Food Additives and Safety Laws

HAVE YOU EVER WONDERED how they get those bright colors in breakfast cereal? Are those bright colors safe to eat? Salt and table sugar are two of the most widely used food additives. However, other additives, such as aspartame, are also put into food. Which foods contain aspartame? Let's find out.

Objective:

Summarize the agencies, laws, approval processes, and controversies related to food additives and food safety.

Key Terms:

Adverse Reaction Monitoring System
carcinogenic
Delaney Clause
economic poisons
EPA
FAO
FDA
GRAS
HACCP
standards of identity
USDA

Food Additives and Food Safety

Many agencies and laws oversee food additives and food safety. Nearly all processed foods contain natural and/or artificial food additives.

AGENCIES

Food additives and food safety are the responsibility of several state and federal agencies. The Food and Drug Adminis-

FIGURE 1. Food additives are put into a variety of fast foods and highly processed foods, such as these individually wrapped cheese slices.

tration (FDA) has the most visible role in safeguarding the U.S. food supply. Numerous other federal, state, and local agencies also play roles.

Food and Drug Administration (FDA)

The **FDA** has the primary responsibility for ensuring that food and food additives are safe and that food packaging is safe and accurate. It is the federal agency that monitors trade and safety standards in the food and drug industry. In addition, the FDA regulates and monitors food product labeling of contents and nutritional levels. For food product contents, the FDA has established standards of food identity. **Standards of identity** require that food products contain what their labels say they contain. If a label claims a product is blueberry jam, the product must contain blueberries (not just colored apple bits and flavoring).

FIGURE 2. Ice cream is an example of a food product that must meet the FDA's standards of identity. Have you noticed other frozen desserts are labeled as soft serve, frosty, ice milk, sherbet, gelato, or Italian ice? This indicates that none meets the standard of identity for ice cream; thus, the products are not allowed to use the name "ice cream." According to CFR Title 21, Part 135.110, ice cream must contain no less than 10 percent milk fat. What visual differences do you see between strawberry ice cream and strawberry-flavored soft-serve frozen yogurt?

United States Department of Agriculture (USDA)

The **USDA** is responsible for the inspection and quality of meat and poultry products throughout their processing. This includes the grade labels (e.g., Choice, Prime, Grade AA, Grade A) that these foods carry. The USDA also has a role in a food product's contents, particularly with indirect additives, such as pesticides and other agricultural chemicals. While the FDA sets the tolerance levels for these additives, the USDA requires and maintains a registration of all these chemicals, which are called **economic poisons**, the legal name for pesticides used with food crops and animals.

Environmental Protection Agency (EPA)

The **EPA** safeguards the food supply by protecting the environment in which foods are produced. The EPA is directly involved through its testing and monitoring of the environmental impacts of chemicals used and the by-products of food production.

Other Federal Agencies

Other federal agencies have minor roles in the use of food additives and food safety. For example, the U.S. Department of Commerce defines the standards for weights and measures

used in food packaging. The National Marine and Fisheries Services (of the National Oceanic and Atmospheric Administration) inspects seafood and shellfish supplies. The Federal Trade Commission regulates what may be stated in advertising and helps ensure that standards of identity are maintained and nutritional claim standards are enforced.

FURTHER EXPLORATION...

ONLINE CONNECTION: What Are Standards of Identity?

Section 401 of the Federal Food, Drug, and Cosmetic Act requires that food must have common names and provides for standards of identity for foods. Three hundred food products are identified with standards of identity. These can be researched under Title 21, Parts 130 to 169. Be prepared for a legal definition of the law. The following is a quotation from the law: "In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

"(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in §101.100 of this chapter.

"(b) If it fails to contain any one or more ingredients required by such definition and standard.

"(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard."

BROADENING AWARENESS...

AMAZING ASPECTS: What Are Economic Poisons?

According to the Economic Poisons Control symposium, "The term 'economic poisons' includes a wide variety of chemicals and chemical compounds which have been developed for use in controlling, destroying, or repelling harmful insects or rodents, and predatory animals or other forms of animal life. The term also includes chemical substances used to defoliate plants and hormone-like substances that regulate growth of plants."

For more information on chemical poisoning, read *Silent Spring* by Rachel Carson. *Silent Spring* is considered one of the top 25 science books of all times. It includes stories of what happened to families. A free study guide can be found at http://thebestnotes.com/booknotes/Silent_Spring/Silent_Spring_Rachel_Carson01.html. Check out the book and get more details.

State and Local Agencies

State agencies also play a role in safeguarding our food. State departments of health and agriculture work with the federal agencies to monitor food safety and regulate intrastate activities. State governments also mandate specific label requirements for foods sold in their states. For example, California's Proposition 65 requires that a food containing any level of potential cancer-causing additive carry a warning label. Local agencies are involved in food safety by monitoring food services, retail stores, and fluid milk operations at the local level.

Food and Agricultural Organization

International agreements on food safety also exist. The **FAO** (Food and Agricultural Organization), located in Rome, Italy, administers an international food code and works to resolve disputes between countries regarding food safety.

PRIMARY LAWS AND REGULATIONS

Food safety has been a concern of ruling groups for much of modern history; ancient Chinese, Greek, and Roman documents all contain records of attempts to control fraudulent food practices and the selling of "adulterated" foods. In the U.S., states had the initial responsibility for making sure that their citizens had safe food, as many people produced and consumed their own foods. As the country developed and more people lived in towns and cities without the ability to produce all of their own food, the federal government started taking a role. Food safety has been a part of federal responsibility since the first federal food law, the Tea Act of 1883, was passed.

UNDER INVESTIGATION...

LAB CONNECTION: Food Additives

Two activities and a lab are part of the Illinois State Board of Education's Food Science Curriculum—Unit 3: Food Additives at http://www.isbe.net/career/pdf/fcs_guide.pdf. The first activity lists the ingredients in eight common foods and asks you to guess the food that contains each ingredient. The answers are listed on a separate page. Try this with your friends, and see if they can identify what they are eating with the ingredient list from some of your food labels.

The "Desirable Food Additives" lab is an experiment that adds sugar, salt, or ascorbic acid (lemon juice) to cut fresh fruits and vegetables. The experiment compares the effect of using an antioxidant food additive with the control that does not have a food additive.

The "Determining Food Additives in Prepared Foods" activity asks you identify food additives used in the various foods you eat and to categorize them by function.

Food and Drug Act of 1906

The Food and Drug Act of 1906 was the first comprehensive federal food law. While it represented a major breakthrough in establishing a role for the federal government in safeguarding our food, it was fairly weak and ineffective, as no federal agency was given the responsibility for enforcement.

Food, Drug, and Cosmetic Act of 1938

The first effective and comprehensive federal food law was the Food, Drug, and Cosmetic Act of 1938. It defined the following terms: food, food preservatives, artificial colors, standards of identity, and quality and fill. It also established standards for food preparation.

Five Major Amendments to the Food, Drug, and Cosmetic Act of 1938

Amendment 1: The Pesticide Chemical Amendment (1954) established tolerance levels for pesticide residue in raw agricultural products and prohibited the sale of these products if residue exceeded these levels.

Amendment 2: The Miller Food Additive Amendment (1958) is the major legislation on food additives. It requires proof that a proposed additive is safe before it is used in food. The company wanting to use the additive is responsible for proving the safety of the additive. There are two very significant sections in this amendment. First, additives that were being used at the time this amendment was passed could continue to be used if they were "generally recognized as safe." **GRAS** is an acronym–**g**enerally **r**ecognized **a**s **s**afe–that indicates food experts consider the food production and processing additive to be safe. Second, the **Delaney Clause** clarifies that no additive is considered safe if any amount of the additive can be shown to cause cancer in humans or any animal. The Delaney Clause has been the subject of much controversy.

Amendment 3: The Color Additive Amendment (1960) established rules for color additives that parallel the rules for other food additives. It does, however, permit color and flavor additives that have shown to induce cancers to be referred to experts for further evaluation of their safety (i.e., it contains no Delaney Clause).

Amendment 4: The Fair Packaging and Labeling Act (1966) established that every label must contain the same basic information, including (1) the common product name, (2) weight, (3) manufacturer information, (4) ingredients, in order by weight, and (5) a statement of artificial color or flavor.

Amendment 5: The Nutrition Labeling and Education Act (1990) established requirements for standardized nutrition labeling on all packaged food products, as well as 20 common fruits and vegetables and 20 common fresh fish items.

FDA Modernization Act of 1997

The FDA Modernization Act of 1997 established a number of improved procedures for food, drug, and cosmetic products that the FDA oversees. For food, this act streamlined the

DIGGING DEEPER...

UNCOVERING ADDITIONAL FACTS: Use and History of Food Additives

A direct food additive is one that is added to a food for a specific purpose. The FDA maintains a database of 3,000 ingredients that are directly added to foods. Direct food additives are added as preservatives, antioxidants (to prevent the spoilage of fat), flavorings or flavor enhancers, coloring, fat replacements, nutrients, emulsifiers (to prevent separation), thickeners, pH controls (to make a product more or less acid), leavening agents (to make a product rise), anti-caking agents, or humectants (to keep a product moist). Examples of ingredients added as direct additives are (1) salt and sucrose (table sugar) for flavor, (2) xanthan gum to add texture to salad dressing, (3) carrageenan (made from edible red seaweed) for the creamy mouth feel in ice cream, and (4) carbon dioxide as a propellant in cooking oil sprays.

Food additives are put into processed foods for a variety of reasons. These include to maintain or improve freshness, nutritional value, taste, texture, and appearance. The deli meats and cheeses in this submarine sandwich typically contain food additives.

An indirect food additive is one that becomes part of the food from the food's packaging, storing, or handling. The FDA regulates both direct and indirect additives.

The Miller Food Additive Amendment exempts two groups of ingredients from the regulation process. Food additives approved before the 1958 amendment, such as the sodium nitrite and potassium nitrate used to preserve luncheon meats, and foods on the GRAS list are exempt from the regulation process. GRAS foods include salt, sugar, spices, and vitamins. For more information and a list of food additives, their purposes, and common foods that contain them, access "Overview of Food Ingredients, Additives & Colors" at http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm#foodadd.

To research the history of food laws and safety, access "A Century of Ensuring Safe Foods and Cosmetics" at http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/CFSAN/ucm083863.htm.

President Theodore Roosevelt signed the Pure Food and Drug Act of 1906 to prevent misbranded and adulterated foods from being sold. Examples of the problems in the food industry included a candy company using "poisonous" colors and strawberry jam being made from coal tar, pectin, artificial flavors, and grass seed (no strawberries). In the same period, the Meat Inspection Act was passed. Read *The Jungle* by Upton Sinclair, and you will understand why the public demanded the Meat Inspection Act be passed.

The Delaney Clause is named after Representative James Delaney of New York. The Delaney Committee started a congressional investigation on the safety of additives. The Delaney Clause prohibits the approval of any food additive shown to induce cancer in humans and animals. This clause has been added to the Miller Food Additive Amendment and to animal drug provisions.

processes for establishing food health claims and approving food contact substances (including packaging).

Bioterrorism Act of 2001

The Bioterrorism Act of 2001 expanded the authority of the FDA to conduct inspections for "adulterated" food, stop the movement of "adulterated" food into the food supply, and prohibit repeat offenders from participating in the food industry.

HACCP Rules

Although HACCP is not a specific law, the FDA and USDA have adopted it. **HACCP** is the Hazard Analysis and Critical Control Point procedures and the rule of law for food processors. HACCP originated as a safety check procedure for NASA astronauts and focused on applying science-based controls at all stages of food processing, from raw materials to finished products, in order to prevent hazards. The rules were intended to get away from conducting simple spot checks and to reacting to existing hazards. HACCP requirements are being phased in according to the type of food processed, and the FDA is considering applying HACCP to all domestic and imported food products.

A HACCP-regulated food processor must establish procedures addressing the following seven principles:

1. Analyze hazards.
2. Identify critical control points.
3. Establish preventive measures with critical limits for each control point.
4. Establish procedures to monitor the critical control points.
5. Establish corrective actions to be taken when monitoring shows that a critical limit has not been met.
6. Establish procedures to verify that the system is working properly.
7. Establish effective record keeping to document the HACCP system.

FIGURE 3. The FDA and USDA use HACCP rules. HACCP is an acronym for Hazard Analysis Critical Control Points.

PROCESS FOR APPROVING A FOOD ADDITIVE

Proving that a new food additive is safe for human consumption is the responsibility of the company that wants to use it or market it. The company must initiate the process with a petition, and the petition goes through the following steps.

Procedure for Petition of a Food Additive

Step 1: A company files a petition for approval with the FDA. This petition must include convincing evidence that the proposed additive, whether a direct additive or an indirect additive, will perform as it is intended to perform. It must also show clear evidence that the additive will not cause harmful effects at the expected level humans consume.

Step 2: The FDA reviews the petition, considering the composition and properties of the substance, the amount likely to be consumed, the probable long-term effects, and various safety factors. It also gathers input from the public, which includes food industry organizations such as the Institute of Food Technologists (IFT), the Grocery Manufacturers' Association (GMA), and/or the Bakery Manufacturers' Association (BMA). The absolute safety of any substance can never be proven. Therefore, the FDA must determine if the additive is safe under the proposed conditions of use, based on the best scientific knowledge available.

Step 3: When an additive is approved, the FDA releases regulations that may include the types of foods in which the additive may be used, the maximum amounts to be used, and how it should be identified on food labels. If the petition includes use of the additive in meat and poultry products, the company must also receive specific authorization by the USDA. Following this process, Americans' consumption of the new additive and results of any new research on its safety are then monitored to assure its use continues to be within safe limits.

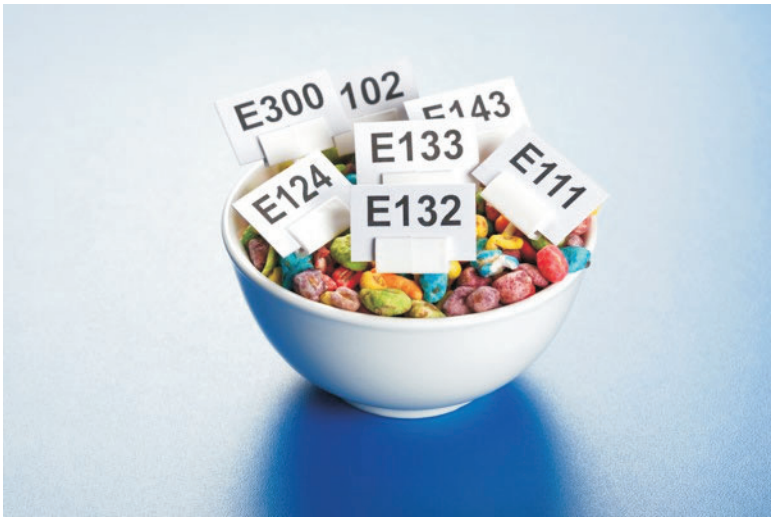

FIGURE 4. Have you ever wondered how manufacturers get those bright colors in breakfast cereal? Among the food additives in this bowl of popped wheat cereal are 300–Ascorbic Acid, 102–Artrazine, 133–Brilliant Blue FCF, 132–Indigotine, and 124–Ponceau 4R. For more examples of food additive codes, see http://apjcn.nhri.org.tw/server/info/books-phds/books/foodfacts/html/options/options1.html.

Adverse Reaction Monitoring System (ARMS)

As a follow-up mechanism, the FDA operates an Adverse Reaction Monitoring System (ARMS). **Adverse Reaction Monitoring System** is an ongoing safety check of all additives. ARMS monitors and investigates all complaints by individuals or their physicians about illnesses that may 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.

RECENT CONTROVERSIES ABOUT FOOD ADDITIVES

Recent subjects of controversy are the use of new food additives and their long-term effects on the food supply. While additives have allowed us to have year-round supplies of safe, wholesome food no matter where we live, a mistrust of advances in food science and technology has led to controversies over time. What we learn today about food additives helps us reevaluate earlier technological advances in food additive uses.

Again, since the absolute safety of any substance can never be fully proven, decisions about the safety of food ingredients are made based on the best scientific evidence available. Scientific knowledge is constantly evolving. Therefore, the FDA often reviews earlier decisions to assure that the safety assessment of a food substance remains up to date. Changes in approvals have been made, and 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.

FD&C Red No. 2

FD&C Red No. 2 was the primary type of red food coloring for some time. FD&C Red No. 2 (also known as Amaranth) was banned under the Delaney Clause because of two Russian studies that indicated it might be carcinogenic. **Carcinogenic** is the capability of producing or inciting cancer. The effort to ban this color additive was spearheaded by consumer groups. Other scientific studies showing its safety were not publicized or considered. The ban was a long, drawn-out public process that pitted research against research, without much scrutiny of the scientific validity of the research.

Finally, FD&C Red No. 2 was banned in 1976 because of insufficient data to demonstrate its safety, although the FDA stated that it did not determine FD&C Red No. 2 to be carcinogenic. The FAO continues to recognize this color additive as safe, and it remains the most commonly used red food additive in the world.

FURTHER EXPLORATION...

ONLINE CONNECTION: FD&C Red No. 2 (Amaranth)

You can research Red No. 2 at http://www.nap.edu/openbook.php?record_id=9453&page=125. FD&C Red No. 2 was approved in 1907 as a "true red" food color that was highly water soluble. In 1984 the JECFA (the Joint FAO/WHO Expert Committee on Food Additives) reevaluated Amaranth and assigned it a permanent ADI (Acceptable Daily Intake) of 0 to 0.5 mg/kg/day. Amaranth is now Red No. 9 and is coded 123. You can research chemical risks and JECFA at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/.

Cyclamates and Saccharin

Cyclamates and saccharin are two sweeteners in use since the early 1900s. Cyclamates and saccharin were classified as GRAS under the 1958 legislation. Cyclamates were widely used as a substitute for sugar in soft drinks. They were also the first artificial sweetener to come under scrutiny, when two studies indicated that high concentrations of cyclamates might be carcinogenic in rats and mice. The Delaney Clause applied, and cyclamates in any quantity were banned from use in 1970.

Saccharin, which was discovered in 1879, had been in use for more than 90 years when a 1972 study suggested a possible link between high saccharin consumption and bladder cancer in rats. As saccharin was the only artificial sweetener on the market at the time, public pressure on Congress resulted in the Saccharin Study and Labeling Act. This act placed a moratorium on the ban of saccharin before the Delaney Clause was fully applied. This moratorium still exists today, and continued studies have indicated that saccharin presents a very low risk to the public. Additionally, the FAO has determined from its review that saccharin is safe.

Aspartame

Aspartame is the latest sweetener / sugar substitute to come under heavy scrutiny. While media reports and websites have cited reactions to aspartame, ranging from headaches to tumors, the FDA has concluded that there is no current scientific evidence that aspartame causes adverse reactions in people. All consumer complaints related to the sweetener have been investigated as thoroughly as possible by federal authorities for more than 10 years, in part under the FDA's Adverse Reaction Monitoring System. In addition, scientific studies conducted during aspartame's pre-approval phase failed to show that it causes any adverse reactions in adults or children. Foods that contain aspartame include diet soda, yogurt, chewing gum, cooking sauces, crisps (chips), tabletop sweeteners, drink powder, flavored water, sugar-free products, and cereals.

One of the most interesting controversies over aspartame is that although it replaces sugar as a sweetener, it may also increase your risk of weight gain. It is 200 times sweeter than sugar with few calories. However, the major components of aspartame (phenylalanine and aspartic acid) may trigger the release of insulin and leptins. Leptins are hormones that encourage the body to store fat.

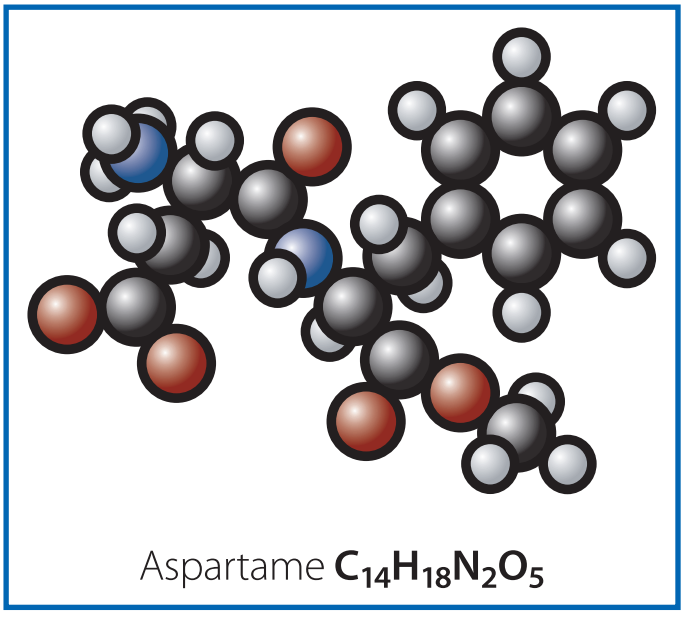

FIGURE 5. This is an image of one molecule of the artificial sweetener aspartame. Learn more about aspartame at http://www.naturalnews.com/035141_aspartame_worst_sources_products.html#ixzz2WDxz3GQJ.

Sulfites

Sulfites (such as sulfur dioxide, sodium sulfate, sodium bisulfite, and potassium bisulfite) are preservatives that have been scrutinized. When added to baked goods, condiments, snack foods, and other products, sulfites are safe for most people. However, a small segment of the population has been found to develop hives, nausea, diarrhea, shortness of breath, or even fatal shock after consuming sulfites. For that reason, in 1986 the FDA banned the use of sulfites on fresh fruits and vegetables intended to be sold or served raw to consumers. When sulfites are added as preservatives to packaged or processed foods, they must be listed on the product labels.

Olestra

Olestra is a zero-calorie fat substitute. As the search for lower-fat foods continues, research on fat substitutes has grown. Olestra is a chemical combination of sugar and fatty acids that acts like fat in food production but is indigestible by humans. While it was approved for use in certain types of snack food, the FDA is requiring that all products containing olestra be labeled with specific health information.

Studies to date have found that although olestra does cause gastrointestinal effects (intestinal cramps and diarrhea) in some individuals, these gastrointestinal effects do not have medical consequences. Also of concern was the fact that olestra absorbs fat-soluble vitamins naturally occurring in foods. However, replacing these vitamins with vitamin additives can compensate for this. Because of the amount of controversy surrounding olestra, the FDA approval also required that the company that wanted it approved conduct studies to monitor consumption as well as studies on the long-term effects of olestra.

Artificial vs. Natural Additives

The artificial versus natural additives debate centers on the safety of artificial additives. Some additives are manufactured from natural sources. For example, soybeans and corn pro-

FURTHER EXPLORATION...

ONLINE CONNECTION: Olestra (Brand name: Olean)

Check out the controversy about olestra at http://www.cspinet.org/olestra/. This Center for Science in the Public Interest (CSPI) website offers information and research about olestra. Olestra was first introduced in 1998 in Frito-Lay's™ WOW! chips. The fat substitute was used to fry the chips, causing an unpleasant side effect of anal leakage. WOW! chips were taken off the market after the FDA-mandated a warning label. The original warning label stated, "This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients." More than 18,000 people submitted an adverse reaction report on olestra to the FDA. Today, many light chips contain olestra. Check the food label on your light chips for olestra or Olean in the food ingredient list.

FIGURE 6. Dehydrated beet powder is used as a natural food colorant to obtain pink, red, and brown coloring in foods. Spinach is a natural green food colorant for pasta, icings, etc. Do some research to find natural alternatives for the yellow, purple, orange, and blue food colorants found in groceries.

vide lecithin to maintain product consistency, and beets provide beet powder used as food coloring. Other useful additives are not found in large enough quantities in nature; thus, they must be manufactured. Artificial additives can be produced more economically and with greater purity and more consistent quality than some of their natural counterparts.

The argument that a natural additive is "chemical-free" is not considered valid. All foods, whether picked from the garden or the grocery 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 the starches, proteins, fats, water, and vitamins found in foods. According to the FDA, whether an additive is natural or artificial has no bearing on its safety.

Summary:

We have a long history of international, federal, state, and local agencies protecting the public with food additive and food safety laws. Controversies still arise about the safety of food additives. Ongoing research continues to help keep our food supply safe. It is important to remember that the federal agencies tend to err on the side of safety, and the ARMS is in place and will work if the public reports any suspected reactions to foods.

Checking Your Knowledge:

1. What are three federal agencies responsible for food additives or food safety?
2. Define the phrase "standards of identity." Give an example.
3. Name and describe three laws related to food safety.

4. Name and describe three amendments related to food safety.
5. Which food additive controversy was the most interesting to you? Why?

Expanding Your Knowledge:

CFR is the Code of Federal Regulations from the U.S. Food and Drug Administration (FDA). Title 21 is related to food and drug rules under the FDA's jurisdiction. Title 21 is revised annually, usually on April 1. Conduct a research study of foods in the CFR Title 21 database. For example, check out the CFR for ice cream, bread, pizza, or another food of interest and read the federal regulations.

Web Links:

Code of Federal Regulations (Annual Edition)
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR&searchPath=Title+21%2FChapter+I%2FSubchapter+B%2FPart+130&oldPath=Title+21%2FChapter+I%2FSubchapter+B&isCollapsed=true&selectedYearFrom=2012&ycord=1571

Code of Federal Regulations—Title 21—Food and Drugs
http://www.fda.gov/medicaldevices/deviceregulationandguidance/databases/ucm135680.htm

Economic Poisons Control—Symposium
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1929264/?page=1

Is Stevia a Safer Sweetener?
http://health.yahoo.net/experts/dayinhealth/stevia-safer-sweetener201

Natural Homemade Food Coloring for Baking, Frosting, and Easter!
http://bonzaiaphrodite.com/2013/03/natural-homemade-food-coloring-for-baking-frosting-and-easter/

Regulating Food—Standards of Identity
http://uspolitics.about.com/od/usgovernment/a/fda_identity.htm