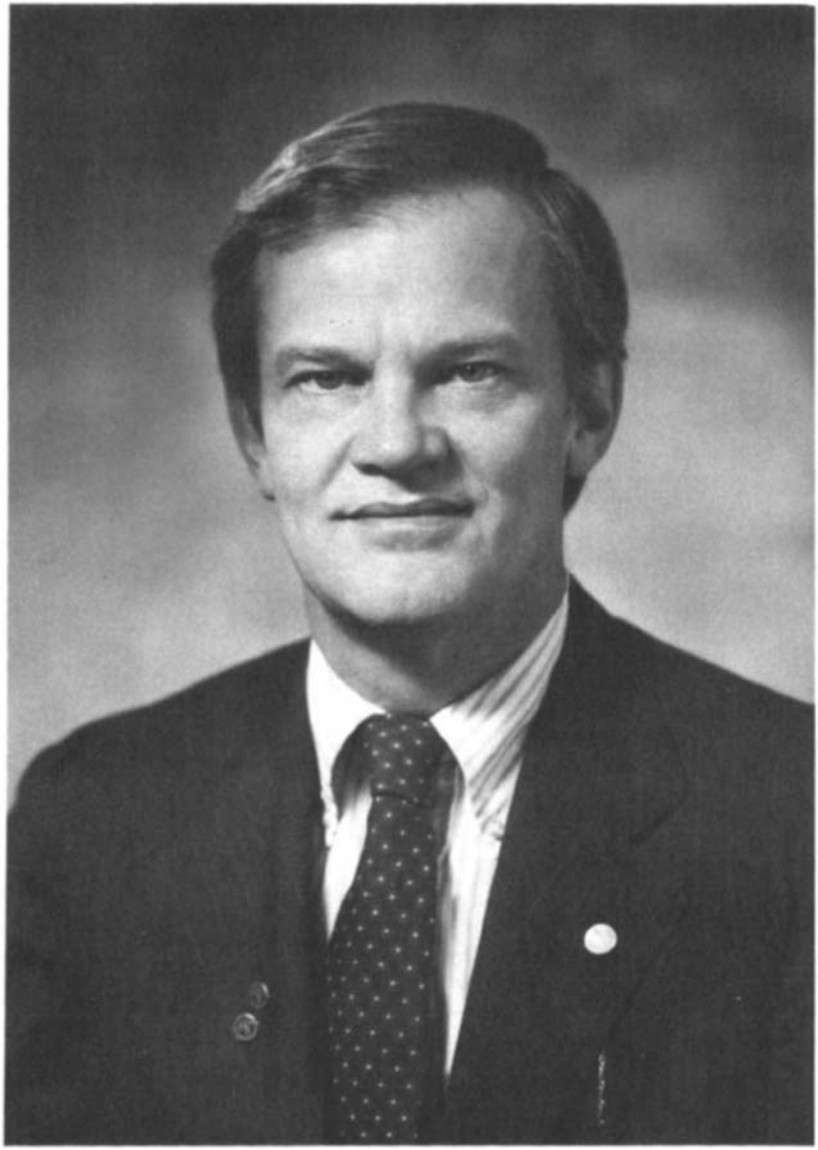

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GOVERNMENT REGULATION OF THE INTEGRITY OF THE FOOD SUPPLY

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CONTENTS

INTRODUCTION

Throughout history, civilized societies have reflected a deep interest in, and concern about, the integrity of the food supply. Long before the development of the distinct scientific discipline of nutrition, philosophers and physicians paid close attention to the role of the daily diet in individual and public health.

For at least 2000 years, indeed, from the time of Hippocrates to the dawn of modern medicine, there was little distinction made between food and drugs. The practice of medicine itself consisted largely of the wise choice of natural food products.

With the beginning of modern therapeutics and nutrition a century ago, and the eventual discovery and understanding of the biochemical role of discreet

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nutrients, the overall importance of the role of diet in human health was temporarily obscured. More recently, however, this factor has come back into focus and now commands as much attention as it did in years past.

For centuries, government has had an essential role in assuring the integrity of the food supply. The focus of the regulatory function has, of course, evolved over the years. It originated essentially as a means to protect against fraud in the marketplace. Very quickly, it expanded into a mechanism for preventing the sale of unsafe food. As the science of nutrition has developed, it has assumed the role of protecting the nutritional integrity of the food supply as well.

This chapter traces these historical developments and places them in the context of related scientific advances. It concludes with thoughts about the future collaboration of regulation and nutrition in the light of new scientific knowledge.

ANCIENT TIMES

Hippocrates (circa 460 BC) clearly recognized the essential relationship between food and health, pointing out that "differences of diseases depend on nutriment" (24). He stated that it is necessary to know "the power possessed severally by all the foods and drinks of our regimen, both the power each of them possessed by nature and the power given them by the constraint of human art" (25). He urged close study of the daily dietary regimen associated with good health: "So in fixing regimen pay attention to age, season, habit, land, and physique, and counteract the prevailing heat and cold. For in this way will the best health be enjoyed" (26). Hippocrates concluded that either too little or too much food "harms the man just as much" (27).

The first great botanical treatise on plants as a source of food and medicine, the *Enquiry Into Plants* written by Theophrastus (370–285 BC), reported on the use of artificial preservatives and flavors in the food supply even at that early date. Theophrastus noted that "even uncompounded substances have certain odors which men endeavor to assist by artificial means even as they assist nature in producing palatable tastes" (58). He reported that items of commerce, such as balsam gum, were mixed with adulterants for economic reasons (57). The treatise *On Agriculture* by Cato (234–149 BC) recommended the addition to wine of boiled-down must, salt, marble dust, and resin, and included a method "to determine whether wine has been watered" (10).

Pliny the Elder (23–79 AD) found widespread adulteration throughout the food supply. He described, for example, the adulteration of bread with chalk, vegetable meals, and even cattle fodder (45). He pointed out that pepper was commonly adulterated with juniper berries (43). Indeed, his *Natural History* is replete with so many references to adulteration of the natural food and drug supply that he observed: "So many poisons are employed to force wine to suit our taste—and we are surprised that it is not wholesome!" (44). Pliny, describ-

ing "the remedies that are in the control of a man's will," stated that "the greatest aid to health is moderation in food" (47). He urged the value of a kitchen garden for "harmless" market supplies (46). Galen (131–201 AD), a renowned Roman physician who followed the philosophical tradition of the School of Hippocrates, similarly warned against the adulteration of common food products, such as pepper (17).

Pliny reflected the layperson's distrust of medical practice that has existed throughout the ages:

> Accordingly, heaven knows, the medical profession is the only one in which anybody professing to be a physician is at once trusted, although nowhere else is an untruth more dangerous. We pay however no attention to the danger, so great for each of us is the seductive sweetness of wishful thinking. Besides this, there is no law to punish criminal ignorance, no instance of retribution. Physicians acquire their knowledge from our dangers, making experiments at the cost of our lives. Only a physician can commit homicide with complete impunity (48).

In contrast, Galen, a physician, reflected complete confidence in the knowledge and ability of physicians to establish sound diets that would advance the public health. Indeed, Galen was the first to emphasize the difference between the art of cookery and the science of nutrition:

> Therefore, as I said a little while ago, as the trainer is the attendant of the gymnast, so the cook is of the physician; and this has now been demonstrated. For the cook prepares either beets or lentils or barley, sometimes in one way sometimes in another, but does not know the effect of the preparation, or which of the preparations is best. But the physician, though not able to prepare any of these things as well as the cook, knows the effect of every preparation (16)

Galen advocated moderation as the principal rule for sound dietary habits: "And in the nature of eating and drinking, in quantity, quality and faculty, the objective again there also is moderation, so as to take neither too much nor too little, but as much as, digested and distributed and nourishing the body well, if need be will supply symmetry to the still growing parts, and leave nothing superfluous or lacking" (18). Despite all the advances in medical science and nutrition during the intervening eighteen centuries, it is doubtful that anyone has improved materially on that fundamental rule of sound nutrition.

The Roman civil law reflected the concern expressed by these early writers about preserving the integrity of the food supply. Fraud in the sale of merchandise not only gave rise to a private right of action, but also constituted the offense of *stellionatus,* which included the adulteration of food: "And, where anyone has substituted some article for another; or has put aside goods which he was obliged to deliver, or has spoiled them, he is also liable for this offense" (52). Although *stellionatus* was technically not a crime, it was comparable to a civil offense under present law, subject to government prosecution, and resulted in such punishment as condemnation to the mines or temporary exile.

THE ENGLISH EXPERIENCE, 1200–1875

Following Galen and the fall of the Roman Empire, nontheological scholarly writing lapsed into disuse for roughly a millenium. At the end of the Dark Ages, however, concern about the food supply once again emerged. Nowhere is this more evident.than in the experience reflected in the laws of England at that time.

Initial governmental concern came in the form of regulating the price of bread, and perhaps other staple food products as well. It did not take long for the English government to realize that the price of food could be regulated only in relation to the quality of that food. Accordingly, the early English regulatory statutes prohibited the adulteration of any staple food that was also subject to price controls.

These regulatory enactments, called assizes, were codified by Parliament in 1266 (80). The 1266 statutes prohibited the sale of any "corrupted wine" or of any meat, fish, bread, or water that was "not wholesome for man's body" or that was kept so long "that it loseth its natural wholesomeness." These laws, with periodic amendments, continued in effect throughout England until 1844 (82). They were supplemented, from time to time, with additional statutes directed at other food commodities that became a source of commerce, such as butter, cheese, and spices (75–79, 81).

In addition to the statutes enacted by Parliament, local cities enacted their own ordinances to prevent food adulteration (49, 50). The judicially-created common law, reflecting the principles underlying the statutes and ordinances, created both a civil cause of action for damages for any aggrieved party, and a criminal offense as well (8, 12). Numerous examples of early enforcement actions against the purveyors of adulterated food may be found in the records of the City of London. (49).

Finally, the trade guilds, which had their origins as early as the Norman conquest, also performed a major regulatory function. These guilds covered every important food category, including the bakers (59), butchers (31), cooks (41), grocers (22), fruiters (20), poulters (30), and salters (73). Using their power to search all premises and to seize all unwholesome products, the guilds exercised a relatively strong regulatory power in policing the marketing of food to the public.

THE DEVELOPMENT OF CHEMISTRY AND THE ACCUM TREATISE

As the Renaissance emerged out of the Middle Ages, a few pioneers in the newly developing discipline of "chymistry" broke away from the philosophic mysticism of alchemy and initiated modern scientific inquiry. While earlier

analyses of food adulteration depended almost completely upon taste and sight, the new science of chemistry, led particularly by Boyle (7), slowly began to develop chemical methods of analysis.

Throughout the 18th century, there were attacks upon the food industry for widespread adulteration of their products (4, 5, 34, 35, 40, 51, 53), as well as staunch defenses of the purity of the food supply (13, 28, 56). The regulatory role of the government in protecting against food adulteration remained intact, but the lack of any sophisticated methods for detecting adulteration undoubtedly precluded enforcement except in clear cases.

By the beginning of the 19th century, however, chemical analysis had advanced to the point where at least qualitative methods had become available for detecting many common food adulterants. In 1820, a German-born chemist, Frederick Accum, working in England, published his landmark *Treatise on Adulterations of Food and Culinary Poisons* (1). In his treatise, Accum undertook to describe both the numerous kinds of adulteration practiced at that time and the various methods available to detect them. His treatise was an immediate and worldwide success. It caught the attention of newspapers and the public everywhere. The treatise spawned a generation of books on food adulteration in England (e.g. Ref. 21), the United States (e.g. Refs. 6, 9, 15, 23), and Europe (e.g. Ref. 11). Ultimately, it resulted in the modern era of food regulatory statutes.

Ironically, Accum's treatise was published near the height of the laissez faire era in England, the first great era of regulatory reform. Countering the trend against regulation at that time, the English Parliament enacted statutes in 1860 (83), 1872 (84), and 1875 (85), replacing the assizes that had been repealed in 1844 (82), to assure strong regulatory authority to protect the integrity of the food supply.

As would be expected, these English statutes reflect only the state of scientific, medical, and nutritional knowledge at that time. There is no specific mention in those statutes of nutrition. Instead, they broadly prohibited any form of food adulteration, thus assuring that food would reach the marketplace and the consumer in its natural and most nutritious state. Indeed, the prohibitions against adulteration contained in these statutes encompass the same prohibitions contained in our most modern food regulatory statutes, and were in fact the models for the 1906 and 1938 legislation (Refs. 178, 181 respectively) enacted in the United States.

THE AMERICAN EXPERIENCE

The people who settled in the American colonies brought with them the tradition of food regulation established in England. Early colonial laws were, indeed, indistinguishable from those that prevailed in England at the time

(29). American common law similarly developed on the basis of English precedent.

The American Revolution did not change food regulation. Early state laws continued to follow the English law. As the United States emerged from a rural economy and urban centers developed that depended more heavily on commerce in food products, additional statutes and ordinances were enacted by cities, counties, and states to assure the integrity of those products. Following Lemuel Shattuck's landmark report on public health and sanitation in 1850, which urged the establishment of local boards of health to control, among other things, the wholesomeness of the food supply (55), the enactment of state laws accelerated in the last half of the 19th century (62).

Congress created a Department of Agriculture in 1862 (166), and included within it a Division of Chemistry (167, 168) that was later to be the focal point for all food protection activities and for the initial departmental interest in nutrition. In 1883, Congress enacted its first specific food protection law, to prevent the importation of adulterated tea (169, 173, 189). This was followed in 1896 by the oleo-margarine statute (170, 183) and in the 1890s by laws intended to prevent the import or export of adulterated food (171, 172, 174, 175).

Throughout the last quarter of the 19th century, however, there was a growing realization of the need for a truly comprehensive and national regulatory statute governing the food supply. Following the appointment of Dr. Harvey W. Wiley as Chief Chemist, The US Department of Agriculture (USDA) issued a number of reports documenting in detail the widespread adulteration of common foods found in the marketplace (60, 71). In 1906, Congress responded by enacting the Food and Drugs Act, the first federal statute broadly prohibiting the misbranding or adulteration of food (178).

The Food And Drugs Act Of 1906

The 1906 Act broadly prohibited the adulteration or misbranding of any food product. Although the legislative history reflected no specific interest in nutrition as such, it was replete with concern about protecting the entire food supply against any form of adulteration. Thus, the final legislation prohibited both economic adulteration (the addition of any substance to make the food less valuable) and safety adulteration (the addition of any substance that may render the food injurious to health).

Although today the provisions in the 1906 Act seem in retrospect relatively primitive and simple, they had an enormous effect on the food supply. The widespread forms of outright adulteration documented by Dr. Wiley quickly came under control. Although controversy continued about the safety of particular food ingredients, a number that were clearly inappropriate for the food supply were abandoned. The new law substantially upgraded the safety and integrity of the entire food supply in the United States.

The 1906 Act lacked, however, two important kinds of provisions that have subsequently become important in protecting the nutritional quality of food: authority to establish standards of identity for particular food products, and authority to require affirmative label declaration of information relating to the nutritional content of food products.

Late in the history of the legislation that ultimately became the 1906 Act, Congress considered provisions that would have authorized USDA to establish standards of identity for food (68, 69). Even when Congress failed to include statutory authorization for food standards in the 1906 Act (70), USDA continued its longstanding efforts to establish such standards informally (54, 61, 63–65, 176, 177). Thus, during the entire period after enactment of the 1906 Act until its replacement by the 1938 Act, USDA adopted, and attempted to enforce in the courts, regulatory standards designed to protect staple food products from adulteration. Some courts upheld these standards (91), but others declined to do so (93). Imaginative labeling, moreover, was held by the courts to be sufficient to take a food product out from under the specific standards that were set (94).

The 1906 Act did not permit USDA to require that specific information on the composition or nutritional value of any food be included on the label. In 1913, Congress amended the 1906 Act specifically to require affirmative label declaration of the net quantity of contents for food products (179), but this was the only information required on food labels.

By 1933, responsibility for the 1906 Act had been transferred to the Food and Drug Administration (FDA), a separate organizational entity established within USDA to administer the Act. FDA concluded that it was time to modernize the 1906 Act, and convinced one of President Roosevelt's close advisors that legislation to accomplish this should become part of the New Deal program (14). It ultimately took from 1933 to 1938 to obtain enactment of the new legislation, and then only after a drug tragedy spurred Congress into action.

The Federal Food, Drug, and Cosmetic Act of 1938

The 1938 Act (181) contained several provisions that have assumed major importance in assuring the nutritional integrity of the American food supply. First, it strengthened the prohibition against economic adulteration of food. Second, it authorized FDA to establish mandatory food standards. Third, it prohibited any false or misleading statement in food labels or labeling. Fourth, it required any imitation food to be labeled as such. Fifth, it required the affirmative labeling of foods with particular information specified in the statute (i.e. the name and address of the manufacturer, the net quantity of contents, the name of the food, and the statement of ingredients), authorized FDA to require additional label information for special dietary foods, and required that food labels affirmatively reveal all facts material in the light of any other representations made for the product.

1938–1970 Following enactment of the 1938 Act, the economic adulteration provisions of the law, so important in assuring the integrity of the food supply in earlier years, gradually dwindled to a position of relative insignificance. The classic cases of watering milk and similar outright frauds became of relatively minor importance. With the beginning of modern food technology and the addition of countless substances to food to serve useful functions (e.g. preservatives, emulsifiers, stabilizers, and thickeners), many traditional concepts of adulteration no longer had the same meaning. It became more and more difficult to determine where unlawful adulteration stopped and lawful use of functional additives began.

FDA therefore relied primarily upon three other provisions in the 1938 Act to regulate the nutritional quality of food: the prohibition against false or misleading labeling, the authority to establish food standards, and the authority to require affirmative labeling for any special dietary food.

False or misleading labeling As the science of nutrition progressed, it became apparent to the food industry that nutritional claims for food, and particularly for vitamin-mineral products, would be very compelling to relatively unsophisticated consumers. Thousands of vitamin-mineral pills were marketed with claims that the food supply alone was inadequate for sound nutrition and with lists of nutritional deficiency diseases that the pills would prevent. Many foods were marketed with vitamin and mineral fortification.

FDA met this challenge with concerted regulatory enforcement against nutritional quackery. The Agency brought hundreds of lawsuits in the 1950s and 1960s against outright nutritional claims that it considered false or misleading and against irrational fortification of food. The cases brought against false or misleading claims were almost uniformly successful (e.g. Refs. 92, 96). The attempt to attack irrational fortification of food products by arguing that the labeling was inherently false or misleading, however, had mixed results (compare Refs. 88, 95 with 90). In a leading case, the court held that FDA could control the content of food only through food standards, as long as the specific labeling was not false or misleading (90 cf 89).

Food standards The medical profession provided the first strong impetus in this country for the fortification of food products. In the early 1930s, the Council on Foods and Nutrition of the American Medical Association (AMA) endorsed the addition of vitamin D to milk and of iodine to table salt (37). In March 1936, the AMA Council adopted the first general policy on food fortification in the United States (32). It stated that fortification should be reserved for exceptional cases where there is convincing evidence of a need for enhanced amounts of the vitamin or mineral in the general food supply and where the food to be fortified is suitable for fortification.

As early as 1938, the problem of irrational fortification of food had already become apparent. In March 1939, the AMA Council approved a statement opposing indiscriminate food fortification but supporting the addition of vitamin D to milk, vitamin A to substitutes for butter, iodine to table salt, and calcium and iron to cereal grain products (33). The statement also encouraged the restoration of vitamins and minerals to preprocessing levels in food products, which led to experimentation with the addition of vitamins to flour and bread.

In mid-1940, the National Academy of Sciences (NAS) established a Subcommittee on Medical Nutrition (which later became the Food and Nutrition Board) at the request of the National Defense Advisory Commission. Although the Subcommittee was established primarily to provide advice to the government on wartime food and nutrition issues, its strong support of food fortification had a significant effect on the food industry.

The 1938 Act authorized FDA to promulgate definitions and standards of identity for any food product. The only statutory limitations were that such standards must be "reasonable" and "promote honesty and fair dealing in the interest of consumers." FDA promptly moved to implement this extremely broad statutory authority.

In August 1940, FDA announced public hearings to establish a standard of identity for flour (119). The enrichment recommendations of AMA and NAS were presented at the hearings, and the industry joined in supporting flour enrichment through FDA standards. This marked the beginning of the FDA regulatory approach to food fortification based on the promulgation of food standards that has endured to this day. The enriched flour standard became effective on January 1, 1942 (116, 121, 122). Fortification of bread and rolls became widespread because of industry's voluntary use of enriched flour and later because the War Food Administration required fortification as well (125).

As a result of increased interest in fortified food, FDA issued a statement in July 1943 setting forth the Agency policy on addition of nutritive ingredients to food (126). FDA took the position that fortification is an implicit promise to consumers that the fortified food contains sufficient vitamins and minerals to make a substantial contribution to the nutritional welfare of persons eating that food in customary amounts. Thus, FDA said that the kinds and quantities of nutrients to be added to the food must be determined in the light of the specific nutrient deficiencies in the diet of the general population and of significant population groups, the place occupied by the food in such diets, and the suitability and effectiveness of the food as a carrier of those nutrients. FDA pointedly stated that most natural foods contain a wide variety of nutrients in significant amounts and that adequate nutrition is better assured through the choice of natural foods than through reliance on food fortification. The Agency

did, however, also endorse restoration of nutrients in those staple foods that lose significant quantities of nutrients during processing. The Agency also agreed that in some instances nutrients may be added at higher than restoration amounts or to fortify unrefined foods to correct deficiencies if the food to be fortified is an efficient carrier. That 1943 FDA statement of policy has never been revoked and remains in effect to this day.

Following World War II, food fortification continued to flourish. Consideration of the enriched bread standard, which was postponed during the war, was reopened, and the standard was promulgated in final form in May 1952 (115, 127–129). By this time, enrichment of flour and bread had been made mandatory under the laws of 26 states. FDA also established standards of identity for various enriched products, such as dairy products (114), macaroni and noodle products (117), and margarine (118).

By the early 1960s, FDA was sufficiently concerned about the possibility of overuse of nutrients that it began to consider a new, more restrictive regulatory approach. The Agency proposed regulations in 1962 to permit fortification of food using only those nutrients recognized as both essential in human nutrition and appropriate for supplementation (131). FDA specifically listed 12 nutrients that fell in this class and the ranges within which supplementation would be appropriate. Eleven other nutrients were recognized as essential but not appropriate for supplementation because deficiency symptoms are induced only under experimental conditions. In this way, FDA sought to contain the growing interest in food fortification.

After the courts held that the statutory prohibition against false or misleading labeling could not readily be used to prevent irrational food fortification (90), FDA proposed another regulation in June 1966 to limit the number of foods that could lawfully be fortified (132–135). FDA listed eight classes of foods that could be fortified and the specific nutrients which could be used in each. The Agency then convened formal public hearings on the proposed regulations (136) that ultimately were held for two years, from 1968 to 1969.

Special dietary foods The 1938 Act also broadly provided that a food shall be deemed to be misbranded "if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as [FDA] determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses." Undoubtedly because interest in food fortification and vitamin-mineral products was in its infancy in the 1930s, there is virtually no legislative history explaining the intended purpose and scope of this provision.

In November 1941, FDA promulgated its first regulations governing label statements about the special dietary properties of food (120, 123, 124). These regulations established the requirements for label declaration of the "minimum

daily requirements" for various vitamins and minerals, which remained in effect for 35 years.

At the same time that FDA proposed new regulations in the 1960s to limit fortification of food, it also proposed the first major revision of its special dietary food regulations since their promulgation in 1941 (131–135). As noted above, FDA proposed that only 12 nutrients be allowed for use in dietary food supplements. The Agency also included in these proposed regulations a prohibition against the more frequent misleading claims used for vitamin-mineral products, hoping to avoid continuous litigation on these claims in the future. All of these issues were included in the two-year public hearing conducted by the Agency during 1968–1969.

1970–1983 Even as the FDA was holding public hearings on its nutrition regulations, a political event intervened to change public attitudes about food fortification dramatically. In response to charges about hunger and malnutrition in America, President Nixon convened a White House Conference on Food, Nutrition and Health in December 1969. The Conference report made several recommendations for fortification of existing and new food products to meet national nutritional needs (74). The thrust of this report was in direct opposition to the 1966 approach of FDA.

The White House Conference represented the death knell of the restrictive approach to food fortification proposed by FDA in 1966. In its place emerged a number of new regulations, based largely on food labeling requirements rather than on rigid standards for nutrient composition.

Nutrition labeling A 1973 regulation states that the addition of any nutrient to a food or the use of any nutritional claim automatically requires full nutrition labeling in the standardized format established by FDA (109, 139, 141, 145). This regulation provides a nutritional profile of more than half the food supply for daily use by consumers.

Definition of imitation FDA defined an imitation food as a product that is designed to substitute for a traditional food but which is nutritionally inferior (108, 143, 149). If the substitute product is fortified in order to make it nutritionally equivalent or superior to the traditional food, it is no longer an imitation. This action discourages debasement of the food supply and requires nutrition labeling for any substitute food that is fortified with a nutrient.

Establishing food names Rather than attempting to adopt comprehensive standards of identity for new fabricated foods, FDA issued regulations establishing descriptive names for these products (111, 140, 147). In many in-

stances, the characteristics that FDA has determined to be important in describing these foods include their nutritional composition.

Nutrition quality guidelines FDA issued general principles governing the establishment of nutrition quality guidelines, together with one specific guideline governing frozen heat-and-serve dinners (112, 138, 148). A nutrition quality guideline prescribes the minimum level or range of nutrient composition appropriate for a given class of food. A product that complies with a guideline may state on the label that "this product provides nutrients in amounts appropriate for this class of food as determined by the US Government." A product within the class governed by the guideline that has been fortified above the level provided in the guideline must bear a label statement that "the addition of _____ to this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food." Additional nutrition guidelines have been proposed by FDA but have been held in abeyance pending promulgation of a comprehensive food fortification policy (151).

Fortification outside standards of identity FDA had long taken the position that addition to a standardized food of any nutrient prohibited by the standard made the product illegal unless it was labeled as an imitation. In the 1970s, FDA reversed this policy. It permitted the marketing, as nonstandardized foods, of the following fortified versions of foods for which existing standards do not permit the fortification involved: enriched macaroni with fortified protein (158), tomato juice enriched with vitamin C (153), and enriched raisin bread (160). FDA no longer regards these products as imitation foods.

Final special dietary food regulations Beginning in 1973, FDA published the final special dietary food regulations resulting from its 1968–1969 hearings (144, 150). Because of perceived restriction on vitamin-mineral pills, the health food industry repeatedly challenged these regulations in court (e.g. Refs. 86, 87) and persuaded Congress in 1976 to amend the 1938 Act to limit FDA authority over these products (185, 190). In the 1976 amendments, however, Congress was careful to limit FDA authority only with respect to vitamin-mineral products in tablet or capsule form, or in liquid form intended for ingestion in drops or similar small units of measure. These new restrictions do not limit FDA's authority over food fortification. They do, however, eliminate FDA's authority to place restrictions on permissible combinations of nutrients or levels of nutrients in vitamin-mineral products except for reasons of safety.

Food fortification policy In place of its 1966 proposal to restrict food fortification to eight specified classes of food, FDA issued a statement of policy on

food fortification in January 1980, setting forth general principles to govern food fortification in the future (113, 152, 161). The policy statement only provides guidelines that are not directly enforceable by FDA as legal requirements. Some food products, such as snacks, are considered by FDA to be inappropriate for any fortification. The statement of policy establishes five principles for appropriate food fortification: to correct dietary insufficiency, to restore lost nutrients, to balance calories with nutrients, to avoid nutritional inferiority, and to comply with other regulations.

Medical foods policy FDA formerly took the position that any reference to therapeutic uses of a food product automatically classified the product as a drug. Since 1970, however it has increasingly permitted limited factual claims of this nature for particular foods. For example, although FDA published a statement of policy in December 1959 declaring any label use of the term "cholesterol" and any labeling claims connecting dietary fat intake with heart disease to be illegal drug claims (130), the final nutrition labeling regulations promulgated in January 1973 specifically permitted information on cholesterol and fatty acid composition (110, 137, 142, 146). More recently, FDA has urged the food industry to disclose voluntarily the sodium content of all food products to help in the prevention of hypertension (164). Because of these and other developing policies, FDA is presently formulating a new approach to the regulation of food products labeled for medical use (36).

Diet And Health

In addition to this pervasive FDA regulation of micronutrients (vitamins and minerals), regulatory interest has increasingly focused on the broader nutritional questions about the relationship between dietary components and personal health. This concern was initially given a low priority because of the more pressing and immediate problems of food adulteration, ingredient safety, and adequate levels of essential nutrients in the food supply. As a result of substantial progress in these other areas, increased attention has been focused in the last few years on the effects of diet on health.

Since publication of the first edition of *Dietary Goals in the United States* by the Senate Select Committee on Nutrition and Human Needs in February 1977 (72), a wide variety of organizations have adopted general or specific dietary recommendations for good health (2, 3, 38, 39, 66, 67). To date, however, only a few modest steps have been taken to implement any of these dietary recommendations through regulatory action.

Eating is, after all, one of life's great pleasures, and when it comes to personal pleasure and enjoyment, Americans are notoriously unconcerned with risk. If health promotion and disease prevention programs depend solely, or even primarily, on personal self-sacrifice and abjuration, they are doomed to

failure. It would be an equally grave error for the federal government to attempt to prohibit even some of the small joys and pleasures of eating. To have any chance for success, programs of health promotion and disease prevention relating to our daily diet must avoid attempts to reduce individual freedom of choice and action, and concentrate instead upon providing attractive alternatives that are voluntarily and freely chosen, or indeed that require no change in lifestyle at all.

Fortunately, the food supply can already be manipulated to some extent to make it more healthful. Recombinant DNA techniques may also permit future manipulation of both plant and animal life to make our food supply more nutritious and healthful, thus obviating changes in the way we eat or the products we have traditionally consumed.

Nonetheless, in any consideration of the implementation of dietary recommendations in the future, the role of regulatory agencies must be given serious attention. Three federal regulatory agencies could, under present laws and regulations, have a major impact in implementing dietary recommendations: FDA, the Federal Trade Commission (FTC), and the Food and Nutrition Service (FNS) of USDA.

THE FOOD AND DRUG ADMINISTRATION The most direct way to approach the implementation of any dietary recommendation is through the regulatory mechanisms available to FDA under the 1938 Act. These mechanisms could be used to regulate the composition and labeling of all food marketed in the United States.

The three basic mechanisms set out in the 1938 Act, through which implementation of dietary recommendations could be achieved by FDA, are the provisions relating to food safety, standards of identity, and requirements for labeling. The first two impose direct control over food composition. The third provides information to consumers which may or may not change their dietary habits.

Food safety The food safety provisions permit FDA to determine when any food substance is unsafe and thus may not lawfully be marketed or must be limited to a specified level. If FDA could substantiate its position on scientific and medical grounds, it could declare that such food components as sugar, salt, saturated fatty acids, or any others, are unsafe, and could either restrict them to some safe level or prohibit them entirely.

Food standards As already discussed, the food standard provisions of the 1938 Act give FDA broad discretion to establish the composition of any item of the diet. FDA could expand current food standards to include an even greater proportion of the food supply and could directly control any food component in order to improve the nutritional quality of the food involved.

Food labeling FDA could also impose a wide variety of labeling requirements to ensure that consumers have the information to make informed decisions about the nutritional quality of the product. Such information might be limited to quantitative data stating the percent or amount of any component of the food, or it might also include additional explanatory information about the health benefits or risks involved.

THE FEDERAL TRADE COMMISSION In 1938, Congress divided the regulation of food claims between FDA and the FTC (180, 181). FDA was given explicit authority to regulate food labeling and the FTC was given explicit authority to regulate food advertising.

During the 1970s, the FTC proposed a comprehensive regulation designed to govern nutrition claims in food advertising (154, 155, 157). The regulation would have prohibited specified nutrition claims as misleading and would have required the disclosure in advertising of a substantial amount of nutrition information about products for which any mention whatsoever was made of nutrition. It was, in short, the FTC equivalent of the earlier FDA regulations governing nutrition labeling. After a lengthy hearing, however, that regulation was abandoned in favor of voluntary industry action (162, 165).

The FTC has also proposed regulations governing the advertising of sugared food products to children (159) and the advertising of protein supplements (156). The former has also been abandoned (163) and the later has not yet been acted upon.

The legal authority exhibited in these regulatory proposals—to prohibit some nutrition claims, to require affirmative disclosure of other nutrition information, and to prohibit of certain types of food—gives the FTC impressive power to implement dietary recommendations. By requiring warnings and affirmative disclosure of information with respect to the composition of food in advertising, or by banning the advertising of food of a certain composition or nature, the FTC could exert a major influence on the formulation of food and on consumer purchasing decisions.

THE FOOD AND NUTRITION SERVICE USDA administers six food programs under which nutritional requirements are, or could be, a significant focus. These programs could have a major effect on the eating habits of both children and needy persons, and more generally on the formulation of food products for the entire population.

Food stamp program The Food Stamp Act of 1977 (107, 186, 188) provides low-income households with food stamps that can be used to purchase food at authorized retail stores. Although it presently provides no legal authorization to implement dietary recommendations, such authority could be added in the future.

Food distribution program Under the National School Lunch Act (106, 182, 191) and a number of other statutory provisions, FNS donates food commodities to a wide variety of needy organizations and institutions. The statutory authorization for the food distribution program does not presently provide independent authority for FNS to make its purchasing and distribution decisions based upon nutritional considerations. Nonetheless, FNS has begun to specify nutrition-related characteristics in bid specifications for products that will be purchased for distribution in this program, and it could increase its efforts in this area in the future.

Special supplemental food program for women, infants, and children The Child Nutrition Act (104, 184, 192) authorizes the WIC program, under which individual pregnant woman, infants, and children are certified as "nutritional risks" because of nutritional need and inadequate income. These individuals receive special food products which, by statute, must be regulated by FNS to assure that the fat, sugar, and salt contents are appropriate. Thus, FNS already is explicitly authorized to implement dietary recommendations for these three food components through the WIC program.

Commodities supplemental food program Pursuant to a series of statutory provisions relating to surplus food commodities, FNS is authorized to administer a supplemental commodity distribution program for needy persons (105, 187). Although there is no direct statutory authorization relating to regulation of dietary components, FNS has adopted a policy of including in this program only nutritious food for persons who are vulnerable to malnutrition, and in the future it could exert more direct control over the composition of the products that are to be distributed.

Child nutrition programs Six separate child nutrition programs are administered by FNS pursuant to the national School Lunch Act and the Child Nutrition Act: the national school lunch program (97), the school breakfast program (99), the child care food program (101), the summer food service program for children (100), the special milk program for children (98), and the food service equipment assistance program (103). The statutory provisions relating to the first four of these programs explicitly authorize FNS to establish minimum nutritional standards for the foods that are included.

Nutrition education and training program The Child Nutrition Act establishes a program of nutrition education involving dissemination of nutrition information specified by FNS to school children, parents, and teachers (102). The statutory language broadly authorizes education about the nutritional value of foods and the relationship of nutrition to human health, and thus permits FNS

to include in this program whatever views on diet and health it believes to be justified.

CONCLUSION

This chapter documents the extraordinary governmental interest, throughout history, in protecting the integrity of the food supply. Governmental regulation of food has progressed in three recognizable stages. The first stage was focused on prevention of food adulteration. The second stage was characterized by provision of information about food to the consuming public. The third stage involved changing the traditional characteristics of food to make it more nutritious and healthful.

It is apparent that existing statutes provide a wide variety of regulatory mechanisms authorizing governmental intervention in the manufacture and labeling of food. Just how far this governmental authority will in fact be utilized in the future will depend upon such diverse factors as the availability of sound scientific data to support specific nutrition recommendations, the degree of expert consensus on such recommendations, voluntary efforts taken by the food industry to reflect such recommendations in the formulation and labeling of products, the political power of agricultural, food, and consumer groups that would be affected by any such recommendations, the extent to which such recommendations could be implemented through regulatory requirements without interfering with consumer choice, and the mood of the country concerning the role of government in regulating dietary preferences.

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