result in a high degree of sensory trait changes therefore, fat replacers must deliver products with the desired textural attributes and taste. Fat replacers include carbohydrate-based replacers protein-based substitutes and synthetic compounds (Olestra and caprenin). Although many of these substitutes are only partially metabolized by the body, translating into 1 to 4 calories per gram, they cannot be classified as non-nutritive food additives.

Carbohydrate based fat replacers can be fully, partially, or non-digestible. These additives are usually used in combination with more than one product in order to achieve the desired texture. Reduced fat products that may use these products are dairy based frozen desserts, salad dressings, baked products, snacks, and frostings. Carbohydrate fat replacers can be one or

more of the following products: xanthan gum, gellan gum, pectin, microcrystalline cellulose, pectin, tapioca dextrin, maltodextrin or polydextrose.

Protein-based fat replacers produce the most similar mouthfeel to fat. Egg whites and wheat can be micro-particulated and used as fat replacers. These are easily used in ice creams and salad dressings, but can be undesirable due to allergenic tendency in consumers. (Eggs and wheat are two of the eight most common food allergens.)

Olestra® (manufactured by Proctor & Gamble) is a sucrose-based product that is too big to be split by lipase, causing it to pass through the digestive system. This product has been known to cause negative side effects such as anal leakage and the possibility of blocking the uptake of fat-soluble vitamins. Olestra was used in many reduced calorie fried snack products in an effort to reduce the fat contents.

Bulking Agents

Bulking agents can be used when fat, sugar, or other components have been eliminated or reduced in a product. These additives are generally made of starch or fiber to minimize volumetric and textural effects. Bulking agents can consist of many different starches and grains, but should be un-reactive and bland in the food system, as their purpose is not to flavor. When sugar (a bulking agent) is replaced with some non-nutritive sweeteners (especially with higher sweetness levels), bulking agents such as maltodextrin can be added to make up for lost volume.

Nutrient Supplements

Vitamins and mineral supplements are added to foods to improve nutritional quality or to replace nutrients lost during processing. Many common food items are enriched, including flour and white bread. Margarine, milk and salt are additional examples of foods to which vitamin A, vitamin D, or iodine have been added. Adding nutrients has decreased the number of people suffering from vitamin and mineral deficiencies such as beriberi (thiamin deficiency), pellagra (niacin deficiency), scurvy (vitamin C deficiency), and goiter (iodine deficiency).

Vitamins. In order to add vitamins to a food, it is important to understand the traits of vitamins. Fat soluble vitamins are A, D, E and K, which can be added to water-based foods when used with gelatin or sugar. These vitamins in water-soluble form usually contain antioxidants. All fat soluble vitamins should be stored in a cool environment, or even a

refrigerator. Vitamin A is highly sensitive to oxygen, light and heat, and should be tested every 6 months to ensure potency of the additive. The oil based forms of Vitamin A have higher stability than dry products. Vitamin E, when added to food as a source of nutrients, should be used as Vitamin E acetate, its esterified form. Vitamin E in its alcohol form is used as an antioxidant. Vitamin K is not a very common nutritive additive, except in infant formula and some meal replacement products. All oil-based vitamin additives can crystallize in cool temperatures, and should be brought to room temperature before use. Fat soluble vitamins and their usage are listed in Table 1.13.

Table 1.13 Fat Soluble Vitamins and Their Usage

Vitamin	Chemical Names	Product usage	Considerations
Vitamin A	Retinol Retinyl acetate Retinyl palmitate	Oils and fats, liquid milk, milk powder, infant formula, breakfast cereals	Soluble in fat and oil
Vitamin D ₂	Ergocalciferol	Liquid milk, milk powder, oil and fats	
Vitamin D ₃	Cholecalciferol	Liquid milk, milk powder, oil and fats, breakfast cereals	Can be found in oil blends (soluble in oil) and dry powders (water dispersible)
Vitamin E	Tocopherol		
	dl-alpha-Tocopherol	Antioxidant in oils, fats, and sausages	Fat and oil soluble
	dl-alpha-Tocopheryl-acetate	Fortification of infant formula, confectionary, oils and fats, fruit drinks, flour, liquid milk, milk powder, breakfast cereal	Water dispersible
Vitamin K ₁	Phytonadione	Fortification of infant formula, liquid milk, oil and fats, dietary products	Can be found in oil blends (soluble in oil) and dry powders (water dispersible)

Water soluble vitamins include Vitamins C and B. B vitamins include thiamin (B₁), riboflavin (B₂), niacin/ niacinamide, pyroxydine (B₆), cyanobalamin (B₁₂), folic acid, pantothenic acid and biotin. Water soluble vitamins come in dry forms and are quite stable. Expected shelf-life is at least one year. Water soluble vitamins and their usage are listed in Table 1.14.

When adding vitamins to food products, it is important to ensure that the vitamins will be viable the entire shelf-life. Therefore, overages of vitamins are included in the product. Food scientists accounting for losses of vitamins must consider the method of packaging, the nature of the product, losses during processing and how the product will be stored throughout shelf-life. Fortified and enriched products should be tested during the development stages to ensure vitamin contents are accurately stated. This testing can be done at an accelerated testing condition of 35°C (95°F) and relative humidity of 45%, taking vitamin assays at day 0, week 1, week 2, and every month for 3 months. Table 1.15 lists each vitamin and their approximate stability.

Table 1.14 Water Soluble Vitamins and Their Usage

Vitamin	Chemical Names	Product usage	Considerations
Vitamin B ₁	Thiamin Thiamin hydrochloride Thiamin mononitrate	flour, breakfast cereal, infant formula, soup, milk drinks, pasta, meal replacement products	Thiamin hydrochloride has better water solubility than thiamin mononitrate
Vitamin B ₂	Riboflavin Riboflavin-5'-phosphate sodium salt	flour, breakfast cereals, sugar, cocoa confections, soups, infant formula, fruit drinks, oils and fats, and meal replacements	Riboflavin-5'-phosphate sodium salt is more water soluble than pure riboflavin
Vitamin B ₆	Pyroxidine Pyroxidine-hydrochloride		Pyroxidine not used in its pure form
Niacin	Nicotinic Acid Niacinamide	flour, breakfast cereal, infant formula, fruit drinks, pasta, meal replacement products	
Pantothenic Acid	Pantothenic acid Calcium-D-pantothenate	infant formula, breakfast cereals, fruit drink, milk drinks, meal replacement products	
Vitamin B ₁₂	Cyanocobalamin	infant formula, meal replacement products, and substitute foods	
Biotin	Biotin		
Folic Acid	Pteroylglutamic acid	infant formula, breakfast cereals, fruit drinks, milk drinks, meal replacement products	
Vitamin C	Ascorbic acid	infant formula, breakfast cereals, fruit drinks, milk drinks, meal replacement products, fruit juices, soft drinks, beer, wine, canned fruit and vegetables, potato products, dairy products	
	Sodium ascorbate	curing agent in cured meats, fortification for dairy products	
	Calcium ascorbate	breakfast cereals, low sodium dietetic products	
	Ascorbyl palmitate	Antioxidant in oils, fats, fat-based products, uncured frozen sausage, processes potatoes, extruded cereals	Solubility in fat and oil: 30 mg / 100 ml

Table 1.15 Vitamins and their Stability in Varying Environments

Vitamin	Optimum pH	Light Exposure	Mineral Exposure	Oxidation	Heat Stability
Vitamin A	> 6	Yes	Yes	Yes	Semi
Thiamin (B ₁)	3-4.5	No	Sulfite	No	No
Riboflavin (B ₂)	---	Yes	No	No	Yes
Niacinamide	---	No	No	No	Yes
Pyroxidine (B ₆)	---	No	Yes	No	Semi
Vitamin B ₁₂	4-5	Yes	No	Yes	Semi
Biotin	---	No	No	No	Yes
Pantothenate	5-7	No	No	No	Semi
Vitamin C	5-7	No	Yes	Yes	No
Vitamin D	---	No	No	Yes	Semi
Vitamin E	---	No	No	No	Yes
Vitamin K	4-7	Yes	No	No	Yes

Minerals

Minerals may also be added to food products. A food scientist should be aware of pH, moisture content, particle size, solubility, taste, odor, color, and interactions with vitamins in a food product before adding minerals. The bioavailability and safety of minerals should be considered. Cost analysis should be done when adding minerals because the cost of adding minerals may outweigh the benefit. During processing and storage, there is very little mineral loss. Overages for minerals are generally not significant.

Stability issues can occur with the addition of minerals in a product. Off odors, colors, and tastes can occur with mineral addition. Dry food products generally have fewer stability issues. In high moisture foods, mineral addition can threaten vitamin and lipid stability.

Minerals additives used in food products are detailed in Table 1.16. Additives vary by usage, bioavailability, and off flavors. Minerals may be undesirable to add to food due to their tendency to react with other compounds and cause off-flavors.

Table 1.16 Minerals, their Additives, and Conditions for Usage in Food

Mineral	Additive	% mineral	Conditions for usage		
			Water solubility	Taste	Bioavailability in pure form
Iron	Ferrous Sulfate anhydrous	36.8% anhydrous	High	Metallic	High
	Ferrous fumarate	32.9% anhydrous	Moderate	Slight	High
	Ferric orthophosphate dihydrous	29.9%	Not	Tasteless	Low
	Reduced Iron	100%	Not	Metallic	Moderate
Calcium	Calcium carbonate	40% anhydrous	Not	Chalky	Moderate – Low
	Calcium glycerophosphate	19.1% anhydrous	Moderate	Tasteless	---
	Calcium lactate pentahydrate	18.4% anhydrous 13.0% hydrous	High in hot water	Tasteless	Moderate
	Calcium phosphate tribasic	38.8% anhydrous	Not	Tasteless	Moderate-Low
	Calcium Phosphate dibasic	30.0% anhydrous	Not	Tasteless	Moderate-Low
Magnesium	Magnesium oxide	60.3% anhydrous	Moderate	Chalky	Moderate
	Magnesium carbonate hydroxide	Varying	Moderate – can give off bubbles	Slightly chalky	High
Zinc	Zinc sulfate monohydrate	40.5% anhydrous 36.4% hydrous	High	Astringent	Moderate
Copper	Cupric gluconate	14.0% anhydrous	High	Astringent	Moderate
	monohydrate	13.5% hydrous			

Preservatives

This class of food additives contains a variety of compounds. The compounds aid in the extension of shelf-life by inhibiting microbial growth or by minimizing the destructive effects of oxygen, metals and other factors that may lead to rancidity.

A common and historical example of a preservative is salt. Salt's effectiveness to suppress microorganisms lies in the fact that only microbes with a high tolerance for salt (halophiles) can survive.

The most important preservative utilized in the meat industry is nitrite. Nitrite inhibits the growth of the deadly bacterium *Clostridium botulinum* and is used extensively in cured meat products. Sodium benzoate or potassium benzoate is typically added to soft drinks. Mold inhibitors like calcium and sodium propionates and sorbates are used in bakery items, such as breads and cakes, while natamycin and sorbic acid is utilized in cheeses to prevent molds. Fumigants, such as ethylene oxide and ethyl formate, are used to control microorganisms on

spices, nuts and dried fruits. Sulfur dioxide, which controls browning of fruits and vegetables caused by enzymes, is yet another example of a preservative.

Stabilizers and Thickeners

Stabilizers and thickeners are food additives that provide uniform consistency and improve the color, texture and flavor in candies, chocolate milk, artificially sweetened beverages, ice cream and other frozen desserts. Other examples of thickeners and stabilizers include vegetable gums such as carrageenan and guar, pectins, agars, starches, and gelatins. Without stabilizers and thickeners, ice crystals form in ice cream and other frozen desserts more quickly, particles of chocolate separate from chocolate milk, and volatile flavor oils evaporate in cakes, puddings and gelatin mixes.

Surface Active Agents

Surface active agents (also known as surfactants) are a group of food additives that include emulsifiers, antifoaming compounds and wetting agents that modify the physical force on the surface of foods. Emulsifiers are used to keep water and oil from separating in products such as margarine, salad dressing, ice cream and other emulsions. Lecithin, a natural emulsifier obtained from soybeans, and mono- and diglycerides, head the list of emulsifiers used in the food industry. Emulsifiers, composed of chains of unsaturated fatty acids, are capable of depressing foam and serve as antifoaming agents in dairy products and egg processing. An example of an emulsifier that also falls into the detergent category is sodium lauryl sulfate. This compound functions as a whipping aid in marshmallows and angel food cake mixes. Wetting, the promotion of liquid spread over a surface, is another important function of surface active agents. This is important in dessert mixes, drink mixes, and instant breakfast drinks. Surface active agents are used to create emulsions or to improve the consumer quality attributes of foods, such as the hydration of an instant drink mix without clumping.

Regulation of Food Additives

The Food and Drug Administration (FDA) regulates food additive usage, including the definition of limits on quantity and quality requirements. In order for new food additives to be deemed safe, tested on at least two animal species is required prior to approval. Scientists

determine the no observable effect level (NOEL), which corresponds to the highest dose of an additive producing no adverse health problems in the laboratory animals. The Food and Drug Administration (FDA) groups food additives into four categories: 1) direct additives, 2) indirect additives, 3) prior-sanctioned, and 4) generally recognized as safe (GRAS) additives.

Direct additives are intentionally added to foods to serve a specific function, such as lemon flavoring being added to pre-packaged lemon bars to enhance the taste. Provisions for direct food additives (21 CFR Part 172.5) include adding the substance in the lowest amount “reasonably required” to achieve the nutritional goal, physical attribute, or sensory quality desired. In addition, this list of food additives details individual ingredients that are permitted in foods and any special usage guidance. The FDA approves the safety of substances for nutritive use, while not endorsing claims regarding effectiveness. Dried yeasts (21 CFR Part 172.86), for example, can be added directly to foods provided the folic acid content does not exceed 0.04 milligram per gram of yeast. Product development teams should consider the regulations for any ingredient in a formula prior to use.

The Delaney Clause, a 1958 amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA), states that additives exhibiting the ability to cause cancer cannot be used as an ingredient in food. This prevents the intentional addition of a compound that has been shown to cause cancer in animals or humans. The Delaney Clause includes all food additives, including pesticides. If a carcinogenic pesticide is found in a processed food tested by the FDA, it should be deemed adulterated. It is important to note that the Delaney Clause is only enforceable on food additives.

Certain substances are considered “safe” according to the FDA and classified as “generally recognized as safe” (GRAS). GRAS substances account for approximately 600 substances used in the food industry. GRAS substances include spices, natural seasonings, baking powder, citric acid, malic acid, mono- and diglycerides, and many others. Determination of an additive as GRAS does not qualify it for use in all applications; the limitations of usage are listed in the Code of Federal Regulations. (21 CFR Ch.1 Part 182, 184, 186)

In the situation of non-GRAS substances, approval by the FDA is granted upon submission of scientific data showing that the substance is harmless in the intended food application at a specific level. The FDA sets limits on the type of foods in which the additive may be used and the maximum concentration of the additive. Therefore, a food additive may be

permitted at a level of 100 parts per million (ppm) in one food, 50 ppm in another, and not allowed in the third. For example, BHT (butylated hydroxytoluene), listed in 21 CFR § 172.115, can be used in emulsion stabilizers for shortening at a level of 200 ppm, while the amount allowed in dry breakfast cereals is 50 ppm.

Manufacturers must present information in a petition to the FDA for a new substance to be approved for addition to foods. A petitioner must establish that the new ingredient is necessary in the production of a specific food product, and is safe. FDA petitions take time to be accepted, but companies that provide all vital information can drastically speed up the lag time.

Consumer Expectations and Demands

Consumption trends of food products change from year to year due to the newest concern in health, the next fad diet, and the latest super food. One consistent growing concern is the consumer desire for a healthier lifestyle. With an increasing demand for more healthy food products, processors have a responsibility to adjust current conventional products to fit consumer needs and desires, including lower fat and lower calorie products. Producers can use food additives to assist in modifying a cookie formulation originally containing 35 percent fat to contain only 5 percent or to extend the shelf-life of flour tortillas by using a potassium sorbate spray. Food processors must be in touch with consumer expectations of tastes when modifying tastes and nutrition along with what the current views are on specific food additives. When contemplating the addition of food additives, food scientists should consult ingredient companies on what the best additive would be and test the new ingredient against a previously formulated control.

Chapter 2 - Labeling

Food labeling laws cover “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article” as defined in the Federal Food, Drug and Cosmetic Act. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and to assist value comparisons.

Food labeling laws are enforced by the U.S. Food and Drug Administration (FDA) for most food products. For meat and poultry items sold in interstate commerce, labeling regulations are enforced by the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). If meat and poultry products are sold only within the state where they are manufactured, labeling regulations are enforced by the state meat inspection service. A label is defined as “a display of written, printed or graphic matter upon the immediate container of any article. To comply with label requirements, the label must be clearly visible while viewing the outside of the package.

Parts of a Food Label

A food label can be separated into several sections, each with specific information and requirements. These sections include a Principal Display Panel, an Information Panel, and an Optional Panel.

Principle Display Panel

The Principal Display Panel (PDP) is defined as “the part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale.” This panel should be large enough to accommodate all mandatory information required to be placed on the PDP without crowding or obscuring. To determine the minimum type size of the net contents statement, the size of the PDP is based on the size of the package according to shape according to Table 2.1. The purpose of the PDP is to give consumers information about the product. This information must include the identity of the contents and the net quantity of the contents.

Table 2.1 Principle Display Panel Size Requirements for Packages

Type of Package	PDP size requirement
Rectangular	Height times the width of largest side.
Cylindrical	40 percent of the height times the circumference.
Special cylindrical containers (tall or short)	40 percent of the height times the circumference or the area of the lid, whichever is greater.
Other shaped packages	40 percent of the total surface.
Tapered tube	40 percent of the height times the average of the top and bottom circumference.
Bottles and Jars	Exclude heels, necks or shoulders in determining the height.

The identity of the contents (called the “statement of identity”) must appear in bold type and be the name of the food as established by law or the accepted common or usual name of the product. This statement must be in a size reasonably related to the most prominent printed matter

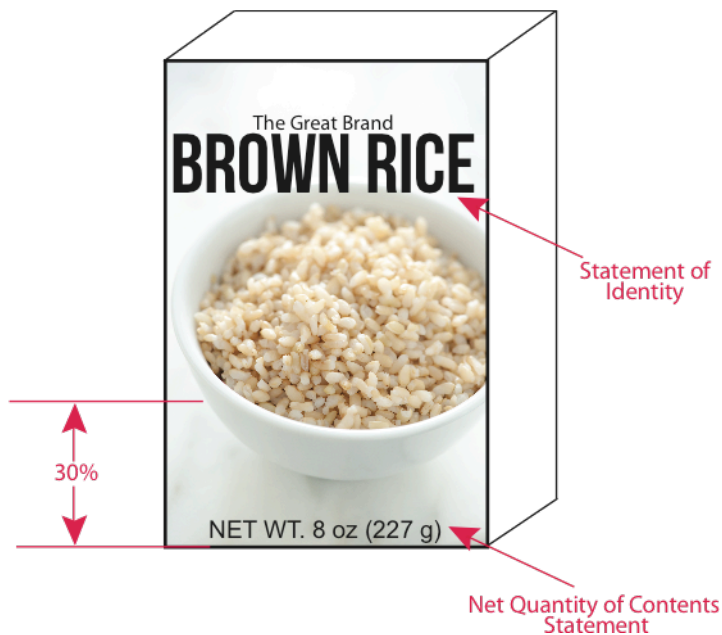


Figure 2.1 Example of a Principle Display Panel

on the PDP and must be in lines generally parallel to the base of the package. If the food is defined by a Standard of Identity, the standard establishes the common or usual name of the food. If neither a Standard of Identity nor a common or usual name exists for a food, an appropriately descriptive term or name commonly used by the public for the food may be used, such as saltine or

English muffin.

Net quantity of contents is a statement that shall accurately reveal the quantity of food in the package exclusive of wrappers and other packaging materials. The weight of each food ingredient, including any water or syrup, is included in the net quantity declared on a label. In some cases where the packing medium is normally discarded, the drained weight is given, e.g., olives and mushrooms. If the food is liquid, the net quantity statement must be in terms of fluid measure (gallon, quart, pint, and fluid-ounce subdivisions and milliliters or liters). If the food is solid, semisolid or viscous, or a mixture of solid and liquid, terms of weight are used (pounds or ounces and grams or kilograms). Also allowed is numerical count of the contents, or a combination of count and weight or measure.

Common or decimal fractions may be used. Fractions are to be in halves, quarters, eighths, sixteenths or thirty-seconds. Fractions are also to be reduced to the lowest terms and decimals are not to be carried more than three places. No qualifying terms such as “jumbo” or “full” may be used.

If the actual quantity falls below the printed declaration, the product is considered “misbranded” and may be subject to confiscation by FDA. Products with short fill are not allowed for retail sale, but may be re-labeled for sale to federal, state or local government operated institutions. For additional regulations concerning short fill, see 21 CFR 101.105.

The net quantity statement must be placed in the bottom 30 percent of the PDP as shown in Figure 2.1. It must appear as a distinct item separated from other printed label information above and below by at least a space equal to the height of the lettering used in the declaration. The use of the term “net content” is optional. There are minimum sizes for type on PDP description which are established for the net quantity statement. This minimum size is based on the package space available for the principal display panel. In addition, letters may be no more than three times as high as they are wide, and letter heights are measured by uppercase or capital letters. If upper and lowercase or all lowercase letters are used, the lower case letter “o” or its equivalent must meet the minimum standard. When fractions are used, each numeral is to be one-half the minimum height requirement. More information about all labeling regulations can be found on www.FDA.gov.

Information Panel

The Information Panel (IP) is defined as “that part of the label immediately contiguous and to the right of the Principal Display Panel as observed by an individual facing the Principal Display Panel.”

If the part of the label immediately contiguous and to the right of the Principal Display Panel is too small to accommodate the necessary information or is otherwise unusable label space, i.e. folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

Ingredient Legends.

Ingredient legends provide a list of the common or usual names of ingredients in descending order of predominance by weight. This includes added water.

Ingredients must be listed by specific, not collective, names except for spices, flavorings and colorings. The ingredient legend must appear on either the IP or PDP.

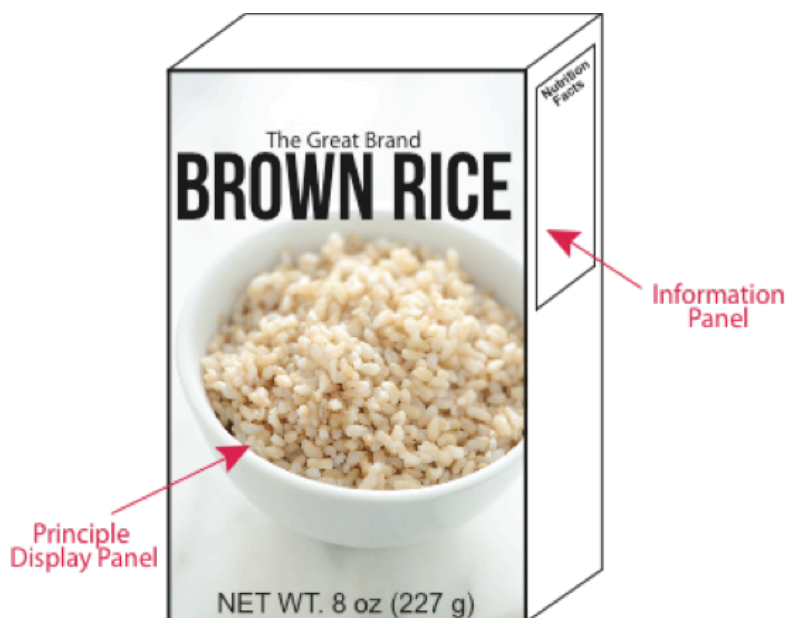


Figure 2.2 Demonstration of Principle Display Panel and Information Panel

For Information Panel labeling, a print or type size

that is prominent, conspicuous and easy to read should be used. Letters should be at least one-sixteenth (1/16) of an inch in height based on the lower case letter “o” unless an exemption is permitted (21 CFR 101.2 part C(1)). The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background to be easy to read. Required information cannot be crowded with artwork or non-required statements.

Declaration of Trace Ingredients. If a substance is an incidental additive and has no function or technical effect in the finished product, then it need not be declared on the label as a trace ingredient. An incidental additive is usually present because it is an ingredient of another

product produced on the same line. Sulfites are considered to be incidental only if present at less than 10 parts per million.

Spices, Flavorings, and Colorants. “The term ‘spice’ means any aromatic vegetable substance in the whole, broken or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed.” (CFR 101.22 (a)(2)) As stated, spices, flavorings and colorings may be listed by the collective terms “spices,” “flavorings” and “colorings” respectively. Exceptions to this include celery, garlic and onion, which are considered foods and must be declared by their specific common or usual name. Paprika, turmeric, saffron and other spices which are also colors should be declared as “spice and coloring” or by their common or usual name. The complete list of spices can be found in 21 CFR 101.22 and in Table 2.2.

Table 2.2 Spices as Defined in 21 CFR 101.22

Allspice	Dill seed	Pepper, black
Anise	Fennel seed	Pepper, white
Basil	Fenugreek	Pepper, red
Bay leaves	Ginger	Rosemary
Caraway seed	Horseradish	Saffron
Cardamom	Mace	Sage
Celery seed	Marjoram	Savory
Chervil	Mustard flour	Star aniseed
Cinnamon	Nutmeg	Tarragon
Cloves	Oregano	Thyme
Coriander	Paprika	Turmeric
Cumin seed	Parsley	

Component Ingredients. Multi-component foods used as ingredients may be listed two ways: 1) parenthetical listings or 2) order of predominance. In parenthetical listings, the ingredient may be declared by its common or usual name followed in parentheses by a list of its ingredients used in the formulation, i.e. catsup (tomatoes, vinegar, corn syrup . . .). Using order of subcomponents present in several ingredients may be combined and listed in their proper order of predominance. This requires the percentage of each component in a multi-component ingredient be known so proper order of predominance can be determined.

Artificial Flavors, Fats and Oils, and Preservatives. Artificial smoke flavors must be declared as artificial flavor or artificial smoke flavor. No reference may be made that foods containing artificial smoke have been smoked or have a true smoked flavor. Fats and oils must be declared by their source and common or usual name, i.e., soybean oil. If the oil is hydrogenated or partially hydrogenated, this process must also be stated. The addition of a preservative must be listed by both the common or usual name and the description of its function, i.e., sodium benzoate (a preservative).

Manufacturer, Packer, or Distributor Statement. The name and place of business of the manufacturer, packer or distributor of the food must be on the label. It must appear on either the PDP or the IP. According to labeling regulations, the ingredient statement and the name and address of the manufacturer/packer/distributor must be adjacent with no intervening material (CFR 101.2 (e)). The address shall include the street address, city, state and zip code. Post office box addresses are not allowed. The street address may be omitted from the label if the business street address is shown in a current city or local telephone directory. This is required so that an interested party can locate the manufacturer, packer or distributor. The requirement for including the zip code on the label applies only to packages intended for consumers.

A minimum type size of 1/16 inch is required. If space is not available for the information panel, required declarations may be included on the PDP.

Optional Panel

This panel is to the left of the Principal Display Panel and provides space for items such as a company story or history statement, nutrition information, or other information required for store use (like the Universal Product Code described next).

Universal Product Code. The Universal Product Code (UPC) is a series of bars of varying thicknesses used by electronic scanners to identify a product and the price set by the seller. This bar code is a 12-digit all-numeric



Figure 2.3 Example of a UPC Code

code that uniquely identifies one item.

The code contains four parts. The first digit represents the manufacturer's retail category or function. The next five digits are the manufacturer's identification number and are unique to each individual manufacturer. The next five digits are the item number, unique to the product, and its pack size. The twelfth digit is a check character used to verify the accuracy of the entire UPC. UPC bar codes are obtained through membership in the Uniform Code Council and can now be purchased on the internet for minimal cost.

Nutrition Labeling

To provide uniformity in labeling among the food industry, the U.S. Congress and FDA took action in 1990, which resulted in the Nutrition Labeling Education Act (NLEA). This act is designed to provide consumers with necessary information to make informed and wise decisions about their diet and to give food processors the incentive to improve the nutritional quality of their products (21 CFR 101.9). The NLEA authorizes preemption of any existing state regulations and also authorizes states to take action in the federal courts to enforce the labeling law. Labeling is required on FDA regulated foods, with a few exemptions.

The requirements for providing nutrition information are based on the package size and label space. If the package is 12 square inches or less, the package is exempt from mandatory labeling and must not have any nutrition claims or other nutritional information. With this small package though, it is required that the manufacturer, packer or distributor provide a telephone number where the information can be obtained. With packages that are between 12 and 40 square inches, the nutrition facts may be displayed in the tabular format if the package shape or size cannot accommodate a standard nutrition facts panel. This size of package can choose to use approved abbreviations and omit the footnote and caloric conversion table by placing an asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000-calorie diet." If the term "Daily Value" is not spelled out in the heading, a statement that "DV" is substituted for "Daily Value" must be used. Packages over 40 square inches should use the standard format, although some modifications can be made for unique shapes and limited space.

Nutrition Facts Panels

The Nutrition facts panel may be presented on any label panel when the total surface available for labeling is 40 or less square inches. Packages with more than 40 square inches of available space must place the nutrition information on either the PDP or information panel as defined in 21 CFR 101.2 unless there is insufficient space, in which case the Nutrition Facts may be placed on any panel that may be seen readily by consumers.

Table 2.3 Nutrients for Mandatory Declaration from 21 CFR 101.9 and 9 CFR 317/381.

Specific Nutrient Declarations for Nutrition Facts Panels		
<i>Mandated Declarations:</i>	<i>Nutrients:</i>	<i>Voluntary:</i>
Calories	Vitamin A	Poly-unsaturated Fat
Calories from fat	Vitamin C	Mono-unsaturated Fat
Fat content	Calcium	Fatty Acids
Daily values of total fat	Iron	Other Carbohydrates
Saturated fat		Sugar Alcohol
Trans fat		Soluble Fiber
Cholesterol		Insoluble Fiber
Sodium		Potassium
Total Carbohydrate		Other Vitamins
Dietary Fiber		Other Minerals
Sugars		
Protein		

There are a few formats used to display nutrition facts panels. These formatting differences allow for companies with small packages to have flexibility when declaring the nutrition facts. The standard format is the most commonly used format. The tabular label is a horizontal rendition of the standard format, and can be used for packages that are better wider than they are tall. Simplified versions of the tabular and standard formats are available for use if at least eight of the following nutrients are present in insignificant amounts: *calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron.*

For packages that are smaller, it may be necessary to use a linear format nutrition facts panel. Examples of these formats can be seen in Figure 2.4. The declaration of certain nutrients (Table 2.3) is mandatory. When a product does not contain very little of a mandated nutrient, they can be omitted from the statement with a qualifying statement.

Standard Format

Nutrition Facts	
Serving Size 1/2 cup (125g)	
Servings Per Container About 6	
Amount Per Serving	
Calories 60	Calories from Fat 10
	% Daily Value*
Total Fat 1g	2%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 220mg	9%
Total Carbohydrate 9g	3%
Dietary Fiber 2g	8%
Sugars 6g	
Protein 4g	
Vitamin A 15%	Vitamin C 2%
Calcium 2%	Iron 2%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Linear Format

Nutrition Facts Serving Size 1/2 cup (125g), Servings Per Container About 6, Amount Per Serving: **Calories 60**, Calories from Fat 10, **Total Fat 1g** (2% DV), Saturated Fat 0g (0% DV), Trans Fat 0g, **Cholesterol 0mg** (0% DV), **Sodium 220mg** (9% DV), **Total Carbohydrate 9g** (3% DV), Dietary Fiber 2g (8% DV), Sugars 6g, **Protein 4g**, Vitamin A (15% DV), Vitamin C (2% DV), Calcium (2% DV), Iron (2% DV). Percent Daily Values are based on a 2,000 calorie diet.

Standard Simplified Format

Nutrition Facts	
Serving Size 1/2 cup (125g)	
Servings Per Container About 6	
Amount Per Serving	
Calories 60	Calories from Fat 10
	% Daily Value*
Total Fat 1g	2%
Sodium 220mg	9%
Total Carbohydrate 9g	3%
Dietary Fiber 2g	8%
Sugars 6g	
Protein 4g	
Vitamin A 15%	Vitamin C 2%
Calcium 2%	Iron 2%

Not a significant source of saturated fat, trans fat and cholesterol.
*Percent Daily Values are based on a 2,000 calorie diet.

Tabular Format

Nutrition Facts	Amount / Serving	% Daily Value*	Amount / Serving	% Daily Value*	*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2,000 2,500 Total Fat Less than 65g 80g Saturated Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4
Serving Size 1/2 cup (125g) Servings Per Container About 6 Calories 60 Calories from Fat 10	Total Fat 1g	2%	Total Carbohydrate 9g	3%	
	Saturated Fat 0g	0%	Dietary Fiber 2g	8%	
	Trans Fat 0g		Sugars 6g		
	Cholesterol 0mg	0%	Protein 4g		
	Sodium 220mg	9%	Calcium 2%	Iron 2%	
	Vitamin A 15%	Vitamin C 2%			

Figure 2.4 Examples of Nutrition Facts Panels Formats

Serving Size

A system has been established by the FDA based on the amounts of food/products per eating occasion called the reference amounts customarily consumer (RACC). The reference amounts are expressed in household units, such as 1 slice, 1 cup, 1/4 pizza, and in discrete units (g, oz). If a unit weights less than 50% of the RACC, the serving size is the number of whole units closest to the reference. If a unit weighs more than 50% but less than 67% of the RACC, a company can choose to use 1 or 2 servings. If an item being sold individually is more the 67% of the RACC but less than 200%, the serving size would be 1 unit.

A company is producing cookies and would like to figure out how many cookies is equal to a serving. The RACC for cookies is 30 grams. Each of the company's cookies weighs 13 grams, therefore they could claim that the serving size was 2 cookies (26 grams).

Serving sizes must be declared in common household measures. This is defined in 21 CFR 101.9(b)(5) as a cup, tablespoon, teaspoon, piece, slice, fraction, ounce, fluid ounce or other common household equipment used to package food products such as jar, tray, etc. Other stipulations include:

- **Cups:** must be expressed in 1/4 or 1/3 cup increments.
- **Tablespoons:** must be expressed in the whole number of tablespoons for quantities less than 1/4 cup but greater than or equal to 2 tablespoons; fractions such as 1/3, 1/2, and 2/3 may be used between 1 and 2 tablespoons.
- **Teaspoons:** must be expressed in the whole number of teaspoons for quantities less than 1 tablespoon but greater or equal to 1 teaspoon; 1/4 teaspoon increments are used for amounts less than 1 teaspoon.
- **Ounces:** must be listed in 0.5-ounce increments.

Daily Values

The daily value percentages seen on nutrition facts panels are based on the daily reference values (DRV) and recommended daily intakes (RDI). These values assist consumers in interpreting information about the amount of a nutrient that is present in a food and in comparing nutritional values of food products. DRVs are established for adults and children four or more years of age, as are RDIs, with the exception of protein. DRVs are provided for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein. RDIs are provided for vitamins and minerals and for protein for children less than four years of age and for pregnant and lactating women. In order to limit consumer confusion, however, the label includes a single daily value term to designate both the DRVs and RDIs. Specifically, the label includes the % DV. The only exception is that the % DV for protein is not required unless a protein claim is made for the product or if the product is to be used by infants or children under four years of age. The daily value amounts for nutrients are listed in Table 2.4.

Claims

Companies that make claims on their packages attempt to catch consumers' attention or differentiate their product by demonstrating the nutritional, health, or function of their products. Claims should be carefully chosen by companies in order to eliminate the chance of FDA seizure

due to misbranding and misleading customers about the benefits of the product. The two types of claims covered in this chapter are nutrient content claims and health claims.

Table 2.4 Food Components and Recommended Daily Values.

Food Component	DV	Food Component	DV
<i>Total Fat</i>	65 g	<i>Niacin</i>	20 mg
<i>Saturated Fat</i>	20 g	<i>Vitamin B6</i>	2 mg
<i>Cholesterol</i>	300 mg	<i>Folate</i>	400 µg
<i>Sodium</i>	2,400 mg	<i>Vitamin B12</i>	6 µg
<i>Potassium</i>	3,500 mg	<i>Biotin</i>	300 µg
<i>Total Carbohydrate</i>	300 g	<i>Pantothenic acid</i>	10 mg
<i>Dietary Fiber</i>	25 g	<i>Phosphorus</i>	1,000 mg
<i>Protein</i>	50 g	<i>Iodine</i>	150 µg
<i>Vitamin A</i>	5,000 IU	<i>Magnesium</i>	400 mg
<i>Vitamin C</i>	60 mg	<i>Zinc</i>	15 mg
<i>Calcium</i>	1,000 mg	<i>Selenium</i>	70 µg
<i>Iron</i>	18 mg	<i>Copper</i>	2 mg
<i>Vitamin D</i>	400 IU	<i>Manganese</i>	2 mg
<i>Vitamin E</i>	30 IU	<i>Chromium</i>	120 µg
<i>Vitamin K</i>	80 µg	<i>Molybdenum</i>	75 µg
<i>Thiamin</i>	1.5 mg	<i>Chloride</i>	3,400 mg
<i>Riboflavin</i>	1.7 mg		

Source: www.FDA.gov: Guidance for Industry: A Food Labeling Guide (2009)

Abbreviations used: g: grams mg: milligrams IU: international units µg: micrograms

Nutrient Content Claims

An “implied claim” is a statement that leads a consumer to assume or perceive something about a product. When the label contains a nutrient content claim, a statement referring the consumer to the nutrition label is needed. The nutrient content claim should have a type size no larger than two times the name of the product. There are claims for specific nutritional components as seen in Table 2.5. A general outline of descriptors such as “free,” “lean,” “light”

and “reduced” have been redefined so that consumers will be clear about their meaning (as seen in Table 2.6).

Table 2.5 Nutrient Content Claims for Specific Nutrients

Ingredient	Free	Low	Reduced
Total Fat	Less than 0.5 grams of fat per serving and per reference amount	3 g or less per reference amount	At least 25% less fat per reference amount
Saturated Fat	Less than 0.5 grams of fat per serving and per reference amount and less than 0.5 g <i>trans</i> fat	1 g or less per reference amount	At least 25% less saturated fat per reference amount
Cholesterol	Less than 2 mg of cholesterol per serving and reference amount, the food contains 2 grams or less of saturated fatty acids per serving	20 mg or less per reference amount	At least 25% less cholesterol per reference amount
Sodium	Contains less than 5 milligrams of sodium per serving/reference amount and no added salt, can also be referred to as “unsalted” or “no salt added”	140 mg or less per reference amount	At least 25% less sodium per reference amount
Sugar	Food containing less than 0.5 grams of sugars per serving/ reference amount, contains no added sugars, must be labeled as a “low calorie” or “reduced calorie” food or the term “sugar free” is accompanied in immediate proximity by a statement “not a reduced calorie food.”	Not defined.	At least 25% less sugar per reference amount
Calories	Less than 5 calories per serving, may also use “free of calories,” “no calories” or “zero calories.”	40 calories or less per reference amount	At least 25% less calories per reference amount

Source: A Guide for Industry: A Guide for Food Labeling, a publication by FDA (2009).

Table 2.6 Nutrient Content Claim Descriptors

Claim Descriptor	Definition
Free	A product contains no amount or only a trivial amount of fat, saturated fat, cholesterol, sodium, sugars or calories. Synonyms include “without,” “no,” and “zero.”
Low	Used on foods that could be eaten frequently without exceeding the dietary guidelines for fat, saturated fat, cholesterol, sodium or calories.
Lean	“Lean” is used to describe the fat content of meat, poultry, seafood and game meats. Defined as less than 10 grams of fat, less than 4 grams of saturated fat, and less than 95 milligrams of cholesterol per serving and per 100 grams.
Extra Lean	Used to describe the fat content of meat, poultry, seafood and game meats. Less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per serving per 100 grams.
Healthy	Foods must meet the criteria for “low fat” and “low saturated fat,” and provide at least 10 percent of the daily value of either vitamin A, vitamin C, iron, calcium, protein, or fiber.
High, Excellent Source, or Rich In...	Can be used if the food contains 20 percent or more of the daily value for a particular nutrient in a serving
Good Source	One serving of a food that contains 10 to 19 percent of the daily value for a particular nutrient.
More, Fortified, Enriched, Added, Plus	Contains at least 10 percent more than the DV of the comparative item. Can be used for the level of protein, vitamins, minerals, dietary fiber or potassium, but should not be used for certain meal items.
Reduced	A nutritionally altered product contains 25 percent less of a nutrient or of calories than the regular or reference product. However, a reduced claim cannot be made on a product if its reference food already meets the requirement for a “low” claim.
Less	A food that contains 25 percent less of a nutrient or calories than the reference food. “Fewer” may also be used.

Source: A Guide for Industry: A Guide for Food Labeling, a publication by FDA (2009).

Health Claims

Health claim means any claim made on the label or in labeling of a food that characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition. (*A guidance for industry: A guide to food labeling*.2009) To help prevent the display of false claims, the NLEA established claims about foods that are linked to health benefits. These health claims are “qualified health claims,” listed in Table 2.7, that have been scientifically linked to a positive effect or decrease in the risk of disease.

Table 2.7 Qualified Health Claims

Ingredients	Health Benefit	Qualifications to Use Claims
Calcium, Vitamin D	Reduction in risk of osteoporosis	Must be “high” in calcium and Vitamin D
Tomatoes and/or Tomato Sauce	Prostate, Ovarian, Gastric, and Pancreatic Cancers	Cooked, Raw, Dried, or Canned Tomatoes can be used. Tomato Sauces that contain at least 8.37 percent salt-free tomato solids.
Green Tea	Cancer	Green tea-containing foods when the food does not contain excess fat, saturated fat, cholesterol, and sodium. Must contain a minimum 10% green tea
Nuts	Heart disease	Whole or chopped nuts that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored; Nut-containing products other than whole or chopped nuts that contain at least 11 g of one or more of the nuts listed below per RACC. Eligible nuts for this claim are restricted to almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachio nuts, and walnuts. Should not exceed 4 g saturated fat per 50 g of nuts.
Monounsaturated Fatty Acids From Olive Oil	Coronary heart disease	Products including salad dressing, vegetable oil and shortening must contain more than 6 g per RACC of olive oil

Source: www.FDA.gov

Further, health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. Health claims are required to be reviewed and evaluated by FDA prior to use. An example of an authorized health claim, is: “Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving.” (*A guidance for industry: A guide to food labeling*.2009)

Qualified health claims must be approved by the FDA through a petition. Organizations can submit their desired health claim and evidence to the FDA for approval. Approved health claims include the link between sufficient intake of calcium and vitamin D and a reduced risk of osteoporosis, and many others.

Accuracy of Claims

Added nutrients in fortified or fabricated foods (Class I) must present 100 percent or more of the label declaration. Naturally occurring (indigenous) nutrients (Class II) must be at least 80 percent or more. Other matters such as calories, sugars, total fat, etc., must be no more than 120 percent of the label declaration.

Calculating Overages to Ensure Accuracy of Nutrient Claims

The accuracy of stated nutrients should be guaranteed (with a margin of error) throughout the complete shelf-life of the product. Product developers may have to calculate the percent overages of nutrients that deteriorate over time, such as vitamins. Here are a few related situations:

A company is producing a flavored juice drink with 100% DRI of Vitamin C.

- a. Since the pasteurization process for the drink destroys 25% of the total ascorbic acid, how much Vitamin C should be added to a 8,000 fl. oz. batch.
- b. The drink is given a shelf-life of 20 weeks at refrigeration. Company studies show that 20% of the Vitamin C content is lost at the end of that period. Re-calculate the amount of Vitamin C that should be added to the 8,000 fl. oz. batch so that the apple juice’s vitamin contents can remain at 100% throughout the entire shelf period.

Misbranded Products

Failure to comply with labeling regulations may provide cause for the enforcing agency to bring action against a product and the manufacturer. Reasons for failure of a label to be prominent and conspicuous include, but are not limited to:

- Failure of required information on PDP or IP.
- Failure to use available space for prominence.
- Use of available space for information that is not required or to give greater prominence to some required information.
- Minimum type size requirement are not met.
- Insufficient background contrast.
- Obscuring design.
- Crowding with other written, printed, or graphic material.

Nutrition Databases

Software is available to help companies calculate the nutrition of foods in development. Nutrition databases can help companies formulate products, especially when they have specific nutritional goals or claims that are essential for the product's health benefit aims. Software programs are also available to help produce nutrition facts panels and ingredient legends. The USDA also keeps a nutritional database with a vast amount of information about products on the market and standard food items called the USDA National Nutrient Database for Standard Reference. It can be found at <http://ndb.nal.usda.gov>.

Exemptions from Labeling

Packaged products must meet all of the requirements for labeling consumer products. Products that are unwrapped until selected by the consumer are exempt from the labeling requirements. Foods sold through vending machines must meet all the requirements for labeling, except they are exempt from mandatory nutrition labeling.

Mail-order products are considered packaged consumer foods sold directly to retail customers. They are subject to the same requirements as products sold through supermarkets or other retail outlets. Mandatory information must not be misleading or false and must be visible to the customer prior to opening the package, even though it may not be available prior to purchase from a catalog. This information may appear on the shipping container or on a separately packaged inner container. Retail and in-store bakeries fall into two different types of categories:

1. self-service sales.
2. displayed for sale unwrapped and packaged as ordered by the customer.

Many food products are exempt from providing nutrition information. These include foods manufactured by small processors with fewer than 200 employees and fewer than 200,000 units sold. The number of employees is based on the average number of full-time employees a company has over a twelve-month period. In all cases, the exemption is lost if an explicit or implied nutrition claim or any other nutrition information is provided on packaging or advertising. Businesses must file an exemption notice with the FDA and claim a small business exemption based on the number of employees and units of products. No exemption is allowed for a company that has more than the required number of full-time employees, regardless of the number of units sold. Other exempt products include:

- Foods served in restaurants or other facilities where food is served for immediate consumption.
- Foods that contain insignificant amounts of all of the nutrients and food components required on the nutrient declaration.
- Raw fruits and vegetables
- Foods in small packages with total available label area less than 12 square inches.

Under FDA's current laws and regulations, no label approval is needed prior to the food product's distribution. It is the responsibility of the food producer to comply with current food labeling regulations. Both the FDA and USDA offer informal reviews of a food product's label.

Summary

Law, regulations, and policies regarding labeling are complex and vary depending on the facility producing the food, the intended consumer, packaging, and method of sales. Ensuring that your label meets all standards is important to eliminate the risk of non-compliance. Claims are carefully regulated, therefore companies should verify that their product meets all guidelines before printing a misleading claim. Requirements are different dependent on the number of employees, the amount of units sold, the arena for sales, the customer, and many other factors. Researching label requirements can save food companies a lot of headaches.

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