

Food Additives

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Food additives play a vital role in today's bountiful and nutritious food supply. They allow our growing urban population to enjoy a variety of safe, wholesome and tasty foods year-round. And, they make possible an array of convenience foods without the inconvenience of daily shopping.

Although salt, baking soda, vanilla and yeast are commonly used in foods today, many people tend to think of any additives added to foods as complex chemical compounds. All food additives are carefully regulated by federal authorities and various international organizations to ensure that foods are safe to eat and are accurately labeled. The purpose of this brochure is to provide helpful background information about food additives, why they are used in foods and how regulations govern their safe use in the food supply.

Why Are Additives Used in Foods?

Additives perform a variety of useful functions in foods that are often taken for granted. Since most people no longer live on farms, additives help keep food wholesome and appealing while en route to markets sometimes thousands of miles away from where it is grown or manufactured. Additives also improve the nutritional value of certain foods and can make them more appealing by improving their taste, texture, consistency or color.

Some additives could be eliminated if we were willing to grow our own food, harvest and grind it, spend many hours cooking and canning, or accept increased risks of food spoilage. But most people today have come to rely on the many technological, aesthetic and convenience benefits that additives provide in food. Additives are used in foods for five main reasons:

1. To maintain product consistency.

Emulsifiers give products a consistent texture and prevent them from separating. Stabilizers and thickeners give smooth uniform texture. Anticaking agents help substances such as salt to flow freely.

2. To improve or maintain nutritional value.

Vitamins and minerals are added to many common foods such as milk, flour, cereal and margarine to make up for those likely to be lacking in a person's diet or lost in processing. Such fortification and enrichment has helped reduce malnutrition among the U.S. population. All products containing added nutrients must be appropriately labeled.

3. To maintain palatability and wholesomeness.

Preservatives retard product spoilage caused by mold, air, bacteria, fungi or yeast. Bacterial contamination can cause foodborne illness, including life-threatening botulism. Antioxidants are preservatives that prevent fats and oils in baked goods and other foods from becoming rancid or developing an off-flavor. They also prevent cut fresh fruits such as apples from turning brown when exposed to air.

4. To provide leavening or control acidity/ alkalinity.

Leavening agents that release acids when heated can react with baking soda to help cakes, biscuits and other goods to rise during baking. Other additives help modify the acidity and alkalinity of foods for proper flavor, taste and color.

5. To enhance flavor or impart desired color.

Many spices and natural and synthetic flavors enhance the taste of foods. Colors, likewise, enhance the appearance of certain foods to meet consumer expectations.

Many substances added to food may seem foreign when listed on the ingredient label, but are actually quite familiar. For example, ascorbic acid is another name for vitamin C; alpha-tocopherol is another name for vitamin E; and beta-carotene is a source of vitamin A. Although there are no easy synonyms for all additives, it is helpful to remember that all food is made up of chemicals. Carbon, hydrogen and other chemical elements provide the basic building blocks of everything in life.

How Are Additives Regulated?

Additives are not always byproducts of 20th century technology or modern know-how. Our ancestors used salt to preserve meats and fish; added herbs and spices to improve the flavor of foods; preserved fruit with sugar; and pickled cucumbers in a vinegar solution.

Over the years, however, improvements have been made in increasing the efficiency and ensuring the safety of all additives. Today food and color additives are more strictly regulated than at any other time in history. The basis of modern food law is the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, which gives the Food and Drug Administration (FDA) authority over food and food ingredients and defines requirements for truthful labeling of ingredients.

The Food Additives Amendment to the FD&C Act, passed in 1958, requires FDA approval for the use of an additive prior to its inclusion in food. It also requires the manufacturer to prove an additive's safety for the ways it will be used.

The Food Additives Amendment exempted two groups of substances from the food additive regulation process. All substances that FDA or the U.S. Department of Agriculture (USDA) had determined were safe for use in a specific food prior to the 1958 amendment were designated as prior-sanctioned substances. Examples of prior-sanctioned substances are sodium nitrite and potassium nitrite used to preserve luncheon meats.

A second category of substances excluded from the food additive regulation process are generally recognized as safe or GRAS substances. GRAS substances are those whose use is generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence. Salt, sugar, spices, vitamins and monosodium glutamate are classified as GRAS substances, along with several hundred other substances. Manufacturers may also request FDA to review the use of a substance to determine if it is GRAS.

Since 1958, FDA and USDA have continued to monitor all prior-sanctioned and GRAS substances in light of new scientific information. If new evidence suggests that a GRAS or prior-sanctioned substance may be unsafe, federal authorities can prohibit its use or require further studies to determine its safety.

In 1960, Congress passed similar legislation governing color additives. The Color Additive Amendments to the FD&C Act require dyes used in foods, drugs, cosmetics and certain medical devices to be approved by FDA prior to their marketing.

In contrast to food additives, colors in use before the legislation were allowed continued use only if they underwent further testing to confirm their safety. Of the original 200 provisionally listed color additives, 90 have been listed as safe and the remainder have either been removed from use by FDA or withdrawn by industry.

Both the Food Additives Amendment and the Color Additive Amendments include a provision which prohibits the approval of an additive if it is found to cause cancer in humans or animals. This clause is often referred to as the Delaney Clause, named for its Congressional sponsor, Rep. James Delaney (D-N.Y.).

Regulations known as Good Manufacturing Practices (GMP) limit the amount of food and color additives used in foods. Manufacturers use only the amount of an additive necessary to achieve the desired effect.

How Are Additives Approved for Use in Foods?

To market a new food or color additive, a manufacturer must first petition FDA for its approval. Approximately 100 new food and color additive petitions are submitted to FDA annually. Most of these petitions are for indirect additives such as packaging materials.

A food or color additive petition must provide convincing evidence that the proposed additive performs as it is intended. Animal studies using large doses of the additive for long periods are often necessary to show that the substance would not cause harmful effects at expected levels of human consumption. Studies of the additive in humans also may be submitted to FDA.

In deciding whether an additive should be approved, the agency considers the composition and properties of the substance, the amount likely to be consumed, its probable long-term effects and various safety factors. Absolute safety of any substance can never be proven. Therefore, FDA must determine if the additive is safe under the proposed conditions of use, based on the best scientific knowledge available.

If an additive is approved, FDA issues regulations that may include the types of foods in which it can be used, the maximum amounts to be used, and how it should be identified on food labels. Additives proposed for use in meat and poultry products also must receive specific authorization by USDA. Federal officials then carefully monitor the extent of Americans' consumption of the new additive and results of any new research on its safety to assure its use continues to be within safe limits.

In addition, FDA operates an Adverse Reaction Monitoring System (ARMS) to help serve as an ongoing safety check of all additives. The system monitors and investigates all complaints by individuals or their physicians that are believed to be related to specific foods; food and color additives; or vitamin and mineral supplements. The ARMS computerized database helps officials decide whether reported adverse reactions represent a real public health hazard associated with food, so that appropriate action can be taken.

What is the difference between "natural" and "artificial" additives?

Some additives are manufactured from natural sources such as soybeans and corn, which provide lecithin to maintain product consistency, or beets, which provide beet powder used as food coloring. Other useful additives are not found in nature and must be man-made. Artificial additives can be produced more economically, with greater purity and more consistent quality than some of their natural counterparts. Whether an additive is natural or artificial has no bearing on its safety.

Is a natural additive safer because it is chemical-free?

No. All foods, whether picked from your garden or your supermarket shelf, are made up of chemicals. For example, the vitamin C or ascorbic acid found in an orange is identical to that produced in a laboratory. Indeed, all things in the world consist of the chemical building blocks of carbon, hydrogen, nitrogen, oxygen and other elements. These elements are combined in various ways to produce starches, proteins, fats, water and vitamins found in foods.

Are sulfites safe?

Sulfiting agents are sometimes used to preserve the color of foods such as dried fruits and vegetables, and to inhibit the growth of microorganisms in fermented foods such as wine. They are also sometimes used in baked goods, condiments, snack foods and other products. Sulfites are safe for most people. A small segment of the population, however, has been found to develop shortness of breath or fatal shock shortly after exposure to these preservatives. Sulfites are capable of producing severe asthma attacks in sulfite-sensitive asthmatics. For that reason, in 1986 the Food and Drug Administration (FDA) banned the use of sulfites on fresh fruits and vegetables (except potatoes) intended to be sold or served raw to consumers. Sulfites added to all packaged and processed foods must be listed on the product label.

What are erythorbates?

Erythorbates are food ingredients that inhibit the change of flavor and color in food when exposed to air, such as when a cut apple is exposed to air. Produced from sugar, erythorbates are similar in chemical structure to vitamin C. Two forms of erythorbates, erythorbic acid and

sodium erythorbate, are commonly used in hot dogs, luncheon meats, cured meats, fresh pork, poultry, frozen bananas, dehydrated apples and other foods. Erythorbates are classified by the FDA as GRAS, and have been used for more than 30 years. Whenever erythorbates are added to foods, it is designated on the label.

Does FD&C Yellow No. 5 cause adverse reactions?

FD&C Yellow No. 5, or tartrazine, is used to color beverages, dessert powders, candy, ice cream, custards and other foods. The color additive may cause hives in fewer than one out of 10,000 people. By law, whenever the color is added to food or taken internally, it must be listed on the label. This allows the small portion of people who may be sensitive to FD&C Yellow No. 5 to avoid it.

Does the low-calorie sweetener aspartame cause adverse reactions?

In carefully controlled clinical studies, aspartame has not been shown to cause allergic reactions in adults or children. In addition, consumer complaints of possible adverse reactions have been monitored for more than 10 years by the FDA. Experts in food safety have concluded there is no convincing evidence of a cause and effect relationship between aspartame and the various sensitivities reported. Whenever aspartame is added to foods, it is listed on the product label. Individuals who have concerns about possible adverse reactions to aspartame or other substances should contact their physicians.

Do additives cause childhood hyperactivity?

No. Although this theory was popularized in the 1970's, well-controlled studies conducted since that time have produced no evidence that food additives cause hyperactivity or learning disabilities in children. A Consensus Development Panel of the National Institutes of Health concluded in 1982 that there was no scientific evidence to support the claim that additives or colorings cause hyperactivity. However, for some children with attention deficit hyperactivity disorder (ADHD) and confirmed food allergy, dietary modification has produced some improvement in behavior.

Why are decisions sometimes changed about the safety of food ingredients?

Since absolute safety of any substance can never be proven, decisions about the safety of food ingredients are made on the best scientific evidence available. Scientific knowledge is constantly evolving. Therefore, federal officials often review earlier decisions to assure that the safety assessment of a food substance remains up-to-date. Any change made in previous clearances should be recognized as an assurance that the latest and best scientific knowledge is being applied to enhance the safety of the food supply.

What are some other food additives that may be used in the future?

Among other petitions, FDA is carefully evaluating requests to use ingredients that would replace either sugar or fat in food. In 1990, FDA confirmed the GRAS status of Simplese®, a fat replacement made from milk or egg white protein, for use in frozen desserts. The agency also is evaluating a food additive petition for olestra, which would partially replace the fat in oils and shortenings.

What is the role of modern technology in producing food additives?

Many new techniques are being researched that will allow the production of additives in ways not previously possible. One approach, known as biotechnology, uses simple organisms to produce additives that are the same as food components found in nature. In 1990, FDA approved the first bioengineered enzyme, rennin, which traditionally has been extracted from calves' stomachs for use in making cheese.

What Is a Food Additive?

In its broadest sense, a food additive is any substance added to food. Legally, the term refers to "any substance the intended use of which results or may reasonably be expected to result Ñ

directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food." This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food.

If a substance is added to a food for a specific purpose in that food, it is referred to as a direct additive. For example, the low-calorie sweetener aspartame, which is used in beverages, puddings, yogurt, chewing gum and other foods, is considered a direct additive. Many direct additives are identified on the ingredient label of foods.

Indirect food additives are those that become part of the food in trace amounts due to its packaging, storage or other handling. For instance, minute amounts of packaging substances may find their way into foods during storage. Food packaging manufacturers must prove to the U.S. Food and Drug Administration (FDA) that all materials coming in contact with food are safe, before they are permitted for use in such a manner.

What Is a Color Additive?

A color additive is any dye, pigment or substance that can impart color when added or applied to a food, drug or cosmetic, or to the human body. Color additives may be used in foods, drugs, cosmetics and certain medical devices such as contact lenses.

Color additives are used in foods for many reasons, including to offset color loss due to storage or processing of foods and to correct natural variations in food color.

Colors permitted for use in foods are classified as certified or exempt from certification. Certified colors are man-made, with each batch being tested by the manufacturer and FDA to ensure that they meet strict specifications for purity. There are nine certified colors approved for use in the United States. One example is FD&C Yellow No. 6, which is used in cereals, bakery goods, snack foods and other foods.

The Nutrition Labeling and Education Act of 1990 requires that any certified color added to food be listed in the ingredient statement by its common or usual name.

Color additives that are exempt from certification include pigments derived from natural sources such as vegetables, minerals or animals. For example, caramel color is produced commercially by heating sugar and other carbohydrates under strictly controlled conditions for use in sauces, gravies, soft drinks, baked goods and other foods. Colors exempt from certification also must meet certain legal criteria for specifications and purity.

Common Uses of Additives

1. Impart/Maintain Desired Consistency

Alginates, Lecithin, Mono- & Diglycerides, Methyl Cellulose, Carrageenan, Glycerine, Pectin, Guar Gum, Sodium Aluminosilicate Foods Where Likely Used Baked Goods, Cake Mixes, Salad Dressings, Ice Cream, Process Cheese, Coconut, Table Salt, Chocolate

2. Impart/Maintain Desired Consistency

Alginates, Lecithin, Mono- & Diglycerides, Methyl Cellulose, Carrageenan, Glycerine, Pectin, Guar Gum, Sodium Aluminosilicate Foods Where Likely Used Flour, Bread, Biscuits, Breakfast Cereals, Pasta, Margarine, Milk, Iodized Salt, Gelatin Desserts

3. Maintain Palatability and Wholesomeness

Propionic Acid and its Salts, Ascorbic Acid, Butylated Hydroxyanisole (BHA), Butylated Hydroxytoluene (BHT), Benzoates, Sodium Nitrite, Citric Acid, Erythorbates Foods Where Likely Used Bread, Cheese, Crackers, Frozen and Dried Fruit, Margarine, Lard, Potato Chips, Cake Mixes, Meat

4. Produce Light Texture; Control Acidity/Alkalinity Yeast,

Sodium Bicarbonate, Citric Acid, Fumaric Acid, Phosphoric Acid, Lactic Acid, Tartrates Foods Where Likely Used Cakes, Cookies, Quick Breads, Crackers, Butter, Soft Drinks

5. Enhance Flavor or Impart Desired Color

Cloves, Ginger, Fructose, Aspartame, Saccharin, FD&C Red No. 40, Monosodium Glutamate, Caramel, Annatto, Limonene, Turmeric Foods Where Likely Used Spice Cake, Gingerbread, Soft Drinks, Yogurt, Soup, Confections, Baked Goods, Cheeses, Jams, Gum

Summary

Additives have been used for many years to preserve, flavor, blend, thicken and color foods, and have played an important role in reducing serious nutritional deficiencies among Americans. Additives help assure the availability of wholesome, appetizing and affordable foods that meet consumer demands from season to season.

Today, food and color additives are more strictly regulated than at any time in history. Federal regulations require evidence that each substance is safe at its intended level of use before it may be added to foods. All additives are subject to ongoing safety review as scientific understanding and methods of testing continue to improve.