PART I

The role of food fortification in the control of micronutrient malnutrition

CHAPTER 1

Micronutrient malnutrition: a public health problem

1.1 Global prevalence of micronutrient malnutrition

Micronutrient malnutrition (MNM) is widespread in the industrialized nations, but even more so in the developing regions of the world. It can affect all age groups, but young children and women of reproductive age tend to be among those most at risk of developing micronutrient deficiencies. Micronutrient malnutrition has many adverse effects on human health, not all of which are clinically evident. Even moderate levels of deficiency (which can be detected by biochemical or clinical measurements) can have serious detrimental effects on human function. Thus, in addition to the obvious and direct health effects, the existence of MNM has profound implications for economic development and productivity, particularly in terms of the potentially huge public health costs and the loss of human capital formation.

Worldwide, the three most common forms of MNM are iron, vitamin A and iodine deficiency. Together, these affect at least one third of the world's population, the majority of whom are in developing countries. Of the three, iron deficiency is the most prevalent. It is estimated that just over 2 billion people are anaemic, just under 2 billion have inadequate iodine nutrition and 254 million preschool-aged children are vitamin A deficient (**Table 1.1**).

From a public health viewpoint, MNM is a concern not just because such large numbers of people are affected, but also because MNM, being a risk factor for many diseases, can contribute to high rates of morbidity and even mortality. It has been estimated that micronutrient deficiencies account for about 7.3% of the global burden of disease, with iron and vitamin A deficiency ranking among the 15 leading causes of the global disease burden (*4*).

According to WHO mortality data, around 0.8 million deaths (1.5% of the total) can be attributed to iron deficiency each year, and a similar number to vitamin A deficiency. In terms of the loss of healthy life, expressed in disability-adjusted life years (DALYs), iron-deficiency anaemia results in 25 million DALYs lost (or 2.4% of the global total), vitamin A deficiency in 18 million DALYs lost (or 1.8% of the global total) and iodine deficiency in 2.5 million DALYs lost (or 0.2% of the global total) (*4*).

The scale and impact of deficiencies in other micronutrients is much more difficult to quantify, although it is likely that some forms of MNM, including

TABLE 1.1

Prevalence of the three major micronutrient deficiencies by WHO region

WHO region	Anaemia[a] (total population)		Insufficient iodine intake[b] (total population)		Vitamin A deficiency[c] (preschool children)	
	No. (millions)	% of total	No. (millions)	% of total	No. (millions)	% of total
Africa	244	46	260	43	53	49
Americas	141	19	75	10	16	20
South-East Asia	779	57	624	40	127	69
Europe	84	10	436	57	No data available	
Eastern Mediterranean	184	45	229	54	16	22
Western Pacific	598	38	365	24	42	27
Total	2030	37	1989	35	254	42

[a] Based on the proportion of the population with haemoglobin concentrations below established cut-off levels.
[b] Based on the proportion of the population with urinary iodine <100 µg/l.
[c] Based on the proportion of the population with clinical eye signs and/or serum retinol ≤0.70 µmol/l.

Sources: references (*1–3*).

zinc, folate and vitamin D deficiency, make a substantial contribution to the global burden of disease. However, there are few data on the prevalence of deficiencies in these micronutrients, and as their adverse effects on health are sometimes non-specific, the public health implications are less well understood.

In the poorer regions of the world, MNM is certain to exist wherever there is undernutrition due to food shortages and is likely to be common where diets lack diversity. Generally speaking, whereas wealthier population groups are able to augment dietary staples with micronutrient-rich foods (such as meat, fish, poultry, eggs, milk and dairy products) and have greater access to a variety of fruits and vegetables, poorer people tend to consume only small amounts of such foods, relying instead on more monotonous diets based on cereals, roots and tubers. The micronutrient content of cereals (especially after milling), roots and tubers is low, so these foods typically provide only a small proportion of the daily requirements for most vitamins and minerals. Fat intake among such groups is also often very low and given the role of fat in facilitating the absorption of a range of micronutrients across the gut wall, the low level of dietary fat puts such populations at further risk of MNM. Consequently, populations that consume few animal source foods may suffer from a high prevalence of several micronutrient deficiencies simultaneously.

In the wealthier countries, higher incomes, greater access to a wider variety of micronutrient-rich and fortified foods, and better health services, are all factors that contribute to the lowering of the risk and prevalence of MNM.

However, consumption of a diet that contains a high proportion of energy-dense but micronutrient-poor processed foods can put some population groups at risk of MNM. Although at present this practice is more common in industrialized countries, it is rapidly becoming more prevalent among countries undergoing social and economic transition.

Table 1.2 provides an overview of the prevalence, risk factors, and health consequences of deficiencies in each of the 15 micronutrients covered in thesee guidelines. For reasons stated above, prevalence estimates are only provided for iron vitamin A and iodine deficiencies. Further information is available from the WHO Vitamin and Mineral Nutrition Information System[1].

Up until the 1980s, efforts to alleviate undernutrition in developing countries were focused on protein–energy malnutrition (PEM). While PEM certainly remains an important concern, we have since come to appreciate the significance of micronutrient malnutrition in terms of its effect on human health and function. As a result, the past two decades have seen an increase in activities that seek to understand and control specific micronutrient deficiencies (*7*). Efforts to control iodine deficiency in developing countries, for example, were given new impetus in the early 1980s when it was recognized that iodine deficiency was the most common cause of preventable brain damage and mental retardation in childhood (*8,9*). There were also reports of increased risks of stillbirths and low-birth-weight infants in iodine deficient areas (*10,11*). Importantly, the technology to prevent iodine deficiency – salt iodization – already existed and, moreover, was easy to implement and affordable even by governments with limited health budgets. It therefore seemed likely that salt iodization could be a feasible option for preventing iodine deficiency on a global scale.

Similarly, having established that vitamin A status is an important determinant of child survival – in addition to preventing and treating eye disorders, supplementation of vitamin A-deficient children lowers their risk of morbidity (particularly that related to severe diarrhoea), and reduces mortality from measles and all-cause mortality (*12,13*) – measures to control vitamin A deficiency have been initiated in several world regions. Reports that iron supplementation of iron-deficient individuals can improve cognitive function, school performance and work capacity (*14,15*), and that severe anaemia increases the risk of maternal and child mortality (*16*), have provided a strong rationale for iron interventions. Intervention trials have also revealed that zinc supplementation improves the growth of stunted, zinc-deficient children (*17*), lowers rates of diarrhoea and pneumonia (the two leading causes of child death), and shortens the duration of diarrhoeal episodes (*18,19*).

In the wake of such accumulated evidence, the international community has increasingly come to recognize the public health importance of MNM. In 1990,

[1] See http://www.who.int/nutrition/en

TABLE 1.2

Micronutrient deficiencies: prevalence, risk factors and health consequences

Micronutrient[a]	Prevalence of deficiency	Risk factors	Health consequences
Iron	There are an estimated 2 billion cases of anaemia worldwide In developing countries, anaemia prevalence rates are estimated to be about 50% in pregnant women and infants under 2 years, 40% in school-aged children and 25–55% in other women and children Iron deficiency is estimated to be responsible for around 50% of all anaemia cases There are approximately 1 billion cases of iron-deficiency anaemia and a further 1 billion cases of iron deficiency without anaemia worldwide	Low intakes of meat/fish/poultry and high intakes of cereals and legumes Preterm delivery or low birth weight Pregnancy and adolescence (periods during which requirements for iron are especially high) Heavy menstrual losses Parasite infections (i.e. hookworm, schistosomiasis, ascaris) which cause heavy blood losses Malaria (causes anaemia not iron deficiency) Low intakes of vitamin C (ascorbic acid) Allergy to cow's milk	Reduced cognitive performance Lower work performance and endurance Impaired iodine and vitamin A metabolism Anaemia Increased risk of maternal mortality and child mortality (with more severe anaemia)
Vitamin A	An estimated 254 million preschool children are vitamin A deficient	Low intakes of dairy products, eggs and β-carotene from fruits and vegetables Presence of helminth infection, ascaris	Increased risk of mortality in children and pregnant women Night blindness, xerophthalmia

Iodine	An estimated 2 billion people have inadequate iodine nutrition and therefore are at risk of iodine deficiency disorders	Residence in areas with low levels of iodine in soil and water Living in high altitude regions, river plains or far from the sea Consumption of non-detoxified cassava	Birth defects Increased risk of stillbirth and infant mortality Cognitive and neurological impairment including cretinism Impaired cognitive function Hypothyroidism Goitre
Zinc	Insufficient data, but prevalence of deficiency is likely to be moderate to high in developing countries, especially those in Africa, South-East Asia and the Western Pacific	Low intakes of animal products High phytate intakes Malabsorption and infection with intestinal parasites Diarrhoea, especially persistent Genetic disorders	Non-specific if marginal deficiency Possibly poor pregnancy outcomes Impaired growth (stunting) Decreased resistance to infectious diseases Severe deficiency results in dermatitis, retarded growth, diarrhoea, mental disturbance, delayed sexual maturation and/or recurrent infections
Folate (vitamin B_9)	Insufficient data	Low intakes of fruits and vegetables, legumes and dairy products Malabsorption and intestinal parasites infections (e.g. *Giardia Lamblia*) Genetic disorder of folic acid metabolism	Megaloblastic anaemia Risk factor for: — neural tube defects and other birth defects (oro-facial clefts, heart defects) and adverse pregnancy outcomes; — elevated plasma homocysteine; — heart disease and stroke — impaired cognitive function — depression

TABLE 1.2

Micronutrient deficiencies: prevalence, risk factors and health consequences (*Continued*)

Micronutrient[a]	Prevalence of deficiency	Risk factors	Health consequences
Vitamin B_{12} (cobalamin)	Insufficient data	Low intakes of animal products Malabsorption from food due to gastric atrophy induced by *Helicobacter pylori*, or bacterial overgrowth Genetic disorder of vitamin B_{12} metabolism	Megaloblastic anaemia Severe deficiency can cause developmental delays, poor neurobehavioral performance and growth in infants and children, nerve demyelination and neurological dysfunction Risk factor for: — neural tube defects; — elevated plasma homocysteine; — impaired cognitive function
Vitamin B_1 (thiamine)	Insufficient data on marginal deficiency Severe deficiency (beriberi) is reported in parts of Japan and north-east Thailand Regularly reported in famine situations and among displaced populations	High consumption of refined rice and cereals Low intakes of animal and dairy products, and legumes Consumption of thiaminase (found in raw fish) Breastfeeding (from deficient mothers) Chronic alcoholism Genetic disorder of thiamine metabolism	Beriberi presents in two forms: — a cardiac form with risk of heart failure (predominant in neonates) — a neurological form with chronic peripheral neuropathy (loss of sensation and reflexes) Wernicke-Korsakov syndrome (usually in alcoholics) with confusion, lack of coordination and paralysis
Vitamin B_2 (riboflavin)	Insufficient data, but some evidence that it might be very common in developing countries	Low intakes of animal and dairy products Chronic alcoholism	Symptoms are non-specific and can include fatigue, eye changes and in more severe cases, dermatitis (stomatitis, cheilosis), brain dysfunction and microcytic anaemia Impaired iron absorption and utilization

Vitamin B_3 (niacin)	Insufficient data on marginal deficiency Severe deficiency (pellagra) still common in Africa, China and India and recently reported among displaced populations (south-eastern Africa) and in famine situations	Low intakes of animal and dairy products High consumption of refined cereals Maize-based diets (not lime treated)	Severe deficiency results in pellagra, which is characterized by: — dermatitis (symmetrical pigmented rash on skin areas exposed to sunlight); — digestive mucosa disorders (diarrhoea and vomiting); — neurological symptoms, depression and loss of memory
Vitamin B_6	Insufficient data, but recent reports from Egypt and Indonesia suggest deficiency is likely to be widespread in developing countries Rather uncommon in isolation, being typically associated with deficiencies in the other B vitamins	Low intakes of animal products High consumption of refined cereals Chronic alcoholism	Symptoms are non-specific and may include: — neurological disorders with convulsions; — dermatitis (stomatitis and cheilosis) Anaemia (possibly) Deficiency is a risk factor for elevated plasma homocysteine
Vitamin C (ascorbic acid)	Insufficient data on moderate deficiencies Severe deficiency (scurvy) regularly reported in famine situations (e.g. east Africa) and among displaced people dependent on food aid for long periods (e.g. east Africa, Nepal)	Low intakes of fresh vitamin C-rich fruits and vegetables Prolonged cooking	Severe deficiency results in scurvy with haemorrhagic syndrome (i.e. bleeding gums, joint and muscle pain, peripheral oedema) Anaemia
Vitamin D	Insufficient data, but likely to be common in both industrialized and developing countries Higher at more northerly and southerly latitudes where daylight hours are limited during the winter months	Low exposure to ultra-violet radiation from the sun Wearing excess clothing Having darkly pigmented skin	Severe forms result in rickets in children and osteomalacia in adults

TABLE 1.2

Micronutrient deficiencies: prevalence, risk factors and health consequences (*Continued*)

Micronutrient[a]	Prevalence of deficiency	Risk factors	Health consequences
Calcium	Insufficient data, but low intakes very common	Low intakes of dairy products	Decreased bone mineralization Increased risk of osteoporosis in adults Increased risk of rickets in children
Selenium	Insufficient data on moderate deficiency Severe deficiency reported in some regions of China, Japan, Korea, New Zealand, Scandinavia and Siberia	Residing in low selenium environments Low intakes of animal products Some evidence that symptoms are not due to selenium deficiency alone, but also to the presence of the cocksackie virus (Keshan disease) or mycotoxins (Kaschin-Beck disease)	Severe deficiency presents as: — cardiomyopathy (Keshan disease), or — osteoarthropathy in children (Kaschin-Beck disease) Increased risk of cancer and cardiovascular disease Exacerbation of thyroid dysfunction caused by iodine deficiency
Fluoride	NA	Residing in areas with low fluoride levels in water	Increased risk of dental decay

NA, not applicable.

[a] Micronutrients are listed in order of their public health significance.

Sources: adapted from references (*1–3,5,6*).

the World Health Assembly passed a landmark resolution urging action by Member States "to prevent and control iodine deficiency disorders" (*20*). Later that year, at the World Summit for Children, the world's leaders endorsed the "virtual elimination of iodine and vitamin A deficiency and a reduction of the prevalence of iron-deficiency anaemia in women by one third". These goals have been reiterated at a number of subsequent international fora, including the Montreal conference on Ending Hidden Hunger in 1991, the 1992 FAO/WHO International Conference on Nutrition held in Rome, the 1993 World Health Assembly held in Geneva, and the Special Session on Children of the United Nations General Assembly, which was held in New York in 2002. There has been remarkable degree of consensus and support for MNM control between governments, United Nations agencies, multilateral and bilateral agencies, academic and research institutions, nongovernmental organizations (NGOs) and donor foundations. More recently, following recognition of the essential role played by industry – in particular, the salt, food and drug industries – stronger links with the private sector have been forged. This is reflected by the implementation of several public–private coalitions aimed at addressing the main micronutrient deficiencies, which include the Global Alliance for Improved Nutrition[1] and The Global Network for Sustained Elimination of Iodine Deficiency[2].

1.2 Strategies for the control of micronutrient malnutrition

The control of vitamin and mineral deficiencies is an essential part of the overall effort to fight hunger and malnutrition. Countries need to adopt and support a comprehensive approach that addresses the causes of malnutrition and the often associated "hidden hunger" which rest intinsic to in poverty and unsustainable livelihoods. Actions that promote an increase in the supply, access, consumption and utilization of an adequate quantity, quality and variety of foods for all populations groups should be supported. The aim is for all people to be able to obtain from their diet all the energy, macro- and micronutrients they need to enjoy a healthy and productive life.

Policy and programme responses include food-based strategies such as dietary diversification and food fortification, as well as nutrition education, public health and food safety measures, and finally supplementation. These approaches should be regarded as complementary, with their relative importance depending on local conditions and the specific mix of local needs.

Of the three options that are aimed at increasing the intake of micronutrients, programmes that deliver micronutrient supplements often provide the fastest improvement in the micronutrient status of individuals or targeted population

[1] See http://www.gainhealth.org.

[2] See http://www.iodinenetwork.net.

groups. Food fortification tends to have a less immediate but nevertheless a much wider and more sustained impact. Although increasing dietary diversity is generally regarded as the most desirable and sustainable option, it takes the longest to implement.

1.2.1 Increasing the diversity of foods consumed

Increasing dietary diversity means increasing both the quantity and the range of micronutrient-rich foods consumed. In practice, this requires the implementation of programmes that improve the availability and consumption of, and access to, different types of micronutrient-rich foods (such as animal products, fruits and vegetables) in adequate quantities, especially among those who at risk for, or vulnerable to, MNM. In poorer communities, attention also needs to be paid to ensuring that dietary intakes of oils and fats are adequate for enhancing the absorption of the limited supplies of micronutrients.

Increasing dietary diversity is the preferred way of improving the nutrition of a population because it has the potential to improve the intake of many food constituents – not just micronutrients – simultaneously. Ongoing research suggests that micronutrient-rich foods also provide a range of antioxidants and probiotic substances that are important for protection against selected non-communicable diseases and for enhancing immune function. However, as a strategy for combating MNM, increasing dietary diversity is not without its limitations, the main one being the need for behaviour change and for education about how certain foods provide essential micronutrients and other nutritive substances. A lack of resources for producing and purchasing higher quality foods can sometimes present a barrier to achieving greater dietary diversity, especially in the case of poorer populations. The importance of animal source foods for dietary quality is increasingly being recognized, and innovative approaches to increase their production and consumption in poorer regions of the world are currently being explored (*21*). Efforts are also underway to help poorer communities identify, domesticate and cultivate traditional and wild micronutrient-rich foods as a simple and affordable means of satisfying micronutrient needs (*22–24*).

For infants, ensuring a diet of breast milk is an effective way of preventing micronutrient deficiencies. In much of the developing world, breast milk is the main source of micronutrients during the first year of life (with the exception of iron). Exclusive breastfeeding for the first 6 months of life and continuation into the second year should thus be promoted. Moreover, all lactating women should be encouraged to consume a healthful and varied diet so that adequate levels of micronutrients are secreted in their milk. After the age of 6 months, it is important that the complementary foods provided to breast-fed infants are as diverse and as rich in micronutrients as possible.

1.2.2 Food fortification

Food fortification refers to the addition of micronutrients to processed foods. In many situations, this strategy can lead to relatively rapid improvements in the micronutrient status of a population, and at a very reasonable cost, especially if advantage can be taken of existing technology and local distribution networks. Since the benefits are potentially large, food fortification can be a very cost-effective public health intervention. However, an obvious requirement is that the fortified food(s) needs to be consumed in adequate amounts by a large proportion of the target individuals in a population. It is also necessary to have access to, and to use, fortificants that are well absorbed yet do not affect the sensory properties of foods. In most cases, it is preferable to use food vehicles that are centrally processed, and to have the support of the food industry.

Fortification of food with micronutrients is a valid technology for reducing micronutrient malnutrition as part of a food-based approach when and where existing food supplies and limited access fail to provide adequate levels of the respective nutrients in the diet. In such cases, food fortification reinforces and supports ongoing nutrition improvement programmes and should be regarded as part of a broader, integrated approach to prevent MNM, thereby complementing other approaches to improve micronutrient status.

1.2.3 Supplementation

Supplementation is the term used to describe the provision of relatively large doses of micronutrients, usually in the form of pills, capsules or syrups. It has the advantage of being capable of supplying an optimal amount of a specific nutrient or nutrients, in a highly absorbable form, and is often the fastest way to control deficiency in individuals or population groups that have been identified as being deficient.

In developing countries, supplementation programmes have been widely used to provide iron and folic acid to pregnant women, and vitamin A to infants, children under 5 years of age and postpartum women. Because a single high-dose vitamin A supplement improves vitamin A stores for about 4–6 months, supplementation two or three times a year is usually adequate. However, in the case of the more water-soluble vitamins and minerals, supplements need to be consumed more frequently. Supplementation usually requires the procurement and purchase of micronutrients in a relatively expensive pre-packaged form, an effective distribution system and a high degree of consumer compliance (especially if supplements need to be consumed on a long-term basis). A lack of supplies and poor compliance are consistently reported by many supplementation programme managers as being the main barriers to success.

1.2.4 Public health measures

In addition to the specific interventions outlined above, public health measures of a more general nature are often required to help prevent and correct MNM, because MNM is often associated with poor overall nutritional status and with a high prevalence of infection. Such measures include infection control (e.g. immunization, malaria and parasite control), and improvement of water and sanitation. Other factors, such as the quality of child care and maternal education, also need to be taken into consideration when developing public health responses to MNM.

1.3 Food fortification in practice

Food fortification has a long history of use in industrialized countries for the successful control of deficiencies of vitamins A and D, several B vitamins (thiamine, riboflavin and niacin), iodine and iron. Salt iodization was introduced in the early 1920s in both Switzerland (*25*) and the United States of America (*26*) and has since expanded progressively all over the world to the extent that iodized salt is now used in most countries. From the early 1940s onwards, the fortification of cereal products with thiamine, riboflavin and niacin became common practice. Margarine was fortified with vitamin A in Denmark and milk with vitamin D in the United States. Foods for young children were fortified with iron, a practice which has substantially reduced the risk of iron-deficiency anaemia in this age group. In more recent years, folic acid fortification of wheat has become widespread in the Americas, a strategy adopted by Canada and the United States and about 20 Latin American countries.

In the less industrialized countries, fortification has become an increasingly attractive option in recent years, so much so that planned programmes have moved forward to the implementation phase more rapidly than previously thought possible. Given the success of the relatively long-running programme to fortify sugar with vitamin A in Central America, where the prevalence of vitamin A deficiency has been reduced considerably, similar initiatives are being attempted in other world regions. Currently, the first sugar fortification experience in sub-Saharan Africa is taking place in Zambia, and if successful will be emulated elsewhere. Darnton-Hill and Nalubola (*27*) have identified at least 27 developing countries that could benefit from programmes to fortify one or more foods.

Despite apparent past successes, to date, very few fortification programmes have formally evaluated their impact on nutritional status. However, without a specific evaluation component, once a fortification programme has been initiated, it is difficult to know whether subsequent improvements in the nutritional status of a population are due to the intervention or to other changes, such as, improvements in socioeconomic status or in public health provision, that occurred over the same period of time. Evidence that food fortification programmes do indeed improve nutritional status has therefore tended to come from either efficacy trials and/or reports of programme effectiveness. Efficacy trials, i.e. trials conducted in controlled feeding situations, are relatively numerous and have usefully documented the impact of fortified foods on nutritional status and other outcomes. Evidence of programme effectiveness, which is obtained by assessing changes in nutritional status and other outcomes once a programme has been implemented, is less widely available. Of the few effectiveness studies that have been conducted, even fewer included a non-intervention control group, an omission that weakens the evidence that can be obtained from studies of this type.

1.3.1 Efficacy trials

As indicated above, efficacy trials evaluate the impact of a test intervention under ideal circumstances. In the case of food fortification, this typically involves all test subjects consuming a known amount of the fortified food. In the majority of efficacy trials conducted to date, fortified foods have been shown to improve micronutrient status. Selected examples, involving a range of micronutrients, are briefly described below. The general principles of programme impact evaluation, including the design of efficacy trials, are discussed in greater detail in Chapter 8 of these guidelines.

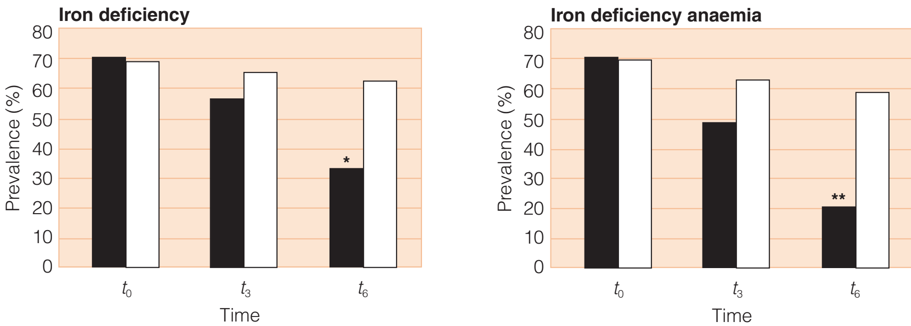
1.3.1.1 Iron fortification

In Viet Nam, 6-month efficacy trials have established that fortification of fish sauce with iron can significantly improve iron status and reduce anaemia and iron deficiency (*28*). The subjects were non-pregnant anaemic female factory workers who consumed 10 ml per day of a sauce that was fortified with 100 mg iron (as NaFeEDTA) per 100 ml. **Figure 1.1** illustrates the effect of the intervention on iron deficiency and iron-deficiency anaemia; both were significantly reduced after 6 months in the group receiving the fortified sauce relative to the placebo control group.

In China, a series of studies have been conducted to assess the efficacy, effectiveness and feasibility of fortifying soy sauce with iron (in the form of NaFeEDTA). Daily consumption of 5 mg or 20 mg iron in the fortified sauce was reported to be very effective in the treatment of iron-deficiency anaemia in children; positive effects were seen within 3 months of the start of the intervention (J. Chen, cited in (*29*). In a double-blind placebo-controlled effectiveness trial of the iron-fortified sauce, involving about 10 000 children and women, a reduction in the prevalence of anaemia was observed within 6 months (see also section 1.3.2.2).

FIGURE 1.1

Effect of iron fortification of fish sauce on iron status of non-pregnant anaemic female Vietnamese factory workers



Prevalence of iron deficiency and iron deficiency anaemia at baseline, and after 3 and 6 months of intervention in the iron intervention group ■ (10 mg iron/day in NaFeEDTA-fortified fish sauce (n = 64)) and the control group □ (n = 72) in anaemic Vietnamese women.

Source: reproduced from reference (*28*), with the permission of the publishers.

In an iron-deficient Indian population in South Africa, fortification of curry powder with NaFeEDTA produced significant improvements in blood haemoglobin, ferritin levels and iron stores in women, and in ferritin levels in men (*30*). During the 2-year study, the prevalence of iron-deficiency anaemia in women fell from 22% to just 5%.

Regrettably, well-designed trials of the impact of iron fortification of flour are lacking at the present time.

1.3.1.2 Vitamin A fortification

Trials conducted in the Philippines have revealed that fortification of monosodium glutamate with vitamin A produces positive effects on child mortality, and improved growth and haemoglobin levels in children (*31*). Later studies with preschool-aged children, who consumed 27 g of vitamin A-fortified margarine per day for a period of 6 months, reported a reduction in the prevalence of low serum retinol concentrations from 26% to 10% (*32*). Wheat flour fortified with vitamin A and fed as buns to Filipino schoolchildren for 30 weeks had the effect of halving the number that had low liver stores of the vitamin (*33*).

1.3.1.3 Multiple fortification

A number of trials have evaluated the efficacy of specially-formulated foods and beverages as vehicles for multiple fortification. In South Africa, for example, fortification of biscuits with iron, β-carotene and iodine improved the status of all of these nutrients in schoolchildren (*34*). Vitamin A and iron status deteriorated during the long school holidays when the biscuits were not fed. Fortification of a flavoured beverage with 10 micronutrients increased serum retinol and reduced iron deficiency in Tanzanian schoolchildren, and also improved their growth rates (*35*). Similarly, in Botswana, regular consumption of a 12-micronutrient enriched beverage by school-aged children increased their weight gain and mid-upper arm circumference, and improved their iron, folate, riboflavin and zinc status (*36*).

1.3.2 Effectiveness evaluations

The aim of an effectiveness evaluation is to assess the impact of an intervention or programme in actual practice, as opposed to under controlled conditions. Because of factors such as the lack of consumption of the fortified food, the magnitude of the impact of an intervention is likely to be less than that in an efficacy trial (see also Chapter 8: Monitoring and evaluation).

1.3.2.1 Iodine fortification

Numerous studies, particularly from the developed world, have clearly established that salt iodization is an effective means of controlling iodine deficiency. In the United States, large-scale iodization of salt in Michigan reduced the goitre rate from about 40% to below 10% (*26*). In the early 20th century almost all Swiss schoolchildren had goitre and 0.5% of the population had cretinism. When salt iodization was introduced in 1922, the prevalence of goitre and deaf mutism in children dropped dramatically. Since then, a sustained salt iodization programme has ensured an adequate iodine status among the whole Swiss population (*25*). Despite such convincing evidence in support of salt iodization, in as recently as 2003, it was estimated that 54 countries still have inadequate iodine nutrition (i.e. median urinary iodine $< 100\,\mu g/l$) (*2*).

1.3.2.2 Iron fortification

The effectiveness of iron fortification has been demonstrated in several world regions. Iron fortification of infant formulas has been associated with a fall in the prevalence of anaemia in children aged under 5 years in the United States (*37,38*). In Venezuela, wheat and maize flours have been fortified with iron (as a mixture of ferrous fumarate and elemental iron), vitamin A and various B vitamins since 1993. A comparison of the prevalence of iron deficiency and anaemia pre- and post-intervention showed a significant reduction in the prevalence of these conditions in children (*39*). Fortification of milk with iron and vitamin C (ascorbic acid) in Chile produced a rapid reduction in the prevalence of iron deficiency in infants and young children (*40,41*). The effectiveness of the fortification of soy sauce with iron is currently being evaluated in a population of 10 000 Chinese women and children with a high risk of anaemia. Preliminary results of the 2-year double-blind placebo-controlled study have shown a reduction in anaemia prevalence rates for all age groups after the first 6 months (J. Chen, cited in (*29*).

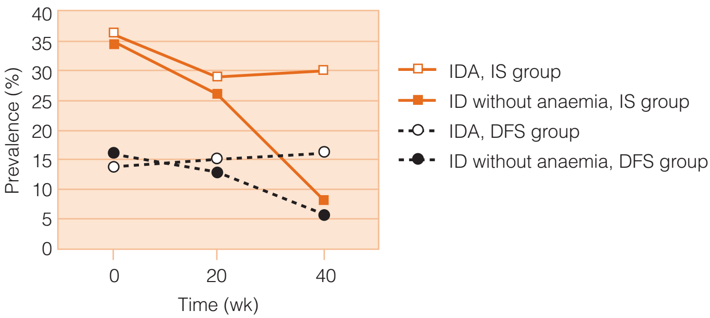
Unfortunately, very few other iron fortification programmes have been evaluated. Information about the efficacy and effectiveness of flour fortification in particular is urgently needed (*42*).

1.3.2.3 Combined iron and iodine fortification

A randomized, double-blind effectiveness trial in Moroccan schoolchildren (n = 367) has demonstrated that the dual fortification of salt with iron and iodine can improve both iron and iodine status (*43*). Results of the 40-week trial, in which salt was fortified with iron at a level of 1 mg Fe/g salt (as ferrous sulfate microencapsulated with partially hydrogenated vegetable oil) are summarized in **Figure 1.2**. In addition to improved iron status, by the end of the trial the iron-fortified group had significantly lower thyroid volumes. Because iron is required for thyroxine synthesis, iron deficiency reduces the efficacy of iodine prophylaxis. Thus, by supplying both iodine and iron, the impact of iodine fortification is maximized.

FIGURE 1.2

Effect of dual-fortified salt (iron and iodine) on the iron status of Moroccan schoolchildren



The probability of iron deficiency anaemia (IDA) and iron deficiency without anaemia (ID) was significantly less in 6–15 year-old children receiving dual-fortified salt (DFS) containing both iron and iodine (n = 183) than in those receiving iodized salt (IS) (n = 184). For both IDA and ID without anaemia, the difference between the IS and DFS groups increased significantly with time ($P < 0.01$).

Source: reproduced from reference (*44*).

1.3.2.4 Vitamin A fortification

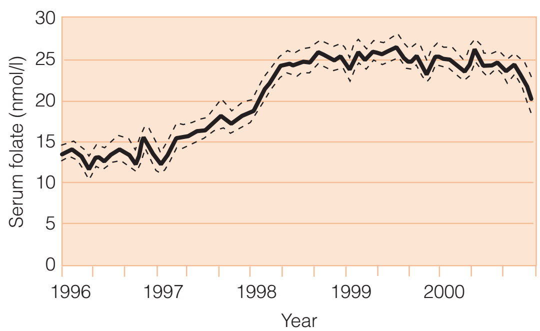
Fortification of sugar with vitamin A is a strategy that has been used extensively throughout Central America. Starting in Guatemala in 1974, and extending to other countries in the region in subsequent years, the effect of this programme has been to reduce the prevalence of low serum retinol values – from 27% in 1965 to 9% in 1977 (*45,46*). There is also evidence to suggest that sugar fortification substantially increases the concentration of vitamin A in breast milk (*47*). When the programme was temporarily discontinued in parts of the region, the prevalence of low serum retinol again increased. Vitamin A fortification of sugar is, however, still ongoing in Guatemala.

1.3.2.5 Folic acid fortification

The introduction of the mandatory fortification of wheat flour with folic acid in the United States in 1998 was accompanied by a significant reduction in the prevalence of neural tube defects (*48*) and in plasma levels of homocysteine. (Elevated plasma homocysteine has been identified as a risk factor for cardiovascular disease and other health problems (*49*). Even though these outcomes may have been due to other factors, there was certainly an increase in folate intakes (*50*) and an improvement in folate status (*49*) among the population in the period immediately following the implementation of the new legislation. Similar improvements in folate status have been seen after the commencement of folic acid fortification of wheat flour in Canada (*51*) (**see Figure 1.3**).

FIGURE 1.3

Effect of flour fortification with folic acid on the folate status of elderly Canadian women



Serum folate concentrations in a cross-section of 15 664 Canadian women aged 65 years and older in relation to the introduction of flour fortification in mid-1997. Data are presented as mean values (solid line) with 95% confidence limits (dotted lines)

Source: reproduced from reference (*53*), with the permission of the publishers.

Likewise, in Chile, a national programme of flour fortification with folic acid increased serum folate and reduced serum homocysteine in a group of elderly people (*52*).

1.3.2.6 Fortification with other B vitamins

Beriberi, riboflavin deficiency, pellagra and anaemia were relatively widespread public health problems during the 1930s in several countries, including the United States. In an attempt to reduce the prevalence of these conditions, a decision was taken to add thiamine, riboflavin, niacin and iron to wheat flour. With the implementation of fortification programmes for these micronutrients during the early 1940s in the United States and in some European countries, these deficiencies largely disappeared (*54*). While it can be argued that other factors – such as improved dietary diversity – also played a role, enriched flour continues to make an important contribution to meeting recommended nutrient intakes for the B-complex vitamins and iron in these and many other countries today.

1.3.2.7 Vitamin D fortification

The virtual elimination of childhood rickets in the industrialized countries has been largely attributed to the addition of vitamin D to milk, a practice that commenced in the 1930s in Canada and the United States. However, there are some signs that rickets is re-emerging as a public health problem in these countries (*55*). In a recent study of African American women, a low intake of vitamin D fortified milk was found to be a significant predictor of a high prevalence of vitamin D deficiency (*56*). Vitamin D fortification of milk also reduces the risk of osteoporosis in the elderly, especially in higher latitude regions where levels of incident ultraviolet light are lower during the winter months (*57,58*).

1.4 Advantages and limitations of food fortification as a strategy to combat MNM

Being a food-based approach, food fortification offers a number of advantages over other interventions aimed at preventing and controlling MNM. These include:

- If consumed on a regular and frequent basis, fortified foods will maintain body stores of nutrients more efficiently and more effectively than will intermittent supplements. Fortified foods are also better at lowering the risk of the multiple deficiencies that can result from seasonal deficits in the food supply or a poor quality diet. This is an important advantage to growing children who need a sustained supply of micronutrients for growth and development, and to women of fertile age who need to enter periods of pregnancy and lactation with adequate nutrient stores. Fortification can be an excellent way of increasing the content of vitamins in breast milk and thus reducing the need for supplementation in postpartum women and infants.

- Fortification generally aims to supply micronutrients in amounts that approximate to those provided by a good, well-balanced diet. Consequently, fortified staple foods will contain "natural" or near natural levels of micronutrients, which may not necessarily be the case with supplements.
- Fortification of widely distributed and widely consumed foods has the potential to improve the nutritional status of a large proportion of the population, both poor and wealthy.
- Fortification requires neither changes in existing food patterns – which are notoriously difficult to achieve, especially in the short-term – nor individual compliance.
- In most settings, the delivery system for fortified foods is already in place, generally through the private sector. The global tendency towards urbanization means that an ever increasing proportion of the population, including that in developing countries is consuming industry-processed, rather than locally-produced, foods. This affords many countries the opportunity to develop effective strategies to combat MNM based on the fortification of centrally-processed dietary staples that once would have reached only a very small proportion of the population.
- Multiple micronutrient deficiencies often coexist in a population that has a poor diet. It follows that multiple micronutrient fortification is frequently desirable. In most cases, it is feasible to fortify foods with several micronutrients simultaneously.
- It is usually possible to add one or several micronutrients without adding substantially to the total cost of the food product at the point of manufacture.
- When properly regulated, fortification carries a minimal risk of chronic toxicity.
- Fortification is often more cost-effective than other strategies, especially if the technology already exists and if an appropriate food distribution system is in place (*59,60*).

Although it is generally recognized that food fortification can have an enormous positive impact on public health, there are, however, some limitations to this strategy for MNM control:

- While fortified foods contain increased amounts of selected micronutrients, they are not a substitute for a good quality diet that supplies adequate amounts of energy, protein, essential fats and other food constituents required for optimal health.

- A specific fortified foodstuff might not be consumed by all members of a target population. Conversely, everyone in the population is exposed to increased levels of micronutrients in food, irrespective of whether or not they will benefit from fortification.
- Infants and young children, who consume relatively small amounts of food, are less likely to be able to obtain their recommended intakes of all micronutrients from universally fortified staples or condiments alone; fortified complementary foods may be appropriate for these age groups. It is also likely that in many locations fortified foods will not supply adequate amounts of some micronutrients, such as iron for pregnant women, in which case supplements will still be needed to satisfy the requirements of selected population groups.
- Fortified foods often fail to reach the poorest segments of the general population who are at the greatest risk of micronutrient deficiency. This is because such groups often have restricted access to fortified foods due to low purchasing power and an underdeveloped distribution channel. Many undernourished population groups often live on the margins of the market economy, relying on own-grown or locally produced food. Availability, access and consumption of adequate quantities and a variety of micronutrient-rich foods, such as animal foods and fruits and vegetables, is limited. Access to the food distribution system is similarly restricted and these population groups will purchase only small amounts of processed foods. Rice production, in particular, tends to be domestic or local, as does maize production. In populations who rely on these staples, it may be difficult to find an appropriate food to fortify. Fortification of sugar, sauces, seasonings and other condiments may provide a solution to this problem in some countries, if such products are consumed in sufficient amounts by target groups.
- Very low-income population groups are known to have coexisting multiple micronutrient deficiencies, as a result of inadequate intakes of the traditional diet. Although multiple micronutrient fortification is technically possible, the reality is that the poor will be unable to obtain recommended intakes of all micronutrients from fortified foods alone.
- Technological issues relating to food fortification have yet to be fully resolved, especially with regard to appropriate levels of nutrients, stability of fortificants, nutrient interactions, physical properties, as well as acceptability by consumers including cooking properties and taste (see Part III).

- The nature of the food vehicle, and/or the fortificant, may limit the amount of fortificant that can be successfully added. For example, some iron fortificants change the colour and flavour of many foods to which they are added, and can cause the destruction of fortificant vitamin A and iodine. Ways of solving some of these problems (e.g. microencapsulation of fortificants with protective coatings) have been developed, but some difficulties remain (see Part III).
- While it is generally possible to add a mixture of vitamins and minerals to relatively inert and dry foods, such as cereals, interactions can occur between fortificant nutrients that adversely affect the organoleptic qualities of the food or the stability of the nutrients. Knowledge is lacking about the quantitative impact of interactions among nutrients that are added as a mixture on the absorption of the individual nutrients. This complicates the estimation of how much of each nutrient should be added. For example, the presence of large amounts of calcium can inhibit the absorption of iron from a fortified food; the presence of vitamin C has the opposite effect and increases iron absorption.
- Although often more cost-effective than other strategies, there are nevertheless significant costs associated with the food fortification process, which might limit the implementation and effectiveness of food fortification programmes. These typically include start-up costs, the expense of conducting trials for micronutrient levels, physical qualities and taste, a realistic analysis of the purchasing power of the expected beneficiaries, the recurrent costs involved in creating and maintaining the demand for these products, as well as the cost of an effective national surveillance system to ensure that fortification is both effective and safe (see Chapter 9).

To ensure their success and sustainability, especially in resource-poor countries, food fortification programmes should be implemented in concert with poverty reduction programmes and other agricultural, health, education and social intervention programmes that promote the consumption and utilization of adequate quantities of good quality nutritious foods among the nutritionally vulnerable. Food fortification should thus be viewed as a complementary strategy for improving micronutrient status.

CHAPTER 2

Food fortification: basic principles

Food fortification is usually regarded as the deliberate addition of one or more micronutrients to particular foods, so as to increase the intake of these micronutrient(s) in order to correct or prevent a demonstrated deficiency and provide a health benefit. The extent to which a national or regional food supply is fortified varies considerably. The concentration of just one micronutrient might be increased in a single foodstuff (e.g. the iodization of salt), or, at the other end of the scale, there might be a whole range of food–micronutrient combinations. The public health impact of food fortification depends on a number of parameters, but predominantly the level of fortification, the bioavailability of the fortificants, and the amount of fortified food consumed. As a general rule, however, the more widely and regularly a fortified food is consumed, the greater the proportion of the population likely to benefit from food fortification.

2.1 Terminology

2.1.1 Food fortification

For the purpose of these guidelines, food fortification is defined as the practice of deliberately increasing the content of essential[1] micronutrients – that is to say, vitamins and minerals (including trace elements) – in a food so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health. The public health benefits of fortification may either be demonstrable, or indicated as potential or plausible by generally accepted scientific research, and include:

- Prevention or minimization of the risk of occurrence of micronutrient deficiency in a population or specific population groups.
- Contribution to the correction of a demonstrated micronutrient deficiency in a population or specific population groups.

[1] The word "essential" means any substance that is normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body (*61*).

- A potential for an improvement in nutritional status and dietary intakes that may be, or may become, suboptimal as a result of changes in dietary habits/lifestyles.
- Plausible beneficial effects of micronutrients consistent with maintaining or improving health (e.g. there is some evidence to suggest that a diet rich in selected anitoxidants might help to prevent cancer and other diseases).

The Codex *General Principles for the Addition of Essential Nutrients to Foods* (*61*) defines "fortification", or synonymously "enrichment", as "the addition of one or more essential nutrients to a food whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups". The Codex General Principles go on to state that the first-mentioned condition for the fulfilment of any fortification programme "should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits" (*61*).

The broad definition of fortification used in these guidelines extends the interpretation of public health need prescribed by the Codex *General Principles for the Addition of Essential Nutrients to Foods* (*61*) in that it also incorporates plausible public health benefits that may be derived from increased micronutrient intakes (as opposed to merely demonstrable benefits), based on new and evolving scientific knowledge. The broader definition thus encompasses the growing range of different types of food fortification initiatives that have been implemented in recent years in response to an increasingly diverse set of public health circumstances.

Clearly, the public health significance of the potential benefits of food fortification is primarily a function of the extent of the public health problem. Generally speaking, therefore, when deciding to implement a fortification programme, priority should be given to controlling those nutrient deficiencies that are most common in the population and that have the greatest adverse effect on health and function. In Part II of these guidelines, appropriate criteria that can be applied to the determination of the significance of the public health problem are described; these criteria are largely expressed in terms of the prevalence and severity of MNM. Ideally this should be determined at the country or regional level.

2.1.2 Related codex terminology

The following definitions are used in these guidelines as follows:

- *Restoration* is the addition of essential nutrients to foods to restore amounts originally present in the natural product that are unavoidably lost during processing (e.g. milling), storage or handling.
- *Nutritional equivalence* is achieved when an essential nutrient is added to a product that is designed to resemble a common food in appearance, texture, flavour and odour in amounts such that the substitute product has a similar nutritive value, in terms of the amount and bioavailability of the added essential nutrient. An example is the addition of vitamin A to margarine sold as a butter substitute, in an amount equal to butter's natural content.
- *Appropriate nutrient composition of a special purpose food* describes the addition of an essential nutrient to a food that is designed to perform a specific function (such as meal replacement or a complementary food for young children), or that is processed or formulated to satisfy particular dietary requirements, in amounts that ensure that the nutrient content of the food is adequate and appropriate for its purpose.

Whereas restoration and nutritional equivalence are strategies aimed at correcting food supply changes that could otherwise adversely affect public health, the term "fortification" tends to be reserved for essential nutrient additions that address specific public health needs. Nevertheless, all the Codex categories of nutrient additions adopt, albeit to a varying degree, the general aim of providing a public health benefit.

2.2 Types of fortification

Food fortification can take several forms. It is possible to fortify foods that are widely consumed by the general population (mass fortification[1]), to fortify foods designed for specific population subgroups, such as complementary foods for young children or rations for displaced populations (targeted fortification) and/or to allow food manufacturers to voluntarily fortify foods available in the market place (market-driven fortification[2]).

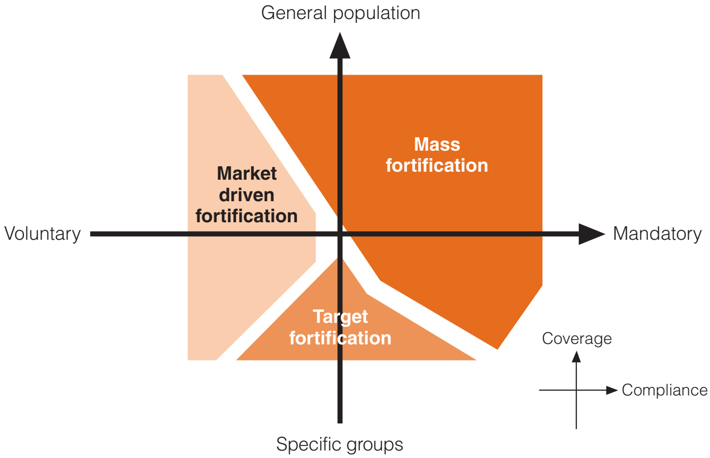
Generally speaking, mass fortification is nearly always mandatory, targeted fortification can be either mandatory or voluntary depending on the public health significance of the problem it is seeking to address, and market-driven fortification is always voluntary, but governed by regulatory limits (**Figure 2.1**). The choice between mandatory or voluntary food fortification usually depends on national circumstances. For example, in countries where a large proportion of maize flour is produced by small mills, enforcement of mandatory fortifica-

[1] Mass fortification is sometimes called "universal fortification".

[2] Market-driven fortification is sometimes called "industry-driven fortification", "open-market" or "free-market" fortification.

FIGURE 2.1

The interrelationships between the levels of coverage and compliance and the different types of food fortification



tion might be impractical. Under such circumstances, one option would be, if feasible, to allow small mills to fortify their product on a voluntary basis but following specified regulations.

2.2.1 Mass fortification

As indicated above, mass fortification is the term used to describe the addition of one or more micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk. It is usually instigated, mandated and regulated by the government sector.

Mass fortification is generally the best option when the majority of the population has an unacceptable risk, in terms of public health, of being or becoming deficient in specific micronutrients. In some situations, deficiency may be demonstrable, as evidenced by unacceptably low intakes and/or biochemical signs of deficiency. In others, the population may not actually be deficient according to usual biochemical or dietary criteria, but are likely to benefit from fortification. The mandatory addition of folic acid to wheat flour with a view to lowering the risk of birth defects, a practice which has been introduced in Canada and the United States, and also in many Latin American countries, is one example of the latter scenario.

2.2.2 Targeted fortification

In targeted food fortification programmes, foods aimed at specific subgroups of the population are fortified, thereby increasing the intake of that particular group

TABLE 2.1
Targeted food fortification programmes

Country	Food	Target population
Guatemala	Incaparina	
Indonesia	Complementary foods	Infants
Mexico	Progresa	
Peru	Ali Alimentu	Schoolchildren
South Africa	Biscuits	Schoolchildren

rather than that of the population as a whole. Examples include complementary foods for infants and young children, foods developed for school feeding programmes, special biscuits for children and pregnant women, and rations (blended foods) for emergency feeding and displaced persons (**Table 2.1**). In some cases, such foods may be required to provide a substantial proportion of daily micronutrient requirements of the target group.

The majority of blended foods for feeding refugees and displaced persons are managed by the World Food Programme (WFP) and guidelines covering their fortification (including wheat soy blends and corn soy blends) are already available (*62*). Although blended foods usually supply all or nearly all of the energy and protein intake of refugees and displaced individuals, especially in the earlier stages of dislocation, for historical reasons such foods may not always provide adequate amounts of all micronutrients. Therefore, other sources of micronutrients may need to be provided. In particular, it may be necessary to add iodized salt to foods, provide iron supplements to pregnant women or supply high-dose vitamin A supplements to young children and postpartum women. Whenever possible, fresh fruits and vegetables should be added to the diets of displaced persons relying on blended foods (see Chapter 4: section 4.5). Fortified foods for displaced persons are often targeted at children and pregnant or lactating women.

2.2.3 Market-driven fortification

The term "market-driven fortification" is applied to situations whereby a food manufacturer takes a business-oriented initiative to add specific amounts of one or more micronutrients to processed foods. Although voluntary, this type of food fortification usually takes place within government-set regulatory limits (see Chapter 11: National food law).

Market-driven fortification can play a positive role in public health by contributing to meeting nutrient requirements and thereby reducing the risk of micronutrient deficiency. In the European Union, fortified processed foods have been shown to be a substantial source of micronutrients such as iron, and vitamins A and D (*63,64*). Market-driven fortification can also improve the supply of micronutrients that are otherwise difficult to add in sufficient amounts through the mass fortification of staple foods and condiments because of safety, technological or cost constraints. Examples include certain minerals (e.g. iron, calcium) and sometimes selected vitamins (e.g. vitamin C, vitamin B_2).

Market-driven fortification is more widespread in industrialized countries, whereas in most developing countries the public health impact of market-driven food interventions is still rather limited. However, their importance is likely to be greater in the future, because of increasing urbanization and wider availability of such foods.

The predicted increase in the availability of fortified processed foods in developing countries has given rise to a number of concerns. Firstly, these fortified foods – especially those that are attractive to consumers – could divert consumers from their usual dietary pattern and result in, for example, an increased consumption of sugar, or a lower consumption of fibre. Secondly, because in most developing countries foods fortified through market-driven fortification currently receive scant regulatory attention even though such foods are intended for wide-scale consumption (see section 2.3), there is a potential risk that unnecessarily high levels of micronutrients may be delivered to children if the same serving size of the fortified food (such as breakfast cereals, beverages and nutrition bars) is intended for all members of a household. Regulation is thus necessary to ensure that the consumption of these foods will not result in an excessive intake of micronutrients. Furthermore, manufacturers of processed fortified foods should be encouraged to follow the same quality control and assurance procedures as those that are prescribed for mandatory mass-fortified products (see Chapter 8: Monitoring and evaluation).

2.2.4 Other types of fortification

2.2.4.1 Household and community fortification

Efforts are under way in a number of countries to develop and test practical ways of adding micronutrients to foods at the household level, in particular, to complementary foods for young children. In effect, this approach is a combination of supplementation and fortification, and has been referred to by some as "complementary food supplementation" (*65*).

The efficacy and effectiveness of several different types of products, including soluble or crushable tablets, micronutrient-based powder ("sprinkles") and micronutrient-rich spreads are currently being evaluated (**Table 2.2**). Crushable tablets, and especially micronutrient-based powder, are relatively expensive ways of increasing micronutrient intakes, certainly more costly than mass fortification, but may be especially useful for improving local foods fed to infants and young children, or where universal fortification is not possible (*66*). The

TABLE 2.2
Foods for fortification at the household level

Product	Comments
Micronutrient powder which can be sprinkled onto food	■ Contain several micronutrients, including iron, encapsulated to minimize adverse interactions between micronutrients and sensory changes to the food to which they are added; available in sachets
Soluble micronutrient tablets which can be dissolved in water and fed as a drink	■ Suitable for young children; ■ Tested by WHO
Crushable micronutrient tablets for adding to foods	■ For infants and young children ■ Tested by UNICEF
Fat-based spread fortified with micronutrient	■ Popular with children ■ Can be produced locally as the technology required is easy to implement

Sources: references (*66,67*).

micronutrient-dense fortified spreads have been found to be very popular with children (*67*).

Fortification of foods at the community level is also still at the experimental stage. One such approach involves the addition of a commercial micronutrient premix, available in sachets, to small batches of flour during the milling process (*68*). Although feasible in theory, major challenges to local-scale fortification programmes include the initial cost of the mixing equipment, the price of the premix (which would need to be imported in most cases), achieving and maintaining an adequate standard of quality control (e.g. in uniformity of mixing), and sustaining monitoring and distribution systems.

2.2.4.2 Biofortification of staple foods

The biofortification of staple foods, i.e. the breeding and genetic modification of plants so as to improve their nutrient content and/or absorption is another novel approach that is currently being considered. The potential for plant breeding to increase the micronutrient content of various cereals, legumes and tubers certainly exists; for instance, it is possible to select certain cereals (such as rice) and legumes for their high iron content, various varieties of carrots and sweet potatoes for their favourable β-carotene levels, and maizes for their low phytate content (which improves the absorption of iron and zinc) (*69–71*). However, much more work still needs to be done before the efficacy and effectiveness of these foods are proven, and current concerns about their safety, cost and impact on the environment are alleviated (*72*).

2.3 Legal considerations: mandatory versus voluntary fortification

The huge diversity in national circumstances and public health goals worldwide has resulted in the development of many different approaches to the regulation of food fortification. In most industrialized countries, food fortification parameters are established by law or through cooperative arrangements. Elsewhere, and representing the other end of the spectrum, fortified foods are produced without any form of governmental guidance or control at all. Since it is the role of government to protect public health, it is generally recommended that all forms of food fortification be appropriately regulated in order to ensure the safety of all consumers and the maximum benefit to target groups.

Within the legal context, fortification can be categorized as either mandatory or voluntary. These terms refer to the level of obligation required of food producers to comply with government intentions expressed in law.

The fundamental distinction between mandatory and voluntary regulation as it applies to food fortification is the level of certainty over time that a particular category of food will contain a pre-determined amount of a micronutrient. By providing a higher level of certainty, mandatory fortification is more likely to deliver a sustained source of fortified food for consumption by the relevant population group, and, in turn, a public health benefit.

2.3.1 Mandatory fortification

2.3.1.1 Key characteristics

Mandatory fortification occurs when governments legally oblige food producers to fortify particular foods or categories of foods with specified micronutrients. Mandatory fortification, especially when supported by a properly resourced enforcement and information dissemination system, delivers a high level of certainty that the selected food(s) will be appropriately fortified and in constant supply.

In deciding the precise form of mandatory fortification regulation, governments are responsible for ensuring that the combination of the food vehicle and the fortificants will be both *efficacious* and *effective* for the target group, yet safe for target and non-target groups alike. Food vehicles range from basic commodities, such as various types of flour, sugar and salt which are available on the retail market for use by consumers as well as ingredients of processed foods, to processed foods that are fortified at the point of manufacture. Given their widespread and regular consumption, basic commodities are more suited to mass fortification (i.e. intended to reach the whole population), whereas certain processed formulated foods are usually the better vehicle for targeted fortification initiatives (i.e. those aimed at specific population groups).

Globally, mandatory regulations are most often applied to the fortification of food with micronutrients such as iodine, iron, vitamin A, and increasingly folic acid. Of these, the iodization of salt is probably the most widely adopted form of mandatory mass fortification. In the Philippines, for example, the legal standard for iodized salt, which is appended to the Philippine Act Promoting Salt Iodization Nationwide, requires a minimum level of iodine fortification of all food-grade salt destined for human consumption (*6*). This form of mandatory regulation is used in many other countries. Other examples of mandatory mass fortification include the addition of vitamin A to sugar and margarine, and the fortification of flour with iron (usually together with restoration of vitamins B_1, B_2 and niacin), and, more recently, with folic acid and vitamin B_{12}.

The types of food vehicles that are subjected to mandatory fortification are usually characterized by either a physical or an intrinsic attribute, or a specific purpose. A requisite flour, for example, could be described as either white or wholemeal and/or milled from a particular grain, or destined for bread making. Alternatively, the prescribed fortification requirements may apply only to a food that is identified and labelled in a certain way. In the United States, for instance, only those flours and other grain products identified and labelled as "enriched" are required by law to contain added folic acid (and some other essential micronutrients). Similarly, Australia and New Zealand mandate the addition of iodine only to salt identified and labelled as "iodized salt". Although the potential public health impact is more variable, mass fortification can be achieved under these conditions, particularly if the labelled fortified foods constitute a major and stable share of the market for that food class as a whole.

2.3.1.2 Mandatory fortification in relation to public health

Governments tend to institute mandatory fortification in situations where a proportion of the general population – either the majority (mass fortification) or an identified population group (target fortification) – has a significant public health need, or is at risk of being, or becoming, deficient in a specific micronutrient(s), and where such needs or risks can be ameliorated or minimized by a sustained supply and regular consumption of particular fortified food(s) containing those micronutrients.

Mandatory fortification is usually prompted by evidence that a given population is deficient or inadequately nourished, such as clinical or biochemical signs of deficiency and/or unacceptably low levels of micronutrient intake. In some circumstances, a demonstrated public health benefit of an increased consumption of a given micronutrient might be considered sufficient grounds to warrant mandatory fortification even if the population is not considered to be seriously at risk according to conventional biochemical or dietary intake criteria. The mandatory addition of folic acid to flour to reduce the risk of birth defects is a case in point.

2.3.2 Voluntary fortification

2.3.2.1 Key characteristics

Fortification is described as voluntary when a food manufacturer freely chooses to fortify particular foods in response to permission given in food law, or under special circumstances, is encouraged by government to do so.

The impetus for voluntary fortification usually stems from industry and consumers seeking to obtain possible health benefits through an increase in micronutrient intakes. Occasionally, however, government provides the driving force. Given this diversity in the circumstances that drive voluntary fortification, it is not surprising that the public health impacts range from negligible to substantial. Indeed, depending on the nutritional quality of their basic diet, those individuals who regularly consume fortified foods might well gain discernable benefits.

However, it is important that governments exercise an appropriate degree of control over voluntary fortification through food laws or other cooperative arrangements, such as industry codes of practice. The degree of control should at least be commensurate with the inherent level of risk. Regulatory controls of this nature should also ensure the safety of fortified foods for all consumers, as well as provide opportunities for industry to produce fortified foods that offer consumers nutritional and/or other health benefits. The potential benefits may be demonstrable, or indicated as potential or plausible by generally accepted scientific data.

When instituting voluntary fortification arrangements, governments have a duty to ensure that consumers are not misled or deceived by fortification practices and may also wish to be satisfied that market promotion of fortified foods does not conflict with, or compromise, any national food and nutrition policies on healthy eating. This could be achieved through regulations on the range of foods eligible for voluntary fortification and on the permitted combinations of particular micronutrients and foods (see Chapter 11: National food law).

Currently many countries permit voluntary fortification, but the range of foods that may be fortified varies considerably from country to country. Some Scandinavian countries allow only a narrow range of foods to be fortified, whereas the range of products that can be fortified is much greater in the United States. Similarly, the permitted fortificants range from a select few to almost all micronutrients that are considered essential.

The level of industry uptake of fortification practice is greatly influenced by prevailing market conditions. For example, in many industrialized countries, the vast majority of processed breakfast cereals are moderately fortified with various combinations of micronutrients, sometimes differentiated according to the target market; the remaining few are either highly or extensively fortified (where permitted) and/or unfortified. Other food categories, such as fruit juices or dairy products, tend to exhibit a greater variability in fortification rates, this being influenced by market differentiation and brand identity. For some permitted categories there may be no industry interest in fortification.

2.3.2.2 Voluntary fortification in relation to public health

Voluntary fortification tends to be used when there are lower order risks to public health, i.e. when the risks to public health are not as serious or demonstrable so as to warrant mass fortification. Inadequate micronutrient intakes that arise because of changes in lifestyles that tend to follow changing social and economic circumstances are more likely to be associated with lower order public health risks than inadequate intakes that arise because of significantly modified eating habits and dietary behaviour. In addition, for certain nutrients, dietary requirements have been reappraised in light of evolving scientific knowledge about their physiological role and the beneficial effects on certain physiological processes and health conditions.

Because of uncertainty about the level of industry uptake of fortification within each food product category, and the fact that regular consumers of a given fortified food may vary over time and thus do not constitute a readily identifiable group, voluntary fortification is less likely than mandatory fortification to deliver a guaranteed favourable outcome in terms of increased intakes of micronutrients across a target population. Apart from the extent to which a given food category is fortified, the public health impact of voluntary fortification depends on the contribution of that food category to the diet of the population as whole, and also whether or not those individuals who would benefit most from fortification regularly consume and have access to that food category.

Despite these inherent difficulties, a consistent supply of appropriately regulated, voluntarily-fortified foods, produced under free-market conditions and widely and regularly consumed by a given population group, can have a beneficial impact on public health by positively contributing to micronutrient balance and thereby reducing the risk of deficiency. For example, in the European Union where fortification of margarine is voluntary, it is estimated that the addition of vitamins A and D to margarine and spreadable fats contributes about 20% of the reference nutrient intake for vitamin A and 30% of that for vitamin D (*63*). It has also been reported that by the 1990s fortified breakfast cereals had become the principal source of iron for young children in the United Kingdom (*64*).

2.3.3 Special voluntary fortification

Some voluntary fortification programmes are capable of achieving similar outcomes to mandatory fortification, thus avoiding the need for complex mandatory legal requirements. A notable example is the Swiss programme of salt iodization. Circumstances that contribute to the success of voluntary fortification in Switzerland and elsewhere include the existence of an industry that comprises only a few producers or manufacturers and a strong government interest in industry practice (e.g. one that provides subsidies and ensures sustainable fortification practices). Voluntary fortification initiatives are also more likely to succeed when supported by public education activities that increase public awareness of the importance of consuming the fortified food (see Chapter 10: Communication, social marketing and advocacy).

2.3.4 Criteria governing the selection of mandatory or voluntary fortification

For any given population group, which may be either the entire population or a specific subgroup(s), there are five key factors that together determine whether mandatory or voluntary fortification is likely to be the most appropriate option for the prevailing conditions. In brief, they are: the significance of the public health need; the size and scale of the food industry sector; the level of awareness among the population about nutritional needs; the political environment; and food consumption patterns. These five factors are described in more detail below, and in each case, an indication given of the circumstances that favour one or the other of the two main regulatory mechanisms.

1. *The significance of the public health need or risk of deficiency, as determined by the severity of the problem and its prevalence within a population group.* The significance of the public health problem is of primary importance and should be determined at the country or regional level, ideally with reference to set criteria that describe the severity of the public health problem. The public health need or risk can be assessed according to evidence of clinical or subclinical deficiency, inadequate nutrient intake, or potential health benefit (see Part II: Evaluating the public health significance of micronutrient malnutrition).

- **Mandatory fortification** is more suited to cases of serious public health need or risk, and **voluntary fortification** to cases of lower order public health need or risk, or where the potential exists for some individuals to benefit from, or to exercise, consumer choice.
- Under certain conditions, **voluntary fortification** can achieve similar public health impacts as mandatory fortification.

2. *The features of the food industry sector that will responsible for the production of the proposed food vehicle.* The aspects of the food industry sector that are especially relevant in this context are the number, capacity and geographical distribution of the producers, the presence of any government support or control, and the prevailing commercial environment.

- In developing countries in particular, **mandatory fortification** is more likely to succeed when the industry sector in question is either relatively centralized (i.e confined to a handful of major producers) and/or well organized. If it consists of numerous small, widely dispersed producers, mandatory fortification will be more difficult to achieve, unless these small units have some form of collective arrangement in place, such as an established industry association. It is also the better option in settings where governments seeking high rates of industry participation do not have any alternative legal or administrative arrangements that could potentially be used to institute voluntary cooperative arrangements within the industry.
- **Voluntary fortification** does not need to take account of industry arrangements but where there is a monopoly or a government-sponsored industry, the impact of voluntary arrangements can match those achieved by mandatory fortification.

3. *The relevant population's present level of knowledge about the importance of consuming fortified foods or their interest in consuming fortified foods.* The level of resources available for implementing and sustaining specific nutrition education programmes is also an important factor to consider when choosing the most suitable regulatory environment for a food fortification programme.

- **Mandatory fortification** is likely to be the more effective option when consumer knowledge is poor or demand for voluntarily-fortified products is low, and there are few opportunities for community nutrition education.
- **Voluntary fortification** generally relies on consumer interest and/or demand for fortified foods. Although consumer behaviour is influenced by many factors, it could be engendered by commercial promotion or specific nutrition education programmes.

4. *The political environment.* In terms of the political environment, the acceptable level of government intervention and the value placed on informed consumer choice are probably the most significant factors that affecting regulatory decisions.

- In environments where consumer choice is highly valued, both **voluntary and mandatory fortification** could be appropriate. In such settings, **mandatory fortification** tends to be limited to a subset of products within one or more proposed food categories, in order to maintain some degree of consumer choice.
- **Voluntary fortification** usually confers a higher level of consumer choice; however, this is not the main issue in many developing countries, where poverty remains the limiting factor to access to processed foods for the majority of the population.

5. *Food consumption patterns.* Clearly, food consumption patterns, especially in terms of the relative contributions of certain foods to the diet of the target population, will have a bearing on the choice of mandatory or voluntary fortification. Linked to this factor is the issue of the technical suitability of the candidate food as a vehicle for fortification.

- Foods considered for **mandatory fortification** should be widely and regularly consumed by the population group that the fortification is intended to benefit. In addition, the fortification itself should be technically feasible.
- The likelihood of all at-risk consumers increasing their usual micronutrient intake through **voluntary fortification** is lower than with mandatory fortification. However, the likelihood rises as the particular micronutrient is added to a wider range of voluntarily-fortified foods, assuming they are accessible to consumers.