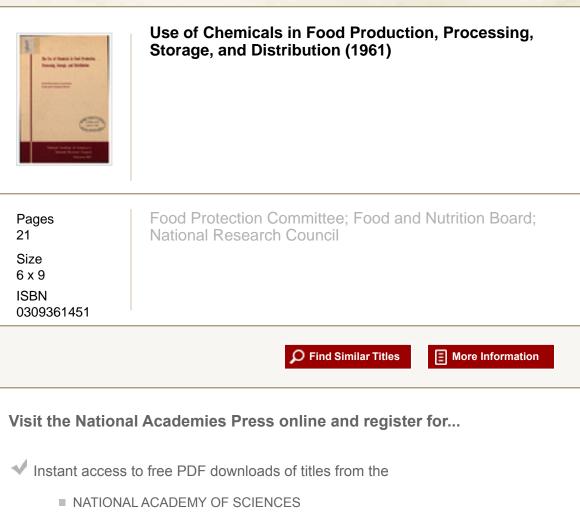
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The Food and Nutrition Board, established in 1940 under the Division of Biology and Agriculture of the National Academy of Sciences—National Research Council, serves as an advisory body in the field of food and nutrition. It promotes needed research in the broad field and helps interpret nutritional science in the interests of the public welfare. The Board may act on its own initiative or on request from public or private agencies.

The members of the Board are appointed from among leaders in the sciences related to food and nutrition on the basis of their qualifications of experience and judgment to deal with the broad problems that come before the Board. Appropriate contact with Federal agencies, scientific societies, and other associations is maintained through liaison representatives appointed from their respective organizations. Specific activities of the Board are carried on by committees composed of experts in each field. Members of the Board and its committees serve without compensation beyond their actual expenses.

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The Use of Chemicals in Food Production, Processing, Storage, and Distribution

NRC · Food Protection Committee .

 "Food and Nutrition Board



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Introduction

The American people have available the most abundant and varied food supply of any nation in history. This has been brought about in part by the application of science to food production and food technology.

In colonial times in this country, nine farm workers produced enough food for themselves and one city dweller. By 1940 one farm worker could produce enough for himself and nine others. Today approximately 25 urban dwellers depend on each farm worker. This efficiency has been achieved despite increasing difficulties from disease and insect pests, the loss of approximately one-half million acres per year through soil erosion and deterioration, and the use of large areas of fertile land for the construction of highways and suburban developments.

Food processors have matched the progress on the farm. One hundred years ago, commercial food processing was largely limited to salting, smoking, fermenting, and drying of a few products. Today there is available in every community a steady supply of fresh fruits and vegetables and processed products that retain practically all of the nutritive quality and flavor of the fresh product. Dairy products and baked goods are distributed regularly to rural and urban customers.

The application of many new discoveries in biology, chemistry, and engineering; the invention and use of a great variety of labor-saving machines; and the development of improved storage facilities, packaging materials, and means of distribution helped make this possible. The engineering and mechanical aids to this abundance are clearly evident to most people. Many, however, have not been aware of the contribution of chemistry or the nature of the problems associated with the use of chemicals. Presented here is a discussion of some of the technologic reasons for the use of chemicals in food production, processing, storage, and distribution, the problems associated with this use, the research undertaken by industry and government to solve these problems, and the legal measures established to ensure protection of the public by governing the use of chemicals in foods.

Chemicals Naturally in Foods

All components of foods are chemicals. The great bulk of foods is comprised of chemicals classified as carbohydrates, fats, proteins, minerals, and water. Foods also contain small amounts of accessory chemicals including the vitamins and natural antioxidants, antimycotics, buffers, thickeners, emulsifiers, chelating agents, colors, and flavors. The carbohydrates consist of various sugars, starches, dextrins, celluloses, and gums. Most of these are oxidized in the body to release energy for muscular activity and other body functions. The fats and oils supply energy and essential fatty acids and facilitate absorption of fat soluble vitamins. The proteins are composed of amino acids which, when made available by digestive processes, are used as building materials for the proteins of soft tissues of the body and bone matrix or as a source of energy. The minerals have many functions. Some are used primarily in building skeletal structures and teeth, while others are essential aids in metabolism. The various vitamins regulate cell functions and are also essential to normal metabolism. The colors and flavor-imparting compounds may have nutrient value but most frequently are primarily of esthetic value. Such factors as the variety of crop, soil fertility and nutrient content, duration and intensity of sunlight during growth, rainfall, disease, and methods of harvest, handling, and storage may affect the chemical composition and hence the flavor, quality, and nutritional value of each plant product. Chemical composition of animal products is also influenced to some extent by environmental factors, and particularly by species.

Each foodstuff consists of chemicals that are more or less characteristic of it, but because of the natural variation, it is frequently necessary to adjust the composition in order to provide a product of constant quality. Milk, for example, consists of variable amounts of butterfat, milk sugar (lactose), proteins (principally casein and lactalbumin), minerals (notably calcium and phosphorus), various vitamins, and other constituents. The composition of milk varies somewhat according to the breed, the individual cow, the period of lactation, and the nature of the feed of the cow. Milk from Holstein cows is somewhat lower in fat and carotenoid pigments than that of either Jersey or Guernsey cows. Milk destined for general distribution comes from different sources and is generally blended or standardized to a uniform level of butterfat. Milk received at evaporating plants at different seasons and from different herds varies in stability to heat. This property is dependent upon the balance in the milk of the natural mineral salts, particularly the proportions of calcium, phosphate, and citrate. It is often necessary, therefore, to add one or the other of these chemicals in order to produce sufficient heat-stability for an acceptable product. This is a case of adding a constituent normal to a food to help standardize it.

Standardization procedures comparable to those described for milk are carried out with other foods as, for example, in the blending of wheat varieties to secure a flour of uniform baking quality.

It is perhaps appropriate at this point to draw attention to the fact that natural foodstuffs contain substances that are of no known nutritive value and substances that are harmful if taken in amounts much larger than those encountered in normal usage of the food. Coffee and tea, for example, contain caffeine and theobromine which have a well-known pharmacological effect. Cocoa contains a related compound. Small amounts of arsenic and other toxic metals are found in most foodstuffs. Substances that interfere with thyroid function resulting in development of goitre have been identified in rutabagas and other species of the genus *Brassica*, and oxalates are present in rhubarb, spinach, and chard. Many foodstuffs contain traces of toxic alkaloids and cyanide-generating compounds. We accept these foods, however, since long usage has indicated that the substances in question are apparently inconsequential in the amounts likely to be consumed.

What is a Food Additive?

In addition to the natural chemical composition of foodstuffs, chemicals may be incorporated, either directly or indirectly, during the growing, storage, or processing of foods. These chemicals may be described for convenience as "food additives."¹ When they are purposely introduced to aid in processing or to preserve or improve the quality of the product, they are called intentional additives. Such materials as colors, flavors, sweeteners, vitamins and minerals for enrichment, mold inhibitors, bactericides, antioxidants, and emulsifiers are intentional additives. They are added to the food product in carefully controlled amounts during processing, and the amounts necessary to achieve the desired effect are usually very small. For example, less than four grams of synthetic color per person per year are used for coloring our foods.

In addition to the intentional additives, certain other chemicals may find their way into foods as a result of their use in some phase of the production, handling, or processing of food products. These are known as "incidental additives." Under provisions of the Federal food and drug laws such additives are permitted in foods only if they cannot be avoided by good production and processing practices, and then only if the amounts that occur under these conditions are known to be safe.

Common Types of Intentional Food Additives

Every chemical used in food production and processing should serve one or more of these purposes: improve nutritional value, enhance quality or consumer acceptability, improve the keeping quality, make the food more readily available, or facilitate its preparation. The purpose of intentional additives and the technological benefits of their use can be best illustrated by considering the more important classes of these substances.

Acids, Alkalies, Buffers, Neutralizing Agents

The degree of acidity or alkalinity is a very important property of many processed foods. In the baking industry chemical leavening agents are used to produce carbon dioxide, which makes the batter light and porous, thereby providing a finished product of good volume, crumb texture, and palatability. This reaction requires an ingredient that acts as an acid in the presence of moisture or heat. The acid ingredients used are such compounds as potassium acid tartrate, sodium aluminum phosphate, tartaric acid, monocalcium phosphate, and sodium acid pyrophosphate.

¹ Throughout this report, unless otherwise indicated, the term "food additive" is used as defined by the Food Protection Committee: A food additive is a substance or a mixture of substances, other than a basic foodstuff, which is present in a food as a result of any aspect of production, processing, storage, or packaging. The term does not include chance contaminants. This definition differs from the legal definition which appears on page 15.

Sodium bicarbonate is the gas-producing substance normally used although ammonium carbonate and ammonium bicarbonate are employed in the commercial production of some cookies and crackers.

The tart taste of soft drinks other than those of the cola-type is imparted by the addition of organic acids from either natural or synthetic sources. Citric acid (a component of citrus fruits), malic acid (a component of apples), and tartaric acid (a component of grapes) are the major organic acids employed. Buffering agents, generally the sodium salts of these acids, are frequently used to control the degree of acidity in soft drinks. The concentrations of acids and buffers employed are essentially the same as the levels at which these substances occur naturally in fruits. In cola-type beverages the most commonly used acidulant is phosphoric acid.

Adjustment of acidity is necessary in the production and use of several dairy products: for example, excessive acidity which may develop in cream must be neutralized for satisfactory churning and to produce a butter of acceptable flavor and keeping quality. Emulsification and a desired tartness in process cheese and cheese spreads are obtained by the addition of acids such as citric, lactic, malic, tartaric, and phosphoric. Acids are also used as flavoring agents in confections, and alkalies may be employed in the processing of chocolate.

Bleaching and Maturing Agents, Bread Improvers

Wheat flour in its natural, freshly-milled state has a pale yellowish tint. When such flour is stored, it slowly becomes white and undergoes an aging process that improves its baking qualities. About 50 years ago it was discovered that certain oxidizing agents added to the flour in small amounts would markedly speed up this process, thus reducing storage costs and the hazards of spoilage and insect and rodent infestation. Some of the permitted compounds, e.g., benzoyl peroxide, exert only a bleaching action and are without influence on baking properties. Others, such as the oxides of nitrogen, chlorine dioxide, nitrosyl chloride, and chlorine, have both bleaching and maturing or improving properties.

Bread improvers used by the baking industry contain small amounts of oxidizing substances such as potassium bromate, potassium iodate, and calcium peroxide. They also contain inorganic salts, e.g., ammonium chloride, ammonium sulfate, calcium sulfate, and ammonium and calcium phosphates, which serve as yeast food and dough conditioners. The quantity of oxidizing substances required is small, and since excessive treatment results in an inferior product, their use is self-limiting. Bleaching agents may also be used in the preparation of certain cheeses in order to improve the appearance of the finished product.

Emulsifying, Stabilizing, and Thickening Agents

Emulsifying agents are used in baked goods, cake mixes, ice cream, frozen desserts, and confectionery products. Some of those used are lecithin, mono- and diglycerides, and certain sorbitan and polyoxyethylene fatty esters. In bakery products these substances improve volume, uniformity, and fineness of grain. They facilitate machining in bread doughs, and the resulting bread has a softer crumb and a somewhat slower firming rate than do breads prepared without their use. The whipping properties and physical nature of frozen desserts are improved by the use of small amounts of emulsifier. In candies, they are employed to maintain homogeneity and improve keeping quality. Sorbitan derivatives are also used to retard "bloom," the whitish deposits of high-melting components of cocoa butter which occasionally appear on the surface of chocolate candies.

The texture of ice cream and other frozen desserts is dependent, in part, on the size of the ice crystals in the product which is controlled by the addition of small amounts of stabilizing agents. Agar-agar, gelatin, cellulose gum, and other vegetable gums are among the substances used. Certain of these compounds are also used in chocolate milk to increase the viscosity of the product and thus prevent the settling of cocoa particles to the bottom of the container. Gelatin, pectin, and starch are used in confectionery products to give a specific texture. Agar-agar, alginates, gum arabic, and gum tragacanth are used as stabilizers or thickeners in certain types of hard gums.

Sugar-sweetened beverages normally possess a certain amount of "body." Since beverages which are sweetened with non-nutritive sweeteners do not have this property, so-called "bodying agents" are used in their production. These include such natural gums as sodium alginate and pectins, cellulose gum derivatives, and sorbitol. The foaming properties of brewed beer can also be improved by the addition of certain of these stabilizing agents.

Flavoring Materials

A wide variety of spices, natural extractives, oleoresins, and essential oils are used in processed foods. In addition, the modern flavor chemist has produced many synthetic flavors. Both types of products are used extensively in soft drinks, baked goods, ice cream, and confectionery. They are usually employed in small amounts ranging from a few to 300 parts per million. Amyl acetate, benzaldehyde, carvone, ethyl acetate, ethyl butyrate, and methyl salicylate are representative of compounds which are employed in the preparation of flavoring materials. It should be noted that many of the compounds which are used in flavoring preparations are also found in natural products or are esters of natural acids.

Many spices and spice extractives are used in sausages and prepared meats. Monosodium glutamate and protein hydrolysates are also employed to enhance the flavor of some foods.

Food Colors

Food colors of both natural and synthetic origin are extensively used in processed foods and they play a major role in increasing the acceptability and attractiveness of these products. However, the indiscriminate use of color can conceal damage or inferiority, or make the product appear better than it actually is. In view of these factors, food colors must be used with discretion. Classes of foods that are frequently colored include confectionery, bakery goods, soft drinks, and some dairy products such as butter, cheese, and ice cream. Natural colors used in foods include annatto, alkanet, carotene, cochineal, chlorophyll, saffron, and turmeric.

Nutrient Supplements

Vitamins and minerals are frequently added to processed foods to improve their nutritive value. It is recognized, for example, that the processing of cereal grains to produce refined milled products removes a large portion of the vitamins and minerals originally present. Definitions and standards of identity have therefore been established by the Food and Drug Administration for the enrichment of wheat flour, farina, cornmeal, corn grits, macaroni, noodle products, and rice. These standards define the minimum and maximum levels of thiamine, riboflavin, niacin, and iron permitted to be added, and in some cases provide for the optional addition of sources of calcium and vitamin D. Many manufacturers of ready-to-eat breakfast foods add thiamine, riboflavin, niacin, and iron on a voluntary basis to provide products that contain amounts of these nutrients corresponding to those present in the cereals from which the foods are made.

Vitamin A is added to margarine, and vitamin D to both fluid and evaporated milk. Vitamin A may also be added to blue cheese and gorgonzola cheese to replace that lost in the bleaching process and to low-fat milk to compensate for that removed with the separated butterfat. Iodized salt contains a small amount of potassium iodide to furnish the iodine necessary to prevent simple goitre.

Preservatives, Antioxidants

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Preservatives are substances added to foods to prevent or inhibit microbial growth. A number of different types are used, depending on the food product and the spoilage organism involved.

Although the baking process destroys the spores of molds and most bacteria present in flour and other ingredients, baked goods are constantly exposed to spores present in the air and on baking equipment. Under summer conditions, the organisms become active and produce a condition in the bread called "rope" which renders the product inedible. Sodium diacetate, the propionates of sodium and calcium, and such acidic substances as acetic acid, lactic acid, and monocalcium phosphate are effective in retarding the growth of molds and "rope" bacteria. Sorbic acid and its sodium and potassium salts are used as antimycotic agents in cheeses, sirups, and pie fillings. Benzoic acid and sodium benzoate are employed in oleomargarine, certain fruit juices, pickles, and confections to inhibit bacterial or mold growth. Sulfur dioxide is widely used for the preservation of dried fruits. Sugar, salt, and vinegar are also effective in preventing microbial spoilage.

Fatty foods are susceptible to oxidative changes that take place in the fat molecule with the production of off-flavors and odors. The substances used to prevent this type of spoilage are known as antioxidants. The compounds most widely employed for this purpose are butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, and nordihydroguaiaretic acid. They are used in such foods as lard, shortening, crackers, soup bases, and potato chips. It has been found that certain acidic substances, e.g., citric acid, ascorbic acid, and phosphoric acid, enhance the properties of the antioxidant, and these substances are frequently added in combination with the antioxidant. Ascorbyl palmitate is employed in candy, and ascorbic acid has been found effective in preventing the oxidative discoloration of frozen fruits such as sliced peaches.

Miscellaneous Intentional Additives

A number of additional substances are employed for various purposes. Certain sugar substitutes are used in foods for persons who must or wish to restrict their intake of ordinary sweets. Saccharin and the calcium and sodium cyclamates (cyclohexysulfamates) are commonly used for this purpose. Clarifying agents, e.g., tannin, gelatin, and albumin, are used to remove small particles and minute traces of copper and iron in the production of vinegar and certain beverages.

Sequestering agents such as ethylenediaminetetracetic acid and its salts prevent the adverse effects of the presence of metallic ions in certain food products by forming chemically inactive complexes with the metals. Humectants are necessary in the production of some types of confections and candy to prevent drying out. Without a humectant, shredded coconut, for example, would not remain soft and pliable. Substances used for this purpose include glycerine, propylene glycol, and sorbitol. Glazes and polishes such as waxes and gum benzoin are used on coated confections to give luster to an otherwise dull surface. Magnesium carbonate and tricalcium phosphate are employed as anticaking agents in table salt, and calcium stearate is used for a similar purpose in garlic salt.

Chemicals are sometimes added to processed fruit and vegetable products in order to improve their texture. Canned tomatoes, potatoes, and apple slices tend to become soft and fall apart. A small amount of calcium chloride or other calcium salt added to the product acts as a firming agent. Sodium nitrate and nitrite are used in the curing of meats to develop and stabilize the pink color associated with these products. Nitrogen, carbon dioxide, and nitrous oxide are employed in pressurepacked containers of certain foods to act as whipping agents or to serve merely as propellants.

The foregoing is not intended as a comprehensive discussion of all intentional additives currently in use. It is rather an attempt to direct the attention of the reader to examples of the various classes of intentional additives used in our food supply.

Some Possible Sources of Incidental Additives

As indicated earlier, incidental additives are not deliberately added to foods but unavoidably appear in them as a result of operations essential to the production, storage, processing, packaging, or marketing of the product. Some of the functions of, and reasons for using, chemicals in these operations are reviewed.

Pesticides

Maintenance and improvement of the nutritional status of the American public is contingent upon the continued production of an adequate food supply. Plant and animal pests are foremost causes of curtailed agricultural production and of food destruction, food deterioration, and food contamination. From the standpoint both of quantity and quality of food produced, the necessity of protecting growing crops and produce from serious attack by insects, plant diseases, and other pests is clearly recognized.

The weight of the insects produced in our pastures and meadows frequently exceeds the weight gains of the domestic animals feeding thereon. In some pastures unused weed growth exceeds the production of palatable forage. Cultivated crops in North America are attacked by over 300 economically important species of insects, as many plant disease agents, and unestimated numbers of species of nematodes, rodents, weeds, and other pests. In 1954, the United States Department of Agriculture estimated that to offset the pest losses in agricultural production, an extra 88 million acres must be cultivated, and that losses subsequent to harvest equal the production of an additional 32 million acres. Estimates made independently by other agencies of the destruction caused by agricultural pests range between 8 and 15 billion dollars annually—a quarter of our annual production—and this despite the widespread use of the best control practices now available.

Standards of food quality and acceptance have continually risen. The modern housewife would not be satisfied with produce that was readily accepted 50 years ago, nor could such products meet present grade standards established by the United States Department of Agriculture. Much of the insect- and rodent-contaminated food acceptable years ago could not move in interstate commerce under current Food and Drug Laws.

Many factors have contributed to the increased prevalence and destructiveness of insects, weeds, fungi, bacteria, nematodes, and viruses during the past 100 years: (1) As farmers began to use the same fields over and over, the pests had less and less difficulty finding suitable host plants. (2) Certain organisms which at first rarely attacked the newly introduced cultivated crop plants developed, after several generations, an appetite for these plants and became so well adapted to the new environment that they became extremely destructive pests. (3) The breeding of crops for increased yields, uniformity, and other desirable characteristics resulted in many instances in an increased susceptibility to one or more pests. (4) The early migration of the pioneers inadvertently spread many pests widely through the country as they moved from place to place. Still other pests arrived as undesirable immigrants from abroad. As a matter of fact, by far the majority of our most destructive pests are of foreign origin.

In nature, species control is largely biological and ecological in character. Most species have tremendous reproductive powers, but against each species there is arrayed a variety of dynamic forces which tend to keep plant and animal populations in a state of near equilibrium. Since these natural forces are effective in establishing limitations on species, man has attempted to emulate them in controlling those organisms he classifies as pests, with considerable success in some instances.

In considering control from the long-term point of view, pest population management is, or should be, our ultimate objective, and to this end biological and ecological studies have become an integral part of state and federal research programs. In general, biological and ecological control measures, when developed and properly applied, have a long-lasting, and in some cases, perhaps, a permanent effect on a pest population. The almost universal adoption of such measures is necessary for effective control, however, and potentially valuable ecological control measures are in reality frequently ineffective and impractical because such widespread adoption is unattainable.

For many years man has used cultural practices to control insects and crop diseases. Plant pathologists and entomologists generally recommend that crop refuse in which pests live over winter be plowed under or destroyed. Some insects and diseases are held in check by spraying the plant refuse or by use of a dormant spray on the trees or bushes. Crop rotation is practiced quite generally, one purpose being to break the food chain and thus starve out pests.

Producers of specialty and seed crops search for geographical areas where certain pests are known not to occur and for fields where disease and insect pests are not likely to strike. Insofar as it is practical, farmers try to observe planting dates that will be most unfavorable for specific pests. And finally, strenuous efforts are being made to breed crops for resistance to diseases and insects. Although the development and adoption of such practices have resulted in important gains, the practices have limitations and usually cannot be relied upon to solve completely a pest control problem. For example, a resistant crop variety may prove effective against a specific pest for a limited time only since a strain of the pest that these plants cannot tolerate or resist may emerge. The introduction and dissemination of parasites, predators, and disease organisms have proved advantageous in controlling some insects, but these practices have definite limitations.

There are many pests for which no suitable biological or ecological control measures have been developed, and the use of pesticides is the only established practice available for economically combating the majority of our pest species.

If the use of pesticidal chemicals were to be banned, the yield of many crops would be reduced from 10 to 90 percent, and surplus food stocks would soon disappear. The prices of most food items would increase greatly. This was well illustrated in 1946 when late blight of tomatoes destroyed 25 to 50 per cent of the crop in the eastern states. In some areas canning factories were closed and the price of tomatoes on the market jumped from \$2.50 to \$12.00 or more per bushel. Some items, notably fruits and vegetables, would be very inferior in quality or totally disappear from open markets.

We know from studies conducted over the years that 40 to 80 per cent of apples produced without pesticide protection will be damaged by codling moth, and 60 to 80 per cent will be damaged by apple scab. An equal or even greater degree of damage to the fruit will be caused by other insects and diseases. In addition, the destruction caused by wood borers, scale insects, and other pests will result in the devitalization and eventual destruction of the trees themselves.

The Irish potato has not been successfully produced without the use of insecticides since 1867. In the early 1940's potato growers thought they had attained nearly maximum potato yields; they were unaware that the copper compounds used to repel leafhoppers and control plant diseases in some way inhibited yields. Then after the advent of DDT and the new carbamate type fungicides which replaced the copper compounds, potato production per acre rose rapidly from 82.9 cwt. in 1944 to 168.5 in 1954. Without the benefit of pesticides, the yield of staple fiber, cereal, and forage crops could be expected to drop drastically. Data accumulated by the United States Department of Agriculture in two studies made over periods of 32 and 20 years showed that the omission of insecticide treatments reduced cotton yields 25.5 and 41.8 per cent respectively.

Agronomists are well aware that a given acre of land is able to produce just so much dry matter in any given season. Whatever production potential is wasted in weed production cannot be used for producing the crop. With weeds partially uncontrolled, crop yields are reduced, and rampant, uncontrolled weed growth can result in almost complete suppression of crop plants so that yields are practically nil.

Other benefits to maintenance of the quality and quantity of the food supply from use of pesticides have been demonstrated. Dairy cattle produced 15 to 20 per cent more milk after fly control programs using the new organic insecticides were introduced. Treated beef cattle in Kansas averaged 50 pounds more gain per animal than did unprotected cattle when all the animals had the same food supply. The control of grasshoppers in Montana and Wyoming in one year saved enough pasture grass to produce about eleven million pounds of beef. These random examples give some indication of how severely a single insect or disease may affect agricultural production. It must be remembered that there are thousands of these pests, each attacking crops and livestock in varying degrees. The battle lines between them and man are well drawn. Pests must be controlled or the food supply of the nation will decrease markedly in quantity and quality. These inescapable facts make it plain that chemicals are destined to continue as much a part of farming as the tractor.

Fertilizers

Thousands of tons of commercial fertilizers are used each year in the production of crops. Hundreds of different chemical and physical combinations of the mineral elements essential for plant growth are used. The plant food elements applied in fertilizers are taken up and utilized by plants in the same manner as are the elements occurring naturally in soils. Unused moieties of the chemical compounds in which the essential elements were applied and carrier materials used in the fertilizer mixtures remain behind.

Feed Adjuvants and Drugs

Research has shown that physiologic response of animals can be influenced by many chemicals. Some of the responses have practical significance in that they can be translated into improved efficiency of production of commercially important animal products. Thus it has become common practice for livestock feeders to include in the animal ration feed adjuvants—antibiotics, hormones, tranquilizers, and enzymes—that increase the efficiency of feed utilization and thus of animal production. Drugs may also be added to animal feeds for prophylactic or therapeutic purposes. Traces of some of these chemicals may appear in animal products used for food and thus are additives. Regulations concerning their safety are the same as those pertaining to other additives.

Packaging Materials

Present day food packages are designed to protect their contents during storage,

both before sale and in the home, from contamination by dirt and other foreign material, infestation by insects, rodents, and microorganisms, and loss or gain of moisture. They frequently are designed to protect the food from deterioration resulting from contact with air, light, heat, and contaminating gases. They may serve as containers in which the food is processed as well as receptacles in which the food is heated for serving. Highly processed foods, the convenience foods such as "heat and serve" products, prepared dinners, mixes, and the like may have specific and exacting packaging requirements.

A large number and variety of materials are required to meet all the functional needs of food packages. They range from materials of simple composition as, for example, a metal foil, to chemically complex synthetic films. The primary packaging materials, e.g., metals, glass, wood, fabric, paper, and synthetic films, are modified in many ways for particular purposes. They may be treated to withstand the solvent action of acidic, basic, neutral, alcoholic, or fatty foods they will contain, or the abrasive action of the foods; specially formulated to exclude or permit passage of gases and moisture; made shrinkable by heat or relatively heat-stable or cold-resistant, flexible or rigid, colored, transparent, or opaque.

The basic packaging materials are simple or complex chemicals and they are modified as indicated, usually by chemical means. Because they are closely associated with foods, they may contribute incidental additives to the foods they contain. This source of additives is recognized by those responsible in industry and government for the safety of the food supply.

The Safe Use of Food Additives

Use of a chemical additive, whether an intentional or incidental one, should not be permitted until its safety under conditions of the proposed use has been established beyond reasonable doubt as judged by competent experts.

Results of investigations of the physiologic, metabolic, and toxicologic effects of a proposed additive with various species of laboratory animals can establish beyond reasonable doubt whether use of an additive at specified levels is safe. Analytical methods adequate for the estimation of the additive and its conversion products in all foods in which it will be found can assure that such levels are not exceeded. The extent of the studies required on a chemical proposed for use as an additive varies with several factors, including the toxicity of the material and the amount likely to be consumed by man. The principles underlying these considerations have been discussed by the Food Protection Committee, the Joint FAO/WHO Expert Committee on Food Additives, and the Food and Drug Administration.²

² 1. Food Protection Committee. Principles and Procedures for Evaluating the Safety of Food Additives. National Academy of Sciences-National Research Council Publ.

<sup>of Food Additives. National Academy of Sciences-National Research Council Publ. 750, Washington, 1959.
2. Joint FAO/WHO Expert Committee on Food Additives. Second Report: Procedures for the Testing of Intentional Food Additives to Establish Their Safety for Use. WHO Technical Report Series No. 144, Geneva, 1958. (FAO Nutrition Meetings Report Series No. 17, Rome, 1958.)
3. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the United States, Baltimore, 1959.</sup>

The evaluation of the hazard associated with a proposed use of an additive is based on a number of factors. Some of the important ones are: mature, conservative judgment of what the results of laboratory studies mean in terms of human toxicity; knowledge of the maximum amount of the additive likely to be present in any reasonable diet; and knowledge of whether and to what extent other similar or similarly acting chemicals are present in the diet.

Hazard versus Toxicity

Distinction must be made between the hazard associated with use of an additive and the toxicity of the material. *Toxicity* is the capacity of a substance to produce injury; *hazard* is the probability that injury will result from use of a substance in a proposed quantity and manner. *Safety* is the practical certainty that injury will not result from such use.

The fact that an additive may give rise to adverse effects when taken in large amounts does not necessarily mean that its proper use will entail a hazard to man. As already indicated, additives can be used without hazard in food on the basis of information gained from investigations carried out to determine the toxicity of the materials to laboratory animals. Through consideration of the toxicity of the additive, the amount proposed for inclusion in foods, and the variety and types of foods to which it is proposed to be added, it is possible to reach a reasonable judgment of the hazard involved. Legal measures are designed to protect the public from the presence, in the food supply, of any additives that have not been demonstrated to be safe under the recommended conditions of use.

Present Situation

In recent years there has been considerable discussion of the possibility that hazards may result from the use of additives in the production and processing of foods. There has been no justification for any of the exaggerated viewpoints that have been expressed, but it is true that many new chemicals have been and are being introduced and that it is well to examine the existing situation.

The use of a few materials as food additives has been discontinued as a result of new information concerning their toxicology in animals, even though such use had caused no observable effects in man. Thus, coumarin, a component of vanilla-like flavoring preparations; safrole, a flavoring material used in some beverages; nitrogen trichloride or Agene which was used at one time to bleach flour; and several synthetic food colorings are no longer approved, under Food and Drug Administration regulations, for food use. However, there is no evidence that consumption of food in which these additives were properly used, or that the proper use of any of the new materials in crop production or processing of food, has resulted in epidemics or endangered health. On the contrary, the nutritional quality and sanitary characteristics of the food supply have been maintained and improved by the use of chemicals in the production, processing, and storing of foods. Extensive study and the exercise of great care by both industry and government have contributed to this result.

Responsibilities and Activities of Industry in Assuring Safety

The first evaluation of toxicity of chemicals that might be used in foods is made by the companies which create them. This is necessary to protect the employees who handle the materials in laboratories and factories. Toxicologic investigations are started as soon as a new material shows promise of being useful. The first experiments may be made in the manufacturers' own laboratories or in private toxicologic laboratories. In addition, some of these companies have developed fellowship and grant-in-aid programs with colleges, universities, and hospitals where they can secure research services and advice from competent scientists.

Most pesticide manufacturers have conducted acute toxicity measurements on at least one animal species by the time they have completed laboratory studies on the usefulness of chemicals under consideration. Chronic toxicity studies may be made while the material is being tested in experimental field plots. Governmental agencies cooperate with industry so that the necessary field experiments can be conducted on a limited commercial scale while toxicologic research is still in progress. Pesticidal chemicals are rarely accepted for use with less than three to five years of experimentation.

Many food processors also have established their own laboratories, and much of the progress in detecting residues of pesticides and in developing methods of removing traces of these chemicals has come from these sources. In addition, they have sponsored extensive research in colleges and universities.

Although responsible chemical manufacturers and food processors carry out extensive toxicity studies on the food additives they are recommending for use, there may be honest differences of opinion in assessing the hazards involved. These differences of opinion can usually be resolved by further study and consultation with appropriate governmental or scientific agencies.

Functions of Federal and State Agencies in Assuring Safety

Several federal agencies participate in assuring the safety of the food supply. They function by the administration of different laws and usually have both regulatory and research responsibilities.

The United States Public Health Service is responsible for public health in its broadest aspects. Investigations are made into the use of chemicals to control diseases and insects affecting man, the effects of exposure of man to these chemicals during manufacturing and application in the field, and the effect of the ingested chemicals on man. In addition to using small animals for research, the Service also performs epidemiological studies and carries out clinical investigations on human subjects. The Public Health Service also acts in an advisory capacity to state and local health departments in devising and enforcing ordinances regulating the handling of food and milk. And finally, it sponsors an extensive program in support of research in the fields of toxicology, nutrition, and environmental health.

The Meat Inspection Division of the United States Department of Agriculture controls the use of chemical additives in meat and meat food products under authority of the Meat Inspection Act of 1907, which provides for special inspectors in any establishment processing meat foods for interstate or foreign commerce. Under this Act, no chemical additives may be used in meat or meat products without the approval of the Division. Similarly, the Inspection Branch of the Poultry Division administers the Poultry Products Inspection Act of 1957.

The Plant Pest Control Division of the United States Department of Agriculture is responsible for the registration of all pesticides under the Insecticide, Fungicide, and Rodenticide Act of 1947. Before any pesticide can be sold interstate, data must be submitted on its ability to control pests, its safety for use by spray operators and on crops, its effects on quality and safety of food, and the potential damage to other forms of life and to soil. This Division does not conduct research of this type, but depends on scientists in the Agricultural Research Administration for advice on usefulness, and on the toxicologists in the Public Health Service and in the Food and Drug Administration for opinions on safety for the proposed use.

The Secretary of Health, Education, and Welfare is charged with the responsibility of enforcing the Food, Drug and Cosmetic Act of 1938. He has, among other powers, the power to prevent shipment in interstate commerce of any adulterated or misbranded food, and is also responsible for the establishment of definitions and standards of identity for food products. The Food and Drug Administration is the agency through which the Secretary acts in this capacity. It maintains elaborate toxicology laboratories.

In order to provide effective control over the use of pesticide chemicals and to minimize the potential hazard from their misuse, Congress in 1954 amended the Federal Food, Drug and Cosmetic Act. The amendment provides a means of establishing safe tolerances for residues of pesticide chemicals in or on raw agricultural commodities. The term "pesticide chemical" as used in this legislation covers insecticides and other agricultural chemicals used to control a wide variety of pests. This law provides that a food shall not be marketed if it bears residues of a pesticide chemical unless

- (1) The pesticide chemical is generally recognized by experts as safe, or
- (2) Upon consideration of an adequate amount of scientific evidence, the government has established a safe tolerance for residues of the chemical or has exempted it from the requirements of a tolerance, and
- (3) If a tolerance has been established, the residues remaining on the food are within the safe tolerance.

This law requires that before a safe tolerance for a pesticide can be established, the petitioner must submit to the government the following information:

- (1) The name, chemical identity, and composition of the pesticide chemical,
- (2) the amount, frequency, and time of application of the pesticide chemical,
- (3) full reports of investigations made with respect to the safety of the pesticide chemical,
- (4) the results of tests on the amount of residue remaining, including description of the analytical methods used, and
- (5) practicable methods for removing residues if excessive.

The petition should also give the proposed tolerance, if any, and reasonable grounds in support of this request. Since 1954, the Food and Drug Administration has established over 2,000 tolerances at different levels and for various crops for

over 100 pesticide chemicals. Continuous checks are conducted for residues of pesticides on raw agricultural commodities. In general, residues found are well within the limits established, but occasionally it is necessary to remove a shipment of food from interstate commerce owing to excessive amounts. However, most of these instances are the result of the misuse of the pesticide.

The Federal Food, Drug and Cosmetic Act of 1938 prohibited the addition of any poisonous or deleterious substance to a food. However, it did not provide adequate protection against those chemicals which might be used before being tested sufficiently to determine whether or not they were harmful. The law was amended in 1958, therefore, to provide such protection.

The term "food additive" under this new legislation means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use."³ For the purposes of this amendment, pesticide chemicals in or on raw agricultural commodities (since the use of these materials is governed by other provisions of the law) and substances used in accordance with a sanction or approval granted prior to the enactment of this legislation are not classified as additives.

Food and chemical manufacturers are now required to file a petition with respect to any intended use of a food additive, as defined in this legislation, proposing the issuance of a regulation prescribing the conditions under which the additive may be safely used. Such a petition must contain the following information:

- (1) the name and all pertinent information including, where available, the chemical identity and composition,
- (2) a statement of the conditions of the proposed use of such additive,
- (3) all relevant data on the effect the additive is intended to produce and the quantity required,
- (4) a description of a practicable method for the determination of the additive in or on food, and
- (5) full reports of investigations made with respect to the safety for use of the additive.

If, after consideration of these data, the scientists of the Food and Drug Administration believe that the additive will be safe, a regulation is issued permitting its use. Such a regulation may place a limit or tolerance on the amount that may be used. However, according to the 1958 amendment, "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is

^a This legal definition differs from that given on page 3 which defines "food additive" as used throughout this statement.

found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." If the evidence regarding the safety for use of the substance is not considered adequate, the additive will not be permitted. The law applies to any residues which may carry over into meat, milk, or eggs as a result of the use of the substance in animal feeds. It further specifies that the additive shall not be used in an amount greater than that required to produce the desired effect and shall not result in deception of the consumer. The Food and Drug inspectors are continuously on the lookout for foods containing any additives not cleared by FDA under the new law.

In 1960 the Federal Food, Drug and Cosmetic Act was further amended to bring the sections dealing with color additives into accord with those pertaining to other additives.

In addition to the federal law, most states have laws pertaining to the safety of foods. These laws are administered by either the department of public health or department of agriculture of the various states. Some of these laws are modeled on a uniform pattern, while others vary from the pattern in important respects. Efforts are being made to encourage the standardization of the state laws so that all foods will meet uniform standards of safety.

Looking Ahead

As our population grows and becomes increasingly urbanized, less and less agricultural land per capita and proportionately less of the population can be devoted to the production of food. To provide a constant, wholesome, and adequate supply of food for this population, increased production per acre and per man, and increased reliance on protection of the food from deterioration during storage and distribution, will be required. Technologic and scientific applications will have to assume increasing roles in providing and protecting the food supply. New chemical aids to production, processing, packaging, and distribution will be among those applications.

Experience has amply demonstrated that chemical aids of this kind can be used safely and beneficially. Competent, strong regulatory agencies and a public spirited, ethical industry give confidence that they will be so used in the future.