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A Primer on Food Additives

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Consumers today are very concerned about what goes into their food. This primer on food additives describes what food additives do and why modern food technology has made them necessary, and recounts how Congress and the Federal Government have responded to consumer demands for controls.

After spending many months with the mid-European immigrants who found work, and mistreatment, in Chicago's packing houses at the turn of the century, Upton Sinclair's book, "The Jungle," revealed that dangerous filth accompanied the production of meat and meat products and that plant owners were callous toward the welfare of their workers.

The readers' loud reactions became a powerful, moving force that helped persuade Congress to pass the Pure Food and Drugs Act of 1906 as well as the Meat Inspection Act of the same year.

The First Food Revolution

Before the Civil War people raised most of what they ate and processed it themselves. Food additives were limited mostly to home-grown colorings and substances needed for preservation in storage—vegetable and fruit juices, salt, spices, smoke.

Our system of food supply changed after the Civil War. The thousands of rural people who flocked to the cities to work in factories needed food grown and preserved by someone else. Manufacturers of food products sprang up almost everywhere.

Food purity as such was not a major consideration. Cheap and handy methods of preserving foods were important to profits, and scientific knowledge of food chemistry was practically nonexistent.

Dangerous adulteration of foods was commonplace. Chemicals to keep products looking good until they reached the consumer or just to hide the smell and look of spoilage were used without much restraint.

The problem of food additives was especially acute. Supplying the rapidly growing urban population required constantly expanding facilities, and speed of production took precedence over quality and safety. For example, copper sulphate, a powerful emetic also known as blue vitriol, was added to canned vegetables to give them a fresh, green look. Salicylic acid, borax and formaldehyde were used generously —and carelessly.

The Government Steps In

The strong leadership of Harvey Washington Wiley finally made food and drug protection an operating function of the Federal Government. Dr. Wiley, chief chemist for the U. S. Department of Agriculture in Washington, D. C., said publicly that the American people were being steadily poisoned by the dangerous chemicals that were were being added to food with reckless abandon.

To dramatize the problem, and to learn more about the reactions of the human body to ingestion of these chemicals, he formed, in 1902, what became known as "Dr. Wiley's Poison Squad." Twelve young healthy men, recruited from the Department of Agriculture, pledged to eat nothing except what Dr. Wiley prescribed.

Dr. Wiley explained later: "I wanted young, robust fellows, with a maximum resistance to deleterious effects of adulterated foods. If they should show signs of injury after they were fed with such substances for a period of time, the deduction would naturally follow that children

and older persons, more susceptible than they, would be greater sufferers from similar causes."

Over a period of 5 years, Poison Squad members were fed measured doses of many kinds of commonly-used food additives. Dr. Wiley was not only concerned about determining the effects of these additives, he was also interested in stirring up the public about the need for a pure food law. His dual efforts were highly successful.

President Theodore Roosevelt signed the Food and Drugs Act into law on June 30, 1906, and enforcement of the Act began January 1, 1907.

Factory conditions began to improve. Now that there was a law, complete with inspections and penalties for convicted transgressors, the food additive situation began to change, as did attitudes toward sanitation. The 1906 law defined as adulterated foods containing "any added poisonous or other added deleterious ingredient which may render such article injurious to health." Many toxic materials were kept out of the food supply by this law but it failed to work in the case of pesticide residues.

Pesticides were necessary, but there was no legal authority to determine and set safe tolerances for residues. Lead arsenate, used in those days for the coddling moth on apples, was a major problem. Efforts to enforce an informal FDA tolerance led to hundreds of seizures, but caused great opposition from the apple growers who sought help from their Congressmen.

Under the 1906 Act, the Government had to prove in each case that the residues present would be injurious—a difficult burden. When funds for research on the toxicity of sprays were cut off, FDA was forced to discontinue the program.

During the quarter century after 1906, great changes were taking place in food technology. Stronger controls were needed—compulsory inspections of food plants, for example.

Under the 1906 Act, inspectors could enter a plant only if allowed to do so by plant management. Penalties were too light to bring about significant changes in sanitation and labeling practices, and official standards were urgently needed to define the composition of basic food products. The deficiencies of the original Act were becoming increasingly evident.

President Franklin D. Roosevelt gave new backing in 1933 to the reforms the Food and Drug officials had been calling for. After 5 years of trying, the 1938 Food, Drug, and Cosmetic Act was passed. It stands today, amended many times as changing conditions have been brought to the attention of Congress.

Sufficient power to insure safe use of pesticides was one of the most pressing needs for the stronger Act of 1938. The new law prohibited the addition of poisonous or deleterious substances to food, but provided for exemptions and safe tolerances for substances that were necessary in production or unavoidable. It did not require any showing to the FDA that such substances were safe before they were introduced into the food supply.

FDA attempted to set a tolerance for a necessary pesticide, but after protracted hearings and an adverse court decision it became clear that the procedure required by the 1938 Act also was unworkable.

American consumers are protected by the most stringent food laws in the world.

By this time FDA's problem with chemicals in foods had become unmanageable. Literally thousands of new compounds were being used in crop production, food processing and packaging. Some were so acutely toxic as to require emergency action by FDA. Such cases were relatively simple; it was no great problem to prove in court that they were harmful. The big problem was the host of substances which had not been sufficiently tested to show that they were safe.

The total situation so concerned FDA's Commissioner Charles W. Crawford that he decided to discuss it with the late Congressman Frank B. Keefe of Wisconsin, a strong advocate of pure foods.

On May 9, 1949, Mr. Keefe introduced a resolution calling for a special committee to investigate the use of chemicals in foods. Death ended the career of Congressman Keefe, and Representative James J. Delaney of New York was named chairman of the investigating committee. The "Delaney Hearings" became the platform for a long parade of scientific, legal, agricultural and medical experts who gave their advice on how the chemicals-in-food problem should be handled.

Early in the deliberations it became clear that "chemicals in foods" would have to be regulated in at least two separate categories—pesticides, which were used on raw agricultural commodities, and "food additives," which were substances added to improve food products or to facilitate processing or packaging.

The Pesticide Chemicals Act became law in 1954, the Food Additives Amendment was approved in 1958, and the Color Additive Amendments in 1960. In all these laws, the intention of Congress was not to ban the use of food chemicals but to insure their safety when properly used. All these laws required industry to be responsible for proving by scientific research acceptable to the FDA that the substances would be safe as used.

Three basic definitions help explain the provisions of the 1958 law:

1. Food additives are components of food. They can be added directly to the food or get into the food from its surroundings, its packaging, the machinery used, or from any other source.

In vegetable soup, the raw agricultural products would be classed as "GRAS "substances."

The law goes further: If there is a possibility or "reasonable expectation" of a material becoming a food component when used in a particular manner, then it must be considered a food additive.

2. Other ingredients added to food, while considered as food additives in laymen's terms, are not legally classed as food additives.

Certain substances added to food, which qualified scientists generally recognized as safe

under the conditions of their intended use, are not "food additvies," and are exempt from the premarketing clearance requirements. This classification of "generally recognized as safe" (GRAS) may be made either on the basis of data derived from scientific procedure or, in the case of substances in use prior to January 1, 1958, on the basis of experience drawn from common and safe use in food.

Thus, the term "food additive" or the term "GRAS substance" is not limited to the artificial or synthetic chemicals that people so often associate with it. "Food additives" or "GRAS substances" include all raw agricultural products as well as components of fabricated foods.

It is easy to wonder how a substance, commonly known as "food," such as a potato or a carrot, for example, could also be considered a "food additive" or a "GRAS substance." When used as components of a food, however, these foods fall into one of these two classifications under the Food, Drug, and Cosmetic Act.

A good example of this might be vegetable soup. The raw agricultural products would be classed as "GRAS substances," while other possible ingredients would either have to be classified as "GRAS" or be subject to a food additive regulation.

The reasoning for the two classifications is fundamental. There is nothing about a natural product that is inherently more safe than a synthetic product. Many synthetic products are simply chemical counterparts of natural products. To say that natural products as such are safer or more desirable than synthetic products is to make a statement that is just not so.

Shortly after the enactment of the 1958 Amendment, FDA published a list of GRAS substances as part of its regulations. As of June 30, 1972, approximately 560 substances for direct use in food for humans, 108 substances for use in food packaging, and 46 compounds for adding trace minerals to animal foods were listed as GRAS.

3. The Delaney Clause is also a part of the 1958 Amendments. Sponsored by Congressman Delaney, the clause requires that no food additive is found to induce cancer when ingested by man or animal.

This clause is binding on Government agencies and food manufacturers alike, regardless of the amount of the additive planned to be consumed over the lifetime of either man or animal. The enactment of this clause was an expression by the Congress about the degree of risk to cancer to which the public could be exposed; as far as the Congress was concerned, no degree of risk was acceptable.

How Are Food Additives Approved?

The requirements for approving food additives are not as complicated as they sound.

Any substance newly proposed for addition to food must undergo strict testing. Information must be presented to FDA showing the identity of the new additive, its chemical composition, how it is manufactured and the methods to be used to detect and measure its presence in the food supply at the levels of expected use. Data must establish that the proposed testing methods are of sufficient sensitivity to determine compliance with the regulations.

There must also be data establishing that the additive will accomplish the intended physical or technical effect in the food, and that the amount proposed is no higher than that reasonably necessary to accomplish this effect.

Finally, data must be provided establishing that the additive is safe for its intended use. This requires scientific evidence ordinarily obtained from feeding studies and other tests using the proposed additive at various levels in the diets of two or more species of animals.

Can You Really Test for Safety?

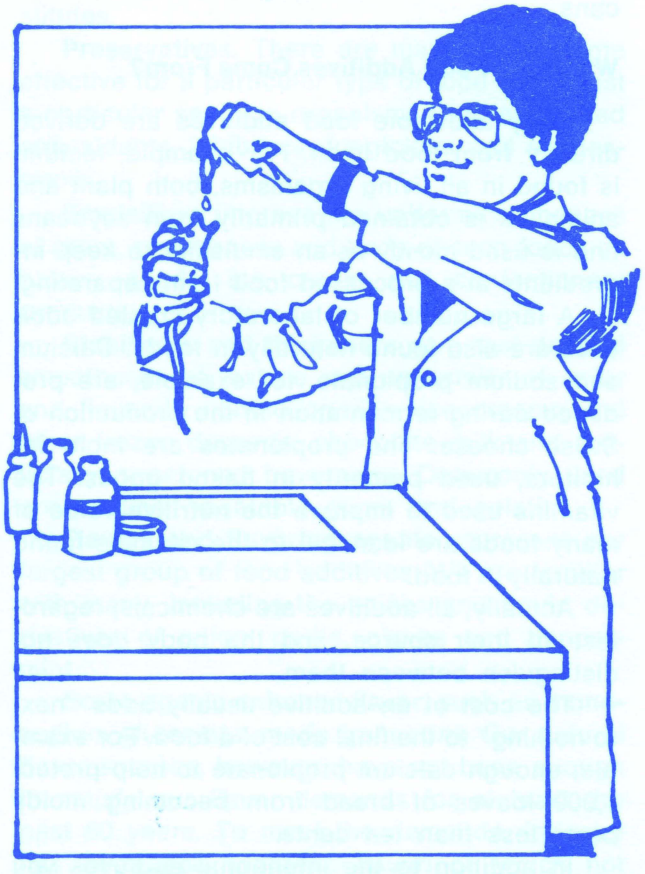
In a very real sense, you cannot test for safety; you can only test for the presence of known hazards. If the hazards are not found, the additive is assumed to be safe. If someone discovers a new hazard the testing must be done again.

This pattern has been repeated many times in FDA's history as scientific knowledge increases. Of course, a new food additive cannot be legally used unless, in addition to being safe, it will accomplish some intended effect in the production, manufacture or storage of the food.

How Safe Is Safe?

Testing food additives to determine their degree of hazard or safety obviously cannot be done with humans as the primary testing agents. The young men who made up Dr. Wiley's Poison Squad today would be required to sample additives numbering in the thousands and today's standards of measurement accuracy, plus our modern concepts of human safety, would make the earlier approach unacceptable and we no longer allow human subjects to be used for such tests.

A typical testing sequence involves at least two animal species and often more. FDA realizes that no animal reacts exactly like man and that a multiple-species testing program, often running through two generations or more, is far more productive of dependable results than is the testing of one species alone for a brief time.



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Even this careful testing is not considered enough. FDA uses a measuring stick which might be called the philosophy of the minimum. These are the essential factors.

- A tolerance or limitation will not exceed the smallest amount needed, even though a higher tolerance may be safe.
- After determining the maximum amount that will not produce any undesirable effect on the test animals used, 1/100th of that amount is normally the maximum allowed for use by man. Of course man might react differently from the test animals; when we know something from human experience or human studies, it is possible that a smaller safety factor than 1/100th can be used. On the other hand, if it is proved that even a smaller amount than 1/100th will do the job, that smaller amount will be used instead.
- It is quite human to think of desired safety—in anything—in the realm of 100 percent only. Such "perfection" is literally impossible. It helps here to realize that the risks are minute and the benefits, more often than not, are highly desirable and in many cases essential for the maintenance of an adequate, nutritious and safe food supply.

Just How Much Is Allowed?

A logical compromise between normal concern and test results seems to lie with the question, "How Much?" After all, we need salt in our diet, but we could die from eating too much salt.

FDA allows food additives to be used only if there is a practical certainty that no harm will result from their normal, allowed used over a lifetime.

The permitted amounts of additives vary depending on the kind of food, the safety limits of the additive, and the least amount needed to accomplish the desired result. FDA laboratories can measure these in amounts so small that

they are commonly expressed in parts per million, and sometimes parts per trillion.

To relate these minute amounts to something more easily understood, let's take two commonly used additives. BHA and BHT are frequently listed on labels of baked goods, cereals and other foods using oils and fats in their manufacture. Their complete names are butylated hydroxyanisole and butylated hydroxytoluene, which not only take up a lot of space on a small food label but might frighten anyone who is not a chemist.

BHA and BHT are preservatives and antioxidants—without them, many foods would turn rancid in a short time. In the average American diet both BHA and BHT are consumed in amounts slightly less than 4 ppm—four parts per million. This proportion may be easier to grasp if you consider:

- 4 ppm equals one-eighth of one ounce for each ton of food.
- A large needle in a 1-ton haystack could be 4 ppm by weight.
- 4 ppm in all the food a person might eat in a normal lifetime would equal about four mouthfuls.
- Parts per trillion? This is more difficult to describe. If you filled an olympic-size swimming pool with iced tea and dropped one grain of sugar into the pool—and stirred the mixture thoroughly—you might have one part per trillion. And an FDA scientist could determine just how much sweetening you used.

Can We Get Along Without Additives?

We can get along without food additives, but not as well. Were it not for food additives, we would have to go back to the old concept of bakery freshness—good today, stale tomorrow.

Many of us remember when the cottage cheese separated, cookies dried up in two days, any food with fat or oil in it became rancid, canned vegetables and fruits were soft and mushy, and marshmallows got too hard to toast. Without additives the variety and quality of foods would return to those familiar to grandmother.

The quantities available would definitely be less, and convenience foods would be nonexistent. FDA believes that its work assures the safe use of food additives.

Those "Poisonouschemicals"

Some people have expressed their feelings by coining a term that does not actually exist, "poisonouschemicals." If all chemicals are poisonous, then people should stop eating, because all foods are chemicals. Some familiar additives are pure chemicals, such as the potassium iodide in table salt and many familiar vitamins—all essential to man's health.

Expressing foods in chemical terms can be a lengthy job. For example, milk is made of water, 12 fats, 6 proteins, lactose (milk sugar), 9 salts, 7 acids, 3 pigments, 7 enzymes, 18 vitamins, 6 nitrogenous compounds and 3 gases —and the chemical names of these would take another page, at least. Milk is a formidable chemical, but hardly poisonous to most Americans.

Where Do Food Additives Come From?

Many allowable food additives are derived directly from food itself. For example, lecithin is found in all living organisms, both plant and animal. It is obtained primarily from soybeans and is used mostly as an emulsifier to keep ingredients in a processed food from separating.

A large number of laboratory-created additives are also found naturally in foods. Calcium and sodium propionate, for example, are produced during fermentation in the production of Swiss cheese. The propionates are mold inhibitors, used primarily in baked goods. The vitamins used to improve the nutritive value of many foods are identical to the vitamins found naturally in food.

Actually, all additives are chemicals, regardless of their source, and the body does not distinguish between them.

The cost of an additive usually adds "next to nothing" to the final cost of a food. For example, enough calcium propionate to help protect 1,000 loaves of bread from becoming moldy costs less than ten cents.

In addition to the intentional additives you have been reading about, there are also incidental additives, which have no planned func-

tion in food, but become a part of it during some phase of processing, packaging or storing.

Good examples are substances that might migrate from a packaging material to the food. The safety of incidental additives is scientifically controlled by FDA to the same high degree as are the intentional additives.

The Many Uses of Additives

A food additive must be of some benefit to a food or its production. Some additives are regulated with a specific group in mind—children, say, or diabetics.

Nutrient supplements are the vitamins and minerals added to foods to improve nutritive value and sometimes to replace those that are lost during processing, as in enriched bread. Vitamins A and D are added to margarine and vitamin D to milk. Potassium iodide is added to salt to furnish the iodine necessary to prevent simple goiter.

Nonnutritive sweeteners are the sugar substitutes.

Preservatives. There are many kinds, some effective for a particular type of food or against a particular spoilage organism. They are called antioxidants, inhibitors, fungicides and sequestrants.

Emulsifiers improve the uniformity, fineness of grain, smoothness and body of such foods as bakery goods, ice cream and confectionery products.

Stabilizers and thickeners give that desired smoothness of texture and uniformity of color and flavor to confectioneries, ice creams and other frozen desserts, chocolate milk and artificially sweetened beverages. Commonly used are pectins, vegetable gums and gelatins.

Flavors and flavoring agents represent our largest group of food additives. We are familiar with many, including the spices and liquid derivatives of onion, garlic, cloves and peppermint.

Some agents enhance flavor, such as monosodium glutamate, made from corn. Our natural flavor sources, however, have not been enough to satisfy our flavor demands for at least the past 80 years. To meet the demands, industry has developed synthetic flavorings which not only resemble accurately natural flavor but have the advantage of stability.

Many artificial flavors cannot be told from the natural ones, and many added flavors are derived from natural sources, such as amyl acetate—banana flavor extracted from bananas, and methyl salicylate—oil of wintergreen from the leaves of the wintergreen plant.

Bleaching agents and maturing agents speed up the aging process which improves the breadmaking quality of flour. Freshly milled flour is yellowish in color and makes very poor bread.

Colors are considered highly important although they do not improve eating qualities. We are so used to a certain color in a specific food that we would refuse to buy and eat it if some other color was present, or the expected color was too pale to look "healthy."

Additives have many other uses, including hardening, drying, leavening, anti-foaming, firming, crisping, anti-sticking, whipping, creaming, clarifying and sterilizing.

Without these many aids to food processing, today's grocery stores would need a lot less room to sell what foods would be left.

The Job Is Never Done

Food additives are a part of today's modern food technology. The first impetus for Federal control involved Dr. Wiley and his Poison Squad. The second strong push came during and after World War II, when hundreds of new chemicals were suddenly tried and then used to protect and enhance food, particularly for military purposes. Some of these were subsequently taken off the market when there was time for adequate testing with newer machines and techniques for detection and measurement.

Today, there are thousands of tested and approved food additives. Many are approved only for certain products and in exact amounts. New techniques and improved machinery keep pace with new additives which, if approved by FDA, will further improve our food supply.

Food technology came first; then came Federal regulation. The path from the original USDA's Bureau of Chemistry to FDA's Bureau of Foods has been long and full of technical, legal and scientific changes. Its general direction, however, has always been protection of the American consumer.

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