

3

Overview of Food Fortification in the United States and Canada

The addition of nutrients to food, food constituents, or supplements, termed fortification, has a complex history in the United States and Canada. The purpose of this chapter is not to review the rationale for fortification, which remains debated in many circles, but to provide a brief overview of the history and current status of policies, guidelines, and regulations related to fortification. In the United States, mandatory fortification (usually called enrichment) refers to the situation when a product is formulated to conform to the standard of identity promulgated by the Food and Drug Administration (FDA) for the enriched version of the food. Discretionary fortification refers to all other forms of the addition of nutrients to food, including unenriched versions of products for which an enrichment standard has been promulgated by FDA. The addition of vitamins and minerals (micronutrients) to food in Canada is controlled under regulatory provisions first declared in 1964 (Part D Division 3 of the Food and Drug Regulations [FDRs]). These regulations list the food to which micronutrients may be added, which micronutrients may be added, and the levels to which they may be added (Health Canada, 2002).

HISTORY AND CURRENT STATUS OF U.S. FOOD FORTIFICATION POLICY

Early Fortification

In the United States, as in most parts of the world, fortification of food was initiated as a systematic approach to correct identified

nutrient deficiencies in the population. In 1924 iodine was first added to salt on a voluntary basis in an attempt to address the prevalent health problem of goiter in the United States. This program was begun only after a number of prominent national health organizations of the time, the American Public Health Association, the Council on Foods and Nutrition of the American Medical Association (AMA), and the Committee on Food and Nutrition of the National Academy of Sciences, recommended this step based on new research demonstrating that sodium iodide prevented goiter (Quick and Murphy, 1982). This initial fortification effort was followed in 1933 by the fortification of milk with vitamin D based on recommendations from similar groups. The addition of vitamin D to milk was originally accomplished by irradiating milk or by feeding the cows irradiated yeast. This technique was replaced in the 1940s by the simpler and more effective method of adding vitamin D concentrate to milk, as is currently practiced today (Quick and Murphy, 1982).

In the 1930s and 1940s specific deficiency disease syndromes were first identified and documented in the United States (Foltz et al., 1944; McLester, 1939; Williams et al., 1943). Based on this new science, in 1940 the Committee on Food and Nutrition (now the Food and Nutrition Board [FNB]) recommended the addition of thiamin, niacin, riboflavin, and iron to flour (NRC, 1974). About that time FDA first established a standard of identity for enriched flour that identified specific nutrients and amounts required for addition to any flour labeled as “enriched” in order to improve the nutritional status of the population (FDA, 1941). The approach of using a standard of identity, which establishes the specific type and level of fortification required for particular staple food to be labeled as enriched, has remained a key aspect of fortification regulations and policy in the United States. These standards have been amended over the years, but they continue as the basis for the addition of thiamin, niacin, riboflavin, folic acid, and iron to enriched flour, with the addition of calcium as optional.

Concurrent with these activities, the nutritional status of Americans was being questioned as a result of the poor nutritional status of young men enlisting for service during World War II. These concerns led to the National Nutrition Conference for Defense in May 1941, convened by President Roosevelt. An outcome of this conference was the recommendation for flour and bread enrichment using the existing standards developed by FDA (Quick and Murphy, 1982).

Although the original FDA standard was not amended to include bread for several years, the enrichment of bread began in 1941 as a

result of discussions among FNB, AMA, FDA, and the American Bakers Association. The voluntary cooperation of bakery-associated industries led to 75 percent of the white bread in the United States being fortified by the middle of 1942 (Quick and Murphy 1982). The first War Food Order, enacted in 1943, stated that all flour sold for interstate commerce would be enriched according to FDA standards. This order was later repealed in 1946, but was followed in 1952 with official standards of identity for enriched bread (FDA, 1952a, 1952b). Under this new regulation, fortification of flour and bread products was not mandatory, but if a product was labeled as "enriched" it was required to meet the standards of identity described in the regulation.

FDA made a decision in the 1940s that it would not require mandatory fortification for any food product; this policy is still in place. For every standard of identity for which there is an enriched version of a food, there is a corresponding standard of identity for an unenriched version. Prior to 1990 individual states could enact laws that addressed fortification of products sold within their boundaries. For example, by the time the enriched bread standard was finally promulgated by FDA in 1952, the enrichment of flour and bread was mandatory in 26 states (Hutt, 1984). The National Labeling Education Act of 1990 provided for federal preemption of standards of identity, however, thus nullifying these state laws.

Since the 1950s standards of identity have been issued for the fortification of food, such as oleomargarine and rice and other cereal grains, and have been proposed for formulated meal replacements. The most recent standard of identity change for these products was the regulation, effective in January 1998, regarding folate. To meet the standard of identity for most breads, flours, corn meals, rice, noodles, macaroni, and other grain products labeled as enriched, folic acid is to be added at the level of 0.43 mg to 1.4 mg/lb of product. This decision reflects an overall approach within the United States that incorporates six underlying principles first presented in a joint statement of FNB and the Council on Foods and Nutrition of AMA (NRC/AMA, 1968):

- The intake of the nutrient, in the absence of fortification, is below the desirable level in the diets of a significant number of people.
- The food from which the nutrient is to be derived is likely to be consumed in quantities that will make a significant contribution to the diet of the population in need.
- The addition of the nutrient is unlikely to create an imbalance of essential nutrients.

- The nutrient added is stable under proper conditions of storage and use.
- The nutrient is physiologically available from the food to which it will be added.
- There is a reasonable assurance against intake sufficiently in excess to be toxic.

Fortification Policies and Regulations Since the 1960s

In the 1960s FDA proposed a more restrictive regulatory approach in response to increased fortification of food that it feared might lead to overfortification. These were the first major regulatory changes related to food fortification that had been proposed since 1941. In 1962 FDA proposed to limit fortification to only nutrients essential to human health and appropriate for supplementation. The agency listed 12 essential nutrients with a suitable range for their supplementation and 11 nutrients that were considered essential but not appropriate for supplementation because signs of deficiency only occurred under experimental situations (Hutt, 1980, 1984). The previous year FDA had brought legal action against New Dextra Brand Fortified Cane Sugar claiming in part that the sugar's labeling was misleading because its 19 added nutrients inherently claimed that it was more nutritious than other sugars and that the nutrients were present in sufficient amounts to significantly improve the diet. Another element of the legal action claimed that sugar was an inappropriate vehicle for fortification. FDA's "misbranding" approach was not upheld in the U.S. District Court, and the U.S. Court of Appeals agreed.¹ The court held that FDA had no legal authority to prohibit food fortification unless it can be shown to be unsafe. The United States District Court concluded (as upheld by the United States Court of Appeals):

The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the marketplace simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug, and Cosmetic Act did not vest in the Food and Drug Administration or any other federal agency the power to determine what foods should be included in the American diet; this is the function of the marketplace. . . .¹

¹United States v. 119 Cases . . . "New Dextra Brand Fortified Sugar," 231 F. Supp. 551 (D. Fla. 1963), *aff'd per curiam*, 334 F 2d 238 (5th Cir. 1964).

Still attempting to reduce indiscriminant food fortification and dietary supplement products, in 1966 the FDA proposed to limit the number of food products that could be fortified to eight classes and to specify the nutrients that could be used with each class. This proposed regulation was worded in the context of two new standards of identity: one for vitamin and mineral dietary supplements and the other for a limited number of food products (FDA, 1966). FDA convened public hearings on these proposed regulations in 1968 and 1969 (Hutt, 1980). This proposed regulation and a subsequent proposal in 1974 of general rules governing the addition of nutrients to food, along with provisions to enforce the rules (FDA, 1974), were eventually abandoned due to objections and comments in public hearings and due to other events.

Two events in particular changed the course of FDA's regulatory approach in the 1960s and 1970s: President Nixon's White House Conference on Food, Nutrition and Health in 1969 and Congress's enactment of the new Section 411 of the Food, Drug, and Cosmetic Act (FD&C) in 1976. The White House Conference issued a report that recommended fortification of existing and new food products to reduce malnutrition, which was in many ways the opposite of the 1966 FDA proposed regulation (Hutt, 1980; WHC, 1970). After FDA published regulations based on its 1968 and 1969 hearings, Congress was persuaded in 1976 to amend the FD&C Act to limit FDA's authority over vitamin and mineral supplements. This amendment explicitly prohibited FDA from imposing maximum limits on the potency of any vitamin or mineral in a dietary supplement in tablet, capsule, or small measured liquid form except for safety reasons. The 1976 statute also prohibited FDA from limiting the combination or number of safe nutrients in a dietary supplement (21 U.S.C. §350). The FDA Modernization Act of 1997 extended this to include dietary supplements in food form (P.L. 105-115). When FDA attempted to limit the amount of vitamin A and vitamin D fortification by declaring any level higher than 150 percent of the U.S. Recommended Daily Allowances (US RDAs) to be a prescription drug, this approach was also struck down by the courts.²

Current Fortification Policies

In 1943, due to the heightened interest in fortified food, FDA issued a policy statement (which has never been withdrawn) on the

²National Nutritional Foods Association v. Mathews, 557 F.2d 325 (2d Cir. 1977).

addition of nutritive ingredients to food. In this policy FDA stated that implicit in fortification is the promise to consumers that the fortified food, through its fortificants, contributes substantially to the nutritional well being of the individual who consumes usual amounts of the food. This aspect of the policy was rejected by the courts in the New Dextra Sugar case and by the 1976 vitamin-mineral amendments to the FD&C Act. The FDA policy also said that the specific nutrient deficiencies in the diet of the general population and population subgroups, the overall place of the food item in the diet of this population, and the effectiveness and suitability of the food vehicle should determine the type and amount of nutrients to be added to food. This policy further affirmed the importance of natural food in the diet, endorsed the restoration of nutrients lost during food processing, and indicated that it was appropriate, in some instances, to fortify processed food above restoration amounts and to fortify unprocessed food in order to correct deficiencies if the food in question is a particularly effective vehicle for fortification (Hutt, 1980, 1984).

In 1974 FDA proposed regulations that moved beyond the standard of identity approach and included a more comprehensive viewpoint of the addition of nutrients to food (FDA, 1974). In 1980 these views were published not as regulations, but as a policy statement that manufacturers “. . . are urged to follow if they elect to add nutrients to a manufactured or processed food” (FDA, 1980, p. 6314). The policy was codified in 21 C.F.R. 104.20 (FDA, 1980). This policy is the current statement of the agency regarding fortification. It is important to note that this statement, as a policy, it is not enforceable.

Of key relevance to this report, the codified policy includes situations and conditions in which the fortification of food with the nutrients listed in the policy is considered appropriate:

- 1) . . . to correct a dietary insufficiency that is recognized by the scientific community to exist and known to result in nutrient deficiency disease . . . ;
- 2) . . . to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling and processing . . . ;
- 3) . . . in proportion to the total caloric content of the food, to balance the vitamin, mineral, and protein content . . . ;
- and 4) . . . that replaces traditional food in the diet to avoid nutritional inferiority . . . (FDA, 1980, p. 6323)

In the codified policy there are a number of qualifications listed with each condition of fortification. For example, the policy recom-

mends that vitamins, minerals, and protein be added in proportion to the total caloric content of the food for which the stated caloric reference value is “. . . per 100 kilocalories based on a 2,000-kilocalorie total intake as a daily standard . . .” (FDA, 1980). This section includes a listing of the nutrients the policy recommends as appropriate to add as fortificants and cites the US RDAs as the reference standards for amounts of nutrients to be added per 100 kilocalories.³ The FDA fortification policy thus recommends using the same reference standards for fortification that are used for the nutrition labeling of food.

The policy includes statements that nutrients added to food should be stable, physiologically available, present at a level that will not led to excess intake, suitable for fortification purposes, and acceptable in terms of food safety regulations. The policy concludes with links to food labeling in that it specifies that claims and statements on the label cannot be false or misleading. Another point mentioned in the fortification policy is that FDA “does not consider it appropriate to fortify” fresh produce, meat, poultry, or fish products, sugars, or snack foods (e.g., candies and carbonated beverages).

Historically the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) has followed an unwritten policy prohibiting indiscriminant fortification of the products it regulates (Post, 2002). In 1980 it adopted FDA’s policy guidelines on the addition of nutrients to food (21 C.F.R.104.20). In 1982 an FSIS review of the policy concluded that the food it regulated would continue to follow FDA policy guidelines (Quick and Murphy, 1982). Meat and poultry regulations do, however, permit some limited addition of nutrients for specific purposes, such as the addition of ascorbic acid (vitamin C) to accelerate the curing process and the addition of thiamin hydrochloride for flavoring. With the exception of margarine, there are no FSIS food standards that permit or require the addition of nutrients (Post, 2002). The diversity of food products in the marketplace that fall under FSIS regulation has grown, and FSIS has found that products may contain label claims for fortification that are not addressed by the 1980 guidelines (Post, 2002). FSIS has made some accommodation for these food products by allowing label statements about nutrients contributed by fortified ingredients approved by FDA (e.g., calcium-enriched egg noodles) (Post, 2002).

³The US RDA reference standards were updated on January 6, 1993 (FDA, 1993c) to use FDA’s Recommended Daily Intakes and Daily Reference Values.

HISTORY AND CURRENT STATUS OF CANADIAN FOOD FORTIFICATION POLICY

Canada has a long history of fortification that is based, as in the United States, on previous conditions of nutrient deficiency in the population. The diversity of climate, sunlight exposure, soil biogeochemistry, food commerce, and population size across the country led to significant regional differences in the need and demand for fortification of the food supply within Canada.

Nutrition Issues

In the early 1900s there were occasional observations of illness, such as beriberi and blindness, in segments of the population in Newfoundland and Labrador that were attributed to nutrient deficiencies (Aykroyd, 1928; Little, 1912). A survey of the clinical and biochemical nutritional status of 868 people in St. John's and several outposts of Newfoundland was carried out in 1944 (Adamson et al., 1945). Clinical and biochemical signs of deficiencies of vitamin A, B vitamins, and ascorbic acid were prevalent in the group examined.

The first comprehensive nutrition surveys that were conducted in British Columbia and Saskatchewan in 1946 indicated that about 21 percent of children had a least one sign of clinical vitamin A deficiency and about 50 percent of school children had evidence of past rickets (Pett and Hanley, 1947). Newfoundland, not part of Canada at that time, promulgated the mandatory addition of nutrients to food to reduce nutrient deficiencies in the population, including adding calcium (as bone meal), iron, and B vitamins to flour and vitamin A to margarine (Lotfi, 2002).

The first comprehensive national nutrition survey, Nutrition Canada, was conducted in 1970–1972 and involved approximately 13,000 people. Many segments of the population had dietary intake inadequacies based on a 24-hour dietary recall, particularly of iron, calcium, vitamin D, and protein. Biochemical indicators confirmed iron deficiency among all groups in the population and low serum vitamin A levels in children and adolescents, but no clinical evidence of vitamin A deficiency or rickets (Canada, 1973). The survey also revealed that approximately 50 percent of the population was overweight (Canada, 1973, as cited in Lotfi, 2002).

Fortification Policies

The addition of vitamins and minerals to food is strictly controlled under the FDRs. The FDRs list the foods to which micronutrients

may be added, which micronutrients may be added, and the level to which they may be added. This is an example of a “positive listing” approach. These regulations apply to all food sold in Canada.

When vitamins became available for addition to food, no regulatory controls were in place. Concern about fraudulent practices in the addition of vitamins to food led the government to set minimum levels for this addition in 1942, followed in 1949 with maximum levels (Cheney and Lee, 1994). Newfoundland had required the enrichment of flour since 1944, and following the entry of Newfoundland into the Canadian Confederation, the standard for flour was amended to permit the same nutrient enrichment (Health Canada, 1999).

The Canadian government has used mandatory fortification to address documented deficiencies. Iodination of salt, which became mandatory in 1949, virtually eliminated goiter throughout the country; a highly targeted approach to vitamin D fortification turned around a widespread problem with rickets (Cheney and Lee, 1994; Health Canada, 1999). In particular, Canada’s experience with a high incidence of severe rickets and death from vitamin D deficiency is cited as an example of how thoughtful, full-coverage fortification of a targeted food category can address a widespread deficiency. In the 1940s and 1950s all unstandardized food could be fortified within the specified minimum and maximum levels of vitamin D. While rickets continued to be documented in infants and young children, one survey indicated that some of the young children in Ontario were consuming very high levels of vitamin D from supplements and food (Broadfoot et al., 1966). Nationwide food-intake surveys had not been conducted at that time, but concern about the apparent contradictions related to vitamin D status (very high intakes at the same time as a continuing problem of rickets) led in 1964 to the present controls on the addition of vitamins and minerals to food (Cheney and Lee, 1994). Although the addition of vitamin D to evaporated and dried milks had been permitted since 1950, the change in the regulations in 1964, which led to cessation of vitamin D fortification of many food products, resulted in an increase in rickets (Cheney and Lee, 1994; Health Canada, 1999). Health Canada attributes this rise to its overlooking “a fundamental principle of food fortification—the selection of an appropriate vehicle to reach the target population” (Health Canada, 1999, p. 6). In the case of vitamin D, while evaporated and powdered milk was fortified, fluid milk was not. The regulations were amended in 1965 to include fluid milk, and rickets cases began to decline. Educational campaigns in the late 1960s, coupled with a further broadening of the

regulations to include fortification of all milks in 1975, eliminated rickets as a public health problem beginning in the late 1970s (Cheney and Lee, 1994).

The “positive list” approach to fortification was initiated with the 1964 regulations. The inclusion of a list of food that may be fortified, as well as the specific micronutrients and maximum levels to which they may be added, is viewed by Health Canada as a successful fortification program that addresses inadequacies and protects the population from excesses of fortificants (Cheney, 2000; Health Canada, 1999). Extensions to food fortification are guided by policies first enunciated in 1971 (Canada, 1971) and later in accordance with the general principles for the addition of essential nutrients to foods of the Codex Alimentarius Commission⁴ (1994).

Fortification of food in Canada is also permitted to maintain nutritional equivalence for substitute food, to restore nutrients lost during manufacturing, and to ensure the nutrient composition of a special-purpose food in a carefully regulated fashion. The principles in the Codex Alimentarius Commission’s (1994) general principles include definitions and approaches for fortification that cover issues such as “. . . safety, nutrient interactions, bioavailability, technical feasibility, and choice of food vehicle . . . ” (Health Canada, 1999, p. 29).

Canadian regulations apply to all food sold in Canada, regardless of where it is produced. Canada permits discretionary fortification with defined limits, and therefore it does not have a reference standard for levels of nutrient addition.

In 1998 Health Canada began a policy review of the addition of vitamins and minerals to food through an iterative consultation process that resulted in the 1999 publication of new proposed policy recommendations (Health Canada, 1999). This proposal includes five recommendations that continue to support the existing fortification policies. One important change, however, is the proposal for discretionary fortification, as indicated in Recommendation 1c, which states:

⁴“The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations” (Codex Alimentarius Commission, 2003).

It is recommended that fortification programs be expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes (p. 14).

This recommendation is a result of the view of a variety of groups in Canada that the current food fortification policies are too restrictive. If the proposal is adopted, it should provide the opportunity for more choices of fortified food, a wider distribution of nutrients in the food supply, and greater flexibility in the regulatory framework.

SUMMARY

The United States and Canada have current policies and regulations regarding fortification that differ in many ways. In the United States FDA has maintained its decision to not require mandatory fortification of any food product, and it has parallel standards of identity for versions of food products that are enriched and those that are not. FDA currently has a policy statement that identifies fortification practices that manufacturers are encouraged to follow. However, this policy cannot be enforced, and FDA employs labeling requirements rather than rigid standards for nutrient composition to assist consumers. In Canada the situation with food fortification is changing. For many years food fortification has been tightly regulated. The policy currently being crafted will likely result in expanded options for food fortification, particularly in the area of discretionary fortification.