The Pure Food Law

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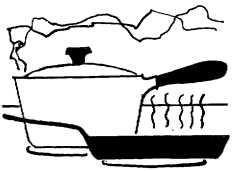

MANY consumers are worried about the safety and nutritive value of our foods. They ask if the chemicals used in them are harmless, whether modern processing methods rob foods of their natural vitamins, and whether there is any basis for the information peddled by nutrition cultists and quacks with "health foods" to sell.

The public does not know enough about the workings of food standards and the other instruments for protecting consumers under Federal law.

Federal food laws for more than half a century have been dedicated to safety, wholesomeness, and the type of labeling that will permit citizens to make intelligent selections in their purchases. Telling people what to eat is attempted by education rather than by regulation. Their choice affects the whole food industry, for in the long run the practices of manufacturers reflect consumers' wishes.

The Federal Food, Drug, and Cosmetic Act (our national pure food and drug law) prohibits the movement in interstate commerce of adulterated or misbranded food. It broadly defines adulteration and misbranding and directs the Secretary of Health, Education, and Welfare to supplement some provisions of the law with more detailed and technical specifications by administrative regulations.

These supplementary regulations for foods include definitions and standards, selection and certification of safe and suitable coal tar colors, labeling requirements for special dietary foods, and tolerances for safe amounts of pesticidal residues that may remain on raw agricultural commodities and for safe amounts of additives in food.

The Food and Drug Administration is the agency named to enforce this law and the regulations implementing it for products other than meat and poultry.

A small organization as Government agencies go, the Food and Drug Administration has a staff of about 1,400 to cover not only foods but drugs, devices, and cosmetics as well. About 60 percent of its employees are assigned to the 17 district offices throughout the country, from which factory and warehouse inspections are made and samples are collected for testing in district laboratories or in Washington staff laboratories when special analyses are required.

Adulterated and misbranded prod-

ucts may be removed from the market by Federal court seizures. Persons and firms responsible for the violations may be prosecuted under criminal court proceedings, and potential violators may be restrained by the court from unlawful practices.

The Food and Drug Administration in 1958 seized 824 shipments of food, filed 91 criminal prosecutions against alleged violators of the food provisions of the act, and requested 17 injunctions to restrain manufacturers and storers of food from further violative practices.

Filth or decomposition accounted for most of the actions and for 78 percent (5,466 tons) of the total volume seized. An additional 19 percent (1,333 tons) resulted from contamination by deleterious ingredients, mainly excessive residues of pesticides.

Most manufacturers have the will and the knowledge to produce clean, safe, and accurately labeled foods and voluntarily consult with the Food and Drug Administration when new problems develop. In general, court proceedings are needed only to protect the public from the ignorant, the heedless, and the greedy.

The many skills needed to administer the law call for a scientific organization. New manufacturing processes require new methods of inspection and analysis and may require long studies of safety and effects on nutrient values. Normal composition of foods must be established before debasement can be detected and proved to the satisfaction of the court. Proof that claims in adroitly phrased labeling are misleading may require the help of experts in public opinion analysis to determine the impression prospective purchasers may gain from the label.

It is becoming easier to conceal substitution or inferiority from ordinary observation in today's processed, compounded, packaged foods. The housewife is becoming more and more dependent on the enforcement of labeling requirements.

No official standards have been promulgated to specify the proportion of the more desirable ingredients such products as ready mixes and heat-and-serve items must contain, and price competition frequently leads to lowering of quality. The law comes into play, however, to require the labeling of unstandardized foods to be truthful and to avoid sins of omission.

Failure to reveal material facts on the label constitutes misbranding if it may lead to deception of the consumer. Valuable constituents may not be omitted or abstracted without appropriate declaration on the label.

FOOD STANDARDS promote honesty and nutritional advances.

The definitions and standards of identity that have been established for many of our staple foods have been called the Nation's most important cookbook. They specify the normal composition of the food—the required ingredients and certain permissible ingredients that may be added at the option of the manufacturer.

Once a standard goes into effect, only the products that meet the specifications may bear the name of that food.

The standards are issued to promote honesty and fair dealing in the interest of consumers. Although the housewife may not know the details of the specifications, she knows what to expect when she buys a standardized food by name. The label need not list the required ingredients, but some optional ingredients, such as the type of sirup used in canned fruit, are stated.

The manufacturer knows the specifications. He knows that he and his competitors must follow them. They are a protection for the honest manufacturer against the chiselers.

The enforcement officer uses them as a yardstick to determine whether a food is adulterated or misbranded. Trial courts do not have to determine, as they did under the 1906 law, what the standard should be for a product charged to be in violation but only

whether it meets the official standard.

Originally the law provided that public hearings be held for interested parties to present their views on new standards or amendments to existing ones and that the final regulation be based entirely on the evidence recorded. Many of the hearings were long and costly to all concerned under this procedure.

The law was amended in 1954 to require hearings only when genuine controversy arises concerning specific proposals. All interested parties have the opportunity, as before, to comment on the proposed regulations, which are published in the Federal Register.

Definitions and standards of identity cover plain and enriched foods, with no middle ground for the type of partial enrichment that may mislead the purchaser. Leading nutritionists of the country have assisted in formulating the criteria for supplementing foods to meet the country's nutritional needs.

Basically, this policy is aimed at maintaining good nutrition as well as correcting deficiencies in the diets of significant segments of the general population. If a particular nutrient is to be added to a specific food, there should be clear indications of probable advantage from increased intake of the nutrient, assurance that the food concerned will be an effective vehicle for distributing the nutrient to be added, and evidence that such an addition will not interfere with the achievement of a diet that is good in other respects.

These principles were originally formulated by the Food and Nutrition Board of the National Academy of Sciences-National Research Council in response to a request of the Commissioner of Food and Drugs in 1941. The Council on Foods and Nutrition of the American Medical Association joined the Food and Nutrition Board in issuing a revision of the statement in 1953. They have been invaluable guides to the Food and Drug Administration.

Legal standards for the following staple foods containing added nutritive ingredients have been established: Enriched flour, enriched cornmeal and grits, enriched rice, enriched macaroni and noodles, enriched bread and rolls, evaporated milk with vitamin D, and margarine with added vitamin A. Standards for the same kind of foods without vitamin and mineral addition have also been established. This gives the public a freedom of choice, except in States that require that all items in certain classes be enriched. Even in other States, public preference for enriched foods has virtually eliminated plain foods in some of these classes from the retail market.

Our present knowledge of nutrition has developed, to a large degree, since the passage of the Food and Drugs Act of 1906.

The word "vitamin" was coined in 1912, but not until 1926 were regulatory examinations made of products for their vitamin content. Cod-liver oil was the first. Discoveries between 1910 and 1930 that established that vitamins A, B, C, and D are essential to man resulted in commercial production during the next decade.

The commercial application of the rapidly increasing knowledge of nutrition was still in its infancy, however, when the Food, Drug, and Cosmetic Act of 1938 was passed. This revised law gave broad authority to regulate the labeling of foods claiming special nutritive benefits.

In recognition of the difficult labeling problems for foods for special dietary uses, the Secretary of the Department of Health, Education, and Welfare is given administrative power to prescribe the type of labeling necessary to inform purchasers of the value of such foods for their intended uses.

SPECIAL DIETARY FOODS must be informatively labeled.

Public hearings were conducted in 1940 to establish regulations for the labeling of foods for special dietary uses, and the regulations published in November 1941 were based on the evidence recorded at the hearings.

The unit of measurement adopted for vitamins and minerals and the products enriched with them is based on Minimum Daily Requirements for them, called MDR for short. The percentage of the MDR that will be supplied by the quantity of the dietary item normally consumed in a day must be declared on the label. If the article contains vitamins and minerals other than those for which the MDR has been established, that fact must be stated on the label.

Apart from vitamin or mineral content, some foods for special dietary purposes are used in the management of diseases, such as diabetes and certain types of heart conditions. Others are used for infants, the aged, the obese, the allergic, and the pregnant.

Without going into details about the labeling of each, which are available in Food, Drug, and Cosmetic Regulations, Part 125, let us consider the problems and resulting regulations for low-sodium foods. These products became important a few years ago when it was shown that a low intake of sodium was important in the control of certain types of high blood pressure.

Many consumers started to demand unsalted foods, and processors promptly responded. Some had the false impression that foods with "no salt added" would accomplish the results scientists had announced. They did not know that sodium is a natural constituent of many foods and that others are increased in sodium content by the addition of monosodium glutamate seasoning, or of sodium propionate to prevent mold, or from other processing practices.

A survey of "low-salt" and "low-sodium" foods on the market disclosed this lack of uniformity and frequently the misleading nature of the composition and labeling of such products. The Food and Drug Administration formulated new regulations on the basis of the survey, and a public hearing was held.

The regulations, announced on June 30, 1954, require that if a food is offered as a means of regulating the intake of sodium or salt, the label shall state the number of milligrams of sodium in 100 grams of the product and in the quantity constituting an average serving of it. Declaration of the sodium content of average servings is needed particularly in dealing with condiments, crackers, and other items ordinarily consumed in small amounts. A relatively small number of seizures have been necessary because of failure to label low-sodium products as required or to measure the sodium content accurately. Some of the early producers of such items, who did not have the equipment or expert skills required, have turned to other fields that require less precision.

NUTRITIONAL QUACKERY is a health problem as well as an economic one.

In the wake of scientific advances there often follows a host of persons who will misinterpret them and exploit them for private gain.

That has been true in the field of nutrition. The nutritionist studies the long-range benefits to the public health from new scientific findings, withholds premature endorsement, and has confidence that future research holds great promise. For example, the 1939 Yearbook of Agriculture, in the chapter, "Are There More Vitamins?" said that studies of the use of milk in deficiency diseases have added much to practical knowledge, and added: "But it is obvious that this knowledge is very rapidly changing and still incomplete, and that it must be consistently reappraised in the light of more recent developments."

The exploiting promoter of food supplements, on the other hand, does not wait for the facts or the possibility of different findings in the future. He hastens to cash in before all the facts are known.

Those interested only in profits employ clever copywriters to promote products by pseudoscientific statements, using half-truths, innuendo, and gross exaggeration to build up a

scare psychology that will persuade people to buy nutritional supplements. Some of these sold on a "contract basis" cost as much as 20 dollars a month for each adult in the family and about half that for each child. This cost is often taken from the family food budget, which would supply an adequate diet if used for foods readily available throughout the country.

The American Medical Association estimates that nutritional quackery is costing 10 million Americans more than 500 million dollars a year.

Misleading promotion of food supplements relies heavily on the false theory that today's food supply does not provide essential nutrients.

An extensive mythology of nutrition has been built up through pseudoscientific periodicals, books, magazine articles, and other media, as well as product advertising. Much of this is highly critical of modern commercial foods; at the same time it promotes various so-called natural or organically grown food items. Many readers of such literature accept it blindly with great faith and zeal. Always ready to believe every new idea and to buy every new "health food" that is suggested to them, they keep the promoters of diet fads in business.

The latter occasionally misjudge, and break, the law. Two such went to jail in 1957 for making "medicine man" claims in selling simple food supplements. One was a lecture-hall promoter. The other sold his vitamin products through door-to-door agents.

It is estimated that approximately 50 thousand canvassers now sell vitamin and mineral food supplements in the United States. These agents are not qualified to advise the public on matters of diet and health, yet many of them are in a sense "practicing medicine without a license." To make sales, they do not hesitate, in the privacy of the home, to recommend their products for the treatment of any disease condition. When this leads to delay in obtaining competent medical treatment, it is very serious.

Sales agents for vitamins are a fertile source of misinformation about food. To pave the way for sales, they commonly utilize a number of false theories that are calculated to undermine confidence in the food supply.

This type of false and misleading information was involved in the second of the two cases I mentioned. The manufacturer was convicted for supplying sales literature to agents, which falsely represented that "Nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods. . . . All illnesses and diseases of mankind are due to improper nutrition. . . . Said articles would be effective in the cure, treatment, and prevention of the ills and diseases of mankind."

It was also claimed that certain specific diseases would be effectively treated or prevented, including diabetes, polio, tuberculosis, and cancer—all conditions that are not subject to treatment with vitamins or food supplements.

Each of these charges was contested and litigated in the trial. Testimony of outstanding medical and nutrition experts was introduced by the Government to disprove not only the claims for treatment of disease but also the false statements concerning the effects of soil depletion and food processing. The jury found the defendant guilty, and he was sentenced to a year in prison. The court of appeals upheld the conviction in a detailed opinion, which the Supreme Court declined to review.

Regarding soil depletion as a cause of malnutrition, there is no scientific basis for the theory that crops grown on poor soil or with the help of chemical fertilizers are nutritionally inferior in any way. On the contrary, research has shown that while soils may be so depleted that they will no longer yield good crops, the nutritional values of such crops are not affected by the soil or the fertilizer.

L. A. Maynard, who testified for the Government at the trial, summarized these findings in the Journal of the American Medical Association, August 11, 1956, page 1478. The only disease of man that is known to be associated with any deficiency of soil or water is simple goiter due to the lack of iodine in some areas. This disease has become quite rare as a result of the widespread use of iodized salt.

It is true that some methods of food processing and cooking do result in removing or reducing some vitamins and minerals contained in foods. But this is routinely exaggerated by food quacks, who conveniently overlook the fact that modern food-processing methods have been devised to preserve nutritional values or to restore them to foods. Also ignored is the great variety of the American food supply, which in itself is a protection against deficiencies in diet.

The other man jailed for such claims in 1957 is a "health lecturer" with a number of prior convictions in both State and Federal courts. He invited the public to introductory free lectures, during which he sold tickets for a paid series. The lecture tuition was less than 10 percent of the cost of the products his pupils purchased. He recommended his own proprietary brand of such items as whole-wheat flour, peppermint tea, wheat germ, and honey for the prevention and cure of arthritis, cancer, liver trouble, heart trouble, and most other ills, and to "put off death to the very last minute." He repeatedly told his audiences not to buy other brands of these products; only his own (sold at several times their normal price) would achieve the promised results, he said.

After a month-long trial, the jury brought in a verdict of guilty. While on bail, pending appeal, he conducted another extensive lecture tour, during which he successfully solicited contributions from his audiences to continue his struggle against "persecution" by the "medical trust," the Better Business Bureau, and the Food and Drug Administration.

He was sentenced to a year and a day in the penitentiary. He appealed the sentence and filed suit against the Federal judge who sentenced him. The appeals court upheld the conviction.

Operators of this type, and there have been many others who followed similar patterns, are virtual successors to the medicine men who blatantly promoted patent medicines at the turn of the century. Their attempts to build up a fanatic zeal in their followers are too often successful. To combat it will require increased efforts to teach the public the facts about good nutrition, and that even the best nutrition is not a substitute for competent medical care.

The Food and Drug Administration each year seizes numerous products with exaggerated claims made by promoters who take advantage of developments of current interest in medicine and science.

A good example is the exploitation of research seeking to determine the relationship, if any, between certain heart ailments and the type of fats consumed in the diet. Food-fad promoters did not wait for the additional research needed on this question, but promptly started to market products supposed to protect the public against heart disease, for which they were worthless. A number of products containing vegetable oils and unsaturated fatty acids combined with vitamins were seized in 1958 for such claims.

Increased interest in the problems of the aging has brought forth numerous nostrums falsely claiming to benefit older people. Royal jelly in various diluted forms, offered at exorbitant prices, has been seized for rejuvenation claims on the labeling. Royal jelly is the bee food that makes queen bees productive and long lived, but is of no practical value for human beings. So much misleading information about this material appeared in certain periodicals that many people were led to

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buy it by name, without the direct labeling claims which would have made it subject to regulatory action.

Other items seized for false representations for chronic diseases of the aging include powdered grapefruit, lecithin, honey, kelp, and mixtures of vitamins and minerals with other ingredients such as oyster and egg shell, seaweed, parsley, alfalfa, rose hips, lemon peel, chlorophyll, powdered bone, and clay.

The public should distrust any suggestion of self-medication with vitamins or minerals to cure diseases of the nerves, bones, blood, liver, kidneys, heart, or digestive tract. Although a physician may employ these products in certain cases, such conditions require competent medical diagnosis and treatment.

Also to be distrusted is the claim that anyone who has "that tired feeling," or an ache or pain in almost any part of the body, is probably suffering from a "subclinical deficiency" and needs to supplement his diet with some concoction. A "subclinical vitamin deficiency" is defined as a condition in which it is not possible to obtain any observable evidence of a vitamin deficiency, but a deficiency is suspected.

Of course, no normal person can go through even a small part of his life without experiencing some of these symptoms. There is no basis for believing that they are usually due to subclinical deficiencies. Such symptoms may be caused by many other conditions than vitamin or mineral deficiencies. Advice of a competent physician is needed to identify vitamin or mineral deficiencies and to prescribe their proper treatment. The competent physician will not overlook such "musts" as calcium during pregnancy and vitamins C and D for babies and young children.

FOOD ADDITIVES present a problem that is very old. Dr. Harvey W. Wiley's campaign for the pure food law of 1906 was to a large extent a fight against chemical preservatives.

The too-common misconception that all chemicals are harmful fails to take into account salt, baking soda, vinegar, and other common chemicals used in every kitchen. Only those that may be harmful require regulation.

The law as written in 1938 protected the public against food additives that could be clearly proved to be injurious. It did not, however, require that chemicals be adequately tested and shown to be safe before they are marketed, except for coal tar colors.

Lists have been established of coal tar colors that may be used in foods, drugs, and cosmetics. Each batch of color must be tested in the Washington laboratories of the Food and Drug Administration to determine that it is of satisfactory quality and purity. Several colors were removed from the permitted list in 1955 because modern testing procedures showed that they did not meet the law's requirements.

When we talk about chemical food additives, people often bring up the use of insecticides on our fruit and vegetable crops. There are more than a hundred of these pesticide chemicals. Some are relatively harmless to people. Some are highly toxic. Some quickly disappear before the crop is harvested. Many leave traces of residue which might be harmful if the residue were excessive.

The law now contains a requirement that these materials be tested for safety before they are submitted to the Government with a request that residue tolerances be established. Under the Miller pesticide amendment, passed in 1954, safe tolerances are required to be set up limiting the amount of residue that may remain on the food crop after it is harvested. If these tolerances are exceeded, the foods can be seized and taken off the market.

The 1938 act restricted the use of most chemicals in food—even in safe quantities—unless they were required in good manufacturing practices or could not be avoided. This philosophy was unscientific because it deprived

consumers of the benefits to be derived safely from modern scientific research.

Another, more serious, defect of the 1938 law was that it did not require a manufacturer to test a new chemical before using it in food. If a manufacturer decided to use a new substance without testing it, the public was exposed unnecessarily during the 2 or 3 years required for adequate tests by the Government.

This deficiency of the 1938 act was studied by the Congress from 1950, when it formed a Select Committee to Investigate the Use of Chemicals in Food, until 1958, when it passed the food additives amendment.

The substances covered by this amendment are those additives not recognized by competent experts as having been shown to be safe under the conditions of their intended use. Antioxidants, mold inhibitors, rancidity prevention agents and other preservatives, emulsifiers, and stabilizers are examples of the types of additives that are covered.

Substances commonly used in food before January 1, 1958, and generally recognized as safe because of experience based on such use, are exempt from the law. Thus a great many ingredients do not have to go through the clearance procedures of the bill.

Substances that get into food accidentally, such as lead ores, for example, are not covered by the legislation. These substances, if proper precautions are taken, would not reasonably be expected to get into food, and if they do get in, the food is illegal under the basic 1938 law.

Other additives not covered by the new amendment are pesticide chemicals, which, as I mentioned, are already taken care of under the pesticide chemicals amendment, and substances that have already been approved by the Government for use in food under the Food, Drug, and Cosmetic Act, the Meat Inspection Act, or the Poultry Products Inspection Act.

The person who wants to promote a new food additive will have to test it for safety on animals and submit the results of the safety tests to the Food and Drug Administration.

Scientists of the Food and Drug Administration will study the safety data and reach an independent decision as to the suitability of the new ingredient for use in our food supply. If the evidence clearly demonstrates that the material is a suitable component of food, then the Department of Health, Education, and Welfare will issue a regulation stating safe permissible uses for the material. But if there is a question as to the safety of the additive, it will not be permitted, and the public health will be safeguarded in a way that was not possible before.

Use of an additive that promotes deception of consumers is not sanctioned. If the additive can only be used in a limited amount, to safeguard health, only the quantity needed to accomplish the intended technical or physical effect will be allowed, and this amount will be allowed only if it is safe. In case the Government and industry are unable to agree about the contemplated use of food additives, industry has a right to a public hearing on the suitability of a proposed additive and the right to appeal an adverse Government decision to the circuit court of appeals.

With this amendment, the country has the best safeguards it has been possible to develop. It provides for advances in food technology without risk to human health. The additives that go into food are there to improve the food and bring it to the housewife in better condition and in a more convenient form. The 1958 amendment is a significant advance in the protection of the welfare of consumers—all of us.

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