PART IV

Implementing effective and sustainable food fortification programmes

Introduction

As the preceding chapters have demonstrated, food fortification has a long history of successful practice. Notable successes have been in achieved in the case of the iodization of salt, the fortification of flour with various B vitamins, and the fortification of margarines with vitamin A. It would, however, be something of an overstatement to say that these past successes have been the result of formal, scientifically-rigorous evaluations of the nutritional status and needs of the target population. In many cases, decisions about how much fortificant to add to a chosen food vehicle were based on what was known to be technically possible at the time, and governed by budgetary limits.

With a view to putting fortification programme planning on a sounder footing, this section of the present Guidelines sets out a systematic and methodological approach to designing and planning a food fortification programme. The key elements are as follows:

— defining and setting nutritional goals (i.e. framing decisions about how much micronutrient(s) to add to which foods);

— programme monitoring and evaluation (i.e. establishing procedures which check that fortified foods contain the intended amount of micronutrient(s) and that they are being consumed by the target population in adequate amounts);

— communicating and marketing fortification programmes (i.e. informing the target population about the benefits of fortification so that they chose to consume fortified foods).

In order to be able to correct a micronutrient deficiency in a population, which is after all the ultimate goal of any fortification programme, it is necessary to first ascertain the extent of the deficiency and then the increase in intake that is needed to satisfy the daily requirement for that micronutrient. Chapter 7 explains the application of the Estimated Average Requirement (EAR) cut-point method to the problem of calculating the level of micronutrient additions that is needed to bring the prevalence of low intakes among a target population to an acceptably small level. This is the WHO recommended method and is applicable to all micronutrients covered in these Guidelines, with the exception of

iron (for which an alternative methodology is described). The information needs for such computations, e.g. data on food and nutrient intake distributions, are also outlined. Having estimated the ideal level of micronutrient addition required to achieve a given nutritional goal, programme planners are then advised to consider whether this level of fortification is feasible given current technology and any safety or cost constraints that may be operating, or whether, additional measures (e.g. supplementation), may be a better way of reaching nutritional targets, at least for some population subgroups. Technological, cost and safety limits are thus defined and a series of examples are provided to show how these can be used to shape the final decision about fortification levels appropriate to a given situation.

The primary objective of monitoring and evaluation activities is to ascertain whether or not a fortification programme is achieving its nutritional goals once it has been implemented. These are critical to the success of any fortification programme and should be viewed as an integral part of overall programme design. Monitoring and evaluation activities take place at a number of levels. The main purpose of monitoring is to track the operational performance (or implementation efficiency) of a programme. Only after monitoring has established that a fortified product of the desired quality is available and accessible to the target population in adequate amounts, can the impact of the intervention be evaluated. To date, relatively few fortification programmes have been properly evaluated, partly because impact evaluation is widely perceived to be both a complex and costly exercise. The methodologies outlined in Chapter 8 aim to demystify the process of evaluating the impact of fortification programmes. Chapter 9 explores the potential usefulness of the application of cost-effectiveness and cost–benefit analysis techniques to food fortification interventions, something that is also in its infancy. The examples given clearly demonstrate that fortification has the potential to be a particularly cost-effective solution to the problem of micronutrient malnutrition in many settings.

In order to ensure that fortified foods are consumed in adequate amounts by those who require them most, all fortification programmes will need to be supported by the right mix of educational and social marketing activities. Like monitoring and evaluation, this third key element should also be thought about at the design and planning stages of a fortification programme. Chapter 10 outlines the communication needs of all the various parties involved in the running of fortification programmes, not just the consumer, and provides guidance on how messages might be framed to best meet these needs. An understanding of the regulatory environment is also essential, and therefore these Guidelines conclude with an overview of the mechanisms for regulating fortification through national food laws. Reference to the international context is made wherever relevant.

CHAPTER 7

Defining and setting programme goals

7.1 Information needs

In order to be able to design a successful fortification programme that achieves its nutritional objectives, it is necessary to have first gathered some background information and nutritional data, in particular:

- biochemical/chemical data on nutritional status (i.e. data on the scale and severity of specific nutrient deficiencies in different population groups; see Part II);
- data on dietary patterns (i.e. the composition of the usual diet);
- detailed information on dietary intakes of micronutrients of interest (i.e. the distribution of usual intakes of specific micronutrients in a population).

This information is required to confirm the need and provide a rationale for a fortification programme. Having established the need for an intervention, the same information and data can then be used to identify and prioritize the target population groups, decide which micronutrients (and in what amounts) should be added to which foods, and to identify and understand any constraints (e.g. safety, cost, technological) that may impact on the amounts of nutrients that can be added to given foods. Specific data needs are outlined in greater detail below, whereas related issues of a more general nature, but equally important with regards to the planning stages of fortification programmes, are reviewed in **Box 7.1.**

7.1.1 Biochemical and clinical evidence of specific micronutrient deficiencies

Part II of these Guidelines describes how it is possible to classify the severity of a public health problem caused by specific micronutrient deficiencies using various biochemical and clinical indicators and criteria. Where clinical or biochemical data indicate a high prevalence of deficiency of a specific nutrient, this is usually regarded as being good evidence that the diet is not supplying enough of that particular micronutrient and that fortification is warranted. The more severe and widespread the deficiency, the greater the need for intervention.

BOX 7.1

Planning and designing a fortification programme: preliminary considerations

- The decision to implement a micronutrient fortification programme requires documented evidence that the micronutrient content of the diet is insufficient or that fortification will produce a health benefit. The objective is to lower the prevalence of micronutrient deficiencies in the population and to optimize health.
- In some situations, an insufficient intake of micronutrients is not the only risk factor for micronutrient deficiency. Other factors can play a substantial role, including, for example, the presence of infections and parasites (which, among other things, can contribute to high rates of anaemia). In these situations, it is important to determine whether fortification is a cost-effective strategy compared with other interventions (e.g. the control of infections and parasites).
- The need for a fortification programme should always be examined in the broader context of all the possible options for controlling micronutrient deficiency. It may be that, overall, a combination of interventions (i.e. fortification plus other interventions) provides the most cost-effective option. For instance, supplementation plus fortification might be a better way to ensure that specific population groups (e.g. pregnant women and young children who are often the most vulnerable groups) are protected against micronutrient deficiencies than fortification alone.
- Health authorities looking to initiate a micronutrient fortification programme should not do so without first collecting food intake data, supported by ancillary information such as biochemical data on nutritional status. This information is necessary to justify the programme, to make an informed judgement about the types and amounts of specific nutrients to include, and to understand which foods would make suitable vehicles for fortification. Given the long-term effort and investment required to implement and sustain fortification programmes, and the need to ensure that the outcome is intakes that are adequate and not excessive, it is essential to make this initial investment in the collection of adequate food intake data. Trained nutritionists will be needed for detailed programme planning, as well as for the subsequent monitoring and evaluation stages, the aim of which is to see how the programme has affected the nutrient intakes and nutritional status of the recipients.

In terms of providing reliable information on micronutrient status at the population level, biochemical and clinical data do, however, have a number of limitations. Firstly, available resources are usually such that only a relatively small number of individuals are tested or observed, and those that are sampled are not always representative of all relevant population subgroups. Secondly, some

biochemical data are difficult to interpret because of confounding factors, such as the presence of infections, or interactions among micronutrient deficiencies (see **Tables 3.1, 3.4, 3.6, 4.1, 4.3–4.5, 4.7, 4.8, 4.10, 4.11, 4.13–16**). Biochemical indicators of iron status are especially prone to problems of this nature (**Table 3.1**). It is especially important to recognize situations where non-dietary factors, such as parasitic infections, are likely to be a major cause of observed micronutrient deficiencies; this will be reflected in a greater severity and prevalence of deficiencies than would be predicted from dietary data. Under such circumstances, other public health measures – in addition to fortification – may be needed to reduce the burden of MNM.

A third limitation is a lack of data, either because of the absence of a suitable biomarker of deficiency or simply because, to date, little investigation has taken place. This means that the prevalence of many deficiencies suspected of being relatively common (e.g. riboflavin (vitamin B_2), vitamin B_{12}, zinc and calcium) is not well known (**Table 1.2**). In some cases, however, evidence of a deficiency in one micronutrient predicts the existence of deficiencies in others. For example, a high prevalence of anaemia and vitamin A deficiency is often accompanied by zinc, vitamin B_{12} and riboflavin (vitamin B_2) deficiencies, because the underlying problem in all cases is an inadequate intake of animal source foods (see Chapter 4).

7.1.2 Dietary patterns

Knowledge of the usual foods consumed can be a useful supplement to biochemical and clinical evidence of micronutrient deficiencies, and in the absence of the latter can help pinpoint which micronutrients are most likely to be lacking in the diet. For example, animal source foods are the major source of vitamins A and D, thiamin (vitamin B_1), riboflavin (vitamin B_2), iron, zinc and calcium, and are the *only* source of vitamin B_{12}. They also provide an important amount of fat, the presence of which in the diet improves the absorption of fat-soluble vitamins. Populations with a low intake of animal source foods are thus likely to experience deficiencies in some or all of these nutrients.

It is common for the intake of animal source foods to be low in disadvantaged populations; sometimes these foods are avoided because of religious or other beliefs. Another widespread problem, particularly among refugees and displaced populations, is inadequate consumption of fruits and vegetables and consequently low intakes of vitamin C (ascorbic acid) and folate. In locations where phytate or polyphenol intakes are high, the risk of iron and zinc deficiencies increases because the bioavailability of both of these minerals from foods is reduced in the presence of these compounds.

At the population level, food balance sheets, such as those produced by the Food and Agriculture Organization of the United Nations (FAO), can provide

some useful information about usual dietary patterns and also on the average consumption of certain foods that are rich in micronutrients or in absorption inhibitors, which in turn can be used to predict probable micronutrient deficiencies. Their main limitation is that, in providing information on the average intake by the general population, they do not reflect the distribution of intakes by population subgroups.

7.1.3 Usual dietary intakes

As they are the basis of decisions about which micronutrients to add to which foods and in what amounts, the possession of quantitative food and nutrient intake data is a prerequisite for any food fortification programme. Food intake data are also needed for predicting the probable impact of potential fortification interventions. Food and nutrient intake information should be available for, or collected from, different population groups (e.g. those differing in socioeconomic status, ethnicity or religious beliefs) and from different physiological status groups (e.g. children, women).

In reality, there is usually a wide range of food and nutrient intakes within any given population subgroup. As is explained in more detail later in the chapter, it is this range or the distribution of usual intakes that is of primary interest and which forms the basis for both the planning and the evaluation of food fortification interventions (see sections 7.2 and 7.3).

7.2 Defining nutritional goals: basic concepts

The main goal of a fortification programme is to correct inadequate micronutrient intakes through the fortification of foods, thereby preventing, or reducing, the severity and prevalence of micronutrient deficiencies. Interventions of this nature can involve either fortifying a single food product (e.g. the iodization of salt) or the fortification of several foods.

In practice, food fortification programmes are devised so as to achieve a level of fortification such that, when the programme is in place, the probability of the nutrient intake being inadequate in a given population – either insufficient or excessive – is acceptably low.

The dietary goal of fortification is formally defined in these Guidelines as follows: to provide most (97.5%) of individuals in the population group(s) at greatest risk of deficiency with an adequate intake of specific micronutrients, without causing a risk of excessive intakes in this or other groups.

7.2.1 The EAR cut-point method

The approach recommended in these WHO Guidelines for setting fortificant levels in foods is the *Estimated Average Requirement (EAR)*[1] *cut-point method*. This approach was proposed some years ago, and is described in detail in a report by the United States Food and Nutrition Board of the Institute of Medicine (FNB/IOM) on dietary reference intakes (*333*).

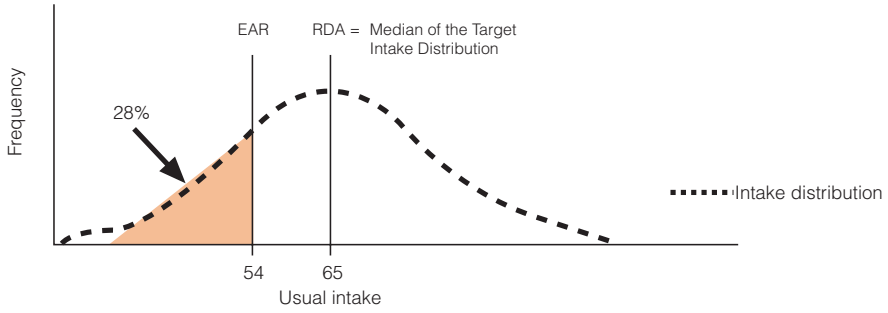
As its starting point, the EAR cut-point method assumes that the proportion of a population with intakes below the EAR for a given nutrient corresponds to the proportion having an inadequate intake of that nutrient (see **Figure 7.1**). The EAR cut-point approach requires a decision to be made about the acceptable prevalence of inadequate (and excessive) intakes (often taken to be 2–3% for reasons which are explained more fully below: see section 7.3.1). Then by combining information on the range of usual intakes of a population subgroup with information on the nutrient requirements for that subgroup (i.e. the EAR), it is possible to derive a level of food fortification that will give an intake distribution such that usual nutrient intakes meet the requirements of all but a small specified proportion of the subgroup. In other words, the method allows its users to find the additional intake of micronutrients that would shift the distribution of intakes upwards so that only a small proportion of the population group is at risk of having an inadequate intake. Here the term "subgroup" refers to various age, gender and physiological status groups of the population (e.g. pregnant or lactating women). The EAR cut-point methodology is outlined in greater detail in section 7.3 and is illustrated by means of a worked example.

The EAR cut-point method is a simplified, easier to use version of the probability method, which requires calculating the probability of inadequacy of intake for each individual in a population subgroup, averaging the probabilities, and then using this average as an estimate of the prevalence of inadequacy (*333*). These two approaches, the EAR cut-point method and the probability method, give similar results as long as the assumptions underlying them are met. For the probability method, there should be little or no correlation between intake and requirements, which is assumed to be true for all nutrients but energy. In the case of the EAR cut-point method, the variation in intake of a nutrient by a population group should be greater than the variation in the requirement for this nutrient (also assumed to be true for most nutrients and most groups), and the distribution of requirements must be symmetrical (believed to be true for all nutrients except iron). Thus for most applications and nutrients, either method is appropriate, with the exception of iron for which only the probability method is valid (see section 7.3.3.1).

[1] The Estimated Average Requirement (EAR) for a micronutrient is defined as the average daily intake that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender subgroup (*332*).

FIGURE 7.1

An example of a usual intake distribution in which the median intake is at the RNI or RDA (the formerly-used approach)



Source: adapted from reference (*333*), with the permission of the United States National Academy Press.

The EAR cut-point approach is different from the past practice of using the Recommended Nutrient Intake (or Recommended Dietary Allowance) of a nutrient as the desirable or "target" intake. For reasons that are explained more fully below, the latter approach is valid for deriving the desired nutritional intake of an individual, but not that of a population.

7.2.2 Dietary reference values: Estimated Average Requirements, Recommended Nutrient Intakes and upper limits

7.2.2.1 Recommended Nutrient Intakes

Dietary requirements for specific micronutrients, aimed at minimizing the risk of nutrient deficit or excess, have been specified by various national and international bodies, including FAO and WHO. The Recommended Nutrient Intake (RNI) is defined by FAO/WHO as the daily dietary intake level that is sufficient to meet the nutrient requirement of almost all (i.e. 97–98%) healthy individuals in a particular age, gender and physiological status group (*93*). For most nutrients, the RNI is set at about 2 standard deviations higher than the average amount required by a population group (i.e. the EAR), in order that the requirements of almost every person in the group are met. The standard deviation (or coefficient of variation)[1] of the requirement for each nutrient varies with age, gender and physiological status but for most nutrients and subgroups is between 10% and 20%.

Table 7.1 lists published FAO/WHO RNI values for all micronutrients covered by these Guidelines for selected age and gender groups (*93*). The

[1] The coefficient of variation is the standard deviation divided by the mean, expressed as a percentage.

TABLE 7.1

FAO/WHO Recommended Nutrient Intakes (RNIs) for selected population subgroups

Nutrient (unit)	1–3 years	4–6 years	19–50 years, female	Pregnant women, second trimester	Lactating women, 0–3 months	19–50 years, male
Vitamin A (μg RE)[a]	400	450	500	800	850	600
Vitamin D (μg)[b]	5	5	5	5	5	5
Vitamin E (mg α-tocopherol)	5.0	5.0	7.5	7.5	7.5	10.0
Vitamin C (mg)	30	30	45	55	70	45
Thiamine (vitamin B_1) (mg)	0.5	0.6	1.1	1.4	1.5	1.2
Riboflavin (vitamin B_2) (mg)	0.5	0.6	1.1	1.4	1.6	1.3
Niacin (vitamin B_3) (mg NE)	6	8	14	18	17	16
Vitamin B_6 (mg)	0.5	0.6	1.3	1.9	2.0	1.3
Folate (μg DFE)[c]	150	200	400	600	500	400
Vitamin B_{12} (μg)	0.9	1.2	2.4	2.6	2.8	2.4
Iron (mg)[d]						
■ 15% bioavailability	3.9	4.2	19.6	>50.0	10.0	9.1
■ 10% bioavailability	5.8	6.3	29.4	>50.0	15.0	13.7
■ 5% bioavailability	11.6	12.6	58.8	>50.0	30.0	27.4
Zinc (mg)[e]						
■ High bioavailability	2.4	2.9	3.0	4.2	5.8	4.2
■ Moderate bioavailability	4.1	4.8	4.9	7.0	9.5	7.0
■ Low bioavailability	8.3	9.6	9.8	14.0	19.0	14.0
Calcium (mg)	500	600	1000	1000	1000	1000
Selenium (μg)	17	22	26	28	35	34
Iodine (μg)	90	90	150	200	200	150

[a] 1 RE = 1 μg retinol = 12 μg β-carotene or 24 μg other provitamin A carotenoids. In oil, the conversion factor for vitamin A (retinol): β-carotene is 1 : 2. The corresponding conversion factor for synthetic β-carotene is uncertain, but a factor of 1 : 6 is generally considered to be reasonable. 1 μg RE = 3.33 IU vitamin A.

[b] In the absence of adequate exposure to sunlight, as calciferol (1 μg calciferol = 40 IU vitamin D).

[c] 1 DFE = Dietary folate equivalent = 1 μg food folate = 0.6 μg folic acid from fortified foods, which means that 1 μg folic acid = 1.7 DFE.

[d] The RNI depends on the composition of the diet. For a diet rich in vitamin C and animal protein, the bioavailability of iron is 15%; for diets rich in cereals but including sources of vitamin C, bioavailability is 10%, and for diets low in vitamin C and animal protein, bioavailability is reduced to 5%.

[e] The RNI depends on the composition of the diet. The bioavailability of zinc is high from diets rich in animal protein, moderate from diets rich in legumes and pulses or diets that include fermented cereals, and low from diets poor in animal protein or zinc-rich plant foods.

Source: reference (*93*), which also provides values for other age and gender groups. T.

BOX 7.2

FAO/WHO RNIs: comparisons with dietary reference values defined by other bodies

1. Food and Nutrition Board, Institute of Medicine (FNB/IOM), United States of America

The FAO/WHO RNI is conceptually equivalent to the *Recommended Dietary Allowance* (RDA), one of the four levels of dietary reference intakes used in Canada and the United States of America. The other three values are the *Estimated Average Requirement* (EAR), the *Adequate Intake* (AI), and the *Tolerable Upper Level* (UL)[1].

2. Department of Health, United Kingdom

The FAO/WHO RNI is conceptually similar to the Reference Nutrient Intake (RNI), one of the four dietary reference values used in the United Kingdom (*334*). The others are the *Estimated Average Requirement*, the *Lower Reference Nutrient Intake* (a concept that is unique to the United Kingdom) and the *Safe Intake*, which is conceptually similar to the Adequate Intake as defined by the United States FNB/IOM.

3. Scientific Committee for Foods, Commission of the European Community

The European Community currently uses three reference values: the *Population Requirement Intake* (PRI), which is conceptually equivalent to FAO/WHO RNI, the *Average Requirement* (AR) and the *Lower Threshold Intake* (LTI) (*335*).

FAO/WHO RNI values are broadly similar to dietary reference values defined by other national and international bodies. Various dietary reference values in common usage, and their equivalence, are summarized in **Box 7.2.**

For the majority of micronutrients, the highest recommended intakes are for adult males, the notable exception being iron. Nevertheless, this population subgroup usually has the lowest risk of micronutrient deficiencies due to its higher food intake and its lower micronutrient requirements per unit body weight. Individuals at most risk of not meeting their RNIs are infants, young children and women of reproductive age, especially pregnant and lactating women. Some of these groups (e.g. pregnant or lactating women) may even have higher requirements for specific nutrients than do adult men.

7.2.2.2 Calculating Estimated Average Requirements from Recommended Nutrient Intakes

Although they form the basis of most RNIs (which are usually set at 2 standard deviations above the corresponding EAR for any given population subgroup),

[1] For further information relating to the work and publications of the Food and Nutrition Board, please refer to the web site of the National Academies Press (http://www.nap.edu).

FAO/WHO do not routinely publish EAR values. However, the FAO/WHO RNIs, or equivalent recommendations made by other countries or regions, can be easily converted into EARs by the application of appropriate conversion factors. The conversion factors, which are presented for the micronutrients covered by these Guidelines in **Annex C**, are the equivalent of subtracting 2 standard deviations from the RNI. For example, the standard deviation of the requirement for vitamin A by 1-3-year-old children is 20%; dividing the relevant RNI (400 µg RE) by 1.4 (i.e. 1 + (2 × 0.2)) gives an EAR of 286 µg RE. The EARs corresponding to RNIs given in **Table 7.1**, and calculated in this way, are listed in **Table 7.2.**

7.2.2.3 Upper levels of intake

The most appropriate reference value for determining whether or not the micronutrient intakes of population subgroups are safe, i.e. do not reach levels at which there is any risk of excessive intake, is the Tolerable Upper Intake Level (UL). The UL is the highest average intake that will not pose a risk of adverse health effects for virtually anyone in the population. The risk of adverse effects increases at intakes above the UL. The risks of excessive intakes are described in detail by FAO/WHO (*93*), and the United States FNB/IOM (*332*,*333*).

Like EARs and RNIs, ULs vary by age and gender but tend to be lower for young children and pregnant women. ULs for a range of micronutrients are given in **Table 7.3.** For those micronutrients for which FAO/WHO have not recommended a UL (i.e. iron, folate, fluoride and iodine), the values given in the table are based on recommendations of either the United States FNB/IOM or the Scientific Committee for Food of the European Community.

7.3 Using the EAR cut-point method to set goals and to evaluate the impact and safety of fortification

In reality, there is usually a wide range of intakes of a nutrient within a population subgroup. This range of usual intakes must be measured and used as the basis for planning and evaluation. As previously mentioned, the goal of fortification is to shift the distribution of usual nutrient intakes of a target population upwards so that only a small proportion of the population is at risk of having an inadequate intake, but not so far that those who consume larger amounts of the food vehicle will be at risk of an excessive intake. The median of the new usual intake distribution is referred to as the "target median intake". It thus follows that one of the first decisions that will need to be made when planning fortification interventions is what is an acceptable prevalence of inadequacy, both for low as well as for high intakes.

TABLE 7.2

Estimated Average Requirements (calculated values) based on FAO/WHO Recommended Nutrient Intakes

Nutrient (unit)	1–3 years	4–6 years	19–50 years, female	Pregnant women, second trimester	Lactating women, 0–3 months	19–50 years, male
Vitamin A (μg RE)[a]	286	321	357	571	607	429
Vitamin D (μg)[b]	5	5	5	5	5	5
Vitamin E (mg α-tocopherol)	4	4	6	6	6	8
Vitamin C (mg)	25	25	37	46	58	37
Thiamine (vitamin B_1) (mg)	0.4	0.5	0.9	1.2	1.3	1.0
Riboflavin (vitamin B_2) (mg)	0.4	0.5	0.9	1.2	1.3	1.1
Niacin (vitamin B_3) (mg NE)	5	6	11	14	13	12
Vitamin B_6 (mg)	0.4	0.5	1.1	1.6	1.7	1.1
Folate (μg DFE)[c]	120	160	320	480	400	320
Vitamin B_{12} (μg)	0.7	1.0	2.0	2.2	2.3	2.0
Iron (mg)[d]						
■ 15% bioavailability	3.9[e]	4.2[e]	19.6[e]	>40.0	7.8	7.2
■ 10% bioavailability	5.8[e]	6.3[e]	29.4[e]	>40.0	11.7	10.8
■ 5% bioavailability	11.6[e]	12.6[e]	58.8[e]	>40.0	23.4	21.6
Zinc (mg)[f]						
■ High bioavailability	2.0	2.4	2.5	3.5	4.8	3.5
■ Moderate bioavailability	3.4	4.0	4.1	5.8	7.9	5.8
■ Low bioavailability	6.9	8.0	8.2	11.7	15.8	11.7
Calcium (mg)	417	500	833	833	833	833
Selenium (μg)	14	17	22	23	29	28
Iodine (μg)	64	64	107	143	143	107

[a] 1 RE = 1 μg retinol = 12 μg β-carotene or 24 μg other provitamin A carotenoids. In oil, the conversion factor for vitamin A (retinol): β-carotene is 1 : 2. The corresponding conversion factor for synthetic β-carotene is uncertain, but a factor of 1 : 6 is generally considered to be reasonable. 1 μg RE = 3.33 IU vitamin A.

[b] In the absence of adequate exposure to sunlight, as calciferol. 1 μg calciferol = 40 IU vitamin D.

[c] 1 DFE = Dietary folate equivalent = 1 μg food folate = 0.6 μg folic acid from fortified foods, which means that 1 μg folic acid = 1.7 DFE.

[d] The RNI and thus the calculated EAR depends on the composition of the diet. For a diet rich in vitamin C and animal protein, the bioavailability of iron is 15%; for diets rich in cereals but including sources of vitamin C, bioavailability is 10%, and for diets low in vitamin C and animal protein, bioavailability is reduced to 5%.

[e] EARs cannot be calculated from RNIs for these age groups because of the skewed distribution of requirements for iron by young children and menstruating women. Instead, the corresponding RNI values are given.

[f] The RNI and thus the calculated EAR depends on the composition of the diet. The bioavailability of zinc is high from diets rich in animal protein, moderate from diets rich in legumes and pulses or diets that include fermented cereals, and low from diets poor in animal protein or zinc-rich plant foods.

Source: calculated from FAO/WHO RNIs, using the factors given in **Annex C** of these Guidelines.

TABLE 7.3

Tolerable Upper Intake Levels (ULs)

Nutrient (unit)[a]	1–3 years	4–8 years	9–13 years	19–70 years
Vitamin A (μg RE)[b]	600	900	1700	3000
Vitamin D (μg)[c]	50	50	50	50
Vitamin E (mg α-tocopherol)	200	300	600	1000
Vitamin C (mg)	400	650	1200	1000[d]
Niacin (vitamin B_3)(mg NE)[e]	10	15	20	35
Vitamin B_6 (mg)	30	40	60	100
Folic acid (μg DFE)[f]	300	400	600	1000
Choline (mg)	1000	1000	2000	3500
Iron (mg)	40	40	40	45
Zinc (mg)	7	12	23	45[g]
Copper (mg)	1	3	5	10
Calcium (mg)	2500	2500	2500	3000[h]
Phosphorus (mg)	3000	3000	4000	4000
Manganese (mg)	2	3	6	11
Molybdenum (μg)	300	600	1100	2000
Selenium (μg)	90	150	280	400
Iodine (μg)	200	300	600	1100
Fluoride (μg)	1300	2200	10000	10000

[a] Although no UL is specified for arsenic, silicon and vanadium, there is no justification for adding these substances to foods.
[b] Refers to preformed vitamin A only (i.e. esters of retinol). 1 μg RE = 3.33 IU vitamin A.
[c] As calciferol, where 1 μg calciferol = 40 IU vitamin D.
[d] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 2000 mg vitamin C/day for adults.
[e] Based on the flushing effects of nicotinic acid. If niacinamide is used as the fortificant, the UL would be much higher. A UL for adults of 900 mg niacinamide/day has been recommended by the European Commission (*319*).
[f] Refers to folic acid derived from fortified foods, or supplemental folic acid.
[g] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 40 mg zinc/day for adults (*91*).
[h] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 2500 mg calcium/day for adults (*193*).

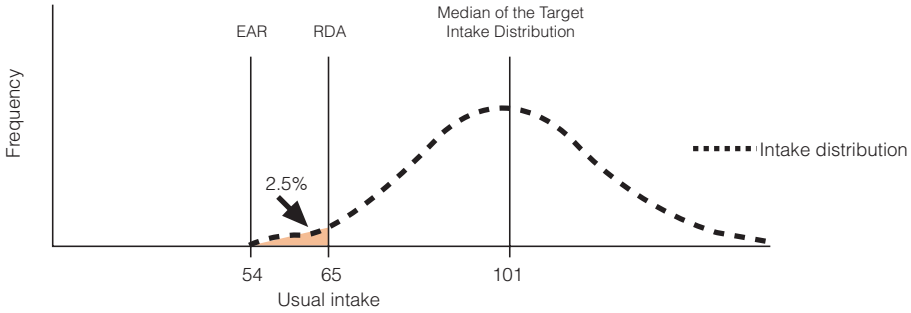
Sources: adapted from references (*91,93*). FAO/WHO have only recommended ULs for vitamins A, B_3 (niacin), B_6, C, D and E, calcium, selenium and zinc for adults. The remaining values are those recommended by the United States Food and Nutrition Board of the Institute of Medicine.

7.3.1 Deciding on an acceptable prevalence of low intakes

Three different ways of planning an intake distribution for a hypothetical nutrient, which has an EAR of 54 and an RDA of 65, are compared below (**Figures 7.1–7.3**). For simplicity, the intake distributions shown in these examples are normally distributed, although in reality, intake distributions are usually slightly skewed.

FIGURE 7.2

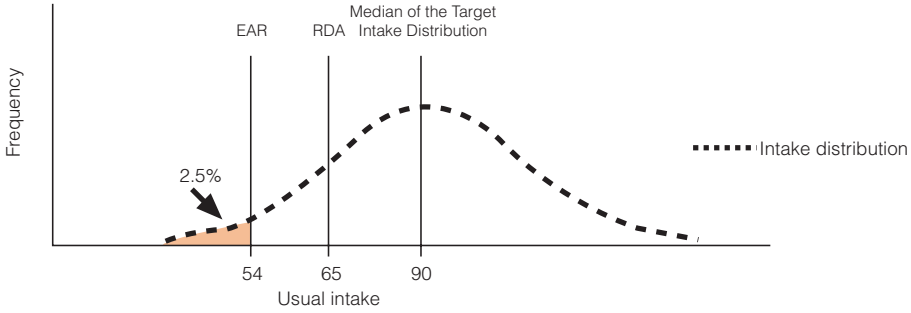
An example of a usual intake distribution in which only 2.5% of the group have intakes below the RNI (or RDA)



Source: adapted from reference (*333*), with the permission of the United States National Academy Press.

FIGURE 7.3

An example of a usual intake distribution in which 2.5% of the group have intakes below the EAR (the recommended approach)



Source: adapted from reference (*333*), with the permission of the United States National Academy Press.

Scenario 1

Until relatively recently, nutritionists used the RNI as the basis for dietary planning and evaluation, and had as their optimum goal a population intake distribution in which the mean or median nutrient intakes for population subgroups met the relevant RNI (or its North American equivalent, the RDA). Assuming that the nutrient intakes are normally distributed, it is clear from **Figure 7.1** that according to this scenario, half of the population subgroup would have intakes that were below the RNI or RDA, while the intakes of the other half would be higher than the RNI (or RDA). More importantly, a relatively large percentage of the population subgroup would have usual intakes below the EAR (28% in this example). A target median intake set at the RNI is now generally

considered to result in an unacceptably high prevalence of inadequate low intakes.

Scenario 2

An approach that plans for the usual intakes of all but 2.5% of the group to be above the RNI (or RDA) is equally unacceptable. For this to happen, the target median intake of the group would need to be set at a very high level, that is to say, at almost twice the RNI (or RDA). Virtually no intakes would be below the EAR (**Figure 7.2**). Adopting this approach increases the risk of exceeding the UL (if there is one), and may also result in adverse effects on the organloleptic properties of foods (due to the relatively high levels of added fortificants). On balance, such an approach is widely regarded as being unrealistic, costly, inefficient and potentially risky.

Scenario 3

The recommended strategy is thus to shift the usual distribution of intakes upwards so that the intake of each nutrient is at least at the EAR for all except 2–3% of the target population group (**Figure 7.3**). In this example, if the micronutrient interventions are planned so that only 2–3% of the group have an intake less than the EAR, the target median intake would have to be about 1.5 times the RNI (or RDA) and approximately 20% of the population group would have intakes below the RNI (or RDA). In other words, the program would be satisfactory when most individuals of the population (97–98%) satisfy the EAR, which may be similar to saying that most individuals of the population satisfy 80% of RNI.

7.3.2 Calculating the magnitude of micronutrient additions

This is the section of the Guidelines in which the application of the EAR cut-point method to the calculation of fortification levels (i.e. the amount of fortificant required to bring about the desired upwards shift in the distribution of usual intakes) is explained in greater detail. There are four steps: the first involves examining the prevalence of inadequate intakes of each nutrient in specific population groups. Having identified which population subgroups have the highest prevalence of inadequate intakes (step 2) and estimated the usual consumption of the chosen food vehicle by this group (step 3), the final step is to calculate the reduction in the prevalence of inadequate intakes (i.e. the proportion below the EAR) and the risk of excessive intakes (i.e. the proportion above the UL) that would be expected to occur at different levels of fortification. The methodology is illustrated with reference to a hypothetical case in which wheat flour is to be fortified with vitamin A.

Step 1. Observe the usual distribution of nutrient intakes in specific population subgroups

As mentioned in section 7.1.3, programme planning requires quantitative dietary intake data, initially for evaluating the current level of nutrient intakes in a population subgroup. This information is also necessary for estimating the amount of micronutrient that would need to be supplied by a micronutrient-delivery programme, and for predicting the impact of adding different amounts of micronutrients to different foods.

It is not necessary to conduct large surveys, although intake data should be collected from a stratified, representative sample of the whole target area. Ideally, all population subgroups should be represented. Collecting information from about 200 individuals in each population subgroup with the highest risk of deficiency (e.g. preschool-aged children and reproductive-age women in the lowest rural income group) and the highest risk of excess (e.g. men in the highest urban income group in the case of staple foods), and any other groups that are locally relevant, should provide sufficient valid information. It is helpful to select population subgroups with similar age ranges as those for which EARs are defined (see **Table 7.2**). Pregnant and lactating women should usually be treated as separate population subgroups.

Quantitative food intake data is usually obtained by 24-hour recall survey techniques or a combination of weighed/measured food intakes and recall, depending on what is locally possible. The distribution of usual intakes obtained in this way will be unrealistically wide, reflecting the fact that individuals may eat atypically small or large amounts on the day their intake was measured. By collecting at least 2 (preferably non-consecutive) days worth of food intake data for each individual, it is possible to estimate the day-to-day or intra-individual variability in intake, and adjust the distribution accordingly. For more detailed information about the statistical techniques that are available for reducing day-to-day variability in dietary intake data, readers are referred to relevant texts on this subject (*332,333,336,337*)[1]. If two days of dietary data per person are not available, or cannot be collected for what is felt to be a representative sample of the target population groups, it will then be necessary to use an estimate of day-to-day variability obtained elsewhere, but preferably one that has been obtained from a similar population. A study of the variability in nutrient intakes in a population in Malawi has recently been published and may be useful in this regard (*338*).

Allowing for day-to-day variation usually has the effect of narrowing the intake distribution, so that fewer individuals will be below the EAR (and above

[1] The statistical method for reducing variability in intake data described by the Food and Nutrition Board of the Institute of Medicine (*332*) is also readable at the following web site: http://www.nap.edu/catalog/9956.html).

the UL). If some form of adjustment for variability is not made, the prevalence of inadequacies could be incorrectly estimated because the distribution does not reflect the usual intakes of the individuals in the group.

Having collated information on the quantities of various foods consumed, local, regional or international food composition tables can then be used to convert such data into amounts of nutrients consumed. If local information is not adequate, there are several international and regional databases that have been established expressly for this purpose. The United Nations group, INFOODS[1], is a repository of databases of this type and also serves as a resource for organizations and individuals interested in food composition data. The INFOODS web site provides links to various software programmes, for example, the *WorldFood Dietary Assessment System*[2], which can be used to calculate nutrient intakes from one-day dietary information. The results, i.e. the distribution of usual intake, for each nutrient and for each population group, are displayed as percentiles.

Example

Analysis of quantitative food intake survey data, according to the methodology outlined above, reveals that in adult women the distribution of vitamin A intakes is such that the median consumption is 240 µg RE per day. 5% of adult women have intakes that are less than 120 µg RE per day and 25% have vitamin A intakes that are below 200 µg RE per day. See **Table 7.4.**

Step 2. Identify the population subgroups at greatest risk of inadequate intakes of specific micronutrients

Certain subgroups of the population (usually children and women) tend to be at higher risk of having an inadequate intake of specific nutrients. On completion of step 1, it will be evident which subgroups have the highest prevalence of inadequate intakes for which nutrients. It is important to identify which population groups are at greatest risk so that a micronutrient-delivery programme can target these groups.

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[1] INFOODS is the acronym of the International Network of Food Data Systems, which was established in 1984, on the recommendation of an international group convened under the auspices of the United Nations University. Its goal is to stimulate and coordinate efforts to improve the quality and availability of food analysis data worldwide and to make sure that accurate and reliable food composition data are readily accessible by all. Further information can be obtained from the web site: http://www.fao.org/infoods (accessed 15 March 2005).

[2] Software links can be accessed via the web site: http://www.fao.org/infoods/software_en.stm, (accessed 15 March 2005).

TABLE 7.4

Predicting the effect on the intake distributions of adult women of fortifying wheat flour with different levels of vitamin A[a]

Percentile	Distribution of usual wheat consumption (g/day)	Distribution of vitamin A intake from all sources (µg/day)			Vitamin A intake in relation to the EAR and the UL		
		Before fortification	After fortification at a level of 3 mg/kg	After fortification at a level of 5 mg/kg	Before fortification	After fortification at a level of 3 mg/kg	After fortification at a level of 5 mg/kg
Group at risk of deficiency							
5	30	120	210	270	–	–	–
10	45	160	295	385	–	–	*
25	120	200	560	800	–	*	*
50	180	240	780	1140	–	*	*
Group at risk of excess							
75	240	600	1320	1800	*	*	*
90	300	1000	1900	2500	*	*	*
95	360	1250	2330	3050	*	*	+
Resulting prevalence of inadequacy and risk of toxicity							
Proportion of women with intakes below the EAR (%)					65	15	8
Proportion of women with intakes above the UL (%)					0	2	6

–, intake is below the EAR; *, intake is above the EAR but below the UL; +, intake above the UL.

[a] For vitamin A an EAR of 357 µg/day is assumed. This is derived from the FAO/WHO RNI for this vitamin of 500 µg/day, to which a conversion factor of 1.4 has been applied (see **Annex C**). The UL is 3000 µg/day. If β-carotene were used rather than preformed vitamin A (retinol), there would be no UL.

Example

In this example, 65% of adult women were found to have inadequate intakes of vitamin A, i.e. intakes that were below the EAR for this vitamin (357 µg/day). The proportion of women who were at risk of exceeding the UL (3 000 µg/d) was very small (**Table 7.4**).

Step 3. Measure the usual amount of the intended food vehicle(s) that is consumed by the population subgroup at greatest risk of inadequate or excessive intakes

It is important that food vehicle consumption estimates are obtained not just for those subgroups that have been found to have the highest prevalence of inadequate intakes in step 2, but also for those subgroups with the highest levels of consumption (i.e. those at greatest risk of excessive intakes). This information will be used to predict the effects of different levels of fortification on the total intake of the nutrient (see step 4).

Example

Hypothetical values for the usual consumption of wheat by adult women, across the percentiles of vitamin A intake, are included in **Table 7.4**. The median consumption of wheat is 180 g/day. Ideally, the intake of the proposed food vehicle needs to be higher in the population groups with the highest prevalence of inadequate intakes, and lower in the relatively well-nourished groups. This would minimize the risk of the vitamin A intakes of the high wheat consumers becoming excessive. Unfortunately, in countries in which wheat flour tends to be consumed in larger amounts by wealthier (i.e. better-nourished) individuals, this is unlikely to be the case. Although Table 7.4 presents the case for adult women, it is important to point out here that the adult males are usually the group that have the highest consumption of staple foods.

Step 4. Simulate the effect of adding different levels of nutrient(s) to the food vehicle

Simulating the effect of micronutrient additions (by recalculating the distribution of vitamin A intakes but this time assuming that the wheat flour contains an additional 3 or 5 mg/kg vitamin A) helps to identify the most appropriate level of fortification for a given food vehicle, i.e. a level that prevents deficiency in a population at risk, yet avoids a high proportion of very high intakes.

Example

The data in Table 7.4 show the effect of fortifying all wheat flour with vitamin A (as retinol), at a level of 3 and 5 mg/kg, on the distribution of total vitamin A intakes in adult women, the population subgroup identified as being at high risk of vitamin A deficiency. Prior to fortification, the prevalence of inadequate intakes in this group was 65% (see step 2).

At a fortification level of 3 mg/kg of wheat, the prevalence of inadequate intakes (that is, the proportion of the group with intakes below the EAR of 357 µg/day) would fall from the pre-fortification level of about 65% (50–75%) to 15% (10–25%). In other words, as a result of fortification, about 50% of adult women have moved from having an inadequate to an adequate vitamin A intake. If the fortification level is increased to 5 mg/kg of wheat, only 8% of women would have an inadequate intake. However, at the 5 mg/kg fortification level, the highest 6% of wheat consumers would have a total vitamin A intake that might exceed the UL of 3000 µg/day.

Given that calculation does not consider vitamin A intake by adult males,, it may be better to select the 3 mg/kg fortification level and then find another food vehicle to fortify or another delivery mechanism to meet the shortfall in vitamin A intake in the 15% of women whose intake remains unsatisfied through the consumption of fortified wheat flour. Decisions of this nature can only be made on the basis of local information, and with due consideration of the potential risks associated with excessive intakes of vitamin A (see section 7.5).

Step 4 would need to be repeated in order to determine the appropriate fortification level for wheat flour with vitamin A for any other at-risk population groups identified in step 2. Steps 3 and 4 would then be repeated for any other nutrients being considered for the fortification programme, in which case the corresponding EARs and current nutrient intake distribution data would be needed.

7.3.3 Adaptations to the EAR cut-point methodology for specific nutrients

7.3.3.1 Iron

The EAR cut-point approach cannot be used to estimate the prevalence of inadequate iron intakes in some population subgroups, notably children, menstruating adolescents and adult women, on account of the fact that their requirements for iron are not normally distributed (*see section 7.2.1*). The requirements of menstruating adolescents and adult women are not normally distributed largely because of the skewed distribution of their iron losses, and of menstrual losses in particular (*91*). Assuming for present purposes that a coefficient of variation (CV) greater than 40% indicates a skewed distribution, then the population

groups with skewed requirements for iron are as follows (based on data from the United States FNB/IOM (*91*):

— children, aged 1–3 years (CV = 67%);

— children, aged 4–8 years (CV = 75%);

— menstruating adolescents, aged 14–18 years (CV = 45%);

— menstruating women (CV = 63%).

For the other population groups, the CV of the distribution of iron requirements is 30% or less.

For those groups with skewed requirements, an alternative approach to the EAR cut-point method must be used, namely a full probability approach. **Table 7.5** gives the probability of an iron intake being inadequate at a given range of usual iron intake for the population subgroups of interest, i.e. young children and menstruating females. Using these values, it is possible to calculate the prevalence of inadequate intakes in a population subgroup from estimates of the percentage of the group with intakes in a given intake range (note that the bioavailability of iron from the usual diet must also be known). For each intake range, a prevalence of inadequacy is obtained by multiplying the percentage of the group with intakes in that range by the probability of inadequacy. Summing the prevalences of inadequacy in each intake range provides an estimate of the total prevalence of inadequacy for the population group of interest.

To illustrate the application of the probability method (using the data in Table 7.5), the prevalence of inadequate iron intakes in a population of adult menstruating women, consuming a diet from which the iron bioavailability is 5%, is calculated in **Table 7.6**. For instance, according to Table 7.5, the women in the lowest iron intake range (i.e. less than 15 mg per day) have a probability of inadequacy of 1.0, which means that all the women in this group have iron intakes that are less than their requirements. Given that 2% of women in the population have intakes in this range, these women contribute 2% to the total prevalence of inadequacy in that population group. Similarly, those women whose iron intake is in the range 23.6–25.7 mg per day will have a probability of an inadequacy of 0.65. If 20% of the women have intakes in this range, the prevalence of inadequacy among women with intakes in this range is 20 × 0.65 or 13% (**Table 7.6**). When similar calculations are performed for each of the other intake ranges, and then summed, an overall prevalence of inadequacy for the group of 66.6% is obtained. In other words, in this example, two thirds of the population of women have intakes that are likely to be below their requirements. Note that such calculations are easily performed with a spreadsheet or a statistical programming language.

TABLE 7.5

Probability of inadequate iron intakes in selected population subgroups at different ranges of usual intake (mg/day)

Probability of inadequacy[a]	Usual intake of children aged 1–3 years consuming a diet from which the bioavailability of iron is			Usual intake of children aged 4–8 years consuming a diet from which the bioavailability of iron is			Usual intake of females aged 14–18 years consuming a diet from which the bioavailability of iron is			Usual intake of menstruating women consuming a diet from which the bioavailability of iron is		
	5%	10%	15%	5%	10%	15%	5%	10%	15%	5%	10%	15%
1.00	<3.6	<1.8	<1.3	<4.8	<2.4	<1.6	<16.2	<8.1	<5.4	<15.0	<7.5	<5.0
0.96	3.6–4.5	1.8–2.3	1.3–1.5	4.8–5.9	2.4–3.0	1.6–2.0	16.2–17.7	8.1–8.8	5.4–5.9	15.0–16.7	7.5–8.4	5.0–5.6
0.93	4.5–5.5	2.3–2.8	1.5–1.8	5.9–7.4	3.0–3.7	2.0–2.4	17.7–19.6	8.8–9.8	5.9–6.5	16.7–18.7	8.4–9.4	5.6–6.2
0.85	5.5–7.1	2.8–3.6	1.8–2.4	7.4–9.5	3.7–4.8	2.4–3.2	19.7–22.1	9.8–11.1	6.5–7.4	18.7–21.4	9.4–10.7	6.2–7.1
0.75	7.1–8.3	3.6–4.2	2.4–2.8	9.5–11.3	4.8–5.7	3.2–3.8	22.1–24.1	11.1–12.0	7.4–8.0	21.4–23.6	10.7–11.8	7.1–7.9
0.65	8.3–9.6	4.2–4.8	2.8–3.2	11.3–13.0	5.7–6.5	3.8–4.3	24.1–26.0	12.0–13.0	8.0–8.7	23.6–25.7	11.8–12.9	7.9–8.6
0.55	9.6–10.8	4.8–5.4	3.2–3.6	13.0–14.8	6.5–7.4	4.3–4.9	26.0–27.8	13.0–13.9	8.7–9.3	25.7–27.8	12.9–13.9	8.6–9.3
0.45	10.8–12.2	5.4–6.1	3.6–4.1	14.8–16.7	7.4–8.4	4.9–5.6	27.8–29.7	13.9–14.8	9.3–9.9	27.8–30.2	13.9–15.1	9.3–10.1
0.35	12.2–13.8	6.1–6.9	4.1–4.6	16.7–19.0	8.4–9.5	5.6–6.3	29.7–32.1	14.8–16.1	9.9–10.7	30.2–33.2	15.1–16.6	10.1–11.1
0.25	13.8–15.8	6.9–7.9	4.6–5.3	19.0–21.9	9.5–11.0	6.3–7.3	32.1–35.2	16.1–17.6	10.7–11.7	33.2–37.3	16.6–18.7	11.1–12.4
0.15	15.8–18.9	7.9–9.5	5.3–6.3	21.9–26.3	11.0–13.2	7.3–8.8	35.2–40.4	17.6–20.2	11.7–13.5	37.3–45.0	18.7–22.5	12.4–15.0
0.08	18.9–21.8	9.5–10.9	6.3–7.3	26.3–30.4	13.2–15.2	8.8–5.1	40.4–45.9	20.2–23.0	13.5–15.3	45.0–53.5	22.5–26.7	15.0–17.8
0.04	21.8–24.5	10.9–12.3	7.3–8.2	30.4–34.3	15.2–17.2	5.1–5.7	45.9–51.8	23.0–25.9	15.3–17.3	53.5–63.0	26.7–31.5	17.8–21.0
0	>24.5	>12.3	>8.2	>34.3	>17.2	>5.7	>51.8	>25.9	>17.3	>63.0	>31.5	>21.0

[a] Probability that the requirement for iron is greater than the usual intake. For the purpose of assessing populations, a probability of 1 has been assigned to usual intakes that are below the 2.5th percentile of requirements, and a probability of 0 has been assigned to usual intakes that fall above the 97.5th percentile of requirements. Usual intakes should be adjusted for intra-individual variance as described in section 7.3.2 (step 1).

Source: adapted from reference (*91*).

TABLE 7.6

Prevalence of inadequate iron intakes for menstruating women consuming a diet from which the average iron bioavailability is 5%: an example calculation

Probability of inadequacy[a]	Intake range with this probability of inadequacy (mg/day)	Proportion of menstruating women with intakes in this range (%)	Prevalence of inadequacy[b] (%)
1.00	<15.0	2	2
0.96	15.0–16.7	10	9.6
0.93	16.7–18.7	10	9.3
0.85	18.7–21.4	10	8.5
0.75	21.4–23.6	15	11.3
0.65	23.6–25.7	20	13
0.55	25.7–27.8	10	5.5
0.45	27.8–30.2	8	3.6
0.35	30.2–33.2	5	1.8
0.25	33.2–37.3	5	1.3
0.15	37.3–45.0	3	0.5
0.08	45.0–53.5	2	0.2
0.04	53.5–63.0	0	0
0.00	>63.0	0	0
Probability of inadequate intakes for all menstruating women			66.6%

[a] Probability that the requirement for iron is greater than the usual intake. For the purpose of assessing populations, a probability of 1 has been assigned to usual intakes that are below the 2.5th percentile of requirements, and a probability of 0 has been assigned to usual intakes that fall above the 97.5th percentile of requirements. Usual intakes should be adjusted for intra-individual variance as described in section 7.3.2 (step 1).

[b] The prevalence of inadequacy = probability of inadequacy for a given intake range × the percentage of women with intakes in that range.

Having established the prevalence of inadequate intakes, the next step is to simulate how the distribution of intakes would shift upwards as a result of the consumption of iron fortified food(s) (in much the same way as was done in steps 3 and 4 for vitamin A above; see Table 7.4) with a view to finding that level of fortification that would bring the estimated prevalence of inadequacy down to an acceptable level, say 2–3%.

7.3.3.2 Iodine

Based on field experience, WHO has recommended fortification levels for iodine in salt (*283*). The current recommendation, designed to provide the adult RNI (i.e. 150 µg/day), is to add 20–40 mg iodine/kg salt. This level of fortification assumes no iodine in the usual diet pre-fortification, and that the usual amount of salt consumed is 10 g per day.

7.3.3.3 Folate/folic acid

Numerous studies have demonstrated that a higher intake of folate by some women can reduce their risk of delivering an infant with a neural tube defect (see section 4.2.3). It is generally accepted that women should consume an additional 400 µg/day as folic acid in fortified foods or supplements periconceptionally (*128*). Currently, it is unknown whether the reduction in risk results from the correction of a folate deficiency or through some other as yet unidentified mechanism. However, increasing intake by just 200 µg/day through fortification has been shown to be effective in improving folate status and in lowering the prevalence of neural tube defects in both Canada (*51*) and the United States (*48,49*). Based on this evidence, the Pan American Health Organization has recommended that throughout Latin America food fortification interventions should provide an additional 200 µg folic acid per day (*339*). It is anticipated that at these levels of additional intake, the usual daily intake of folic acid plus food folate will exceed the EAR and approach the RNI for the majority of the target population. In any case, it would be appropriate to start with the estimation of the nutritional gap for folate, which may be around that value, and hence the decision will have a nutritional justification.

It should be noted that folate intakes are conventionally expressed in units of Dietary Folate Equivalents (DFE), where 1 µg folate in food is equivalent to 1 DFE. Because of its higher bioavailability, 1 µg of folic acid actually supplies 1.7 DFE and so less folic acid (the synthetic form of folate that is used as a fortificant and in supplements) is required to meet a given requirement for folate (*128*).

7.3.3.4 Vitamin D

Vitamin D is produced in the skin on exposure to ultraviolet light. At latitudes between 42°N and 42°S, 30 minutes of skin exposure per day (arms and face) is usually sufficient to provide the body with all the vitamin D it needs. However, as discussed in section 4.6, several factors inhibit the ability of the body to synthesize vitamin D and thus increase the risk of vitamin D deficiency. These factors may include living at a more northerly or more southerly latitude (where the days are shorter during the winter season), leaving little skin exposed to ultraviolet light, and having dark skin.

Any decisions about appropriate levels of vitamin D fortification would need to take exposure to sunlight into account. For instance, in situations where exposure to sunlight is adequate but dietary intake of vitamin D is low, it is quite likely that the risk of vitamin D deficiency in a population will be overestimated if based on intake data alone. For this reason, information on the prevalence of rickets in infants and children, low serum 25-hydroxy vitamin D concentrations in the general population, and osteomalacia and/or osteoporosis

in women, should be evaluated when predicting the level of vitamin D fortification required.

7.3.3.5 Niacin

Niacin (vitamin B_3) is unique in that it can be synthesized from the amino acid, tryptophan (1 mg niacin can be generated from approximately 60 mg tryptophan). Thus, similar to the situation with vitamin D, there will appear to be a high prevalence of inadequate intakes of the vitamin using only the dietary intake, both before and after fortification, if non-dietary sources of niacin (i.e. synthesis from tryptophan) are not considered. However, because the rate of niacin synthesis from tryptophan is not known with certainty, and probably varies with life stage and physiological status (e.g. in pregnancy and for young infants), the most practical approach may be to ignore the contribution of tryptophan when setting fortification levels. Moreover, the risk of niacin toxicity is low, especially if niacinamide is used as the fortificant (see **Table 7.3**).

As maize contains niacin in a bound form and is low in tryptophan, populations whose staple food is maize (especially maize that is untreated with alkali) are most likely to benefit from niacin fortification (see section 4.4.3).

7.3.4 Bioavailability considerations

The methods used to set EARs already include an adjustment for the bioavailability (i.e. % absorption) of a nutrient from foods, and so when formulating fortification levels using the EAR cut-point method there is usually no need to make any further allowance for this factor. If, however, the bioavailability of the fortificant nutrient is likely to be substantially different from that naturally present in the diet, some further adjustment will need to be made. The efficiency of utilization of the form of the fortificant nutrient may also need to be considered. For example, the conversion rate of synthetic β-carotene to retinol in oil is 2:1, but in the absence of oil, the rate is significantly lower (i.e. 6:1) and the utilization much less efficient.

Micronutrients for which differences in bioavailability may be a factor are listed in **Table 7.7**. Electrolytic iron, for instance, is poorly absorbed, and it is recommended that this particular form of iron fortificant be added at twice the quantity of ferrous sulfate iron, which has a similar bioavailability to non-haem iron in the diet (**Table 5.2**). In contrast, the absorption of some fortificants, such as folic acid and vitamin B_{12}, may be substantially higher than their equivalent (i.e. naturally-occurring) forms in foods (see *section 7.3.3.3*).

Ideally, the absorption of the fortificant nutrient should be confirmed in efficacy trials involving the target population, especially in situations where there is uncertainty about its bioavailability. If this is not possible, then as a minimum, absorption data should be obtained from human studies by other

TABLE 7.7

Examples of micronutrients for which the bioavailability of the form used for fortification differs substantially from their bioavailability in the usual diet

Nutrient/fortificant compound	Proportion absorbed relative to usual diet
Iron	
■ Electrolytic iron	0.5 (compared with non-haem iron in foods)
■ NaFeEDTA[a]	3.0 at high phytate, 1.0 at low phytate (compared with non-haem iron in foods)
■ Ferrous bisglycinate	2.0–3.0 (compared with non-haem iron in foods)
Vitamin A	
■ β-carotene[b]	0.15 from fortified foods in the absence of oil, but 0.5 in oil (compared with retinol)
Folate	
■ Folic acid	1.7 (compared with Dietary Folate Equivalents of natural food folates)
Vitamin B_{12}	2.0 (compared with cobalamin in foods)

[a] NaFeEDTA, sodium iron ethylenediaminetetraacetic acid.
[b] When β-carotene is added as a food fortificant, its bioavailability is higher (the conversion factor β-carotene : retinol is 6 : 1 in non-oily foods) than that of naturally-occurring β-carotene (in fruits and vegetables), for which the corresponding conversion factor is 12 : 1.

investigators, and its bioavailability evaluated once the fortification programme is in place.

7.4 Other factors to consider when deciding fortification levels

Experience has shown that in practice, and especially in the case of mass fortification, the amount of micronutrient that can be added to foods is often limited by various safety, technological and/or economic constraints. Of these three limiting factors, cost constraints tend to be the more flexible, whereas safety and technological constraints are more likely to be fixed. However, for some micronutrients there may be ways of overcoming some of the technological constraints. For instance, in the case of iron, undesirable sensory changes in the food vehicle caused by the presence of the fortificant compound might be reduced by using a microencapsulated form of iron instead (see *section 5.1.3.3*). Nor are safety constraints necessarily always cast in stone; with new knowledge and improvements in the precision of ULs, safety constraints may well change over time.

Table 7.8 assesses the strength of each of the three main types of constraint for the range of micronutrients covered by these Guidelines. The assessment of the magnitude of the safety risk is based on the closeness of the EAR to the UL; the closer these two values, the greater the risk. The magnitudes indicated in this table are subjective and are intended only to highlight those areas that may be of concern for a given micronutrient.

TABLE 7.8

Factors that may limit the amount of fortificants that can be added to a single food vehicle

Nutrient	Technological/sensory	Safety	Cost
Vitamin A	X	XXX	XXX[a]
Vitamin D	–	X	X
Vitamin E	–	X	XXX
Vitamin C	XX	X	XXX[b]
Thiamine (vitamin B_1)	–	–	–
Riboflavin (vitamin B_2)	XX	–	–
Niacin (vitamin B_3)	–	XXX[c]	X
Vitamin B_6	–	X	–
Folic acid	–	XXX[d]	–
Vitamin B_{12}	–	–	X
Iron[e]	XXX	XX	X
Zinc	XX	XXX	X
Calcium	X	XX	XXX[f]
Selenium	–	X	X
Iodine	X	XXX	–

–, no constraint; X, a minor constraint; XX, moderate constraint; XXX, major constraint.

[a] If an oil-based form is used to fortify oils or fats, costs can be reduced.

[b] Cost constraints are mainly a consequence of losses during manufacturing, storage, distribution and cooking which mean that a considerable overage is required.

[c] Much less of a concern if niacinamide, as opposed to nicotinic acid, is used as the fortificant.

[d] The risk of adverse effects is minimized by the co-addition of vitamin B_{12}.

[e] Refers to the more bioavailable forms.

[f] Cost constraints are mainly a consequence of the need to add such large amounts.

7.4.1 Safety limits

The safety of fortification can be assessed by comparing predicted micronutrient intakes (in particular the intakes that will occur at higher levels of fortification and at higher intakes of fortified foods, calculated as described in *section 7.3.2*) with the UL (**Table 7.3**). Even if a micronutrient has no recommended UL, high levels of micronutrient additions should be avoided, especially if there is no evidence of derived benefit from levels of intake in excess of the RNI.

7.4.2 Technological limits

The technological limit is defined as the highest possible level of micronutrient addition that does not cause adverse organoleptic changes in the food vehicle. The effects of added micronutrients on the organoleptic properties of the chosen food vehicle must be tested at an early stage, and alternative forms of the fortificant used if necessary (see Part III). Technological incompatibility is usually

less of a constraint in the case of food products fortified through targeted or market-driven interventions; such products tend to be distributed to consumers in specialized individual packages, and as final products (see section 7.5.2).

7.4.3 Cost limits

The cost limit is defined as the highest increase in the cost of the food due to fortification that is acceptable to producers and consumers. Indeed, one of the most important criteria for a successful and sustainable food fortification programme in free trade economies is a low proportional increase in product price as a result of fortification. This is especially true of mass fortified products. The issue of cost is usually less of a constraint in the case of targeted and market-driven processed foods, as the price of the product tends to be sufficiently high to absorb the costs associated with fortification.

Table 7.9 shows the annual investment required to provide an adult male with 100% of his EAR of 14 essential micronutrients, taking into account micronutrient losses during production, distribution and storage as well as during cooking, and also any variability in the fortification process which might lead to a lowering of the amount of fortificant delivered (e.g. uneven mixing). The total cost for a dry non-oily food, such as wheat flour, is approximately US$ 4.00 per year, or US$ 0.01 per day. According to these calculations, the most expensive fortificants are calcium (because larger amounts are needed), vitamin A, vitamin E and vitamin C (because of overage needed to compensate for losses). The cheapest – each costing less than US$ 0.02 per year – are thiamine (vitamin B_1), vitamin B_6, folic acid, zinc and iodine.

The above cost estimates apply to the large-scale centralized fortification of a staple, i.e. fortification that is carried out in just a few large industrial units. Under such circumstances, the purchase price of the micronutrients accounts for by far the greatest proportion (at least 80–90%) of the total fortification cost. When fortification is carried out by multiple, smaller-scale enterprises, both the initial investment costs (e.g. of equipment) and the running costs (e.g. of quality control procedures) are proportionally higher, a factor which might hinder the feasibility and sustainability of the programme. Such considerations notwithstanding, in many settings food fortification can be a very affordable way of correcting inadequate micronutrient intakes, and more often than not, the main challenge is finding a suitable industrially-manufactured food vehicle that is consumed in sufficient amounts by the population at risk.

7.5 Adapting the EAR cut-point methodology to mass, targeted and market-driven fortification interventions

The EAR cut-point method can be used to select appropriate fortification levels and to estimate their impact on the prevalence of inadequate intakes for all three

TABLE 7.9

Estimated costs of selected fortificants[a]

	Adult EAR	Nutrient content of fortificant (%)	Cost of fortificant (US$/kg)	Overage[b] (%)	Annual cost of fortificant (US$)[c]
Vitamin A					
■ Vitamin A (SD-250)	429 µg	7.5	42	50	0.136
■ Vitamin A palmitate, 1 million IU	429 µg	30	52	30	0.042
Vitamin D					
■ Watersoluble	5 µg	0.25	33	20	0.035
■ In oil, 1 million IU/g	5 µg	2.5	80	20	0.008
Vitamin E	8 mg	67	26	20	0.163
Vitamin C	37 mg	100	10	250[d]	0.567
Thiamine (vitamin B_1)	1.0 mg	81	24	40	0.018
Riboflavin (vitamin B_2)	1.1 mg	100	38	30	0.024
Niacin (vitamin B_3)	12 mg	99	9	10	0.053
Vitamin B_6	1.1 mg	82	28	20	0.020
Folic acid	188 µg[e]	100	90	50	0.011
Vitamin B_{12}, 0.1% watersoluble	2.0 µg	0.1	38	30	0.043
Iron[f]					
■ NaFeEDTA	7.0 mg	13	15.45	5	0.383
■ Ferrous bisglycinate	7.0 mg	20	25	5	0.402
■ Ferrous fumarate	10.5 mg	33	5.12	5	0.075
■ $FeSO_4$, dried	10.5 mg	33	2.35	5	0.034
■ $FeSO_4$, encapsulated	10.5 mg	16	12.28	5	0.371
■ Electrolytic iron	21.1 mg	97	5.76	5	0.058
Zinc (as oxide)	6 mg[g]	80	3.35	5	0.012
Calcium (as phosphate)	833 mg	39	2.7	5	2.652
Iodine (as potassium iodate)	107 µg	59	20	25	0.002

NaFeEDTA, sodium iron ethylenediaminetetraaectic acid; $FeSO_4$, ferrous.

[a] The cost of supplying enough micronutrient to meet 100% of the EAR of an adult male, daily for one year (via dry food).

[b] The overage is an additional amount that must be added to compensate for losses during production, storage, food production and distribution.

[c] Includes an overage of +20% to cover variability in the fortification process.

[d] Vitamin C is one of the least stable fortificants and a high overage is normally required. If, however, the fortified food is not subject to heat or oxidation, the overage can be much lower.

[e] As folic acid is 1.7 times more bioavailable than naturally-occurring food folates, the EAR for folate has been divided by 1.7.

[f] The EAR for iron depends on its bioavailability from the diet as well as the identity of the iron compound used as the fortificant. The values given here refer to white wheat flour (low extraction), and apply to diets with similar bioavailabilities. If the diet contains large amounts of iron absorption inhibitors, the EAR should be multiplied by a factor of around 2. Reduced iron is not included; its absorption would be at most about half that of electrolytic iron.

[g] Assuming a moderate bioavailability of zinc.

types of intervention – mass, targeted and market-driven. However, in each case, there are some unique issues that need to be addressed; these are outlined below.

7.5.1 Mass fortification

7.5.1.1 Setting levels of micronutrient additions

Many industrialized and some developing countries have a long history of experience with mass fortification. In many cases, fortification levels were selected empirically, that is to say, were based on a combination of experience elsewhere and technological and cost constraints, rather than on any attempt to derive, in a systematic fashion, fortification levels likely to provide the most benefit. This was especially true of situations and settings where food intake data were not available, yet there was a strong desire to move ahead with fortification. However, unless food and nutrient intake data are used as the basis of programme design and evaluation – as described earlier in this chapter – it cannot be known whether those at greatest risk of deficiency in a specific nutrient (and who have the lowest pre-fortification intakes) will consume enough of the fortified food to improve their nutrient intake significantly, and whether those who have the highest pre-fortification intakes will be at risk of excessive intakes after fortification.

Having emphasized the importance of a more rigorous approach to setting fortification levels, it is nevertheless useful to know what fortification levels are already in use for specific foods in other locations. At the very least, knowledge of what levels are used elsewhere will provide some guidance as to what levels of fortification are technologically and economically feasible in which foods. Interestingly, as can be seen from **Table 7.10**, the band of currently used fortification levels for each type of food is relatively narrow. It must be stressed that the impact of fortification at these levels on nutrient intake and nutritional status has only been adequately evaluated in a handful of settings and that these levels cannot be recommended universally. Furthermore, fortification levels in use in one location may be inappropriate in another, and should not be used without confirming their suitability by using the EAR and UL cut-point method, as described in these Guidelines.

7.5.1.2 Constraints

In the case of mass fortification programmes, which tend to rely on staples and condiments as the food vehicle, cost is often the most significant limiting factor. Staples and condiments are consumed frequently and in large amounts, not only by the population directly but also by food industries. Even small variations in price can thus have profound consequences; opposition to fortified products on the grounds of cost, can, for example, lead to an increase in deceptive practices, even smuggling.

TABLE 7.10

Examples of levels of micronutrients currently added to staples and condiments worldwide (mg/kg)

Nutrient	Milk	Evaporated milk	Powdered milk	Margarine	Vegetable oil	Sugar	Wheat flour	Pasta	Corn masa flour	Pre–cooked maize flour	Maize flour	Maize meal	Soy/fish Sauce	Salt
Vitamin A	0.7–1.0	2–3	4.5–7.5	5–15	5–15	5–15	1–5	–	–	2.8		1–2	–	–
Vitamin D	0.01	0.01	0.05–0.06	0.02–0.15	–	–	0.014	–	–	–	–	–	–	–
Vitamin E	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Vitamin C	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Thiamine (vitamin B_1)	–	–	–	–	–	–	1.5–7.0	8–10	1–6	3.1	2.4	2–3	–	–
Riboflavin (vitamin B_2)	–	–	–	16	–	–	1–5	3–5	1–5	2.5		1.7–2.5	–	–
Niacin (vitamin B_3)	–	–	–	180	–	–	15–55	35–57	25–50	51	1.6	19–30	–	–
Vitamin B_6	–	–	–	20	–	–	2.5	–	–	–	–	2–3	–	–
Folic acid				2	–	–	0.5–3.0	–	0.5–3.0	–	–	0.4–0.5	–	–
Vitamin B_{12}	–	–	–	–	–	–	0.01[a]	–	–	–	–	–	–	–
Iron[b]														
— NaFeEDTA	–	–	–	–	–	–	–	–	–	–	–	–	250	500[c]
— Ferrous bisglycinate	–	–	–	–	–	–	–	–	22	–	–	–	–	–
— Ferrous sulfate or fumarate	–	–	–	–	–	–	30–45	30	30	30+	–	–	–	–
— Electrolytic iron	–	–	–	–	–	–	45–60	25–35	30–60	20+		9–14	–	–
Zinc (oxide)	–	–	–	–	–	–	15–30	–	15–30	–	–	–	–	–
Calcium	–	–	–	–	–	–	2 100–3900	–	–	–	–	–	–	–
Iodine	–	–	–	–	–	–	–	–	–	–	–	–	–	15–60

NaFeEDTA, sodium iron ethylenediaminetetraacetic acid.

[a] As recommended at a recent PAHO/WHO meeting (*339*).

[b] Usually foods are fortified with only one iron compound, but in the case of pre-cooked maize flour trials are currently underway to assess the viability of using more than one iron fortificant.

[c] As encapsulated ferrous sulfate, but to date this has only been used only in experimental trials.

The cost of fortifying one tonne of wheat flour with ferrous fumarate (45 mg Fe/kg), zinc oxide (30 mg/kg), thiamine (6.5 mg/kg), riboflavin (4 mg/kg), niacin (50 mg/kg), folic acid (2.0 mg/kg), vitamin B_{12} (0.010 mg/kg) and vitamin A (2.0 mg/kg) has been estimated to be US$ 5. At a per capita consumption of 100 g of wheat flour a day, this is equivalent to only US$ 0.182 per year or US$ 0.0005 per day per person. Nevertheless, in a country with 10 million consumers, the fortification costs amount to some US$ 5000 per day (US$ 1.825 million per year). At this cost level, some manufacturers might well be tempted to take that as additional profit rather than add the micronutrients.

The cost of fortifying wheat flour with the same micronutrients listed above might increase the price of the flour by US$ 0.30–0.50 per kg, or by 1.0–1.7% relative to that of the unfortified product. Although such increments can be incorporated into the product price, in a free-market economy even small price differentials might be too much to preserve the market share of the fortified product against a non-fortified alternative, especially if the competitive rules are not equal for all. For example, fortification of salt with 20–40 mg iodine/kg using potassium iodate costs US$ 1.25 per tonne, or US$ 0.0000125 per day per person (US$ 0.005 per year per person) assuming a daily consumption of 10 g of salt. This equates to around US$ 45 625 per year for a country of 10 million persons. Thus, although the absolute annual investment is relatively low, this represents an increment in price of 2% over raw salt (assuming the price of salt is US$ 0.06 per kg). Even this modest price increment is disliked by many small producers who fear loss of their market share to the extent that they would avoid adding iodine if not for strict governmental enforcement. Herein lies the reason why salt is currently not more widely used as a vehicle for other micronutrients, even if their addition were technically feasible and biologically efficacious. If, however, mechanisms to overcome impediments of this nature, such as subsidies or effective and reliable enforcement mechanisms, were to be devised, salt may yet become a more attractive option as a vehicle for mass fortification. Salt could also be used in targeted programmes, where price increases due to the cost of fortification tend to be less limiting.

In summary, experience dictates that a mass fortification in an open market economy works best when the increase in the price of the fortified product, relative to the unfortified version, does not exceed 1–2%. However, this is by no means a universal prescription and any decisions relating to cost limits can only be taken by government and industry depending on the situation in any given country.

Annex D describes a procedure that can be used for setting Feasible Fortification Levels for mass fortification programmes based on consideration of safety, technological and cost constraints. If the combined effect of these constraints is to reduce the amount of nutrient that can be added to below that which is required to achieve a given intake goal, then more than one food may

need to be fortified or some nutrients may have to be supplied through other strategies, such as supplementation.

7.5.2 Targeted fortification

With targeted fortification, the various constraints on micronutrient additions are generally less restrictive than those that operate in the case of food products subject to mass fortification. Not only is the target group more clearly defined (refugees, displaced persons and young children are usually the main beneficiaries), but the fortified foods are usually in their final form or are offered in defined serving sizes, so that the risk of exceeding ULs is reduced. In addition, the presentation and sensory properties of foods selected for targeted fortification are such that any changes introduced by the addition of micronutrients are more easily hidden, and the cost of fortification is usually compatible with the price of the product or partly borne by the financial supporters of the programme. Nevertheless, it is always instructive to assess technological compatibility and overall cost of targeted fortified foods at the programme planning stage.

7.5.2.1 Blended foods

Guidelines covering the fortification of blended foods for refugees and displaced persons are available elsewhere (*62*) and thus are not discussed in detail here.

7.5.2.2 Complementary foods

That the micronutrient content of breast milk may be considerably lower in undernourished women is a concern in several parts of the world. Nutrients most likely to be reduced in the breast milk of undernourished mothers include vitamin A, all B vitamins except folate, iodine and selenium. The fortification of complementary foods thus provides a means of supplying additional nutrients to infants and children who are still receiving breast milk. However, because infants and young children also require their diets to have a high nutrient density (i.e. a high concentration of nutrient per kcal), in some settings it may be difficult to achieve a low risk of inadequate nutrient intakes even when complementary foods are fortified.

The process of setting the level of fortification for complementary foods is similar to that described earlier in this chapter (see section 7.3.2). The starting point is again the distribution of usual intakes, although in this case is it necessary to consider the intakes from both breast milk and complementary foods for each nutrient being studied. Breast-milk intakes can be estimated from published information on the composition of breast milk (such as that published by WHO, which includes data from both industrialized and developing countries (*340*),

and intakes from other sources can be collected using 24-hour recall methods for a representative sample of the group of interest.

Having obtained the relevant intake data, the procedure for setting fortification levels is then much the same as previously, the steps being as follows:

Step 1. Determine the prevalence of intakes that are below the EAR

First, review the intake distributions and determine the prevalence of intakes that are below the EAR; decide if this level of inadequate intakes is acceptable. If it is not, then fortification of complementary foods could be considered.

Step 2. Decide what level of prevalence of inadequate intakes is acceptable

Next, decide on an acceptable prevalence of inadequacy (i.e. the percentage of the children with intakes below the EAR). Often 2–3% is taken to be the maximum desirable prevalence of inadequate intakes. Then determine the level of fortification that will move the prevalence of inadequacy down to this acceptable level.

Step 3. Select a food vehicle

Choose the most appropriate vehicle for fortification, i.e. the one that will reach most of the children, or will reach those with the greatest need.

Step 4. Simulate the impact of fortification

Finally, calculate through simulation the likely impact of fortification of the chosen food vehicle on the prevalence of inadequate intakes and proportion of intakes that are in excess of the UL.

With the exception of iron and zinc, EARs are not defined for infants aged 0–12 months. For this age group, recommended intakes are expressed in terms of Adequate Intakes (AIs), in which case the nutritional goal of a fortification programme would be the raising of the mean intake of the target group to the AI.

Simpler alternative approaches to setting fortification levels for complementary foods do, however, exist. One option is to estimate the size of the gap between the usual median intake and the recommended intake (either the EAR or the AI, depending on the nutrient of interest); this then equates to the amount of micronutrient that needs to be added in order to achieve the desired nutritional goal. Dividing the nutritional gap by the daily amount of food consumed gives the amount of micronutrient that needs to be supplied per gram of the fortified food[1].

[1] The fortification level is more conventionally expressed as an amount per 100 g or per serving size (i.e. the amount per gram multiplied by the average serving size, usually 40 g).

The other option, which is the easier of the two because there is no need for intake data, is to simply add a specific proportion of the EAR (or AI) of the target group in the hope that by so doing the nutritional needs of the majority of the children will be met. Again it is necessary to know how much of a given complementary food is consumed per day, and also what the usual serving sizes are in order to derive a fortification level per 100 g of product or per serving size.

The Codex Alimentarius Commission provides recommendations for the composition of certain foods designated for infants and young children. These are subject to a process of continual review and are regularly revised. In the case of supplementary foods for older infants and young children, when the food is supplemented with specific nutrients, the Codex recommendation is to add at least two thirds of the reference daily requirement per 100 g of food (*341*). In practice, this means that if an average serving size for this age group is around 40 g, each serving should provide between 30% and 50% of the EAR in order to satisfy the daily nutrient needs in 2 to 3 servings a day. Obviously, if detailed dietary information is available, the micronutrient content of complementary foods might be adjusted to the exact characteristics and needs of the target group.

7.5.3 Market-driven fortification

Food manufacturers add micronutrients to their products not just to increase their nutritional value but also to increase their appeal to the health conscious consumer. This business-oriented initiative can play a positive role in public health by improving the supply of essential nutrients that are sometimes difficult to provide in sufficient amounts via mass fortification. So far, the public health impact of fortification of market-driven processed foods has been very modest in developing countries but its importance is expected to be greater in the future, largely as a natural consequence of increasing urbanization and availability of such foods.

The main aim of regulating the level of fortificants in processed foods is preserving the nutritional balance and safety of the diet for the population at large. To this end, minimum levels need to be set to ensure that reasonable amounts of micronutrients are added to food products; these must be stated on the product label, and may be referred to when advertising the product. It is important to also fix maximum levels so as to reduce the risk of an excessive nutrient intake through the consumption of fortified foods, especially for those micronutrients with well-established UL values (see Chapter 11). It may also be desirable to regulate which foods can be fortified (see section 7.5.3.3).

7.5.3.1 Nutritional Reference Values (NRVs)

Guidelines on nutrition labelling that are applicable to all foods including fortified foods have been produced by the Codex Alimentarius Commission (*342*). In an attempt to harmonize the labelling of foods with respect to their nutrient contents, the Codex guidelines define a set of Nutrient Reference Values (NRVs), which are based on the FAO/WHO RNI values for adult males, as a reference for the general populaition. Unlike RNIs, NRVs are not given for specific age or physiological groups but are designed to apply to all family members aged over 3 years. The current NRVs (see **Table 7.11**) are based on the 1996 FAO/WHO RNI values (*210*), and will be adjusted in accordance with the more recent RNI values published by the FAO/WHO (*93*).

TABLE 7.11

Codex Nutrient Reference Values (NRVs) for selected micronutrients

Nutrient	Codex NRV[a]	FAO/WHO RNI for adult males[b]
Calcium (mg)	800	1 000
Iodine (µg)	150	150
Iron (mg)	14	13.7
Magnesium (mg)	300	260
Selenium (µg)	–	34
Zinc (mg)	15	7
Biotin (µg)	–	30
Vitamin B_6 (mg)	2	1.3
Folate[b] (µg DFE)	200	400
Vitamin B_{12} (µg)	1	2.4
Niacin (vitamin B_3) (mg)	18	16
Riboflavin (vitamin B_2) (mg)	1.6	1.3
Thiamine (vitamin B_1) (mg)	1.4	1.2
Vitamin C (mg)	60	45
Vitamin A[d] (µg RE)	800	600
Vitamin D[e] (µg)	5	5
Vitamin E (α–tocopherol) (mg)	–	10.0

[a] The Nutrient Reference Value (NRV) is a dietary reference value defined by the Codex Alimentarius Commission for the purposes of harmonizing the nutrition labeling of processed foods and used as a reference for the general population (*342*).

[b] The FAO/WHO RNIs listed here are those published in 1996 (*210*), some of which have since been revised.

[c] 1 DFE = Dietary folate equivalent = 1 µg food folate = 0.6 µg folic acid from fortified foods, which means that 1 µg folic acid = 1.7 DFE.

[d] RE = retinol equivalents (1 µg RE = 3.33 IU vitamin A).

[e] As calciferol (1 µg calciferol = 40 IU vitamin D).

Sources: adapted from references (*210,342*).

7.5.3.2 Setting safe maximum limits for market-driven fortification of processed foods

The fact that market-driven fortified processed foods are usually marketed to all family members, rather than to specific age or physiological groups, presents a number of difficulties in terms of setting maximum limits on the permitted levels of fortificants in such foods. The difficulties are compounded by the fact that the same serving size of the fortified food (breakfast cereals, beverages and nutritional bars, for example) is common to all members of the family. The problem therefore arises that by using maximum limits that are based on the NRVs (i.e. RNIs of adult males; see section 7.5.3.1), unnecessarily large amounts of micronutrients may be delivered to children by fortified foods. In this context, it is worth noting that, for some micronutrients (vitamin A, niacin as nicotinic acid, folate, zinc, calcium and iodine), the UL for children below 8 years of age is very close to the EAR for adult males (see **Tables 7.2 and 7.3**).

Establishing maximum levels for nutrient additions that take into account the above safety concerns thus requires adopting some form of risk assessment appraisal. Such approaches base the calculation of a safe maximum limit on accepted values of the UL for the most vulnerable groups, which in this case are children in the age group 4–8 years. Then, assuming that the amounts of micronutrients provided by the diet and via ongoing mass fortification programmes are known, the maximum micronutrient content per serving size of a market-driven fortified processed food is given by the following equation (a):

$$\text{Maximum micronutrient content per serving size} = \frac{[\text{UL} - (\text{amount of micronutrient provided by the diet} + \text{amount of micronutrient provided by fortified foods in the context of an ongoing mass fortification programme})]}{\text{Number of servings}}$$

In order to apply this equation, it is necessary to estimate the number of servings of processed foods that are consumed. This can done as follows:

The usual serving size for solid foods is generally assumed to be 50 g and that for beverages, 250 ml after reconstitution to liquid. However, for the purposes of this derivation it is better to define the serving size in terms of energy (i.e. in kcal) in order to preserve the nutritional balance of the diet. **Table 7.12** summarizes the usual energy densities of a variety of commercially-available foods, from which it can be seen that the smallest dietary serving size is 40 kcal. Thus, a serving of solid foods (50 g) contains 5 dietary servings, a serving of milk or cereal-based beverages, 6 dietary servings, and sugar-based beverages, 1 dietary serving.

TABLE 7.12
Energy densities of common food presentations

Food presentation	Usual serving size	Energy density per serving	Energy density per 100 g or 100 ml
Solid	50 g	160 kcal	320 kcal
Milk or cereal-based beverages	250 ml	200 kcal	80 kcal
Sugar-based beverages	250 ml	100 kcal	40 kcal

If it is assumed that 30% of an individual's daily energy intake (2000 kcal) is derived from fortified processed foods, the amount of energy provided by these foods would be:

$$2000\,\text{kcal} \times 0.3 = 600\,\text{kcal}.$$

In terms of the number of the smallest dietary serving size, expressed as an energy density (i.e. 40 kcal), this amount of energy equates to:

$$600\,\text{kcal}/40\,\text{kcal} = 15 \text{ servings}.$$

Thus, the previous equation can be transformed as follows:

$$\text{Maximum micronutrient content per 40 kcal serving size} = \frac{[\text{UL} - (\text{amount of micronutrient provided by the diet} + \text{amount of micronutrient provided by fortified foods in the context of an ongoing mass fortification programme})]}{15}$$

Box 7.3 illustrates the use of this procedure for milk and sugar-based beverages.

Under normal circumstances, and after considering nutrient amounts supplied by the diet, it is unlikely that the maximum safe limits per usual serving size for the nutrients mentioned in **Table 7.13** (with the exception of calcium) will be in excess of 30% of the RNI in the case of solid foods and milk- or cereal-based beverages and in excess of 15% of the RNI in the case of sugar-based beverages.

7.5.3.3 Keeping the nutritional balance

Some micronutrients were intentionally omitted from the discussion in the preceding section, because either they do not have a recognized UL (health risks

BOX 7.3

Example: setting maximum safe levels for the fortification of milk and sugar-based beverages with vitamin A

1. Milk

A milk beverage is to be fortified with vitamin A. The fortified product is aimed at a population in which the daily intake of retinol (preformed vitamin A) through the diet and from ongoing mass fortification programmes by children is approximately 300 µg.

Given that the UL for vitamin A in children aged 4–8 years is 900 µg (**Table 7.3**). the maximum content of vitamin A per 40 kcal serving size will be:

(900 – 300 µg vitamin A)/15 servings = 40 µg vitamin A/serving.

By using the relevant conversion factor (**Table 7.14**), we can calculate the maximum safe vitamin A content for a 250 ml serving of milk, as follows:

40 µg vitamin A × 5.0 = 200 µg vitamin A.

Expressed as a percentage of the adult male RNI (see **Table 7.1**), the maximum vitamin A content of a 250 ml serving of the fortified milk is:

200/600 × 100 = 33%,

and expressed as a percentage of the current NRV (see **Table 7.11**), the maximum vitamin A content of a the same sized serving of milk is:

200/800 × 100 = 25%.

2. Sugar-based beverages

A similar calculation for a sugar-based beverage yields a maximum vitamin A content of 100 µg (i.e. 40 µg × 2.5) per 250 ml of beverage (or reconstituted powder), which represents 17% of the adult male RNI and 12.5% of the current NRV for this vitamin.

have not, as yet, been identified), or their UL is high enough to not to raise serious concerns about the safety of high intakes from fortified foods. However, in the interests of maintaining an adequate balance in the diet, it is recommended that these other nutrients be added to processed fortified foods in roughly the same proportion as those micronutrients for which large intakes are undesirable. In practice this means limiting micronutrient additions to between 15% and 30% of the adult RNI in the case of solid foods and milk- or cereal-based beverages, and to half of these values (i.e. 7.5–15%) in the case of sugar-based beverages.

TABLE 7.13

Calculated maximum micronutrient content[a] per 40 kcal-sized serving, assuming no other sources of micronutrient in the diet

Nutrient[b]	UL (children aged 4–8 years)	Maximum amount	
		Per 40 kcal serving	As a % of the RNI[c]
Vitamin A (as retinol) (µg RE)	900 µg	60 µg	10
Niacin (as nicotinic acid[d]) (mg)	15 mg	1.0 mg	6
Folic acid (mg)	400 µg	27 µg	7
Iron (mg)	40 mg	3 mg	22
Zinc (mg)	12 mg	0.6 mg	4
Calcium (mg)	2 500 mg	167 mg	17
Iodine (µg)	300 µg	20 µg	13

UL, Tolerable Upper Intake Limit; RNI, Recommended Nutrient Intake.

[a] Maximum levels listed here should be reduced by an amount proportional to the amount of nutrient supplied by the diet (including though mandatory mass fortification programmes).

[b] There are other micronutrients with UL values, but they are not included here because it would be very difficult to approach the UL through the consumption of fortified foods.

[c] As a percentage of the RNI for adult males.

[d] Niacinamide can be used without this restriction.

TABLE 7.14

Factors for converting maximum micronutrient amounts per 40 kcal-sized servings to maximum amounts for different food presentations and serving sizes

Food presentation	Usual serving size	Conversion factor	
		Per usual serving size	Per 100 g or 100 ml
Solid	50 g	4.0	8.0
Milk or cereal-based beverages	250 ml	5.0	2.0
Sugar-based beverages	250 ml	2.5	1.0

These recommendations are in line with Codex guidelines on nutrition claims and their use, which are only expressed in terms of percentage of the NRV serving for minerals and vitamins (see *section 7.5.3.1*). The Codex Guidelines for Use of Nutrition Claims (*343*) stipulate that a food can only be described as a "source" of a specific nutrient if it supplies 15% of the NRV per usual serving, (or 15% of the NRV per 100 g (solid food), or 5% of the NRV per 100 ml (liquid food), or 5% of the NRV per 100 kcal). In order to qualify as being "high" in a specific nutrient, a food product must contain twice as much of the nutrient as a "source" does. It means that many foods could be classified as a "source", but very few products – mostly those naturally rich in micronutrients – could be classified as "high" in specific micronutrients.

It is generally recommended that nutrient content claims be restricted in accordance with these rules, even if the food product contains – for technological purposes or naturally – more than 30% of the NRV. Claims based on percentages in excess of 30% of the NRV in a given fortified food should be discouraged, on the grounds that such claims might mislead consumers as to what constitutes a properly balanced diet.

Summary

- Authorities taking the decision to launch a micronutrient fortification programme should not do so without collecting food and nutrient intake data, supported by various ancillary information, especially, biochemical data on nutritional status. Such data are necessary to make an informed judgment about the types and amounts of specific nutrients to add to which foods. Given the long-term effort and investment that is needed to implement and sustain fortification programmes, and the need to protect individuals in populations consuming the fortified foods, both for deficiencies as well as for excesses, an initial investment in collecting adequate food intake data is highly recommended.
  - — Biochemical and clinical data can reveal which micronutrients are insufficient in the usual diet and indicate the prevalence and severity of specific micronutrient deficiencies in different population groups.
  - — Information on the distribution of usual dietary intakes of nutrients within population groups provides the most useful basis on which to justify and design a micronutrient fortification programme to correct micronutrient deficiencies.
  - — Knowledge of dietary patterns, although useful, is not sufficient information for making final decisions about which nutrients to add to which foods, and how much of each nutrient to add.
- The amount of micronutrient added to the diet through food fortification should be designed such that the predicted probability of inadequate intakes of that specific nutrient is ≤2.5% for population subgroups of concern, while avoiding risk of excessive intakes in other subgroups of the population.
- Due to technological, safety and cost constraints, it may not be possible to add the amount of nutrient(s) needed to ensure adequate intakes in almost all members of a population by mass fortification. In that case, fortification of several food vehicles, other types of fortification, or supplementation, should be considered.
- While these Guidelines provide information on the rationale for fortification and the implementation of fortification programmes, the final decisions concerning which micronutrients to prioritize in a specific location should be made on the basis of local information and public health priorities.

CHAPTER 8

Monitoring and evaluation

Monitoring and evaluation are essential components of any food fortification programme, systems for which should be developed at the outset of a programme, ideally during the design and planning stages. Monitoring and evaluation provide an opportunity not only to assess the quality of the implementation and delivery of a programme, but also the degree to which it reaches its targeted households and individuals, and achieves its nutritional goals. More importantly, the results of monitoring and evaluation exercises provide programme planners and policy-makers with the necessary information to make decisions about whether to continue, expand, replicate or end a programme.

8.1 Basic concepts and definitions

For a fortification programme to be effective, the chosen food vehicles have to be available nationwide or, at least, in the specific geographical areas targeted by the programme. In practice, this means that the product must be available to purchase from local retail stores or outlets that are accessible to the targeted segments of the population. Furthermore, the fortified products have to be purchased by the target families, and consumed with sufficient frequency and in appropriate amounts by the targeted individuals. Throughout this process, that is to say, from the factory to the retail stores, and right up until the time of consumption by targeted individuals, it is vital that the product maintains its expected quality. Thus to ensure that the planned impact is achieved, a programme's *operational performance* (or *implementation efficiency*) must be monitored; this is best accomplished through a system of continuous data collection at key delivery points. When bottlenecks or operational inefficiencies are identified, information must be directed to the programme entity responsible for implementing remedial actions and for re-directing the programme as needed. This set of actions constitutes programme *monitoring*.

In the context of food fortification, the term "monitoring" thus refers to the continuous collection, review and use of information on programme implementation activities, for the purpose of identifying problems, such as non-compliance, and informing corrective actions so as to fulfil stated objectives (*6*). The ultimate purpose of monitoring a fortification programme is to ensure that

the fortified product, of the desired quality, is made available and is accessible to consumers in sufficient amounts.

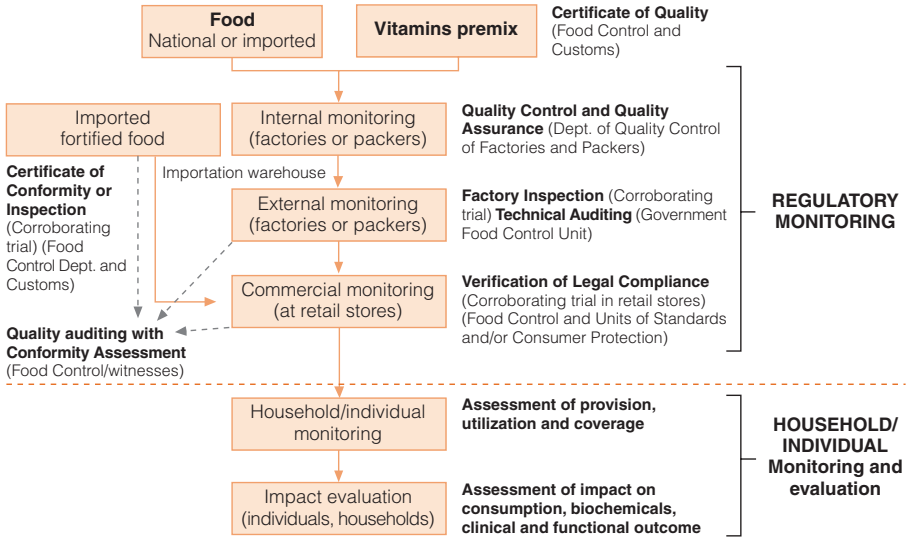
The term "evaluation" on the other hand is used to refer to the assessment of the effectiveness and the impact of a programme on the target population. In the case of food fortification, evaluations are undertaken with the aim of providing evidence that the programme is indeed reaching its nutritional goals, be this an increase in the intake of a fortified food or of specific nutrients, or an improvement in the nutritional status, health or functional outcomes of the target population. Programme evaluation should not be undertaken until a programme has been shown – through appropriate monitoring – that it has been implemented as planned, and is operating efficiently. A poorly implemented programme is unlikely to achieve its desired impact, and thus, resources should not be wasted in undertaking evaluations until programme operational inefficiencies have been corrected.

A schematic representation of a model monitoring and evaluation system for fortification programmes is shown in **Figure 8.1**; this model provides a framework for the various monitoring and evaluation activities that are described in this chapter.

The framework model distinguishes two main categories of monitoring, *regulatory monitoring* and *household/individual monitoring*. The former, regulatory monitoring, encompasses all monitoring activities conducted at the production level (i.e. at factories, packers), as well as monitoring at customs warehouses and

FIGURE 8.1

A monitoring and evaluation system for food fortification programmes



at retail stores, by concerned regulatory authorities as well as by producers themselves as part of self-regulation programmes. Production level regulatory monitoring comprises both *internal* and *external monitoring;* regulatory monitoring at the retail level is referred to here as *commercial monitoring*. The primary aim of regulatory monitoring is to ensure that the fortified foods meet the nutrient, quality and safety standards set prior to programme implementation.

The other category, household/individual monitoring, as its name implies, involves households and their members and has the following objectives (adapted from Habicht et al. (*344*):

— to ensure that targeted individuals and households have access to the fortified food and that the fortified food is of the expected quality (i.e. to measure service *provision*);

— to ensure that targeted individuals and households purchase and consume the fortified food (i.e. to monitor service *utilization*);

— to ensure that targeted individuals and households consume the fortified food in appropriate amounts and frequency (i.e. to measure *coverage*).

Once regulatory and household monitoring have demonstrated that the programme is operating in a satisfactory manner, evaluation of the programme at the household and at the individual level can be undertaken to assess its impact. This is generally referred to as *impact evaluation* (**Figure 8.1**) Some of the data obtained through household monitoring, for example, data on consumption of fortified foods and/or micronutrient intakes, can also be used in programme evaluation (see section 8.4).

Table 8.1 summarizes the key features of each of the three principal framework components of monitoring and evaluation identified above, i.e. regulatory monitoring, household monitoring and impact evaluation. The remainder of this chapter is devoted to discussing each of these components in more detail and concludes by outlining the minimum requirements for a monitoring and evaluation system for a fortification programme (section 8.5).

8.2 Regulatory monitoring

As shown in **Figure 8.1**, regulatory monitoring comprises three parts – internal monitoring, external monitoring and commercial monitoring:

- *Internal monitoring* refers to the quality control and quality assurance (QC/QA) practices conducted by producers, importers and packers.
- *External monitoring* refers to the inspection and auditing activities carried out at production centres (factories and packers) and importation custom sites. Governmental authorities are responsible for external monitoring, which is

TABLE 8.1

Purpose and function of the various components of monitoring and evaluation systems for fortification programmes

Component	Purpose	Specific function
Regulatory monitoring	To ensure that fortified foods meet nutrient quality and safety standards throughout their shelf-life (i.e. from factory to retail store); comprises: — internal monitoring; — external monitoring; — commercial monitoring.	Regulatory monitoring can address questions such as: — Is GMP applied? — Is HACCP in place (when applicable)? — Is QA/QC correctly done? — Are inspection and technical auditing functions at the factory and at packing facilities implemented satisfactorily? — Is verification of legal compliance at retail stores carried out as planned?
Household/ individual monitoring and evaluation	To assess: — provision; — utilization; — coverage.	Household monitoring can address questions such as: — Is the fortified food accessible to the target population? — Is the fortified food of acceptable quality? — Does the targeted population purchase the fortified food? — Is the fortified food being stored, handled/prepares as intended? — Does the targeted population consume the fortified food in appropriate amounts/frequency?
Impact evaluation	To assess impact on outcomes of interest, such as: — consumption of fortified food; — intake of specific nutrient(s); — nutritional status (i.e. biochemical indicators); — health; — other functional outcomes (e.g. growth, cognition).	Impact evaluations can address questions such as: — Has the targeted population reached a pre-established acceptable level of a given outcome of interest (e.g. is prevalence of iron deficiency <20% among pregnant women; is 70% of the target population consuming fortified product; or does 80% of the target population have an adequate intake of a particular micronutrient)? (These are examples of *adequacy*[a] evaluations.) — Does the targeted population have improved outcome(s) since the intervention was implemented (before-and-after); or does the targeted population have better outcome(s) after the intervention compared with a control group; or did targeted population have a greater improvement in outcome(s) following the intervention compared with a control group? (These are examples of *plausibility*[a] evaluations.) — Has the group randomly assigned to receive fortified food achieved a greater improvement (before-and-after) in outcome(s) compared with a randomized control group? (This is an example of a *probability*[a] evaluation.)

GMP, good manufacturing practice; HACCP, hazard analysis critical control points; QA/QC, quality assurance/quality control.

[a] The different types of impact evaluation are described in greater detail in section 8.4 of these Guidelines.

implemented as a mechanism to assure compliance with standards and regulations.

- *Commercial monitoring* is similar to external monitoring in that it is generally the responsibility of the government and its purpose is to verify that the fortified products comply with standards, but is conducted at the level of retail stores.

For each stage of the monitoring process, it is helpful to establish indicators that can be used to measure success. In the case of fortification programmes, success criteria can be expressed in terms of the proportion of samples containing a specified minimum amount of a given nutrient at various stages in the lifecycle of the product, i.e. at the time of production (the Production Minimum), at the point of sale (the Retail or Legal Minimum) and at the point of consumption (the Household Minimum). A sample set of success criteria for monitoring purposes are presented in **Table 8.2.**

To be effective, a monitoring system requires a set of established procedures, methodologies and reporting requirements, all of which make a contribution to ensuring the continuous assessment of a programme. A clear delineation of responsibilities and an efficient feedback mechanism, which facilitate the establishment and implementation of corrective measures when operational problems arise, are also essential. **Table 8.3** (*345*) outlines how some of these facets of

TABLE 8.2

Suggested criteria for measuring success at various monitoring stages for food fortification programmes (expressed as a percentage of samples that must comply with minimum levels and Maximum Tolerable Levels)

Monitoring stage	Minimum levels			Maximum Tolerable Level[d]
	Household[a]	Retail[b]	Production[c]	
Internal	100	100	≥80	<20
External (inspection)	100	≥80	–	<20
Household	≥90	–	–	<10

[a] The Household Minimum Level is the amount of nutrient that must be present in the food at the household level before being used in meal preparation. This value is estimated to reach a nutritional goal after considering losses during food preparation (specific additional intake of certain nutrients).

[b] The Retail Minimum Level (or the Legal Minimum Level) is the nutrient content of the fortified food at retail locations at the moment of sale. Usually it is 20–30% larger for vitamins and iodine, and 3–5% larger for minerals, than the Household Minimum Level.

[c] The Production Minimum Level is the nutrient content of the fortified food in the factory, which considers an overage for losses occurring during production, distribution and storage. It is the decision of the manufacturer/importer which overage to use to ensure that the product retains the Retail Minimum Level during the duration of its commercial life.

[d] The Maximum Tolerable Level (MTL*)* is the maximum allowed content of a specific micronutrient in a fortified food to assure that none of the consumers receives an amount near to the Tolerable Upper Intake Level (UL).

TABLE 8.3

Suggested regulatory monitoring activities for a food fortification programme

Monitoring stage	Action/indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
Internal monitoring (quality control and assurance)	GMP applied	Daily.	*Method:* Follow a GMP manual approved by company directors. *Responsible:* Factory manager.
	HACCP system in place, where applicable	Daily.	*Method:* Follow a HACCP manual approved by company directors. *Responsible:* Factory manager.
	Premixes and preblends available in sufficient amounts for at least 15 days of production	Daily.	*Method*: Continuous inventory of micronutrient premixes and preblends in existence and use. Confirm that batches of premix are used in the same order in which they were produced. *Responsible:* Factory manager.
	Dosage is in the correct proportion	At least once per shift.	*Method:* Ensure premix flows according to the production rate so that the theoretical average is as expected and the Production Minimum Level is always attained. *Responsible:* Factory quality control department.
	Corroborating tests (at least 80% of samples fulfil the Production Minimum Level and less than 20% reach the Maximum Tolerable Level)	At least every 8 hours; if success criteria are not fulfilled, frequency of sampling should be increased to every 2–4 hours.	*Method:* Take a random sample(s) from packaging line. A fast semi-quantitative assay can be used at shorter intervals, but at least one daily-composite sample should be analysed using a quantitative assay. *Responsible:* Factory quality control department.

TABLE 8.3

Suggested regulatory monitoring activities for a food fortification programme (*Continued*)

Monitoring stage	Action/indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
External			
Factory (inspection and technical auditing)	Fortification centre carries out QC/QA procedures and maintains up-to-date registers	At least once every 3–6 months; frequency of visits should be increased to 1–4 times/month if problems are detected.	*Method:* Conduct auditing to verify performance of the QC/QA procedures and registry, and that fortification centres adopt GMP. *Responsible:* Food control authorities.
	Corroborating tests (at least 80% of individual samples fulfil the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Combine testing with visits to examine QC/QA and GMP procedures; if intentional or serious mistakes are suspected, plan a Quality Audit for Evaluation of Conformity.	*Method:* Collect 5 individual samples of packaged product and take 5 samples from the production line, and test for compliance. *Responsible:* Food control authorities.
At importation sites (applies to imported/ donated products)	Obtain Certificate of Conformity[a] of sale from country of origin	Each time a product lot enters the country.	*Method:* Examine documentation, quality and labelling of products in the customs warehouses. *Responsible:* Importation officials in collaboration with food control authorities.
	Corroborating tests (at least 80% of individual samples fulfill the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Combine with examination of importation papers. If intentional or serious mistakes are suspected, plan a Quality Audit for Evaluation of Conformity.	*Method*: Randomly select 5 individual samples from the lot and test for compliance with the Legal Minimum Level and the MTL. *Responsible:* Importation officials in collaboration with food control authorities.

Commercial (inspection at retail stores)	Corroborating tests (at least 80% of samples of each brand fulfill the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Systematic and continuous examination of the product distributed to all regions of the country; each region should be visited at least once a year.	*Method:* Visit stores to collect samples; send samples to official laboratories for quantitative assays. At the local level, semi-quantitative assays may also be used to confirm presence of fortificant if fraud is suspected. *Responsible:* Local personnel from public institutions (e.g. representatives of ministries of health, industry, consumer protection organizations).
Quality Audit for Evaluation of Conformity	Verify production or stored batch complies with standards when analysed using statistical sampling criteria	Whenever it is necessary to take legal actions; can also be requested and financed by producers to certify production lot for exportation.	*Method:* Visit fortification centres suspected of non-compliance with regulations and standards, or when required by exporting industry. Follow technical recommendations of the Codex Alimentarius Commission (*345*) or any equivalent guidelines suitable for this activity. *Responsible*: Personnel of the public agency for food control: as visits to fortification centres are performed under suspicions of non-compliance of regulations and standards, these activities should be carried out in the presence of independent witnesses.

GMP, good manufacturing practice; HACCP, hazard analysis and critical control point; MTL, Maximum Tolerable Level; QC/QA, quality control/quality assurance.

[a] The Certificate of Conformity is a statement that the imported product complies with a set of specific standards.

monitoring might be implemented in practice for each of the three stages of regulatory monitoring, internal, external and commercial.

Table 8.3 lists an additional monitoring stage, namely quality audits for evaluation of conformity. This is the formal examination and testing of a batch of a fortified food product for compliance with standards. It should be reserved for special circumstances, which can either be when intentional non-conformity is suspected (and legal action is required) or when certification of a production lot prior to exportation is necessary.

8.2.1 Internal monitoring (quality control/quality assurance)

Broadly speaking, *quality assurance* (QA) refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically in terms of the results of quality control procedures. *Quality control* (QC) is defined as the techniques and assessments used to document compliance with established technical standards, through the use of objective and measurable indicators that are applicable to the products or services.

Detailed information about QC/QA can be found in any one of the many technical manuals that are devoted to this subject and in publications on good manufacturing practice (GMP) (*346*). In these Guidelines the topic of QA/QC is viewed from a purely public health perspective and focuses on indicators and criteria that are relevant to the process of food fortification. Thus in the context of food fortification, **quality assurance** consists of establishing the following procedures:

— obtain from the providers a certificate of quality[1] for any micronutrient mixes used;

— request, receive and store in a systematic, programmed and timely manner the ingredients and supplies for the preparation of a preblend[2];

— produce the preblend according to a schedule that is adjusted to the rate of food manufacturing and fortification;

— control the adequate performance of the preblend equipment;

— appropriately label and deliver the preblend;

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[1] The micronutrient mixes must be accompanied by a document that certifies their nutrient content. This is usually the case for products shipped by international companies dedicated to this task.

[2] A **preblend** is the combination of the micronutrient mix with another ingredient, often the same food that is to be fortified, with the purpose of reducing the dilution proportion and improving the distribution of the micronutrient mix in the food and guaranteeing that there will be not be separation (segregation) between the food and micronutrient particles.

— use the preblend in the same order of production (i.e. first in, first out);

— verify appropriate functioning of the feeder machines and the mixers in a continuous and systematic manner;

— ensure that the product is adequately packaged, labelled, stored and shipped.

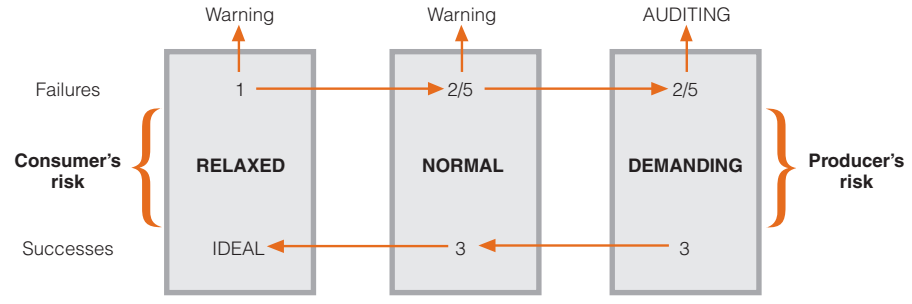
It is possible that other process variables, such as pH and temperature/time exposure, could affect the stability of added micronutrients and should also be considered in the design of quality assurance programmes.

The **quality control** procedures will typically consist of taking samples of the fortified food, either by batch or in a continuous manner depending on the system of production, and determining their micronutrient content. Irrespective of the sampling method, the number of samples required will be governed by the consistency and reliability of the fortification process. A highly homogeneous and consistent operation, regardless of the size of the batch or the rate of production, will need less sampling than one with variable results. Nevertheless, even in the most reproducible conditions it is important to take and analyse samples routinely in order to verify and keep track of whether the technical standards are being met.

Figure 8.2 illustrates the features of a dynamic sampling system suitable for a continuous production process. Under optimal operation, one sample of a product per 8-hour shift might be sufficient; this would be categorized as a *relaxed* intensity of sampling. If the technical specifications of the product are not attained (i.e. the micronutrient content is lower than the factory minimum or higher than the Maximum Tolerable Level), then sampling frequency should

FIGURE 8.2

Suggested frequency and intensity of sampling for monitoring compliance with standards



be increased from the relaxed intensity to a *normal* intensity and corrective actions taken. In a "normal" situation, if 2 out of 5 consecutive samples of the product fail to meet the technical requirements, then the intensity of sampling should be changed to a *demanding* intensity, and corrective actions implemented. Again, if 2 out of 5 consecutive samples do not achieve the technical requirements, then the production should be stopped until the source of error is found and the necessary corrective measures introduced.

When production is reinitiated, sampling should start at the demanding intensity, be switched to a normal and then back down to a relaxed intensity if, each time, three consecutive samples satisfy technical requirements. The relaxed situation implies a degree of consumer risk; if sampling is infrequent, there is a greater chance of some non-compliant batches reaching the market. When sampling is frequent (i.e. as in the demanding situation), the likelihood of detecting even a minor deviation from the standard is increased, and prompts producers to expend time and resources in the resolution of the problem (the producer's risk). Neither the relaxed nor the normal sampling intensity should be viewed as positive or negative; they simply reflect the performance of the fortification process at the moment of the assessment. Results of QC must be carefully recorded and kept, because they document the history of the efficiency and also the producer's supervision of the fortification process.

Because results are needed quickly (so that corrective actions can be implemented promptly), QC procedures demand fast and simple analytical assays. These assays do not necessarily need to have high analytical resolution (i.e. be able to discriminate between small concentration ranges), but it is essential that they are able to determine whether fortification standards are being met (i.e. micronutrient content not less than the production minimum nor more than the Maximum Tolerable Level). In this regard, semi-quantitative assays are potentially very useful and attempts have been made in recent years to develop test kits based on semi-quantitative assays. Test kits for the measurement of iodine in salt, for example, have been developed but, to date, have met with limited success; those currently on the market, have been found to be of questionable reliability (*347*). Clearly, further research is needed in this area before semi-quantitative tests can be applied more widely in the food industry.

8.2.2 External monitoring (inspection and technical auditing)

Some form of external monitoring by governmental food control authorities is essential to assure that producers are complying with the approved technical standards that ensure the quality and safety of food fortification. Awareness that their product might be checked at any time usually provides producers with a strong motivational force to carry out an acceptable production process with the appropriate QA/QC procedures. In industrialized countries, it is usually

sufficient to confirm once a year (or even less frequently) the nutrient content indicated on the food labels from samples taken in the market (see Commercial monitoring, section 8.2.3). However, in much of the developing world, where it is very difficult to trace and to retrieve a defective batch once a food product reaches retail stores, it is advisable to also conduct external monitoring at the factory level.

External monitoring combines two types of actions:

- checking the performance and the records of the producers' quality assurance procedures (*technical auditing*);
- confirming that the technical specifications for the product are being met at factories, packaging sites and points of entry into the country (*inspection*).

Ideally, inspection and verification of legal compliance should be based on the analytical assessment of the micronutrient content of a food product by means of a quantitative assay. All samples should contain the fortificant; at least 80% of samples from factories, importation sites and warehouses should present the Legal Minimum amount, and less than 20% of samples should have a micronutrient content that is above but always near the Maximum Tolerable Level (**Table 8.2**). If this is found not to be the case, then more frequent visits to the factory to carry out technical auditing and inspection activities are justified (see **Figure 8.2**).

Imported products should be treated in a similar manner to locally produced foods, only instead of checking the producers' documented AQ/QC procedures, the certificate of conformity provided by the country of origin should be examined. However, food control authorities can corroborate compliance of the technical standards in samples of the imported shipments.

The intensity of sampling and factory inspection frequency depends on the reproducibility of the fortification process and should be determined for each type of industry under the specific conditions of each country. For example, for salt fortification by small industries this might be every 15 days, for sugar industries every month, and for wheat flour industries every 6 months. In theory, sampling should follow a statistically based approach, such as that recommended by the Codex Alimentarius Commission (*345*). In practice, however, the number of samples and the analytical work required can overwhelm the available human, financial and material resources of the food control entities in many developing countries. For day-to-day monitoring and routine inspection visits, the Codex sampling procedures are often impractical and unrealistic and are thus best reserved for situations that require a quality audit for evaluation of conformity (e.g. for cases when the product requires a certificate of conformity for exportation, or if there is a legal controversy that might lead to serious penalties) (See **Table 8.3**).

A simpler, low-cost monitoring system, based on the concept of *corroborating tests*, has been successfully adopted by some countries in Central America. These tests consist of checking compliance with fortification standards in a small number of samples (e.g. 5–10 product samples from factories) during the moment of the technical auditing visit; samples are taken from the production line and also from storage areas. At least 80% of the samples should contain the Legal Minimum of the micronutrient, and less than 20% should be above, but never too far from the Maximum Tolerable Level. If these criteria are not fulfilled, then a warning statement must be provided and more frequent visits for technical auditing and inspection should be planned to the factories responsible for the product. In extreme cases, a quality audit for evaluation of conformity might be necessary (**Table 8.3**). The concept of corroborating tests is based on the principle that quality is the main responsibility of producers; governmental authorities only act to represent the public, and to guarantee that monitoring is indeed carried out.

8.2.3 Commercial monitoring

As is the case for any other industrially produced food, fortified foods, irrespective of whether fortification is voluntary or in response to public health interest, must be correctly identified with a label. A label should include at least the brand of the product, the address of the responsible entity, and the Legal Minimum Level of the nutrient and, if industry development allows, also the date of minimum durability, the batch number and the production date.

As mentioned in the previous section, in industrialized countries external regulatory monitoring is generally limited to a confirmation of micronutrient content and label claims in samples obtained from retail stores. In the event of a breach of standards, mechanisms exist for the recall of defective products and retraction of misleading claims. Strict governmental enforcement of regulations and stiff penalties for non-compliance, means that it is very rare for a producer to take the risk of not complying with regulations and on the whole, the procedure works well. In the developing world, as indicated previously, it is not always possible to trace and retrieve a defective batch once a food product reaches the market place, and so it is necessary to monitor for compliance with quality standards and label claims at the both the factory and retail levels (see also section 8.2.2).

In many settings, especially in the developing world, commercial monitoring can be particularly useful for identifying brands and factories that deserve closer auditing. A system based on the use of corroborating tests, as suggested for factories above, can equally well be applied to the commercial setting; one or two samples of each brand from each store might be used to check for standard compliance. If anomalies are found, then a technical comprehensive auditing of the

responsible factory or importation firm would be warranted. Semi-quantitative assays to detect the presence of micronutrients might be useful for monitoring at retail stores, and as an enforcement tool at the local level. However, any legal action must be based on results obtained from quantitative assays carried out as part of a quality auditing visit to the responsible factory.

A nation-wide programme to fortify vegetable oils with vitamins A and D_3 was established in Morocco in 2002. The system devised for monitoring the quality of the fortified product is described in detail in **Annex E**, and serves to illustrate the practical application of the principles of regulatory monitoring introduced here.

8.3 Household monitoring

It is generally assumed that having established through regulatory monitoring that a fortified product is of the required quality at the retail store level, the same product will be of a similar quality once it reaches households and individuals. Because the product may have deteriorated during storage, confirmation of this assumption is always recommended. Nor can it be assumed that just because fortified foods are available to buy from shops, they will necessarily be consumed by the target population; consumers may well purchase non-fortified foods in preference to fortified products (if both fortified and non-fortified foods are available locally). Even if officially only fortified products are available at retail stores, consumers may be able to acquire non-fortified (probably cheaper) foods via non-official means, such as smuggling and from door-to-door sellers.

8.3.1 Aims and objectives

In short, the aim of household monitoring is to assess whether or not a programme is providing appropriately fortified products in sufficient amounts and at affordable prices to the targeted population. More specifically, household monitoring can answer questions such as:

- Are the fortified products accessible (i.e. available and affordable) to the targeted households and individuals? Are they of expected quality and are they available from retail stores in targeted regions/communities?
- Are the fortified products being purchased by the targeted households, taking into account tastes and preferences, and patterns of consumption? If not, why are the fortified products not being purchased? Is it because they are unaffordable (cost), because their taste and appearance is altered by the fortification process, or is it because they are not part of the usual consumption pattern of the targeted population?

- Are the fortified products being purchased and consumed in sufficient amounts by specific household members to meet programme nutritional goals (i.e. to increase their micronutrient intake and/or to meet a predefined level of micronutrient requirements)? If not, is it because of cultural practices concerning the appropriateness of feeding these products to specific household members (based on age, physiological status, etc.), or is it because of tastes and preferences of specific household members, or because of inequitable food distribution within the household?
- Which individuals/population groups are not being reached by the fortification programme and why?
- Are individual family members consuming sufficient amounts of fortified products to increase their intake of specific micronutrients (and/or to meet programme nutritional goals for specific age/physiological groups)?

In effect, monitoring at the household level addresses three key aspects of programme performance, that is to say, provision, utilization and coverage (see section 8.1). Household monitoring activities designed to assess each of these aspects of food fortification programme performance are outlined in **Table 8.4**; in each case, suitable indicators and data collection methodologies are proposed.

8.3.2 Methodological considerations

As **Table 8.4** indicates, there are a variety of approaches that can be used to gather data for the purposes of assessing programme performance in terms of provision, utilization and coverage. Primary data collection as part of the programme's overall monitoring and evaluation system is one option. Alternatively, and this is often a more practical solution, it may be possible to join with – or "piggy-back" on to – other programmes that have ongoing or regular data collection components. For example, some countries in Central America carry out school censuses at regular intervals; it is then a relatively simple matter to collect samples of fortified products, such as vitamin A-fortified sugar or iodized salt, by asking pupils to bring a small sample from home to school. Other routine data collection systems which might provide opportunities for "piggy-backing" include 30-cluster surveys, sentinel sites monitoring, and lot quality assurance sampling (LQAS) monitoring systems (*6,348–350*). These types of simple monitoring systems are widely used to monitor immunization coverage, universal salt iodization and other primary health care interventions. If such systems are not already in place, they can be established specifically for the fortification programme. Guidance on how to implement relatively simple data collection systems, and examples of their successful application in health care settings, is available elsewhere (*6,351–353*).

TABLE 8.4

Suggested household monitoring activities for a food fortification programme

Aspect of programme performance	Indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
Provision	Volume of product sold at an affordable price in retail stores in target regions (specific criteria to be determined)	At least annually.	*Method:* Either through new data collection or by adding appropriate questions (i.e. "piggy-backing") onto existing data collection vehicles, such as: — cross-sectional community surveys; — cross-sectional household surveys; — school surveys or censuses; — 30-cluster surveys; — sentinel site monitoring; — lot quality assurance sampling (LQAS); — market surveys. *Responsible:* Programme monitoring and evaluation unit (if applicable), individuals responsible for the existing data collection programme that is being added to, or researchers.
Utilization	Number or proportion of households purchasing fortified product regularly Number or proportion of targeted households in which fortified product is present Number or proportion of household members consuming fortified product regularly	At least annually.	*Method:* As for Provision, excluding market surveys which do not apply here. *Responsible*: As for Provision.

TABLE 8.4

Suggested household monitoring activities for a food fortification programme (*Continued*)

Aspect of programme performance	Indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
Coverage	Proportion of households or household members consuming product with expected frequency and in adequate amounts to meet programme nutritional goals (acceptable level to be determined) Observed changes in nutritional status since implementation of fortification programme through intake of fortified products and regular diet (acceptable changes to be determined)	Once a year until acceptable coverage levels are achieved; thereafter every 3–5 years.	*Method:* Household surveys, either specific to the programme or as an add-on to existing or planned surveys, depending on availability of resources locally. In to derive an appropriate denominator for coverage estimates, a representative order sample of the target population is, however, required. *Responsible:* Programme monitoring and evaluation unit (if applicable) or researchers.

Market surveys are one way of collecting data on the price and availability of fortified products in retail stores; such data are useful for monitoring service provision. Many countries already operate routine systems for collecting price data for a number of food commodities, in which case fortified foods can simply be added to the list of products being monitored. The monitoring of programme utilization and coverage, however, necessitates data collection at the household or individual level. Any of the simple data collection systems mentioned above can be used to collect information relating to utilization. Conducting representative household and community surveys is another option, but these tend to be more costly. Again, it is possible to take advantage of, or piggy-back on, existing data collection vehicles or surveys that are being conducted at the household level. In addition, qualitative approaches, which include observations, informant interviews and focus group discussions, may be useful for gathering information about programme implementation and service delivery, use of the fortified products and users' perceptions about the fortified versus the non-fortified foods.

Coverage of a fortification programme is usually assessed by determining what proportion of at-risk individuals consume the fortified products in sufficient amounts and with sufficient frequency. Thus, to evaluate coverage, information on the number of at-risk individuals is necessary. This can be obtained from either a census or by surveying a representative sample of the population. Estimates of the intake of the fortified product(s) and/or of the micronutrient(s) of interest are also required.

Two approaches are available for evaluating programme coverage. The first involves assessing the total dietary intake of the micronutrient of interest, with and without considering the consumption of the fortified food. This allows the percentage of the population, analysing each of the target groups independently (e.g. preschool-aged children, adolescents, women), that moves from having intakes that are below the relevant EAR to having intakes that are above the EAR to be estimated. The proportion of the population that moves from below to above the EAR provides a measure of the success of the programme**.** The second approach is to estimate the additional intake that would be supplied through consumption of the fortified food. In this case, the measure of the programme's success is given by the proportion of the population fulfilling that additional intake. Success criteria will inevitably vary according to the specific objectives of the programme and should be set accordingly. However, it can be helpful to set stricter criteria for measuring coverage of targeted fortification programmes, in terms of the proportion of the population that will benefit, to ensure that those most in need of fortified foods actually receive them.

8.4 Impact evaluation

The main purpose of evaluating any intervention is to determine whether or not it is reaching its overall goals. In the case of food fortification programmes, the primary objective is to improve the nutritional status of the target population. Impact evaluations of most health and nutrition programmes, including food fortification interventions, are however rarely performed, in part because they are perceived as being complex, costly and sometimes threatening. The results of impact evaluations are nevertheless important decision-making tools, providing answers to important questions such as:

- Has the intake of a specific fortified food increased to expected levels following a food fortification programme?
- Has the intake of specific nutrients of interest increased to expected levels following a food fortification programme?
- Has the nutritional status of specific groups (for selected nutrients) improved, as a result of the fortification programme?
- Has the fortification programme reduced the prevalence of specific micronutrient deficiencies?
- Has the fortification programme reduced the prevalence of poor functional outcomes, such as growth faltering, morbidity from infectious diseases, child mortality, and poor cognitive and motor development?
- Has the fortification programme been more effective in improving status of certain micronutrients and/or among certain age/physiological groups than others?

The following subsections review a range of methodologies that can be used for food fortification programme evaluation, highlighting in each case the purposes and settings for which they are most appropriate. Although not all fortification programme evaluations will necessarily require the more sophisticated and therefore the more costly methodologies, impartiality is always vital. In order to ensure that impact evaluations are impartial, it is recommended that they are carried out under the auspices of independent research groups or international agencies. Ideally, funds for monitoring and evaluation, should be allocated at the time of programme design and budget allocation, but this is not to say that funds cannot be complemented by donor agencies at a later date.

8.4.1 Impact evaluation design

There are a number of different ways in which the evaluation of the impact of a food fortification programme can be tackled. However, the choice of

methodology should be dictated by the specific purpose of the evaluation, and by the availability of resources. The level of precision required to satisfy the needs of decision-makers regarding the effectiveness of their programme is another important factor to bear in mind when selecting an evaluation design.

Habicht et al. (*344*) have devised a useful way of classifying the various approaches to evaluating public health interventions. The classification is based on the premise that the choice of the evaluation method depends on the precision of data required by decision-makers to be able to say that the programme being evaluated has been effective. Three levels of inference are identified: *adequacy*, *plausibility* and *probability*. Application of this classification to fortification programme evaluation is presented in **Table 8.5**.

8.4.1.1 Adequacy evaluation

An *adequacy* evaluation is the appropriate choice if the objective is to assess whether the prevalence of a particular micronutrient deficiency is at or below a pre-determined level. For example, the goal of a fortification programme may be to reduce the prevalence of iron deficiency among children to 10% or less (or any other cut-off point used to define a public health problem). In this case, adequacy would be achieved if the evaluation showed that the prevalence of iron deficiency at the time of the evaluation was lower than the 10% pre-established cut-off point. Similarly, if a programme sought to raise the level of intake of fortified wheat flour by a target population group to a certain pre-determined level, an adequacy evaluation would simply have to demonstrate that this level (or a higher level) of intake has been reached by the targeted population.

Adequacy evaluations are the simplest (and least costly) type of evaluation to carry out, primarily because they do not require randomization or the use of a control group (**Table 8.5**). Nevertheless, adequacy evaluations demand the same level of scientific rigour as any other type of evaluation. Appropriate study designs for this type of evaluation include one-time cross-sectional surveys that focus on the outcome of interest.

8.4.1.2 Plausibility evaluation

A *plausibility* evaluation seeks to demonstrate, with a given level of certainty, that the reduction in say, the prevalence of iron deficiency, is related to the fortification programme being evaluated. Many factors unrelated to food fortification can reduce the prevalence of iron deficiency, and thus the reduction can be wrongly attributed to the fortification programme unless the evaluation takes these factors into consideration. For example, if public health measures to control parasites and infections have been implemented, or if development programmes to raise incomes have resulted in an increased intake of animal products in the targeted population, a failure to control for these external effects could

TABLE 8.5

Evaluating the impact of fortification programmes on nutritional status: a range of approaches

Evaluation type	Aim of the evaluation	Evaluation design requirements
Adequacy	To assess whether the prevalence of specific micronutrient deficiencies (or the intake of specific micronutrients) is acceptable or such that there is a public health problem.	Adequacy evaluations require a cross-sectional survey of nutrient intakes, or of clinical, functional or biochemical indicators of deficiency, at a certain point in time. Prevalence data must be evaluated against established criteria of adequacy, or of a public health problem. Assessment should focus on deficiencies in those micronutrients that are of primary interest, and which can be supplied in fortified foods.
Plausibility	To be able to state that it is plausible that food fortification was the cause of changes in nutritional status.	Plausibility evaluations require a quasi-experimental design such as: — a cross-sectional study which compares households (or individuals) that consumed fortified foods with a comparable group that did not; — a longitudinal study in which measures are recorded in the same individuals before and after a period of fortification; — a longitudinal study in which measures are recorded before and after a period of fortification in a group that received fortified foods, and also in a control group that did not; this allows changes due to other factors (e.g. food prices, national economy) to be accounted for; — a case–control study which compares cases who consumed fortified foods with controls who did not but who are similar in many relevant characteristics, such as socioeconomic status, place of residence (i.e. geographic location, urban vs. rural, household composition), gender, age (i.e. matched controls).
Probability	To determine, with a level of probability that was established before the evaluation, that observed changes in nutritional status are due to fortification.	Probability evaluations require a double-blind, randomized, experimental design that compares responses to fortified foods with non-fortified foods. This requires: — randomization of participants in the “fortified” and “non-fortified” groups; — before-and-after measurements in the same subjects; — that neither the participants nor the evaluators know which treatments are being consumed by whom, during the intervention or during the data analysis (i.e. a double-blind study).

wrongly attribute the reduction in iron deficiency to food fortification. It is therefore important for plausibility evaluations to control for these potential confounding factors and biases through the careful selection of an appropriate study design and through the use of multivariate data analysis techniques. Plausibility evaluations use quasi-experimental or case–control designs (**Table 8.5**): they require either the comparison between an intervention and a control group (who did not receive the intervention), or before-and-after information on a group who received the intervention (a pre–post design), or both (i.e. before-and-after information on both an intervention and a control group).

8.4.1.3 Probability evaluation

Probability evaluations provide the highest level of confidence that the food fortification programme is responsible for the observed reduction in the prevalence of deficiency. Only probability methods can establish causality; these necessitate the use of randomized, controlled experiments, carried out in a double-blind manner whenever possible (**Table 8.5**). The probability evaluation is based on the premise that there is only a small known probability (usually $P < 0.05$, i.e. a less than 5% chance) that the observed differences in iron deficiency (for example) between the group that was randomly assigned to receive fortified foods and the non-fortified food control group are due to chance.

Probability evaluations are complex and expensive to perform because they need a randomized sample and a control group. They may not be feasible in usual field conditions, either for practical reasons or for ethical reasons. For example, if the fortified product is different in appearance and/or taste, it will be impossible to carry out the intervention in a double-blind manner. Similarly, it may not be practical to randomize the population into a food-fortified and a control group. Moreover, using a control group often raises ethical concerns. For these reasons, probability methods are more commonly used for small, pilot efficacy trials (i.e. interventions carried out under controlled conditions to determine efficacy), than for effectiveness trials (large-scale interventions carried out under real-life field conditions, and facing usual implementation constraints). Probability evaluations are the reference standard of efficacy research.

Note that the questions listed above (page 14) assume either a plausibility or a probability evaluation design, rather than an adequacy design. This is because the formulation of these questions implies a change or an improvement that is attributable to the fortification programme. Adequacy evaluation designs can address similar questions, but they would have to be phrased with reference to pre-established criteria of adequacy, rather than with respect to a change attributable to the programme. For example, the first question:

> Has the intake of a specific fortified food increased to expected levels following a food fortification programme?

would become:

> Is the intake of a specific fortified food at the expected level (say, is 90% of the population consuming salt fortified at the mimimum household level)?

Adequacy criteria could also be expressed in terms of biochemical indicators; for instance:

> Is the prevalence of vitamin A deficiency among preschool-aged children lower than say 20% (or any other pre-established criteria) following the food fortification programme?

8.4.2 Methodological considerations

8.4.2.1 Selection of outcome indicators

Outcome indicators that can be used to assess the impact of fortification programmes include measures of intake (which can also be used as indicators of utilization – see section 8.3; Table 8.4); clinical and biochemical indicators of nutritional status (see **Tables 3.1, 3.4, 3.6, 4.1, 4.3–4.5, 4.7, 4.8, 4.10, 4.11, 4.13–4.16**); and functional indicators such as growth, morbidity, mortality or development. Examples of each type of outcome indicator are given in **Table 8.6**, along with suitable methods for their measurement.

Given that the goal of food fortification is to improve the nutritional status of a population, biochemical markers would normally be the indicators of choice for evaluating the impact of fortification programmes. However, the measurement of biochemical status indicators requires considerable resources and technical expertise, for example, for collecting blood samples in the field and for conducting high-quality laboratory analyses, which means that this is not always a practical, or indeed a feasible, option. Fortunately, there are cheaper and less complex alternatives to measuring biochemical status indicators for assessing the impact of a programme, such as measuring the consumption of a fortified product or the intake of a particular micronutrient of interest. These measures are suitable alternatives to biochemical indicators in cases where strong evidence of their validity has been obtained from either rigorous efficacy trials[1] or from effectiveness trials conducted in similar conditions as the programme being evaluated. For example, if it has been established in efficacy trials that consumption of a certain minimum amount of a given fortified product results in a desirable change in one or more biochemical indicators (and prevents micronutrient deficiency), other fortification programmes using the same food vehicle can rely on

[1] An efficacy trial is one that applies an intervention under controlled conditions to determine the magnitude of effect that can be achieved under the best possible circumstances (*344*). Effectiveness trials, on the other hand, test the impact of an intervention under real life conditions, and given usual operational inefficiencies that occur under normal field conditions.

TABLE 8.6

Impact evaluation of a food fortification programme: suggested outcome measures

Outcome measure	Methodology and responsible entity
Intake indicators methods: Adequate or increased intake of fortified food(s)[a] Adequate or increased intake of specific micronutrient(s) of interest	*Method:* Any of the following dietary assessment — weighed intake; — 24-hour recall; — food frequency questionnaire; — assessment of usual intake. *Responsible:* Independent researchers.
Nutritional status indicators Adequate or improved biochemical and clinical status indicators for micronutrient(s) of interest	*Method*: Recommended biochemical and clinical indicators for selected micronutrients are listed in Tables 3.1, 3.4, 3.6, 4.1, 4.3–4.5, 4.7, 4.8, 4.10, 4.11, 4.3–4.16. *Responsible:* Independent researchers.
Functional outcomes Adequate outcomes or improvements in functional outcomes such as growth, morbidity, mortality and motor and cognitive development	*Method:* Standard approaches to the measurement of these functional outcomes should be used, for example: — for growth, anthropometry; — for morbidity, 2-week recall or surveillance data; — for mortality, recall data; — for child cognitive and motor development, the appropriate battery of tests and scales. *Responsible:* Independent researchers.

[a] Monitoring of the intake of fortified products can also be done as part of household monitoring (see Table 8.4).

[b] An impact evaluation should only be performed once programme monitoring has indicated that programme is operating in a satisfactory manner and therefore, is in theory capable of achieving its nutritional goals. Full impact evaluation need only be done once, as long as regular monitoring ensures appropriate fortification levels at all stages (i.e. in factories, retail stores and households), adequate utilization of the product and adequate coverage of the targeted population.

consumption data to measure their impact. This technique is commonly employed in evaluations of salt iodization and immunization programmes. In the case of the former, coverage information is used to measure success, an approach that is valid because there is strong evidence that iodized salt, consumed regularly and in sufficient amounts, is effective in preventing iodine deficiency. The selection of outcome indicators is discussed further in section 8.5 in the context of the minimum requirements for monitoring and evaluation systems for fortification interventions.

8.4.2.2 Data requirements

In order to be able to conduct an impact evaluation using any of the indicators and methodologies listed in **Table 8.6**, it is necessary to first calculate the

number of subjects that will need to be surveyed (i.e. the sample size) so as to ensure a result of adequate precision and sensitivity (i.e. be able to detect differences of a particular size when they exist). Ideally, a random procedure should be used to select subjects for study.

Specific data needs for each category of impact evaluation are as follows:

- *Adequacy evaluations* require data on the chosen outcomes, and also a minimum amount of information about the study subjects (such as age, sex and physiological status) to facilitate interpretation of the results.
- *Plausibility evaluations* demand more detailed information about the study subjects in order to account for confounding factors. However, the more information that is collected on possibly confounding or other explanatory factors, the more rigorous the evaluation design will need to be if it is to demonstrate that the outcome achieved is related to the intervention. It is therefore prudent to collect information on factors unrelated to the fortification programme, but which may have contributed to the changes observed in the outcome of interest. Data from other programmes implemented in the area, on say community improvements, and on household and individual sociodemographic characteristics can all help strengthen the analysis and interpret the findings. This type of information can also be used to understand pathways and mechanisms, and to help interpret lack of impact.
- For *probability evaluations*, if a double-blind experimental study design is used, control for confounding influences is not required. However, it is always useful to have information on intermediary outcomes to help describe mechanisms and dose–response relationships, and to identify subgroups of the population that may have benefited more (or less) than others from the intervention.

8.4.2.3 Timing of an impact evaluation

As noted at the start of this chapter, an evaluation of the impact of a fortification programme should not be undertaken until a certain level of operational performance has been achieved. Say, for example, commercial monitoring establishes that levels of a micronutrient in a product available from retail stores are only 20% of what they should be, conducting an impact evaluation of such a poorly functioning programme would only be a waste of time, effort and money. It is therefore important that fortification programmes establish a priori the minimum criteria for the quality of service delivery that it must achieve before any efforts to evaluate its impact are undertaken.

The timing of programme evaluation is will also depend on how quickly an impact on the biochemical indicators of interest can be expected. In other words, how soon after a programme has been implemented and has been found to be

operating satisfactorily should an impact evaluation be undertaken? Both the type of intervention (fortification versus supplementation, for example) and the nutrient(s) of interest are key factors to consider. In relation to the former, the amount of nutrient(s) delivered daily in fortified foods is usually much less than that which can be administered in a supplement; moreover, the fortified foods may not be consumed every day, or in the expected amounts. The combined effect of these factors is that it will take longer for the biological impact of a micronutrient fortification programme to become detectable than it will for a supplementation programme, probably by as much as several months (especially in the case of effectiveness trials). For instance, it takes about 6–9 months before the effect of iron fortification on iron status is seen.

The rate of change in nutritional status indicators varies substantially by nutrient, and also according to the sensitivity of the indicator. It takes about 1–2 years from the start of a salt iodization programme to see a significant reduction in goitre. Some individuals may take even longer than this to recover, especially if they are also iron deficient (*86*). On the other hand, urinary iodine is a fairly responsive indicator of iodine intake, and should increase significantly within a few weeks of the commencement of an increased iodine consumption. On the whole, changes in biochemical indicators of vitamin status tend to be more rapid than those in indicators of mineral status. For instance, population serum folate and plasma homocysteine concentrations respond within 6 months of the introduction into the diet of flour fortified with folic acid (*49,52*). Similarly, consumption of sugar fortified with vitamin A produces measurable impacts after only 6 months (*46*).

8.4.2.4 Counfounding factors

Finally, when planning an impact evaluation it is important to recognize that a number of factors can affect the ability of individuals to respond to fortification. Particularly significant in this regard is the prevalence of parasitic infestations and infections in a population. Some parasites cause large, continuing micronutrient losses; hookworm, for example, causes intestinal loss of blood and therefore increased losses of iron, vitamin A, vitamin B_{12} and several other nutrients. Parasite control programmes are obviously an effective strategy in these situations and should be instigated in conjunction with food fortification.

The presence of parasites and infections can also affect the sensitivity of indicators of nutritional status, which can make the impact of a fortification programme more difficult to detect. For example, haemoglobin and serum ferritin are responsive to changes in iron status but are also affected by inflammation and infectious disorders. If these conditions are widespread, iron status can only really be assessed using a combination of indicators, that is serum ferritin in combination with serum transferrin receptors or erythrocyte zinc

protoporphyrine, and an indicator of inflammation, such as C-reative protein (*75*) (see also **Table 3.1**). This approach has been adopted with good effect in both Viet Nam (*28*) and in Morocco (*44*) to demonstrate the efficacy of iron fortification of fish sauce and salt, respectively. The presence of malaria presents particular challenges: malaria not only leads to a substantial reduction in haemoglobin concentrations, but also affects many other nutritional status indicators, including serum ferritin, serum transferrin and transferrin receptors, plasma retinol and erythrocyte riboflavin (*152*). Simultaneous assessment of malaria parasites (by blood smears) or more accurately, of malaria antigens using test strips (*152*), and of indicators of inflammation (such as alpha-1 glycoprotein, and C-reactive protein), will assist in the detection of individuals whose test results may be affected by malaria.

8.5 What is the minimum every fortification programme should have in terms of a monitoring and evaluation system?

This chapter has highlighted the importance for food fortification programmes of having a well-planned monitoring and evaluation system. These systems should be designed in such a way that the information provided by monitoring and evaluation is used effectively for decision-making and for overall programme management. In order for this to happen, responsibilities for data collection at the different levels must be clearly established and the system must include feedback loops, which allow the information to flow (in a timely manner) to the entities responsible for taking action at the different levels.

Regulatory monitoring is an essential part of any monitoring and evaluation system and should always be implemented, at least to some degree. Information from internal, external and commercial monitoring activities should be shared regularly with all sectors engaged in the food fortification programme. Feedback activities should include the sharing of information about successes and any follow up on corrective measures required when problems were detected.

Of equal importance is household monitoring. Its value lies in its ability to provide a general appraisal of the impact of the programme, and in the absence of an effective system of nutritional surveillance, it also provides information about the importance of food fortification in the diet of target populations. The annual cost of household monitoring has been estimated at less than US$ 10 000 per fortified food (O. Dary, personal communication, 2004). Despite its relatively low cost, household monitoring is often neglected in many programmes. In many settings, household monitoring is dependent on external donors for financial support, a factor which limits its permanence and sustainability.

The chapter has also stressed the urgent need to measure the impact of food fortification programmes, again to support decision-making, and, in particular,

to assist programme planners and policy-makers in making decisions about programme continuation, modification, expansion or termination. Different types of impact evaluations can be employed; these vary in their level of sophistication and in the intensity of resources required. Decisions about which specific type of evaluation and which outcome indicators to use should be driven primarily by programme objectives and the level of precision required to be able to attribute impact to the programme itself (i.e. this will determine whether an adequacy or a more complex plausibility design is needed, for example).

The choice of outcome indicator(s) for impact evaluations is a pivotal one. Questions that can help guide the selection of an appropriate of outcome indicator are:

- Can intake measures be used instead of more invasive (and often more costly) biochemical indicators?
- How often do impact evaluations have to be carried out?

The answer to these questions largely depends on the availability and strength of evidence from efficacy trials and previous effectiveness evaluations of comparable programmes conducted in similar environments and population groups. The results of only one or just a few efficacy trials are usually sufficient to prove that a fortified food can change the nutritional status (and its associated biological indicators) in a human population, in which case it might not be necessary to repeat such experiments in each community (see also section 8.4.2.1). It thus follows that the first step in planning an impact evaluation is usually to determine whether or not there is strong evidence from existing efficacy trials that the planned intervention causes a given impact when conducted under controlled conditions.

If strong evidence from efficacy trials can be established, effectiveness trials can then be implemented to test whether the same impact can also be achieved when the intervention is delivered under normal field conditions and programme constraints. In the case of fortification programmes, if other effectiveness trials indicate that an impact can be obtained over a given period of time with an intake of a specific amount of micronutrients through the consumption of fortified products, there is no need to invest in the more resource intensive and complex demonstrations of impact on biochemical indicators. It may be sufficient to ensure that the targeted population consumes the fortified food of expected quality in sufficient amounts and with adequate frequency. However, before conclusions obtained from one community can be extrapolated to another, it is important to assure that the conditions are similar. It may be necessary to conduct efficacy trials to corroborate findings once every 5–10 years, especially if environmental, dietary and health conditions of the targeted population change rapidly. This objective might be combined with the function of

general nutrition surveys to monitor the evolution of the nutritional status of the population.

Obviously, in the absence of strong evidence from efficacy trials, there are no short-cuts and a detailed impact evaluation (efficacy trial or probability evaluation), involving appropriate biochemical indicators, will need to be carried out. The comments made previously about the timing of evaluations (section 8.4.2.3) and the need to consider potential confounding factors (section 8.4.2.4) become especially pertinent in these circumstances.

Summary

- A well-designed, well-managed monitoring and evaluation system is essential for ensuring the success and sustainability of any food fortification programme. As integral components of the programme, monitoring and evaluations activities should be formulated and budgeted for during the very early planning stages.
- Some degree of regulatory monitoring is critical. Of the three main categories of regulatory monitoring – internal monitoring (conducted at factories and packers), external monitoring (conducted at factories and packers) and commercial monitoring (conducted at retail stores) – internal monitoring is a must. In settings where effective enforcement mechanisms exist, it is usually sufficient to confirm compliance with regulations in samples taken from retail stores (commercial monitoring). Elsewhere it is prudent to conduct external monitoring at both the factory level and at retail stores.
- Impact evaluations should only be carried once it has been established, through regulatory and household monitoring, that the programme has achieved a predetermined level of operational efficiency.
- Although rigorous impact evaluations of food fortification programmes are urgently needed, not all programmes will require the most costly and sophisticated designs. Judicious choices will have to be made in selecting the most appropriate evaluation for each particular situation.

CHAPTER 9

Estimating the cost-effectiveness and cost–benefit of fortification

Notwithstanding the limitations mentioned in section 1.4, food fortification may often be the least expensive way of achieving a particular nutritional goal, such as a specified reduction in the prevalence of anaemia, iodine deficiency or subclinical vitamin A deficiency. Put another way, fortification is frequently more *cost-effective* than other public health interventions that have the potential to achieve the same health or nutritional outcome, such as supplementation. Indeed, several studies have demonstrated that fortification is not only cost-effective (i.e. is a cheaper way to increase micronutrient intake compared with other interventions that have the same aim), but also has a high *cost–benefit* ratio (i.e. is a good investment).

In this chapter the concepts of cost-effectiveness and cost–benefit are formally defined. Techniques for estimating the cost-effectiveness of an intervention and for performing a cost–benefit analysis are also outlined, and illustrated in the latter half of the chapter by a series of example calculations for a hypothetical low-income country. The methods employed can be readily modified and applied to other countries. Although both cost-effectiveness and cost–benefit analyses are widely used as decision-making tools by policy-makers working in the public health arena, their application to food fortification is a relatively new development. To date, only interventions involving iron, iodine and vitamin A have been evaluated in these terms, and consequently form the focus of the material presented here.

9.1 Basic concepts and definitions

9.1.1 Cost-effectiveness

Cost-effectiveness is defined as the cost of achieving a specified outcome. In the case of food fortification, examples of the desired outcome might include: averting one case of subclinical vitamin A deficiency, averting one case of anaemia, or averting one case of goitre or of iodine deficiency.

Two outcome measures that are frequently employed in cost-effectiveness assessments of health interventions are the "cost per death averted" and the "cost per disability-adjusted life-year saved" (or cost per DALY saved). The former, the cost per death averted, has been successfully used to assess the cost-

effectiveness of various fortification and supplementation interventions, but in this context its application requires making various critical assumptions (see section 9.2.1). For example, costs per death averted have been estimated for vitamin A supplementation for children and for iron supplementation for pregnant women (groups that are particularly susceptible to deficiencies and therefore frequently targeted in intervention programmes). However, it is a less useful calculation in the case of iodine fortification, principally because mortality outcomes are relatively rare, the main benefit being increased productivity (see section 9.3.2).

The advantage of the other widely used effectiveness measure, the cost per DALY saved, lies in the fact that it combines mortality and morbidity outcomes into a single indicator (*354,355*). This measure has been employed to good effect to assess the effectiveness of various health interventions, including fortification and supplementation, as part of WHO's CHOICE project (see **Box 9.1**). However, relative to the alternative measure, the cost per death averted, its calculation is more demanding in terms of data requirements and the assumptions that must be made (see section 9.2.1)

Cost-effectiveness analysis is a particularly useful exercise for comparing different interventions that share the same outcome, for example, for comparing supplementation with vitamin A with fortification with vitamin A, or for comparing vitamin A supplementation with immunization. In both cases the shared outcome is the number of deaths averted. The two pieces of information required for the calculation of the cost-effectiveness of an intervention are: the unit cost of the intervention (i.e. the cost per person assisted per year), and some measure of the effect of the intervention (i.e. the proportion of the target population that achieves some specified outcome). The cost estimates, being less resource intensive, tend to be easier to obtain than the estimates of the effect, which require (at a minimum) a baseline and a follow-up assessment, and (ideally) a control group.

BOX 9.1

Choosing interventions that are cost-effective: WHO's CHOICE Project

CHOICE stands for "CHOosing Interventions that are Cost-Effective", and is a tool developed by WHO to help decision-makers select those interventions and programmes that provide the maximize benefits for the available resources. By generalizing the cost-effectiveness analysis, the application of the CHOICE model indicates which interventions provide the best value for money.

Application of the CHOICE model to data from WHO's Africa D region (mainly West Africa) has demonstrated that micronutrient interventions are

potentially highly cost-effective[1]. In Figure 9.1 the average cost per DALY saved by hypothetical programmes for zinc supplementation in the under-fives (coverage, 80% of the target population), iron supplementation in pregnant women (coverage, 50% of pregnant women), vitamin A/zinc fortification (coverage, 80% of the general population), and iron fortification (coverage, 80% of the general population) are compared. Both the fortification programmes achieve relatively low costs per DALY saved. The same iron and vitamin A/zinc fortification programmes are compared in Figure 9.2, but this time with the following interventions: oral rehydration (coverage, 80% of the target population), case management of pneumonia (coverage, 80% of the target population), and disinfection of water supply at point of use combined with water use education (coverage, 100% target population). Whereas all of these programmes were found to be highly cost-effective, the fortification programmes were particularly so.

FIGURE 9.1

Cost-effectiveness of micronutrient supplementation and fortification

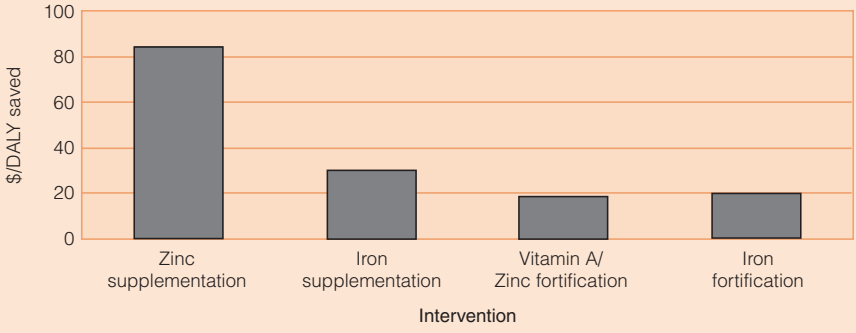
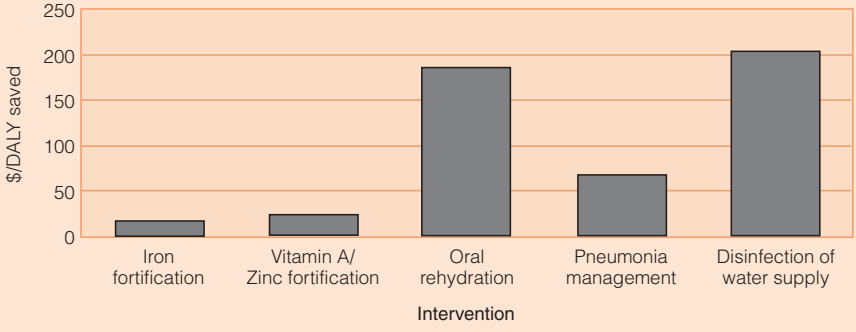


FIGURE 9.2

Cost-effectiveness of selected interventions affecting children



[1] Further information about the CHOICE project, including a description of the methodology employed, can be found on the WHO web site at: http://www.who.int/choice/en/.

9.1.2 Cost–benefit analysis

Cost-effectiveness analyses are valuable tools for comparing interventions that share the same outcome; if however, the objective is to compare interventions with different outcomes, or to compare interventions whose potential benefits or outcomes extend beyond health, then a cost–benefit analysis is needed. In its simplest form, a cost–benefit analysis compares the monetary cost of an intervention with the monetary value of the outcome (i.e. the benefit). The outcomes or benefits may be increased productivity (e.g. iron fortification makes adults less anaemic and hence more productive) or possibly lower health care system costs (e.g. mothers who are less anaemic will incur fewer complications during childbirth). Since cost–benefit analyses can be used to compare the relative merits of health interventions with other kinds of government spending, they are especially helpful for advocating for increased resources for nutrition and health.

A cost–benefit ratio calculation requires much the same unit cost and effect data as a cost-effectiveness analysis. Again, the cost data are typically easier and cheaper to obtain than the effect data. In addition, the benefit or rather the outcome of a health intervention (e.g. a reduction in prevalence of goitre or a change in the mean urinary iodine excretion of a population) has to be expressed in financial terms, that is to say, assigned a monetary value. Most cost–benefit studies do not do this directly, but rely on the findings of other studies that have linked the proximate health outcome to a financial benefit. For example, cost–benefit analyses involving iodine interventions, which are seeking to estimate the financial gain of eliminating one case of goitre (as an intermediate outcome), turn to studies that have estimated the costs associated with the loss of productivity per child born to a mother with goitre. The worked example presented in section 9.3.2 adopts this approach.

9.2 Information needs

9.2.1 Estimating unit costs

Unit cost calculations (i.e. the calculation of the cost of the intervention per person per year) need to take into account not just the recurrent costs of supplying fortificants or supplements, but also a number of other associated costs. For fortification, these typically include:

— the initial investment in the technology required for adding the fortificant to the food vehicle (which will vary depending on the number of processing facilities and the existing level of technology, the micronutrient and the nature of the packaging, storage and/or handling of the final product that is required);

— the cost of "social marketing" to attain public acceptance of (or preference for) the fortified food;

— the cost of quality control and quality assurance by producers and of government monitoring and evaluation activities.

In the case of supplementation, the additional costs may include the time and logistics costs of the distribution of the supplement (which are not always reported), and again, the costs associated with monitoring and evaluation. Typical costs incurred by a wheat flour fortification programme (with iron and zinc) are set out in **Table 9.1**; these include the initial investment costs (amortized over expected lifetime of the equipment), recurrent costs, and the cost of monitoring and evaluation.

The estimated unit costs of various past supplementation and fortification programmes, compiled by Levin et al. (*357*), are listed in **Table 9.2**. According to these data, unit costs for supplementation are consistently higher than those for fortification. Supplementation costs are 10–30 times higher than fortification costs in the case of iodine, 3–30 times higher for iron, and 1.5–3 times higher for vitamin A. The cost differential is largely dependent on what proportion the target population is of the whole population; fortification becomes increasingly cost-effective the higher the proportion of the population in need of the intervention.

Although now rather out of date, the unit cost data reported by Levin et al. (*357*) do provide some useful insight into the relative cost-effectiveness of supplementation and fortification as strategies for correcting micronutrient deficiencies. For instance, in the case of vitamin A, if supplementation costs 2–2.5 times as much as fortification per person, supplementation is potentially the more attractive option when the target group comprises less than 40–50% of the population (e.g. children aged less than 2 years). However, for iron the situation is reversed: per person iron supplementation is at least 10 times more costly than fortification but the prevalence of anaemia is well over 10% in most developing country populations. In this case then, mass fortification would most likely be the more cost-effective strategy. It should be stressed that these conclusions are based on average data and cannot be applied to all settings; the relative cost-effectiveness of supplementation and fortification will vary markedly across countries according to both the unit cost of the intervention and the fraction of population targeted.

Another factor to consider in the supplementation versus fortification debate is the effectiveness of the intervention itself; this can be highly variable. In the case of vitamin A deficiencies, both supplementation and fortification have been shown to be effective in impact evaluations (*33,46*). In areas of endemic iodine deficiency, salt iodization programmes have also been shown to be highly effective (*25,359*). However, the evidence for the effectiveness of iron interventions is less clear cut (see section 1.3.1.1). Recently completed studies from China and Viet Nam, involving soy and fish sauces, respectively, suggest that

TABLE 9.1

Hypothetical annual costs of wheat flour fortification with iron and zinc (assumes an annual flour production of 100 000 tonnes at 1 mill using a continuous fortification system)

	Cost of iron fortification (US$)	Additional cost of including zinc (US$)	Total costs (US$)
Industry costs			
Capital investment	820	0	820
Recurrent costs			
Equipment (maintenance, depreciation)	600	0	600
Ferrous sulfate fortificant[a]	57 090	NA	57 090
Zinc sulfate fortificant[b]	NA	102 600	102 600
Quality control	7 920	2 880[c]	10 800
Total industry costs	66 430	105 480	171 910
Industry costs per tonne fortified wheat flour	0.66	1.05	1.72
State costs			
Capital investment and maintenance	2 625	0	2 625
Mill inspection and monitoring			
Salaries and transportation	3 500	0	3 500
Laboratory analysis and reports (including technician salaries)	1 500	96[d]	1 596
Quality assurance and monitoring training	1 000	500[e]	1 500
Programme monitoring (i.e. dietary intake, travel, per diems, analysis, reports)	1 400	0	1 400
Evaluation			
Travel, per diems, collection of biological samples	3 000	0	3 000
Laboratory analysis and reports (including technician salaries)	5 000	3 600[f]	8 600
Total state costs	18 025	4 196	22 221
Total programme costs	84 455	109 676	194 131
Total cost per tonne fortified wheat flour	0.84	1.10	1.94
Total cost per capita (assuming an intake of 150 g per person per day)	0.05	0.06	0.11

[a] Cost of the ferrous sulfate (US$ 8.65/kg (pure iron)), plus an additional 33% to allow for shipping costs, added to 100 000 tonnes wheat flour at 66 ppm.

[b] Cost of the zinc sulfate (US$ 34.20/kg (pure zinc)), plus an additional 33% to allow for shipping costs, added to 100 000 tonnes wheat flour at 30 ppm.

[c] Assuming 2 samples are analysed per day, for 360 days per year at a cost of US$ 4 per sample.

[d] Assuming 1 sample per month is collected from the marketplace and analysed in duplicate, for 12 months of the year at a cost of US$ 4 per sample.

[e] An additional 50% of the cost of quality assurance and monitoring training was included to cover the zinc assessment.

[f] Programme evaluation based on serum zinc analysis in a sample of 1 500 preschool-aged children: assuming a cost of US$ 4 per sample, and a total of three assessments conducted in a 5 year period (i.e. baseline, after 12–15 months, and 5 years post-programme initiation), the cost is US$ 18 000 over the 5-year period or US$ 3 600 per annum.

Source: adapted from reference (*356*).

TABLE 9.2

Estimated unit costs of selected micronutrient interventions

Intervention	Country, year of programme	Cost per person (US$)	Cost per person (1987 US$)	Cost per person per year of protection (1987 US$)[a]
Iodine				
Oil injection	Zaire, 1977	0.35	0.67	0.14
Oil injection	Peru, 1978	1.30	2.30	0.46
Oil injection	Bangladesh, 1983	0.70	0.76	0.25
Oil injection	Indonesia, 1986	1.00	1.05	0.21
Salt fortification	India, 1987	0.02–0.04	0.02–0.04	0.02–0.04
Water fortification	Italy, 1986	0.04	0.04	0.04
Vitamin A				
Sugar fortification	Guatemala, 1976	0.07	0.14	0.14
Capsule	Indonesia/ Philippines, 1975	0.10	0.21	0.42
Capsule	Haiti, 1978	0.13–0.19	0.23–0.34	0.46–0.68
Capsule	Bangladesh, 1983	0.05	0.05	0.10
Iron				
Salt fortification	India, 1980	0.07	0.10	0.10
Sugar fortification	Guatemala, 1980	0.07	0.10	0.10
Sugar fortification	Indonesia, 1980	0.60	0.84	0.84
Tablets	Kenya/Mexico, 1980	1.89–3.17	2.65–4.44	2.65–4.44

[a] Different interventions supply vitamin and mineral requirements for different lengths of time. The cost per year has therefore been adjusted to take account of these differences in the duration of protection provided by the intervention.

Sources: references (*357,358*).

fortification with NaFeEDTA has been instrumental in reducing iron deficiency anaemia among women (*28*). On the other hand, despite the fact that iron supplementation has proved to be efficacious in controlled trials (*360*), many iron supplementation programmes have been relatively ineffective in improving anaemia status, even in targeted subgroups. One possible explanation for this is apparent discrepancy is that in many cases iron deficiency is not the main cause of the observed anaemia, but rather it is some other factor.

9.2.2 Cost-effectiveness analyses

Most cost-effectiveness analyses rely on a single indicator or outcome measure to reflect the change brought about by the intervention, usually a measure of nutritional status. However, in terms of the magnitude of the calculated cost-effectiveness, different outcome measures do not always yield the same result. Possible outcome indicators for iron, for example, include the change in mean haemoglobin level, the change in mean haemoglobin level of the initially

deficient population, and the proportion of the population removed from anaemia. The first measure gives equal weight to improvements in haemoglobin status irrespective of the initial level of deficiency, the second gives equal weight to all those initially deficient (again, irrespective whether the deficiency was severe or mild), and the third will give a higher weight to improvements in the mildly deficient, but will ignore improvements that don't "bump" people over the threshold, even if their haemoglobin status improves. (As explained in Chapter 3, anaemia is an imperfect indicator of iron status due to the fact that in many populations anaemia has multiple causes).

The most useful outcome or effect measures for cost-effectiveness analyses tend to be those which also provide information on the causes of the change in nutritional status. This is particularly helpful when making comparisons with other studies, which may have employed a different outcome measure. If restricted to using only a single outcome measure, then it is desirable to select the one that can be linked to other outcomes of interest. In the iron example above, the proportion of the population removed from anaemia is the most useful effect indicator, because it is possible to link anaemia status (i.e. anaemic/not anaemic) to productivity outcomes or to pregnancy complication outcomes.

The cost-effectiveness of fortification interventions is likely to vary considerably according to the prevailing conditions, since it is heavily dependent on the following factors:

- the food vehicle used, the storage conditions and the stability of the fortificant during storage;
- the initial level of deficiency in the population (e.g. improvements in iron status may be easier to obtain in initially more deficient populations, because their iron absorption is more efficient and because the cost per case of anaemia averted is lower if more of the population is anaemic);
- dietary patterns, especially with respect to the consumption of foods which inhibit or enhance absorption of the micronutrient of interest in the same meal;
- marketing and processing patterns, and whether the chosen vehicle is consumed by all households in the groups likely to be deficient, including the poor and those living in remote areas.

Despite the inherent variability in the cost-effectiveness of food fortification interventions, it is not necessary to perform analyses for all programmes and for all conditions. Nevertheless, information should be obtained for a selection of programmes operating under a range of conditions.

9.2.3 Cost–benefit analysis

Undertaking a cost–benefit analysis of a fortification programme is generally more involved and certainly more demanding of data (and assumptions) than is a cost-effectiveness analysis. However, only cost–benefit analyses permit comparisons across a broad range of benefits, including non-health outcomes. Issues to bear in mind when undertaking cost–benefit analysis include the following:

- What benefits should be included? Some benefits (e.g. lower health care costs because of improved iron status, and thus reduced numbers of maternal deaths) may be important, but hard to calculate in the developing country context. Omitting important benefits will make the results more conservative.
- Should non-market benefits be taken into account? The effects of food fortification, for example, improved productivity in women, will only partially show up as market benefits. Fortification may well result in important non-market benefits, such as better child-care, which will affect the market productivity of the next generation. Ideally then, non-market benefits should be valued, by using shadow prices or contingent valuation methods.
- How can future benefits be incorporated? Ideally, the present value of the future benefits stream should be included, appropriately discounted, say by 3% (the social rate of discount typically employed in cost–benefit-type analyses). Nevertheless, even this low rate of discount still favours interventions with immediate benefits (e.g. those targeted at adults) relative to those with future benefits (e.g. those targeted at children).
- Cost–benefit analysis (unless equity weights are used) tends to favour interventions that benefit the rich more than the poor (the rich have higher wages, and consequently higher productivity losses when they die or fall ill), and similarly those benefiting men rather than women (as men are the more economically productive, at least in terms of market benefits).
- Because of the assumptions required, it is sometimes desirable to present the results of a cost–benefit analysis in natural units (e.g. in terms of productivity (for iron-deficiency anaemia) or morbidity rates (for vitamin A deficiency) as well as in monetary values.

It is possible to undertake cost–benefit analyses prospectively (i.e. incidence studies), but this necessitates making assumptions about how a new fortification programme will affect the future time path of outcomes, discounting all costs and benefits to the present (*361*). The alternative is a prevalence study, in which costs of fortification are compared with the existing costs attributable to deficiency. The latter requires fewer assumptions, is simpler to undertake, and may be quite useful for advocacy purposes (see Chapter 10). In the series of worked

examples presented in these Guidelines, a prevalence method has been used to estimate the cost–benefit ratio of interventions to correct deficiencies of iodine and iron (see sections 9.3.2 and 9.3.3).

9.3 Estimating the cost-effectiveness and cost–benefit of vitamin A, iodine and iron interventions: worked examples

For the purposes of illustrating of application of cost-effectiveness and cost–benefit analysis methodologies to food fortification, example calculations are set out below for three micronutrients, namely, vitamin A, iodine and iron. Country-specific data required to perform these calculations is given in **Table 9.3** for a hypothetical large, low-income developing country P. These data would be needed to replicate the cost–benefit and cost-effectiveness calculations for another country. Use of generally accepted fortification costs (i.e. those set out in Table 9.3 and which are derived from historical programme data) is recommended, unless country-specific data are available.

The sample calculations require several key assumptions to be made concerning the economic consequences of deficiency (**Table 9.4**). Assumptions must also be made about the effectiveness of a given fortification programme. Although it is clear that effectiveness of fortification depends on the chosen food

TABLE 9.3

Country-specific data required for cost-effectiveness and cost–benefit calculations, country P

Annual per capita GDP	US$ 430
Child death rate	117.4 per 1000
Proportion of children ≤5 years in population	25.6%
Share of labour force in agriculture	25%
Prevalence of subclinical vitamin A deficiency, children ≤5 years	30%
Cost per person per year of vitamin A fortification	US$ 0.10
Prevalence of goitre, women of childbearing age	15%
Cost per person per year of iodine fortification	US$ 0.10
Prevalence of anaemia (population average)	37.25%
Cost per person per year of iron fortification	US$ 0.12
Infant mortality rate	80 per 1000
Maternal mortality rate	200 per 100000
Cost per pregnancy of iron supplementation	US$ 1.70

For the purposes of illustrating of application of cost-effectiveness and cost–benefit analysis methodologies to food fortification, example calculations are set out below for three micronutrients, namely, vitamin A, iodine and iron. Country-specific data required to perform these calculations is given in Table 9.3 for a hypothetical large, low-income developing country P. These data would be needed to replicate the cost–benefit and cost-effectiveness calculations for another country. Use of generally accepted fortification costs (i.e. those set out in Table 9.3 and which are derived from historical programme data) is recommended, unless country-specific data are available.

TABLE 9.4

Key assumptions in estimating cost-effectiveness and cost–benefit of selected micronutrient fortification

Miconutrient	Assumptions	Reference(s)
Vitamin A	The relative risk of mortality for children with subclinical vitamin A deficiency (compared with those that are non-deficient) is on average 1.75 : 1.	(*362*)
Iodine	Of all births to women with goitre, 3.4% are cretins (productivity loss 100%), 10.2% are severely mentally impaired (productivity loss 25%), and the rest suffer minor IQ loss (productivity loss 5%).	(*103,104,355,363*)
Iron	Productivity loss associated with anaemia is 5% (light manual work), 17% (heavy manual work) and 4% in all other kinds of work.	(*361*)
	The odds ratio associated with 10 g/l increase in haemoglobin is 0.80 for maternal mortality, and 0.72 for perinatal mortality in Africa (0.84 in other regions); prenatal supplementation with iron is associated with 11.7 g/l improvement in haemoglobin.	(*364*)

vehicle, the composition of the usual diet, and the pre-existing level of deficiency in the population, it is rarely possible to accurately account for such variations, due to a lack of field data. Under such circumstances, it is instructive to conduct a sensitivity analysis, according to the key assumptions made. This involves repeating the calculations several times, varying each of the key parameters in turn. If the cost-effectiveness ratio does not change dramatically, or the cost–benefit ratio remains robust (i.e. benefits remain large relative to costs), as the parameters are changed, then greater confidence can be placed in the conclusions.

9.3.1 Vitamin A supplementation: a cost-effectiveness calculation

Cost–benefit calculations cannot readily be undertaken for interventions involving vitamin A. Although there are subsequent productivity effects, the more immediate benefit of vitamin A supplementation in children is a reduction in child morbidity and mortality. For this reason, it is rather more helpful to estimate the cost-effectiveness of vitamin A fortification or supplementation (expressed as the cost per death averted or the cost per DALY saved), which can then be compared with other public health interventions that have the potential to achieve the same outcome.

The calculation of the cost-effectiveness of vitamin A fortification, using the cost per death averted as the outcome measure, hinges on the assumption that

all child deaths due to vitamin A deficiency (VAD) can be averted by vitamin A fortification. If this assumption is made, the calculation is simply a matter of estimating the proportion of all child deaths that are due to VAD, this being equivalent to the number of deaths that can be averted by fortification.

The population attributable risk due to vitamin A deficiency (PAR_{VAD})[1] is calculated from the prevalence of VAD in children and probability or risk of dying from VAD, according to the following formula:

$$PAR_{VAD} = [Pre_{VAD} \times (RR_{VAD} - 1)]/[1 + Pre_{VAD} \times (RR_{VAD} - 1)]$$

where:

Pre_{VAD} = the prevalence of vitamin A among children in the under-6 years age group; and

RR_{VAD} = the relative risk[2] of mortality for children with subclinical VAD.

Then, based on the values given in **Tables 9.3** and **9.4**, in country P,

$$PAR_{VAD} = (0.3 \times 0.75)/(1 + 0.3 \times 0.75) = 0.183.$$

In country P, the child death rate (i.e. in the under-fives) is 117.4 per 1000. Hence the number of child deaths per year that theoretically could be prevented by eliminating VAD in this population group is:

$$0.183 \times 117.4 = 21.48 \text{ per } 1000.$$

Suppose that the unit cost of vitamin A fortification per year is US$ 0.10. This represents the cost of providing 100% of the daily requirements of vitamin A for the population in wheat flour, or 75% of the daily requirements of preschool-aged children via margarine (O. Dary, personal communication, 2004). If, in country P, children under 5 years of age account for 25.6% of the population (Table 9.3), then the cost of fortification per child aged under 5 years is:

$$0.10/0.256 = 0.39, \text{ or US\$ } 0.39 \text{ per year.}$$

The cost per death averted is therefore:

[1] The population attributable risk (PAR) is defined as the proportion of cases in the total population that are attributable to the risk factor.

[2] The relative risk (RR) is defined as the ratio of the probability of disease development among exposed individuals to the probability of disease development in non-exposed individuals.

$$0.39/0.02148 = 18.16, \text{ or US\$ } 18.16 \text{ per year.}$$

This cost can then be compared with that of alternative interventions which save children's lives, such as immunization and treatment of infectious disease. The costs per death averted for the latter are typically significantly higher, which suggests that vitamin A fortification would be a very cost-effective intervention for reducing childhood mortality in country P.

9.3.2 Iodine: a cost–benefit analysis

In the cost–benefit calculation for iodine described here, goitre prevalence is used to indicate iodine deficiency and the main economic consequence of iodine deficiency is assumed to be productivity losses in those children born to mothers with goitre (see **Table 9.4**). Although in many respects urinary iodine excretion is a better indicator of iodine deficiency (it tracks improvements in iodine intake more rapidly (*6*), at present, such data are not widely available for many countries. Nor is the relationship between urinary iodine excretion and birth outcomes well documented, although it is anticipated that this will become clearer in the future.

Based on the assumptions given in **Table 9.4**, the average percentage productivity loss per birth to a mother with goitre is:

$$(100\% \times 0.034) + (25\% \times 0.102) + (5\% \times 0.864) = 10.27\%.$$

The per capita productivity loss in country P, where the prevalence of goitre in women is 15%, is given by the formula:

$$\text{Productivity loss per capita} = \text{Prevalence of goitre} \times \text{Average productivity loss} \times \text{Wage share in GDP} \times \text{Per capita GDP.}$$

Note that instead of multiplying an average productivity loss by an average wage expressed in units of currency, and applying a factor which equates to the proportion of the population that works in the market labour force, we use here a simplification, as follows:

We assume that the average wage in the population is given by:

$$\text{Average wage} = (\text{Per capita GDP} \times \text{Wage share in GDP})/\text{Employment proportion,}$$

where the employment proportion is the market labour force as a share of the total population.

If the wage share in GDP in country P is 40%, then application of the above formula gives a per capita productivity loss of:

$$0.15 \times 0.1027 \times 0.40 \times 430 = 2.65, \text{ or US\$ } 2.65.$$

If the unit cost of iodine fortification is US$ 0.10 per person per year (*359*), then the cost–benefit ratio of iodine fortification is 0.10 : 2.65 or 1 : 26.5. If the costs of fortification are as low as US$ 0.01, as has been suggested by Dary (personal communication, 2004) for parts of central America, then the cost–benefit ratio will be even greater. This is a very favourable cost–benefit ratio. These calculations make the critical assumption that iodine fortification programmes are 100% effective, i.e. that they completely remove the possibility of goitre in the population in the long term.

9.3.3 Iron fortification: a cost–benefit analysis

The cost–benefit analysis for iron outlined below uses the prevalence of anaemia as a proxy indicator of iron deficiency. However, it is generally accepted that only about half of the cases of anaemia are in fact iron-deficiency anaemia; conversely, there are a considerable number of iron deficiency cases that are not associated with anaemia (see section 3.1.1). Despite its being an imperfect indicator of iron deficiency, anaemia is nevertheless used in this analysis in the absence of alternative inexpensive and easy-to-apply tests of iron deficiency (see discussion in Ross & Horton (*365*). The present cost–benefit calculation further assumes that the main economic effect of iron deficiency is a loss of manual work, i.e. productivity. Based on the assumptions given in **Table 9.4**, the productivity loss for a known prevalence of anaemia ($Pre_{anaemia}$) is given by the formula:

Productivity loss associated with anaemia over all market work + Additional productivity loss associated with anaemia in light manual labour + Further additional productivity loss associated with anaemia in heavy manual labour,

that is,

$$4\% \times \text{Wage share in GDP} \times \text{Per capita GDP} \times Pre_{anaemia} + 1\% \times \text{Wage share in GDP} \times \text{Per capita GDP} \times Pre_{anaemia} \times \text{Light manual share} + 12\% \times \text{Wage share in GDP} \times \text{Per capita GDP} \times Pre_{anaemia} \times \text{Heavy manual share.}$$

Although the prevalence of anaemia (Pre_{anemia}) is not necessarily congruent with presence of iron deficiency, it is nevertheless an appropriate indicator to use here since the estimates of productivity losses employed (see **Table 9.4**) are derived

from studies involving iron interventions in anaemic populations, not specifically iron-deficient populations.

According to statistics produced by the International Labour Organization (ILO), in low-income countries light manual labour represents about 70% of all market work, 60% in lower-middle income countries, and 50% in upper-middle income countries (*366*). For the purposes of this calculation, it can be assumed that 57.5% of the work in agriculture is heavy manual labour (based on the assumption that half of work in agriculture and construction is heavy manual work, and that construction represents 15% of work in agriculture (*366*).

If in country P, the proportion of employment in agriculture is 25%, the overall prevalence of anaemia in the population is 37.25%, and light manual labour represents 60% of all market work (the country being in the lower-middle income category), then the per capita productivity losses associated with iron deficiency are as follows:

$$(4\% \times 0.4 \times 430 \times 0.3725) + (1\% \times 0.4 \times 0.6 \times 430 \times 0.3725) + (12\% \times 0.4 \times 0.144 \times 430 \times 0.3725) = 4.04 \text{ US\$}.$$

For a unit fortification cost per person of US$ 0.12 (based on data from Venezuela (*39*), this produces a cost–benefit ratio of 0.12 : 4.04. However, as mentioned above, iron fortification cannot correct all anaemia (i.e. it is not 100% effective), and a further adjustment to account for this fact needs to be made.

According to the Venezuelan study conducted by Layrisse et al. (*39*), iron fortification led to a 9% reduction in the prevalence of anaemia. However, the study was limited to children aged 7, 11 and 15 years, and was based on a before-and-after comparison, rather than on an intervention/control design. Layrisse's conclusions are, however, supported by the results of a well-controlled study from Morocco involving double-fortified salt (with iron and iodine). In this case, fortification, albeit at a higher concentration, achieved a 15% decline in the prevalence of iron-deficiency anaemia in children aged 6–14 years, for an estimated annual cost of US$ 0.22 (*44*).

If it is assumed that in country P the same absolute decrease in anaemia prevalence can be obtained as was achieved in Venezuela (for the whole population, not only children), then the proportional reduction in anaemia due to the fortification programme would be:

$$0.09/0.3725, \text{ or } 24\%.$$

So, if the economic benefit of averting iron deficiency in the population is US$ 4.04 per person, and the cost of fortification is US$ 0.12 per person and the

effectiveness is 24% (i.e. a fortification programme reduces the prevalence by 24%), then the cost–benefit ratio becomes:

$$0.12 : 4.04 \times 0.24 \text{ or } 1 : 8.$$

This is a fairly high cost–benefit ratio, and suggests that iron fortification would be a prudent investment in country P. The cost–benefit ratio for iron fortification is lower than that calculated for iodine (see previous section). However, if benefits are assessed in terms of reduced mortality (as opposed to productivity losses), iron fortification produces the better cost–benefit ratio. Additional benefits for both iodine and iron, not taken into account here, include improvements in cognitive development and in school performance in children.

9.3.4 Iron supplementation: a cost-effectiveness calculation

Studies have established that iron supplementation during pregnancy is associated with a 11.7 g/l improvement in haemoglobin levels. In turn, a 10 g/l improvement in haemoglobin levels is associated with an odds ratio of 0.80 for maternal mortality rates (MMR), and an odds ratio of 0.84 for perinatal mortality rates (taken as 40% of the infant mortality rate (IMR)). Based on these data (see **Table 9.4**), it can be assumed that iron supplementation in pregnancy produces a reduction in the MMR from 200/100 000 to 137/100 000 **live births** (or from 2 to 1.37 per 1000 **live births**), and a reduction of the perinatal mortality rate from 32 per 1000 to 23 per 1000 **live births**.

Hence, for an investment of US$ 1700 per 1000 pregnancies, 9.63 deaths are averted (9 perinatal deaths and 0.63 maternal mortalities). This equates to a cost per death averted of US$ 176.5.

While on the surface it appears that iron supplementation during pregnancy is a less cost-effective strategy than vitamin A fortification in children (the cost per death averted is about 10 times higher – see section 9.3.1), it should be remembered that iron supplementation also has immediate productivity benefits that would not be conferred by vitamin A.

Summary

The *cost-effectiveness* of an intervention is expressed in terms of the cost of achieving a specified outcome. Analyses of cost-effectiveness are particularly useful for comparing different interventions that share the same outcome. In assessments of health interventions, the two most widely used effectiveness measures are "cost per death averted" and the "cost per disability adjusted life-year saved" (cost per DALY saved). Both measures can be applied to micronutrient interventions. Although the latter measure combines mortality and morbidity outcomes into a single indicator, its calculation is generally more demanding in terms of data needs and assumptions.

A *cost–benefit* analysis compares the monetary cost of an intervention with the monetary value of a specified outcome (i.e. the benefit). Because cost–benefit analyses are able to compare interventions whose potential benefits or outcomes extend beyond health, they can be used to evaluate the relative merits of health interventions and other kinds of government spending. Cost–benefit analyses are thus especially helpful for advocating for increased resources for nutrition and health.

Cost-effectiveness and cost-benefit analyses have shown that:

- Both iodine and iron fortification have the potential to achieve high cost–benefit ratios, given the prevailing levels of micronutrient deficiency and the economic situation of many low-income countries.
- Food fortification with vitamin A is highly cost-effective in reducing mortality in children, as is supplementation with iron in pregnant women.
- Fortification becomes increasingly cost-effective the higher the proportion of the population in need of the intervention.

CHAPTER 10

Communication, social marketing, & advocacy in support of food fortification programmes

In common with other health promotion programmes, all food fortification programmes share two objectives:

(i) to create an enabling environment – in this case, one that makes adequately fortified foods widely available and provides the means for individuals to acquire them;

(ii) to help individuals adopt healthful behaviours – in this case, behaviours that enhance the contribution of fortified foods to their micronutrient status.

Fulfilment of these objectives not only requires political commitment and corporate support, but also that national laws and regulations, manufacturing and marketing practices, and community norms, policies and structures be strengthened or modified in some way so as to bring adequately fortified foods to those who need them most. Furthermore, individuals are likely to need guidance and encouragement before they willingly incorporate fortified products into their diets, modify their dietary practices that affect the absorption of nutrients in foods, and adopt household storage and cooking techniques that maximize the nutrient value of the foods they eat. Throughout the entirety of this individual behaviour–environment change continuum, communication plays a critical role.

To increase its chances of success, a fortification programme needs to be supported by a range of well-coordinated communication activities that promote individual, community, corporate and political change. In this respect it is important to be aware that messages about the benefits of fortification can be communicated in a number of different ways, using a variety of techniques, to very different effect depending on the intended audience. By outlining some of the options available, the main purpose of this chapter is, therefore, to help micronutrient programme managers understand the different communication needs of various sectors and so direct their communication activities more efficiently.

10.1 Communication strategies: the options

There are a number of recognized methodologies that are available to programme managers for communicating messages about the benefits of micronutrient fortification; these include nutrition education, social marketing and advocacy (see **Table 10.1**). Experience has shown some approaches to be particularly useful for encouraging individuals to adopt healthier behaviours (e.g. health communication, nutrition education, social marketing); others have helped foster community support, led to the introduction of laws or regulations or mobilized entire countries for periodic health actions (e.g. advocacy, social mobilization). In practice, however, it is not simply a question of choosing one approach over another, but finding the right blend of strategies and tactics that together achieve programme objectives (*367*).

A useful framework for analysing communication needs, in which education, marketing and legislation are viewed as interconnected approaches to managing social and health issues, has been suggested by Rothschild (*373*). By describing the relationship between various activities in terms of individual decision-making and perceived costs and benefits (**Figure 10.1**), Rothschild's framework can assist in identifying which approaches are best suited to which tasks.

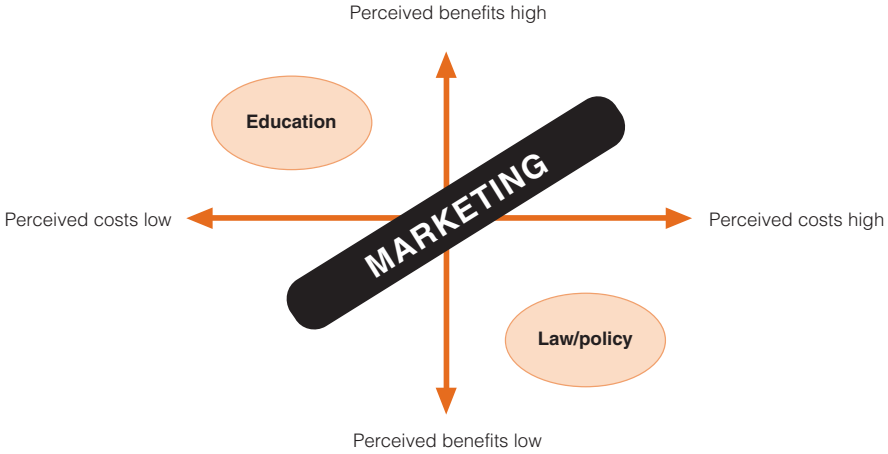
TABLE 10.1

Nutrition promotion methods defined

Concept	Definition
Nutrition education	Any set of learning experiences designed to facilitate the voluntary adoption of eating and other nutrition-related behaviours conducive to health and well-being (*368*).
Health communication	The crafting and delivery of messages and strategies, based on consumer research, to promote the health of individuals and communities (V. Freimuth in (*369*).
Social marketing	"The design, implementation, and control of programmes aimed at increasing the acceptability of a social idea, practice [or product] in one or more groups of target adopters. The process actively involves the target population, who voluntarily exchange their time and attention for help in meeting their health needs as they perceive them" (*370*).
Advocacy	Persuading others to support an issue of concern to an individual, group or community. May involve, "the strategic use of the mass media as a resource to advance a social or public policy initiative" (*371*).
Social mobilization	A broad scale movement to engage large numbers of people in action for achieving a specific development goal through self-reliant effort. Social mobilization is most effective when it is composed of a mix of advocacy, community participation, partnerships and capacity-building activities that together create an enabling environment for sustained action and behaviour change (*372*).

FIGURE 10.1

Relationship between individual decision-making and the perceived costs and benefits of any new behaviour, idea or product



Source: reproduced from reference *(374)*, with the permission of the publishers.

10.1.1 Education

The upper left-hand quadrant of Figure 10.1 is occupied by education or "providing knowledge". This approach is most effective when the benefits of a change are obvious, and the change does not appear costly to the person or group being asked to make the change. It had been assumed in the past that only a minimal amount of communication was needed to "educate" the public, opinion leaders in the scientific community and industry about the benefits of adding nutrients to foods. However, experience with salt iodization has demonstrated that in reality a far more negotiated approach is required.

Fortified products are developed to address a biological need for micronutrients. However, at the individual level this need is largely unrecognized because people neither crave micronutrients nor realize that they are deficient. Instead, a population's need for micronutrients is defined by the health community, usually in terms of a biochemical, clinical or some other marker of deficiency. Since raw data on the prevalence of deficiency are often difficult for the general public to understand, by themselves they do not suffice for providing individuals with a believable rationale for changing their shopping, food preparation or dietary habits. What is needed instead is a more user-friendly message, preferably one that is tailored to suit the information needs and cognitive ability of the recipients (see **Box 10.1**).

Lack of ambiguity in educational messages is vital. Whenever technical experts disagree, the public tends to ignore all scientific evidence until such time

BOX 10.1

Education as a communication strategy: keys to success

Educational approaches work best when the recipient of the information has already expressed a desire or commitment to perform the desired behaviour and is now seeking information on what to do and how to do it.

Information for the purpose of providing knowledge must be simple, clear and unambiguous. It should be:

— adjusted to the cognitive abilities of the learner (i.e. according to age, educational level, literacy and language of maximum understanding);

— adjusted to the communication medium be it oral, visual, or tactile (e.g. mixing instructions);

— answer factual questions such as What? Whom? Where? How?

a unified message has emerged. For fortification programme managers it can sometimes be difficult to achieve a consensus between competing claims of effectiveness, safety, quality and cost of a given intervention. For instance, whereas public health professionals tend to advocate the most appropriate fortificant levels for maximum impact, or recommend use of those fortificant compounds that offer the highest bioavailability, producers will try to minimize changes in product quality and cost. A process which successfully negotiates these varying perspectives among public and private sectors is critical to developing a product profile that has the support of both government and industry – and that ultimately will be accepted by the consumer. Hence, at the outset of food fortification programmes, it is important to attempt to integrate and translate the technical language and jargon of the public health, food science and business sectors into a common vocabulary that all the various professionals involved can understand. Technical language and jargon should be reserved for professional communications; the public will require a more carefully crafted approach altogether, and one that is based on the appearance of scientific consensus in order to achieve maximum penetration.

10.1.2 Laws, policy and advocacy: communicating with policy-makers

In direct contrast to education, and occupying the diagonally opposite quadrant in Figure 10.1, laws (or regulations) are used to prompt societal change when a change appears to be costly and to compromise individual benefits. In the context of health, most laws and regulations are aimed at achieving the collective good over individual desires or profit. Rothschild defines law as "the use of coercion to achieve behaviour in a non-voluntary manner" (*373*), but in

BOX 10.2

Advocacy as a tool for communicating with policy-makers: keys to success

Advocacy frames issues for public attention, the media and policy-makers. For maximum impact, advocacy should be:

— focused on one or a very limited number of issues;

— get to the point quickly and end quickly;

— add emotional content and localization;

— answer the question: Why should we care?

practice laws can really only persuade, as individuals or entities can always choose whether or not to obey a law or regulation according to their own cost–benefit calculation.

When any concerned group organizes to change a law or policy, their primary tool is *advocacy*. Thus the recipient of advocacy is an individual or group with the power to change the law or regulation, i.e. policy-makers. The primary message that needs to be communicated is why this individual or group should care (**Box 10.2**). "Ideally, policy-makers should incorporate scientific information when . . . making decisions. In reality, many decisions are based on short-term demands rather than long-term study, and policies and programmes are frequently developed around anecdotal evidence. Existing health data are often under-utilized and sometimes ignored" (*375*).

Some advocacy groups (and indeed governments and corporations) actively court the mass media to draw attention to a particular issue and to present their standpoint. Micronutrient programme managers wishing to use the media in this way are advised to develop good working relationships with key journalists and thus earn a reputation for being a reliable source of information. It is helpful to develop fact sheets, press briefings and other background materials that can be used by the news media, but in order to maximize their impact, these usually need to be combined with a "newsworthy" event, such as the release of new data, a public meeting or a decision taken by the government. Although media success can be measured by the volume of exposure or "airtime", ensuring that a story is presented the way it was intended is equally, if not more, important. This can be extremely difficult as the news media is increasingly an "entertainment industry," and what drives story placement is often linked to what brings high levels of audience attention. Strategies for increasing media coverage are presented in **Box 10.3**.

BOX 10.3

Using the media: keys to success

Chances of obtaining media coverage are enhanced by:

— conflict, controversy or injustice;

— community involvement;

— irony;

— a hard news "link" (timeliness);

— images, i.e. pictures, video films, photographs, graphs, and expert interviews.

10.1.3 Social marketing

The central part of Figure 10.1 is occupied by marketing, or, more specifically, by social marketing. Social marketing is the use of marketing techniques developed by the private sector (i.e. commercial marketing) to achieve public sector goals. In the area of public health, this technique has been used successfully to support family planning, HIV prevention, oral rehydration, hand washing, and immunization, as well as various nutrition programmes, such as infant feeding, salt iodization, iron supplementation and dietary diversification programmes (*376,377*)

Commercial and social marketing are alike in that both attempt to influence individuals to make choices concerning their behaviour, and/or the products or services (the "offering") they use by increasing the perceived value of the offering and mitigating the perceived obstacles to its use. In commercial marketing, consumers buy a product or service that they judge to be a fair trade for the sum of money paid. The profits generated through this exchange are distributed back to the company that produced the product or service and its stockholders.

The term "social marketing" is generally used to describe the promotion of those "causes judged by persons in positions of power and authority to be beneficial to both individuals and society" (*378*). The potential consumer in a social marketing programme might be asked to use a product (e.g. a polio vaccine, a vitamin A capsule, soap), a service (e.g. well-baby visit, preventive dental check-up) or adopt or modify a behaviour (e.g. mix an oral rehydration solution, refuse an offer of a cigarette, breastfeed exclusively for 6 months). Usually, the potential consumer or "adopter" initially feels no need or desire for this product, service or modified behaviour, and, in fact, uses or does something else instead.

When the exchange is completed, the consumer or adopter will have given up time, a previously held belief or attitude, money, or even all three to acquire the offering. In a social marketing programme, unlike the commercial marketing scenario, the return to the "stockholders" is better health and welfare for the society. However, when social and private sector entities combine to market socially beneficial products, such as fortified foods, a reasonable monetary profit is usually also generated. This means that the venture can be made self-sustaining, and thus avoid having to rely on constant inputs from governments or donor agencies (*379,380*).

As the objective is largely a voluntary exchange, social marketing works best when it involves potential consumers in every aspect of a programme. Potential consumers need to be consulted about product or service development as well as its cost (or "price"), image ("product positioning"), distribution (or "place") and promotion. These factors are referred to as the four "Ps" of social marketing, and are analysed in the context of food fortification in **Box 10.4**.

Social marketing programmes require considerable investment in order to create awareness of the offerings and to demonstrate their value to potential adopters to the extent that adopters are willing to exchange their time, money or dearly held beliefs or habits for them. Social marketing programmes rely heavily on communication, and need time to develop to their full potential. However, social marketing is not just about communication; no amount of advertising, or advocacy, social mobilization, education, information or health communication can sell an inferior product that is badly packaged and distributed and/or unfavourably priced. For these reasons, social marketing objectives should be defined, alongside other programme objectives, at the planning stage of a fortification programme. Social marketing indicators should also be developed at this time; these can used, in combination with other programme indicators, to evaluate programme implementation and performance (see Chapter 9). Consumer behaviour and its antecedents can be useful complementary measures of programme success.

10.2 Communication to support social marketing programmes

As indicated in the previous section, the right mix of social marketing and other strategies can make all the difference to the success of a public health programme. Food fortification programme managers can make use of any one of a number of published resources to guide the development of the communication component of a social marketing programme to support their own fortification initiative. *CDCynergy. A communications guide for micronutrient interventions* is one such resource that not only provides step-by-step guidance in such matters, but draws on examples of successfully marketed micronutrient

BOX 10.4

Keys to success in social marketing: the four "Ps" for fortified foods

Product positioning

- A high quality fortified product should be produced in accordance with good manufacturing practice, WHO technical guidelines or some other form of guidelines and regulations.
- Product presentation should be attractive, tasty and in all ways appealing to the potential consumer.
- Positioning of the product is derived through research with the potential consumer. It makes a promise that can be kept. Eventually this will become a "brand".

Price

- The fortified product should be packaged in quantities and priced so as to be affordable to the potential consumer.
- Different quantities/price points might be developed to satisfy different groups of consumers.

Place

- The fortified product needs to be widely distributed (including rural areas) using commercial food distribution channels, where appropriate.
- All physical barriers to obtaining the fortified product should be eliminated.

Promotion

- Product promotion should be driven by the product's positioning.
- The benefits of fortified foods and the limitations of non-fortified substitutes need to be presented in terms that are meaningful to the consumer.
- The act of purchasing fortified foods needs to be presented as "new", and then eventually, as "normal".
- The consumer should be persuaded to adopt consumption practices that enhance the absorption of micronutrients.
- The consumer should be educated to store fortified foods in ways that protect the product and prolong its shelf-life.

programmes from around the world[1]. In this particular guide, all promotional materials production and messaging is based on a systematic, data-driven process that is centred on the intended audience or the consumer. This process requires the following activities:

- Qualitative and quantitative research to define participating audiences, consumer attitudes and barriers to change.
- Data analysis to define and segment audiences into like groups for communication.
- Research and pre-testing to determine the most motivating benefits for these target audiences.
- Message creation based on key benefits. For each segment, messages must answer the question, "What is the benefit to me?" Background and qualitative research can define the key messages that answer that question.
- Promotions and other activities that are disseminated via channels appropriate to each audience segment.

This approach can be applied to other communication strategies, including advocacy and nutrition education, to make them more tailored and effective. Social marketing research methods can also be used to interact with all participants in a micronutrient programme, i.e. not just potential consumers, but also industry representatives, and government and nongovernmental organizations (NGOs).

The guidance and suggestions for communicating the benefits of fortification that is provided in this part of the Guidelines is necessarily generic. It is recommended that social marketing research be conducted in each country or region in order to identify the right mix of messages and communications that are going to support fortification programme goals to best effect.

10.2.1 Building collaborative partnerships

In some parts of the world, the formation of alliances or networks has led to a more effective collaboration between the main partners involved in the control of MNM. These partnerships typically include representatives from bilateral and multinational agencies, international and national NGOs, research and academic institutions, foundations and increasingly, industry. The Network for Sustained

[1] *CDCynergy. A communications guide for micronutrient interventions* is a comprehensive CD-ROM that helps plan, implement and evaluate communications programmes. The CD-ROM is available, free of charge, from the Centres for Disease Control and Prevention and can be ordered online via: http://www.cdc.gov/nccdphp/dnpa/immpact/tools/order_form.htm.

Elimination of Iodine Deficiency[1] and the Global Alliance for Improved Nutrition (GAIN)[2] and the Flour Fortifcation Initiative[3] are among the better-known examples. The primary role of these alliances has been to mobilize decision-makers with regard to the public health dimension of MNM and to provide support for food fortification programmes.

Within this atmosphere of multisectoral collaboration, the primary role of the food industry is to produce, distribute and market a good quality, competitively-priced fortified product. Ideally, fortification should add no more than a few per cent of product cost to the product price, have no detrimental impact on product quality and not create imbalances in the business or competitive environment. The public sector, on the other hand, is responsible for creating an environment that allows the private sector to invest in fortification. This enabling environment should minimize unfair competition from lower quality or cheaper unfortified foods that make it difficult to pass added costs of fortification on to the consumer.

Inevitably there will be some tension between the public sector emphasis on consumer rights and on equity and health issues, and the private sector focus on consumer demand, commercial viability and revenue generation. Balancing the public and private perspectives requires developing communication channels for negotiating a number of potentially contentious issues, such as:

- Increasing sales is a fundamental goal of private sector marketing. However, this is not necessarily a public or national goal, and for some food vehicles, such as sugar or salt, increased consumption – or sales – is not an explicit goal of the programme. Messages should lead consumers to the fortified product, but not necessarily to increase overall consumption of the commodity (i.e. sugar, oil, salt, flour).

- Whereas private companies strive to maximize revenues, the public sector strives to maximize accessibility and minimize any price rise. A balance thus needs to be struck whereby producers are fairly compensated, while avoiding any sharp price increases for at-risk consumers.

- Logos and endorsements awarded by governments or NGOs can be powerful promotional tools. The difficulty here lies in the fact that, while the private sector promotions are designed to maximize market share, public campaigns cannot be seen to be favouring specific companies. One possible solution is to use public promotions that are generic to fortification, to the micronutrients concerned, to the seal of recognition or to the food vehicle.

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[1] Further information is available via the Internet at: http://www.sph.emory.edu/iodinenetwork/.
[2] Further information is available via the Internet at: http://www.gainhealth.org.
[3] Further information is available via the Internet at: http://www.sph.emory.edu/wheatflour/.

BOX 10.5

Engendering Collaborative Partnerships: The role of a multisectoral fortification task force or committee

Although informal work groups can provide channels for communication, a more formal body, where members officially represent the interests of their organizations, can be more effective in opening communication channels in the right way along the chain – from high-level decision-makers through to consumers. A multisectoral task force or committee is useful for securing commitment, gaining consensus and for coordinating the contributions of various sectors or disciplines (*380*). Participation should include stakeholders involved in the technical implementation of fortification, as well as those offering credible channels to key audiences, institutions and decision-makers. While participants will vary according to national circumstances, the core group might include:

- government health, regulatory and food control agencies involved in regulation, monitoring and surveillance, as well as agencies that deal with special financing needs;
- companies involved in the production of the choosen food vehicle, value-added processing, and the wholesale and retail distribution of the fortified product;
- academic and research institutions (which provide technical input as well as credibility);
- NGOs (which offer support, resources and channels of communication to a range of constituencies).
- Consumer organizations.

In some settings, the best way to make sure that lines of communication between programme partners are open may be to establish a formal multisectoral task force or committee. The role and membership of such a body are discussed further in **Box 10.5.**

10.2.2 Developing messages for government leaders

For many national governments, fortification is an attractive option because it offers an opportunity to achieve national health and nutrition goals that – by shifting the costs to the market – can be substantially financed by the private sector. Naturally, government departments and agencies vary in their priorities and so some will have a greater interest in certain outcomes than others. For instance, the potential for improved productivity and national economic development will be of particular interest to departments responsible for finance and revenue. Messages framed by national economic circumstances are thus more

likely to strike a chord with policy-makers working in these areas[1]. Other examples include:

- Messages defining reduced health care costs will have particular resonance among officials responsible for health budgets[2].
- Outcomes such as improved cognitive ability and improved school performance can be persuasive for agencies investing in educational programmes.
- Agencies dealing with industrial development or public works are most likely to be motivated by estimates of depressed productivity and economic loss.

Depending on national circumstances, some government departments may have very specific concerns about the impact of fortification and thus may be prime targets for advocacy. Having identified, through social marketing research, the specific interests and concerns of each group, advocacy or education sessions can then be tailored to address these. For instance:

- In some countries, government agencies are involved in the production, distribution or subsidy of staple foods. Fortification will impact the budget of ministries or agencies responsible for the financing of these activities.
- Sometimes the selected fortification vehicle (often wheat flour) is imported, in which case, officials may have specific concerns about promoting a product that has a negative impact on the national balance sheet.
- Since fortification is more cost-effective when adopted by larger or more modern industries, agencies responsible for small business development may be concerned about the social and economic impact on small producers, their families and communities.
- Creating an enabling environment for private investment often involves providing exemptions from specific taxes and duties. The ministries responsible for administering these revenue-creating programmes are often deluged with exemption requests.

10.2.3 Developing messages for industry leaders

From the point of view of private producers, fortification cannot be allowed to negatively impact fundamental business goals, i.e. sales and profits. Any new

[1] A number of tools are available for estimating the economic impact of micronutrient deficiencies based on national statistics for prevalence, gross domestic product, workforce structure, health care utilization and other country-specific factors. *Profiles*, a computer simulation developed by the Academy for Education Development, Washington, DC, USA is one such tool. More information is available through the internet at http://www.aedprofiles.org/. Another is that developed by the Micronutrient Initiative, Ottawa, Canada, details of which are given in the report titled, *Economic consequences of iron deficiency* (*365*).

[2] The *Profiles* simulation (see above) includes a methodology for measuring the reduction in health expenditures.

product launch carries with it the risk of consumer resistance and, therefore, a loss of sales and reduced profits. Messages for industry can address this concern by highlighting past successful commercial experiences or ongoing trials that indicate little or no consumer resistance to fortified products.

Although from the consumer perspective, fortification usually entails only a very small annual cost, for a large producer, it can mean a large initial investment. To help overcome any reticence on the part of industry to make the necessary investment, messages directed at the industry sector need to stress public sector commitment to creating an "enabling market environment", that is to say, one that allows business to make a reasonable profit or at the very least recoup their investment. While this involves a number of technical, commercial and regulatory factors, a key element is the creation of consumer awareness and demand. Therefore, messages to industry should also highlight public sector commitment to developing communication channels and to providing support for credible health claims and public endorsements, such as official logos.

Beyond the basic messages about enabling conditions of sales and profits, a number of other messages may be useful for securing industry commitment to fortification programmes. Again, depending on the results of research involving industry and government sector representatives, messages that express the following ideas may be helpful:

- In the eyes of public or government relations departments, the promise of an improved public image and better government relations is often perceived as a benefit to business.
- For technical audiences, fortification could be presented as an opportunity to improve product quality. For example, in the case of flour millers, adding micronutrients can be framed as restoring milled flour to the original nutritional quality of the whole grain.
- For production managers in developing countries, reference to fortification in North America and Europe can suggest industry best practice.
- For some companies, expanded market share and consumer brand loyalty may be perceived as a potential business benefit of fortification. However, although some companies may benefit more than others, there is little evidence that national fortification increases sales overall.

Nor should the power of the argument that fortification is "Doing the right thing" be underestimated. While largely focused on the bottom line, industry does have a social conscience. Moreover, industry is very concerned about consumer awareness and the reaction to a new product. This interest is not confined to the industry sector; policy-makers and business leaders are also sensitive to potential consumer reaction. For government leaders, consumers are also political constituents, and they too need to anticipate potential public reaction

to fortification. Therefore, even though they may not be a direct audience for advocacy, understanding the consumer is critical to answering the concerns of leadership audiences and for developing effective messages.

10.2.4 Developing consumer marketing strategies and education

The goal of consumer marketing and education is to create a perception of value in fortification, so that consumers will accept the new product, choose fortified over non-fortified products, and if necessary, pay a slightly higher price. Creating consumer demand for fortified foods, particularly among lower income consumers, can encounter steep barriers, especially in a highly-competitive environment (see **Box 10.6**).

BOX 10.6

Fortified products and consumer barriers

Possible consumer barriers to fortified foods and products include the following:

- Research in many countries indicates that nutritional benefits, while an important feature, is a low purchase priority. Price, taste, packaging, accessibility and convenience are almost invariably of higher priority.
- The need for micronutrients is often unrecognized by the consumer, and must be made visible. This is a difficult task.
- The benefits of fortification are subtle. Because fortified foods offer a preventive rather than a therapeutic benefit, no immediate satisfaction is felt. Moreover, benefits such as improved school performance and greater productivity accrue only years into the future. Promoting prevention and future benefits is often particularly challenging.
- While the incremental price increase associated with fortification is nearly invisible, low-income consumers are keenly sensitive to any price differential. Consumers, particularly the poor who tend to be at the greatest risk of MNM, are also the most likely to purchase cheaper products or to seek alternatives.
- Staple foods are often seen as pure or natural products. Consumer resistance may emerge from misinformation about adding "foreign" substances or "additives." These range from apprehensions about toxicity or changes in the sensory qualities of a food, to fears about the true goal of the fortification programme.
- Staple foods and condiments are part of cultural identity and consumers may simply resist giving up the old for the new.
- In some cases, there is resistance from sometimes more affluent market segments who feel that they do not need additional micronutrients, and believe they are being forced to purchase and consume fortified products.

Consumer marketing strategies can be divided into two categories, "push" and "pull". A push or *supply-driven* strategy pre-empts the choice between a fortified and unfortified product by universal, and usually mandatory, regulation. In theory, while prices may rise as a result of the introduction of mandatory fortification, there will be no price difference between competitive products as a result of fortification. With little consumer choice or price competition, the consumer plays a less active role and thus communication strategies need to focus on ensuring consumer acceptance, awareness and education.

When fortified foods compete with less expensive non-fortified products in the market-place, a *demand-driven* or pull strategy is needed. In this scenario, a perception of value must be created to compensate for the price difference and the fortified product must be positively differentiated from the competition in order to develop an active consumer preference. Communication strategies focused on generic consumer awareness and understanding may not always be sufficient and sometimes more aggressive commercial marketing techniques are required in order to provide a competitive edge for fortified products.

A collaborative alliance of government, industry and NGO representatives, along the lines previously described (see section 10.2.1) offers opportunities to reach consumers through a broad mix of public and private sector communication channels. These range from government broadcast television and radio, through health or outreach centres, to various points of sale. Each of these sectors also brings their own distinct brand of experience and expertise: public sector agencies and many NGOs have long experience in health and nutrition communications, and in public education activities to raise health awareness and promote healthy behaviours. The private food sector provides expertise in consumer marketing, with which to create product demand and consumer purchasing preference. Opening multisectoral channels of communication and cooperation is central to capitalizing on the unique strengths of each sector.

10.3 Sustaining the programme

Even after fortified products have been launched and established in the market place, consumer and professional awareness remains critical to sustaining fortification programmes. Maintaining consumer support ensures that when governments change, fortification-friendly policies are sustained. Likewise, consumer awareness will help to secure stable and continued industry support despite changes in market conditions which may tempt companies to withdraw from the programme or not comply with regulations, despite initially supporting fortification.

Continued collaboration between organizations and agencies involved in communications and quality assurance is also vital to sustaining interest in fortification. For example, when awarding public sector symbols – logos, seals of

approval or other forms of endorsement – product quality must be regularly assured. The added value of the public symbol is only as good as the products with which it is associated and ultimately it is the credibility of the organization(s) standing behind the endorsement that is at stake. In countries where government food control and enforcement is not fully functional, consumer organizations offer a means by which to monitor the marketplace. Under such circumstances, empowering consumer organizations to work with government and industry – by collecting samples or publishing results of product analysis – can be an important strategy to ensure quality assurance and evaluation.

Summary

The chances of success of a fortification programme are greatly improved if it is supported by a range of activities that collectively help to create an enabling environment for fortification. In practice this means promoting change at all levels – individual, community, corporate and political.

Various ways of communicating messages about the benefits of fortification exist, including nutrition education, social marketing and advocacy. Education strategies work best when the benefits of change are obvious (the perceived benefits are high) and the change does not appear costly to the individual or group being asked to make the change (i.e. perceived costs are low). Conversely, regulatory approaches may be more appropriate when the perceived benefits of the change are low and the perceived costs are high. All fortification programmes will benefit from some form of social marketing, i.e. the use of commercial marketing techniques to achieve public sector goals. Social marketing is at its most effective when it involves the consumer in every aspect of a programme, from product development to product positioning, placement, pricing and promotion, and is based on qualitative and quantitative research that has defined the key consumer groups, their attitudes and barriers to change.

Messages must be unambiguous and tailored to match the information needs and cognitive abilities of the recipient.

Establishing some form of collaborative network or alliance can be a good way of opening and maintaining communication channels among principal stakeholders. This can also provide a forum for negotiating any conflicts of interest that may arise between the private and public sectors.

CHAPTER 11

National food law

Governments have a key role to play in ensuring that food fortification is effective for the population group(s) most at risk from micronutrient malnutrition, but is safe for the population as a whole. Food laws and related measures, together with a broader food control system, are the primary tools that are available to governments for establishing an appropriate level of control over food fortification practices.

This chapter examines some of the technical and legal issues that are involved in the development of national food fortification law. The discussion focuses on the regulation of the composition of fortified foods and the labelling and advertising of pre-packaged fortified food products. Other elements of national food laws, for example those dealing with industry licensing, support or sanctions are beyond the scope of these Guidelines. When establishing provision for fortification within national food law, regulators will need to take account of existing regulations on international trade and the global agreements that today increasingly govern that trade. For this reason, the chapter commences with a brief overview of the international systems for setting food standards and the current global agreements on international trade.

11.1 The international context

Two global trade agreements are relevant to food, both of which are administered by the World Trade Organization (WTO). These are:

- the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement);
- the Agreement on Technical Barriers to Trade (the TBT Agreement) (*381*).

Food fortification measures, whether mandatory or voluntary, are most likely to be covered by the latter, i.e. the TBT Agreement. This agreement recognizes that:

> No country should be prevented from taking measures that are necessary for the protection of human health at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would con-

stitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement.

In other words, countries may adopt provisions that restrict trade for legitimate reasons – health being one of them – providing such measures are in accordance with the five governing principles laid down in the TBT Agreement. These five governing principles act to ensure that unnecessary obstacles to international trade are not created. The key elements of the TBT Agreement relating to coverage, definitions, legitimate objectives and governing principles are explained in **Annex F**.

The TBT Agreement encourages the use of international standards, except where they would be ineffective or inappropriate in the national situation (see www.codexalimentarius.net and **Annex F**) (*382*).

11.2 National food law and fortification

Food law, operating in concert with the broader food control system, is the mechanism commonly used by governments to set technical provisions for fortified foods, the most important of which relate to their composition, labelling and claims. (Claims are statements that manufacturers make in order to inform consumers about their products.) Food law may also be used to impose broader controls on the food industry, and to establish monitoring and public information systems in support of food fortification.

Food law typically has a number of objectives, the most important of which is the protection of public health. Other frequently cited objectives are:

— the provision of adequate information to enable informed choice;

— the prevention of fraud and misleading or deceptive conduct;

— fair trade.

To meet these objectives, fortification provisions in food law should not only ensure that all compositional parameters applicable to both fortificants and food vehicles deliver safe and appropriately efficacious public health outcomes but also that the labelling, claims and advertising of fortified foods is factual and not misleading, and provides sufficient information to enable appropriate consumption.

11.2.1 Forms of food law: legislation, regulation and complementary measures

Food law commonly comprises proclaimed or decreed legislation that establishes the legal framework and the broad principles, accompanied by subordinate

technical regulations that give detailed effect under or within such legislation. Thus food fortification requirements may be established either in an act of the governing legislature (such as a food- or health-related act), or in technical food regulations. An example of an act that is solely dedicated to mandatory fortification is the Philippines' Act Promoting Salt Iodization Nationwide (*6*). This law establishes policy, applicability, industry support, public information and sanctions, and is supported by rules and regulations for the implementation of salt iodization and related purposes; these rules include a technical standard for iodized salt. Other countries use technical regulations (also called standards or other such similar terms), to mandate the specific legal requirements for food fortification, but rely on parent legislation to ensure appropriate implementation. One advantage of setting fortification provisions in regulation, rather than in legislation, is that amendments can be made more quickly and easily, providing of course, that the power to administer regulations is delegated from the primary governing legislature to an appropriate subsidiary or statutory body.

Regardless of the way in which national food law is constructed, all those involved in the food production and distribution system (including importers) must understand the applicable laws and, above all, comply with them. To this end, and to ensure that food law achieves its public health objectives, it must be:

— certain in its operation (i.e. clearly and unambiguously expressed for those engaged in the activity to which the regulation is directed);

— supported by an appropriately structured and resourced information dissemination system and enforcement capability.

Under certain circumstances, complementary measures to government legislation or regulation can be used to fulfil regulatory objectives. These measures take the form of industry self-regulation or a co-regulatory mechanism between industry and government in which government decides the appropriate level of involvement. Such measures are respectively administered by industry alone or jointly by industry and the government sector, and are best suited to matters of process or intermediate outcome. A complementary system only works well when the following recognized "success factors" are present:

— the level of risk to public health and safety, or potential harm to consumers, is low;

— the product is relatively homogeneous across the product category and consumers can readily identify it with the industry;

— the industry is competitive, but also cohesive and represented by an active industry association;

— the industry and/or its association is responsive to consumer complaints;

— companies are keen to enhance their future viability and are concerned about their reputations, future customers and the wider community.

11.2.2 Regulating food fortification: general considerations

Before deciding on the format and detail of fortification provisions, it is vital that regulators understand the factors that shape their country's food supply patterns. Important considerations might include the balance between domestically-produced and imported fortified products; the micronutrient composition of the imported product; the capacity of the domestic industry to produce or increase production of the fortified product; and the industry's overall cohesiveness. Having this understanding is especially pertinent if imported fortified products are going to make a significant contribution to the intake of micronutrients. If compositional parameters in national regulation do not accommodate the fortified imports (e.g. if the minimum iron fortification level set by a newly-introduced law was higher than the iron content of the imported product), an unintended diminution of micronutrient supply may occur, unless the domestic industry can quickly fill the gap.

Regulators also need to be aware of the present level of community nutritional knowledge and any planned nutrition education initiatives, so as to be able to determine the appropriate balance between label information and education, and the type and amount of information required or permitted in labelling and advertising. In this regard, and as previously indicated, regulators also need to bear in mind their obligation to international trade agreements and to international standards (see section 11.1).

Finally, any amendment of a food law that requires industry to change its production practices and/or product labelling should incorporate a transition period. It inevitably takes some time before all domestic manufacturers and importers become aware of new regulatory requirements and are able to modify their production and/or labelling operations accordingly. It may also be appropriate for foods produced in accordance with a previous version of the law to continue to be sold for a given period.

11.3 Mandatory fortification

If a food product is subject to mandatory fortification, then the manufacturer is legally obliged to add one or more micronutrients to that food. Mandatory fortification can reach the general population or an identified target group, depending on the consumption pattern of that food. For instance, fortification of a staple food, such as wheat flour, would increase the majority of the population's intake of a fortificant micronutrient, whereas fortification of, say, formula infant milk or complementary foods would increase the micronutrient intake of a

specific population group only. The conditions appropriate to the selection of mandatory fortification as either a population wide (mass) or specific population group (target) intervention were discussed in Chapter 2 of these Guidelines.

Mandatory fortification is written into food law, usually in the form of regulation which specifies a legal minimum, and where appropriate, a legal maximum level for each micronutrient in the identified food or category of foods. Providing there are no technological impediments, one food or category of foods could be required to contain several added micronutrients. This tends to apply to foods targeted at specific population groups having multiple nutritional needs and whose food variety may be limited.

11.3.1 Composition

In its simplest form, a regulatory requirement governing the composition of a fortified food might be written as follows:

[*Nominated food*] must [*contain*]:

(i) no less than [*x*] mg/kg of [*micronutrient name*],

and, where appropriate

(ii) no more than [*y*] mg/kg of [*micronutrient name*].

Each of the key terms (i.e. those in italic typeface) are discussed in more detail below, with particular reference to the implications for, and possible approaches to, mandatory regulation.

11.3.1.1 The nominated food

The name of the food or food category selected for fortification must be generally and unambiguously understood, or else explicitly defined or described in the regulation. The identity of the selected food(s) should correspond to the food(s) used to derive the level of fortification required to achieve pre-set programme nutritional goals (see section 7.3). Matching as closely as possible to the identity of the foods used in the calculations enables more accurate predictions of programme impact on micronutrient intake to be made.

Potential areas of ambiguity or difficulty to be aware of include the following:

- The definition of a food or a food category may be as broad or as narrow as required. For example, the nominated food could simply be given as "flour", which might mean all flours derived from all types of grain available in a country. Alternatively, a much narrower description could be employed, for instance, "all flour from one or more [specified] grains", or "flour having [par-

ticular compositional characteristics]" (which might be defined by extraction rates); or "flour destined for [a particular use], such as bread making.

- Where necessary, regulations should stipulate whether they apply to foods sold only at the retail level, or only at the wholesale level (for use as ingredients in processed foods), or both. However, more precise descriptions of foods or food categories, in the form of say, "food ingredient destined for [a particular purpose]", for example, bread-making flour or table salt, will automatically determine the market level at which the bulk of the product is sold.
- If necessary, the use of mandatorily fortified wholesale ingredients in certain processed foods could be more precisely controlled by stipulating that such ingredients either should always be or should never used be in particular foods, depending on the level of dietary intake of a given micronutrient that fortification is designed to achieve.

11.3.1.2 "Contain" or similar term

The term "contain", or some such similar term, refers to the *total* amount of micronutrient in the food. In other words, the legal minimum and maximum levels apply to the amount of both naturally-occurring and fortificant micronutrient present in a food, not just to the amount of fortificant that is added. This approach suits those micronutrients whose different chemical forms have similar bioavailabilities; more complex regulation is needed in cases where there are significant differences in bioavailability between naturally-occurring and fortificant forms of the micronutrient in question.

Food manufacturers can adopt slightly different strategies for calculating the amount of micronutrient that needs to be added in order to exceed the minimum requirement depending on whether or not a maximum level is also established by regulation. In cases where only a minimum requirement is set, and providing that the cost of the fortificant is not prohibitive, manufacturers can ignore a food's natural content of a given micronutrient, thus risking exceeding the legal minimum by at least the natural content. However, if a total maximum level of micronutrient is also prescribed, the food's natural content must be taken into account to ensure the total does not exceed the maximum permissible limit. In cases where the natural content is likely to be negligible, the legal minimum (x) and maximum levels (y) approximate to the range of permitted micronutrient addition.

11.3.1.3 Legal minimum and maximum levels

Procedures for determining the legal minimum (x) and maximum (y) total micronutrient content of a fortified food are set out in Chapter 7 of these Guidelines. In conceptual terms, legal minimum levels are established on the basis of

efficacy, whereas maximum levels are determined on the basis of safety or other more conservative criteria. Both the legal minimum and the maximum level serve to protect human health, and thus could be used to justify any restrictions on trade under the relevant international trade agreements.

Sometimes manufacturers need to add extra amounts of micronutrient (an overage) to account for any subsequent losses of fortificant during production, storage and distribution, thereby ensuring that the food meets at least the legal minimum at the relevant distribution point. When calculating overages, manufacturers should bear in mind any maximum levels that may also apply to the food at that same distribution point.

The regulatory limits (i.e. the minimum and maximum levels) represent the extremes of the total permitted micronutrient content of the fortified food at the point(s) in the distribution chain to which the regulation applies. Generally this is taken to be at the point of retail sale. Theoretically then, no individual food sample taken for testing from a retail outlet should have a micronutrient content outside of these boundaries. However, as explained elsewhere in these Guidelines, in some countries regulatory monitoring or enforcement policies may allow a small defined deviation or tolerance from the legal requirements as appropriate to the prevailing conditions (see Chapter 8).

11.3.1.4 Name of micronutrient

The term used to identify the added micronutrient can have significant ramifications for both manufacturers and those involved in related monitoring activities. Usually the generic name of the micronutrient, for example, "iodine", is used; this generally corresponds to that which is measured in laboratory analysis for monitoring purposes. However, most analytical methods employed in the food control system do not discriminate between naturally-occurring and fortificant forms of a micronutrient (a notable exception being folic acid).

Many commercial micronutrient fortificants contain other chemical entities that contribute to the molecular weight (MW) of the compound. For example, iodine is commercially available as potassium iodate (KIO_3, MW = 214), of which about 60% is iodine, or as potassium iodide (KI, MW = 166), of which about 76% is iodine. A regulatory requirement expressed as "mg/kg of [micronutrient name]", refers to the amount of micronutrient (i.e. iodine), not to the amount of the chemical compound (e.g. potassium iodate). This form of expression thus ensures that the same amount of the *actual* micronutrient is added, irrespective of the chemical composition of the fortificant compound used. For example, salt fortification with iodine at a level of 20 mg iodine/kg of salt (assuming a negligible natural content) requires the addition of about 34 mg of potassium iodate or about 26 mg of potassium iodide per kg of salt.

TABLE 11.1

Relationship between legal minimum and maximum levels for iron with regard to its relative bioavailability from selected fortificants

Mineral compound	Legal minimum level	Maximum level
Ferrous sulfate	Natural iron content + Minimum amount iron from ferrous sulfate	Natural iron content + Maximum amount iron from ferrous sulfate
Electrolytic iron[a]	Natural iron content + 2 × Minimum amount iron specified for ferrous sulfate	Natural iron content + 2 × Maximum amount iron specified for ferrous sulfate

[a] The bioavailability of iron from electrolytic iron is approximately half that of iron ferrous sulfate, so twice as much needs to added to deliver an equivalent amount of iron.

11.3.1.5 Permitted micronutrient compounds

Because commercially available fortificant compounds vary in their chemical composition and bioavailability, not all compounds are appropriate for use in all foods (see Part III). This gives rise to a number of options for regulators: regulations can either include a list of all the permitted micronutrient fortificant compounds (leaving the food manufacturer free to chose which particular compound to use), or it can permit the use of specific compounds in given categories of foods. Regulations can go further and stipulate the identity and purity requirements of the permitted compounds, or make reference to pharmacopoeias and other technical publications that set out such requirements.

For some micronutrients, most notably iron, significant differences in the bioavailability of the various iron-containing chemical compounds can affect the efficacy of fortification and thus the amount of fortificant that needs to be added (see section 5.1). **Table 11.1** shows how the legal minimum and maximum levels of total iron can be expressed in order to account for significant differences in the relative bioavailability of iron from the added fortificant compounds through the use of multiples of a reference amount. In this example, the minimum and maximum amounts for ferrous sulfate are given by the sum of naturally-occurring iron and iron that is contributed by the added ferrous sulfate. Regulatory amounts applicable to the second compound, electrolytic iron, are calculated assuming the same base amount of naturally-occurring iron but double the amount of iron from ferrous sulfate, iron being the more bioavailable from the latter.

11.3.2 Labelling and advertising

The purpose of a food labelling is to identify the food inside the package and to provide the consumer with information about the food and its appropriate

handling and use. Basic information such as product name; "use by" or "best before" date; storage instructions and directions for use; and ingredient list is as for all foods and is not discussed further in these Guidelines. In this context consideration may be given to the Codex General Standard for the Labelling of Pre-packaged Foods (*383*).

In the case of fortified foods, governments may establish regulations on labelling, claims and advertising requiring manufacturers to provide certain nutritional information to consumers. The usefulness and detail of such information will depend on the level of nutritional knowledge of target consumers, the assigned role of the label in fulfilling educational objectives of the fortification programme and the cost-effectiveness of this approach compared with alternative communication strategies.

11.3.2.1 Micronutrient declaration

How much qualitative or quantitative nutritional information, such as a standardized listing of the nutrient content of a fortified food, to include on the label (apart from any reference to the micronutrient in the name of the food such as "iodized" or "iron-enriched/fortified" or its declaration as a fortificant ingredient) is an important decision for regulators. Such decisions should be made in the context of the target population's nutritional knowledge and future nutrition education initiatives. For instance, symbols or pictorial presentations, rather than quantitative information, may be more efficacious among target populations with a high illiteracy rate and/or comparatively little knowledge of nutrition. The cost burden of providing nutritional information, initially borne by the manufacturer but subsequently passed to the consumer, is another factor to consider. Several Codex texts provide general guidance regarding labelling and claims and may be helpful to regulators; these are the Codex Guidelines on Nutrition Labelling (*342*) and the Codex Guidelines for Use of Nutrition Claims (*343*) (see also **Annex F**).

Quantitative micronutrient declaration requirements can pose a particular challenge to manufacturers and regulators because of the labile nature of some micronutrients with time. In many regulatory systems, the veracity of label information applies to the product at the point of sale; external monitoring for compliance also tends to occur at this stage. Specific mention of such matters is made in section 3.5 of the Codex Guidelines on Nutrition Labelling (*342*). Regulators may also wish to consider the need for "best before" dates on long shelf-life fortified foods, especially if the non-fortified versions are exempt from date marking (e.g. solid sugars or food grade salt). Stipulating a best-before date provides a means of linking the nutrient declaration to the shelf-life period.

11.3.2.2 Nutrition and health-related claims

Claims are statements that manufacturers voluntarily make to inform consumers about their products. Nutrition and health-related claims focus on the nutritional properties of the food, or its nutritional and, where permitted, health benefits for consumers. Nutrition and health claims are especially relevant to voluntarily fortified foods, and are discussed in more detail in the section on voluntary fortification (see section 11.4.2). Two issues are, however, specific to mandatory fortification. Although there is little incentive for manufacturers to voluntarily make nutrition and health-related claims about their products when all the foods in one category are fortified, if the mandatorily fortified food constitutes only a portion of the entire food category (e.g. table salt *vis a vis* all salt), then manufacturers may choose to make lawful claims about the nutritional properties and potential benefits of consumption of their fortified products. Under these circumstances, the issues for regulators are the same as for voluntary fortification (see section 11.4.2).

Secondly, some mandatorily fortified raw ingredients are used in the manufacture of highly-processed energy-rich foods. The processed foods themselves thus become fortified, albeit indirectly and to a lesser extent. Regulators might wish to consider whether any restrictions should be placed on the ability of indirectly fortified processed foods to bear nutrition and health-related claims that refer to, or are based on, the fortified nature of the product.

11.3.3 Trade considerations

Prescribing mandatory fortification requirements in regulation may impose trade restrictions on imported products, either because they are unfortified or they have been fortified differently. These trade restrictions may cause difficulties for a country's trading partners. Nevertheless, it is clear from WTO jurisprudence that not only do countries have the right to determine the level of health protection they deem to be appropriate – providing such measures do not *unnecessarily* restrict trade – but also the protection of human health is one of several legitimate objectives that countries can cite in justification of a trade restriction (see section 11.1) (*384*).

Such considerations aside, different fortification requirements between nations may well create some practical difficulties for intercountry trade. Nations in the same region, with similar public health nutrition problems and food cultures, may benefit from finding a common position on fortification policy and regulation that could be uniformally adopted. This would not only provide for intraregional trade and potential economies of scale, but also increase the leverage of the region, where necessary, to source an imported fortified product according to the region's particular specifications. Although, mandatorily fortified food moving in international trade can be imported not only by countries

with compatible mandatory fortification regulations but also by those countries whose voluntary fortification regulations accommodate the composition of the imported food, the product labelling may need to be modified so that it is nationally compliant. The need for labelling modification will depend on the flexibility of the labelling requirements of the importing country.

11.4 Voluntary fortification

Voluntary fortification occurs when a manufacturer freely chooses to fortify foods. It is practised widely in most industrialized countries and increasingly in developing countries. The extent to which a manufacturer's decision to fortify a food is voluntary and independent does, however, vary depending on the micronutrient and the prevailing sociopolitical and legal environment. In some cases, the impetus for voluntary fortification flows from government – in the form of incentives, collaborative arrangements or an expectation of cooperation with specific voluntary fortification permissions – often as a milder alternative to mandatory fortification. In several industrialized countries, the regulations governing the fortification of some basic commodities, such as salt and margarine, represent examples of this particular brand of voluntary fortification.

More commonly, voluntary fortification is driven by a desire on the part of industry and the consumer to increase micronutrient intake as a means of obtaining possible health benefits. Perhaps not surprisingly, commercial considerations are frequently decisive factors in the development of voluntarily fortified food products. Such products are promoted, through labelling and advertising, on the basis of their health and nutritional features.

The proliferation of fortified products that has occurred in recent years could have important implications for future micronutrient intakes and dietary habits. Most significantly, increased consumption of fortified products may result in intakes of certain micronutrients that pose potential risks to public health. Therefore, governments are advised to exercise an appropriate degree of control over voluntary fortification, either in the form of food regulation or through cooperative arrangements (e.g. a code of practice). The regulation of voluntary fortification should not only be consistent with overall regulatory objectives, but should also take account of the Codex General Principles for the Addition of Essential Nutrients to Foods (*385*) (see **Annex F**).

As in the case of mandatory fortification, there are several key issues that need addressing when developing regulations for voluntary fortification, in particular, issues which relate to the composition, labelling and advertising, and the trade of fortified products. These are discussed in greater detail below, but in essence are as follows:

- the range of foods suitable for fortification;
- the range and concentrations of micronutrients appropriate for different categories of foods;
- the mode of regulatory expression (i.e. whether there is a need for absolute limits or whether more flexible mechanisms for establishing compositional parameters would be more workable);
- the identity of, and purity specifications for, the listed fortificant compounds;
- controls on nutritional and health claims as well as advertising, and the appropriate level of detail of nutrition label information.

11.4.1 Composition

11.4.1.1 Range of foods

There is considerable debate and certainly no international consensus regarding the extent to which regulators should seek to minimize public health risks due to MNM, particularly in relation to the range of foods that are eligible for voluntary fortification. To date, the debate has centred on whether the choice of foods or food categories for voluntary fortification should be decided by governments, or left entirely to manufacturers, in which case the prevailing technological and/or commercial constraints – such as whether the fortificant adversely affects product characteristics or the cost is dissuasive or prohibitive – will largely determine which products are fortified and which are not.

One view is that, without some regulatory constraint, the proliferation and promotion of fortified foods has the potential to modify food choices and dietary behaviour in ways that are not commensurate with the maintenance of health and well-being. These concerns anticipate that the commercial promotion of voluntarily fortified foods would enhance their appeal to consumers who would expect to gain a health benefit from the consumption of such foods. Furthermore, if consumers responded regularly to such promotional activities, this could lead to dietary distortions in which fortified foods are favoured over naturally nutritious foods. It might also confound consumers' perception and understanding of the nutritional contribution of various foods to a healthful diet, and thus undermine efforts to educate them about the nutritional value of different foods and the importance of a varied diet for ensuring adequate intakes of essential nutrients. Collectively, these influences may have a detrimental effect on the quantity, quality and ratio of intakes of certain macronutrients, and thus constitute a long-term health risk for the population.

Of greater concern is the possibility that some promoted fortified foods will contain relatively high quantities of nutrients that are associated with negative health effects, in particular, total fat, saturated and trans-fatty acids, sodium or

salt, sugar(s) and alcohol. The foods most incriminated are those that nutrition policies often advise against regular consumption, such as confectionery, carbonated soft drinks, sugar-based beverages and desserts, high-salt and high-fat snacks and alcoholic beverages.

At present, the concern about the proliferation of fortified foods is largely based on predictions about future market evolution, which are supported by the observation that manufacturers often use the fact that a food is fortified as a promotional tool. Those who support a liberal approach to the regulation of voluntary fortification cite the lack of evidence from any industrialized country that has a well-developed nutrition education system for such an evolution and past experience with a liberal approach to the addition of micronutrients. According to manufacturers' data, voluntarily fortified foods currently represent 1–6% of the total food supply in such countries, a percentage that has remained stable in recent years. There is also little concrete evidence of any negative effect of fortified foods on the overall balance of population micronutrient intake. Such findings suggest that the key factors to consider when deciding the extent of permissions for voluntary fortification are the strength and sustainability of nutrition education programmes, the level of consumers' nutritional knowledge and the potential for consumer confusion.

The nutritional profile of candidate foods, in particular their content of total fat, saturated and trans-fatty acids, sugar(s), sodium or salt, is clearly one criteria that could be used to select appropriate foods for voluntary fortification. However, a flexible approach that also considers the nutritional merits of a candidate food will avoid the inadvertent exclusion of nutritionally valuable foods from potential fortification. When reviewing candidate foods with respect to their nutritional value, reference should be made to the recently published report of the Joint FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (*386*). However, it is recognized that final decisions about the suitability of foods for fortification will very much depend on the dietary profile and nutritional status of the population and so will vary from country to country. In contrast to the requirements for mandatory fortification (see section 11.3.1.1), the range of foods eligible for voluntary fortification can either be considered to be prohibited unless permitted (i.e. a positive list), or permitted unless prohibited (i.e. a negative list). If the risks to health from unsafe fortification are considerable, it is probably preferable to establish a positive rather than a negative list of foods.

11.4.1.2 The range of micronutrients and their specific chemical forms

A review of the balance between the public health significance and public health risk of individual micronutrients is generally considered to be a suitable basis for drawing up a list of micronutrients that would be appropriate to add to foods

through voluntary fortification. Globally, the micronutrients of greatest public health significance are iron, vitamin A and iodine. A number of other micronutrients also offer broad public health benefits or potential benefits to smaller population groups (see Chapter 4). There may be some micronutrients, however, whose addition to foods may not necessarily confer any further public health benefit because of the surfeit of that micronutrient in the existing food supply, in which case, fortification serves only to promote the "image" of the product. Some would argue that one micronutrient more or less would not have any significant impact on consumer perception of the product, and that therefore these micronutrients should be approved, providing there were no safety concerns.

Ideally, the public health risks of individual micronutrients should be assessed in terms of the magnitude of the difference between some measure of nutrient adequacy and an upper safe intake limit. In recent years, a number of scientific bodies have proposed various risk classification systems for micronutrients, many of which have much in common (*93*). For example, thiamine is commonly rated as low risk whereas selenium is rated as high risk. The classification of micronutrients as moderate to high risk does not preclude their regulatory approval, particularly as these same micronutrients may provide significant benefits; however, it does signal the need for their addition to foods to be carefully regulated. It may also be necessary to make provision for a small number of constituents, such as vanadium, whose status as essential nutrients is uncertain at the present time. In this regard, it should be noted that the definition of fortification given in the Codex General Principles for the Addition of Essential Nutrients to Foods (*385*) refers specifically to the addition of essential nutrients. The overriding consideration must, however, be to ensure the adequate nutritional balance of the diet.

Having decided on the range of approved micronutrients, regulators are advised to include these in regulation in the form of a restrictive list. Further refinements of the permissions or prohibitions on particular food-micronutrient combinations can then be developed from this primary list. A related restrictive list of particular micronutrient fortificant compounds (i.e. the vitamin preparations and mineral salts that are used as sources of vitamins and minerals), would also be required. Regulators should bear in mind that the potential range of foods that can be voluntarily fortified is large, and so too is the range of food production methods. Therefore, the list of approved chemical compounds will need to be as large as the basic criteria for selection (i.e. bioavailability, safety) will allow. Purity criteria for these compounds will also need to be stipulated. These can be developed at the national level but the task is arduous and resource intensive. Purity criteria have been set for most substances at the international level and so reference to texts such as the *Food Chemicals Codex* (*387*) and the *British pharmacopoeia* (*388*) could be made instead.

11.4.1.3 Legal minimum and maximum levels

There are two issues to be considered here: firstly, the setting of minimum and maximum levels and, secondly, the amount of food that will be used as a reference for these levels (i.e. mg per kg or per serving).

Minimum micronutrient levels should set such that fortification results in products that contain a meaningful amount of the micronutrient, that is to say, amounts that would be expected to contribute a benefit when that product was consumed in quantities that would normally be expected as part of an overall adequate and varied diet. An alternative approach, which provides greater flexibility for manufacturers (and also importers), is to establish *minimum claim criteria*). When deciding which is the more suitable approach, regulators should take into account the health benefits that are likely to be gained from voluntary fortification.

The setting of maximum levels is a more complex matter because of the necessity to simultaneously eliminate potential risks to public health from excess intakes of certain nutrients and to preserve the balance of the nutritional composition of the diet. Decisions about the appropriate maximum limits for micronutrients in foods eligible for voluntary fortification should be based on dietary intake assessments that take account of intakes from all dietary sources of the micronutrient under consideration, including that from unfortified foods and dietary supplements. However, this does not necessarily mean that maximum amounts need to be established for all micronutrients according to their risk profile: not only would this be difficult to do for the full range of micronutrients, but the risk of excess intake varies with the micronutrient and with the level of deficiency (and so will be different for different populations). Neither does it mean that the maximum amounts need to be set at the estimated highest safe level in each fortified food category. Allowance would need to be made for the applicability of the upper limits (particularly for the at-risk group), the assumptions made in the dietary assessment (e.g. that supplement use would not become more prevalent), and the magnitude of future intakes of micronutrients from fortified food.

A risk-based approach for setting maximum fortification limits is becoming more commonly accepted, particularly with the development of reference values for upper safe intakes, the approach followed by others is that officially recommended nutrient intakes, i.e. a population measure of dietary adequacy, variously abbreviated in different countries as the DRI, the RDI, the RNI or the DRV, are better guiding criteria. The reasoning behind the latter suggestion stems from acknowledgement of the absence of need for higher intakes and greater compatibility with the amounts of micronutrients found naturally in foods.

It is apparent from the preceding discussion that it would be unwise to allow the addition of those micronutrients that have a narrow margin of safety in significant quantities to all or even a wide range of foods. Therefore, the range of foods to which they may be added should be prioritized or restricted in some way; this can be done on the basis of their nature and importance in the diet of the general population or of certain population groups. Regulators who administer systems in which the foods are restrictively listed and may be incrementally approved through petition should give consideration ahead of time, if possible, to the most appropriate food sources of these micronutrients.

Maximum levels can be established in regulation either for all added micronutrients, or just for those micronutrients that are associated with a known risk, according to the level of risk. As in the case of minimum levels, the concept of *maximum claim levels* may be advantageous. The rationale behind the use of maximum claims is that they allow regulators to set restrictions on the maximum micronutrient levels that are proportionate to the level of risk and, in the absence of a tolerance system, they allow manufacturers (and particularly importers) more latitude in deciding the micronutrient composition of foods lawfully offered for sale. However, for domestic manufacturers, commercial reality also imposes its own constraints in that the manufacturer gains no market advantage by adding considerably more fortificant than the amount that can be claimed.

As indicated above, the quantitative basis for setting minimum and maximum micronutrient levels is a very important consideration. There are three possibilities that would uniformly apply to all eligible foods. These are:

— maximum concentration per unit weight or volume (e.g. per 100 g or ml);

— maximum micronutrient density per unit energy (i.e. per 100 kcal or kJ);

— maximum quantity per nominated serving or reference quantity (e.g. g or ml per serving).

The use of weight- or energy-based criteria requires making assumptions about respective amounts of solids and liquids, or energy ingested by an average consumer in one day. Since these are likely to be broadly similar across national populations, the potential exists for agreement at the regional or international level, providing the basic approach is acceptable. On the down side, both the weight- and energy-based criteria would cause some products to be unduly favoured or penalized (e.g. energy-rich or low-energy foods, foods used in small quantities) so that exceptions would need to be made accordingly. The per serving basis has the attraction of being more relevant for consumers, especially if the label nutrient declaration is made on the same basis. However, it necessitates agreement on the serving size, which is more likely to vary among countries according to cultural food patterns. Agreement on serving size would thus

be more difficult to reach at an international level, and therefore setting levels on this basis would be more likely to create problems for international trade.

11.4.2 Labelling and advertising

As previously mentioned, claims regarding the nutritional properties of fortified food, or its nutritional and, where permitted, health benefits for consumers are frequently made by manufacturers as a means of promoting their products; this is particularly true of voluntarily fortified foods. Examples of nutritional property claims are those which refer to a food "containing" or being a "source" or "high source" of a particular nutrient and those which compare the nutrient content of a food with one or more foods. Health-related claims include nutrient function and reduction of disease risk claims, i.e. they refer to the relationship between a nutrient (or a special ingredient contained in the food) and normal physiological functions of the body or to the reduction in risk of a disease, including nutrient deficiency diseases.

11.4.2.1 Nutrition and health-related claims

Appropriate regulation of claims ensures that the information manufacturers convey to consumers about their products is truthful and not misleading.

The Codex Guidelines for Use of Nutrition Claims (*343*) provides guidance to governments on the conditions for nutrition and health-related claims and establishes the general principle that these claims should be consistent with and support national nutrition policy. At the time of writing, conditions for the use of health claims are under discussion. Regulating claims about the reduction of risk of disease is an especially challenging task and should be tackled with extreme caution. Regulators should bear in mind that anything less than a case-by-case assessment and detailed evaluation of adequately substantiated requests from manufacturers to use disease reduction claims would need to be carefully considered.

The Codex Guidelines for Use of Nutrition Claims (*343*) recommend that claims should be substantiated by generally acceptable scientific data, although the meaning of "generally acceptable scientific data" can give rise to different interpretations. A list of health claims that are considered to be well established and generally acceptable would be a useful tool both for the responsible manufacturer and for food controlling authorities. Ideally, a procedure that allows updates to be made within an agreed time frame should be integral to such a list.

As an alternative to a list of approved health claims, nutrition and health-related claims may be controlled by setting qualifying and disqualifying criteria that are based on other aspects of the food. Currently-held views on this topic have much in common with those previously described in relation to the range

of candidate foods for voluntary fortification. Although it is reasonable to expect that all eligible voluntarily fortified foods should also be eligible to carry nutrition and health-related claims, this approach may introduce discrepancies between the criteria that apply to fortified foods and those that apply to unfortified foods, particularly if foods not permitted direct fortification are made from fortified ingredients. It is therefore useful to consider whether the qualifying criteria for claims for fortified foods should differ from those that would apply to unfortified foods (whose claims are based on a natural micronutrient content), and if so, on what basis.

11.4.2.2 Micronutrient declaration

Because of the positive perception of fortification by the consumer, manufacturers usually wish to promote this aspect of their products by making nutrient content and/or other related claims about their product. This generally triggers nutrition labelling of the food. Even in the absence of a claim, manufacturers may choose to declare micronutrient contents in nutrition labelling.

Provision of (usually quantitative) information about nutrient contents is normally required under the rules on nutrition labelling; this coupled with information about the micronutrient(s) with which the product is fortified, would be a minimum requirement. For those consumers who read and understand nutrition labelling, the declaration of the fortificant micronutrient content in the nutrition information panel could potentially enhance the "image" of the food. It should therefore be considered whether more comprehensive nutrition information should be given for fortified foods in order to provide more balanced information about the product.

The Codex Guidelines on Nutrition Labelling (*342*) provides guidance to governments on nutrition labelling.

11.4.2.3 Other relevant considerations

The labelling and advertising of fortified products should not attribute to them undue nutritional merits. It should also avoid conveying the impression that a normal balanced and varied diet would not provide adequate quantities of nutrients, although regulations should allow for the possibility of scientifically substantiated exceptions to this. Allowing additional advice on the need for a balanced diet is an another option to consider.

11.4.3 Trade considerations

Voluntary fortification regulation, despite being less restrictive than that governing mandatory fortification, may nevertheless limit trade in fortified foods between countries, particularly in cases where the micronutrient concentrations

of fortified foods do not conform to the regulatory provisions of the importing country, or where fortification of a food category is not permitted or is prohibited in the importing country. Different labelling regulations, including those governing nutrition labelling and claims, may mean that product labels would have to be adapted to local requirements. If a common language exists, for reasons of cost and efficiency, it would be preferable to harmonize regional regulations. This would bring the added bonus of minimizing such impediments to trade.