FORTIFICATION OF FLOUR WITH IRON

BASED ON A JOINT WHO / UNICEF / MI STRATEGIC DEVELOPMENT WORKSHOP ON FOOD FORTIFICATION WITH SPECIAL REFERENCE TO IRON FORTIFICATION OF FLOUR, HELD IN MUSCAT, OMAN, 26 - 30 OCTOBER 1996

IN COUNTRIES OF THE EASTERN MEDITERRANEAN MIDDLE EAST AND NORTH AFRICA

WORLD HEALTH ORGANIZATION
UNITED NATIONS CHILDREN'S FUND
THE MICRONUTRIENT INITIATIVE
FORTIFICATION OF FLOUR WITH IRON IN COUNTRIES OF THE EASTERN MEDITERRANEAN MIDDLE EAST AND NORTH AFRICA

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This document is based on the deliberations of the Joint World Health Organization/UNICEF/Micronutrient Initiative Strategic Development Workshop on Food Fortification with Special Reference to Iron Fortification of Flour, which was held in Muscat, Oman, from 26 to 30 October 1996

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Foreword

Iron deficiency anaemia is a serious public health problem in all countries of the Eastern Mediterranean Region of the World Health Organization (WHO) and the Middle East and North Africa Region of the United Nations Children's Fund (UNICEF), and can have a profound effect on psychological and physical development, behaviour and work performance. It is the most common nutritional disorder, both in the Region and in the world as a whole.

Iron-deficient individuals are significantly less productive than those with normal haemoglobin levels. Even mild anaemia can decrease performance in physical labour. An impaired work capacity results in a reduced ability to care for the family, reduced productivity and reduced income. Anaemia in pregnant women can lead to intraterine growth retardation, low birth weight, increased perinatal mortality and increased maternal morbidity and mortality. Morbidity from infectious diseases is increased in iron-deficient populations because the immune system is adversely affected. This is compounded by vitamin A deficiency, even in a subclinical form. Last, but not least, iron deficiency negatively affects cognitive behaviour and learning capacity. It is estimated that iron deficiency may result in as much as a 10-point reduction in a child's potential intelligence quotient (IQ), although this must be seen in light of other nutritional deficiencies prevalent in the Region which also have a negative effect on learning capacity, notably iodine deficiency.

Iron deficiency is a function of the body's requirements, losses from the body and dietary intake. The total dietary iron intake in the Region is generally below recommended levels. This situation is made even worse by the high consumption of foods rich in iron-absorption inhibiting factors, such as tea and unleavened bread. In addition to dietary factors, childbearing patterns, parasitic infections and consanguinity contribute to the high prevalence of iron deficiency anaemia in the Region.

Most countries in the Region have programmes that aim at routine supplementation of pregnant women with iron/folate tablets. However, it is clear from the persistently high prevalence of anaemia that no real improvements have been achieved to date.

In view of the persistence of the problem and the lack of real progress in reaching the target of a reduction of 1990 anaemia levels by 30% agreed at the World Summit for Children (1990) and the International Conference on Nutrition (1992), WHO and UNICEF called a consultation of experts, in October 1995, to develop effective strategies for the control of iron deficiency which would be suitable for countries in the Region.

The consultation recommended that such strategies should address improvement of iron intake, enhanced absorption of the iron consumed and
reduction of iron losses. The strategies agreed upon were dietary measures, including changing eating behaviour, iron supplementation of vulnerable groups, food fortification and public health measures. Based on these strategies, the consultation developed guidelines for iron deficiency control programmes, with priorities for intervention in different socioeconomic settings. These guidelines have been published as a WHO/UNICEF document, Guidelines for the control of iron deficiency in countries of the Eastern Mediterranean, Middle East and North Africa.

The consultation recognized that fortification of suitable foodstuffs, notably flour, had been the single most effective means of improving iron intake in industrialized countries and recommended that countries explore the feasibility of flour fortification as a long-term strategy.

WHO, UNICEF and the Micronutrient Initiative (MI) decided therefore to organize a workshop to share the experiences already gained in countries within and outside the Region and to address the issues involved in food fortification, ranging from the practical details at the technical level to the broader issues of legislation, monitoring and evaluation.

The present document is based on the deliberations and decisions of the workshop and should assist all countries in the Region in the fortification of flour with iron, and possibly with other important micronutrients such as zinc and folic acid. It addresses many important issues in flour fortification with iron, such as mandatory versus voluntary fortification, legislation and standards, technical issues and monitoring and evaluation, and gives Region-specific options and solutions based on the deliberations of the workshop and the consensus reached by the participants.

We expect that this document will be an important guide for countries in the Region in their endeavours to reduce the burden of iron deficiency and anaemia.

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Executive summary

Introduction

A joint WHO/UNICEF/MI Strategy Development Workshop on Food Fortification with Special Reference to Iron Fortification of Flour was held in Muscat, Oman from 26 to 31 October 1996. Representatives from ministries of health, the milling industry, bureaus of standards and ministries of commerce from 11 countries in the Region\(^1\) participated in the workshop.

The general objective of the workshop was to achieve effective food fortification with essential micronutrients, especially iron, by the year 2000 in countries in the Region.

The specific objectives were:

- to develop the capacity for effective food fortification at the national level, including technical know-how, legislation, monitoring and evaluation mechanisms
- to develop a regional support mechanism for follow-up of food fortification in terms of technical expertise, exchange of experiences, standards and legislation and quality control
- to establish a working relationship between the public and private sectors and the consumers in the area of food fortification.

The following is a summary of the decisions taken and actions proposed by the participants to combat iron deficiency anaemia in the Region.

Iron deficiency anaemia

Anaemia, largely due to inadequate intakes of iron, is a major problem in all countries in the Region. The prevalence of anaemia is highest in women and children. Anaemia in children impairs both physical and mental development. Anaemia in pregnancy contributes to maternal mortality and poor pregnancy outcome. In most countries in the Region the prevalence of anaemia in women and children was reported to be moderate or severe.

Participants noted that all of their countries had accepted that the high prevalence of anaemia in their populations was unacceptable, and through various international agreements, for example at the World Summit for Children and the International Conference on Nutrition, had made the commitment to improve the situation.

Micronutrient fortification of food is an effective strategy for improving nutrition. In particular, the fortification of wheat flour with iron

\(^{1}\) The Region refers to the countries of the Eastern Mediterranean Region of WHO and countries of the Middle East and North Africa Region of UNICEF, many of which are the same (Annex 3).
considerably reduce the problem of anaemia in women and children throughout the Region.

**Flour fortification**

Wheat flour has been fortified with iron in many industrialized countries including the United States of America (USA), Canada and the United Kingdom (UK) for over 40 years and has contributed to a reduction in anaemia in these countries. Recent experiences in Latin America suggest that reductions in the prevalence of anaemia are detectable within two years of the introduction of an iron fortification programme.

Wheat is the main staple food consumed in all countries in the Region. It is milled into flour and consumed in the form of bread. Fortification of wheat flour will be simple and cheap in most countries in the Region and will be a major strategy for preventing anaemia. Salt iodization has already been proven to be feasible throughout the Region and provides a model for flour fortification.

Wheat flour is already being fortified with iron in Saudi Arabia and in parts of Egypt and the Islamic Republic of Iran. Wheat flour has been fortified with iron in the past in Oman and Bahrain, and the process will shortly be reintroduced in these countries. Other countries will start to develop plans for the introduction of fortification of wheat flour with iron.

In most countries in the Region, there are large wheat mills, although in Egypt, Morocco and the Islamic Republic of Iran there are also many relatively small mills.

It was agreed that successful iron fortification programmes will be best developed through close cooperation between the milling industry and the government and the involvement of community organizations and consumers, including, for example, women's associations. The scientific community also needs to be involved in the programme from the very start.

**Fortificants**

It was agreed that the compound of choice for the fortification of wheat flour would be ferrous sulfate added at the rate of 30 parts of iron per million parts (ppm) of wheat flour. Where flour is required to be stored for long periods, millers could alternatively use elemental iron at the rate of 60 ppm. In most countries in the Region the technology for adding iron to wheat flour already exists in the flour mills. The growing recognition of the importance of folic acid in preventing birth defects was also noted, and many countries indicated that they would consider adding folic acid to wheat flour in addition to iron. This could be done at little extra cost. While there was also interest in the potential of adding vitamin A to wheat flour, some countries concluded
that edible oils were a better vehicle for this vitamin, and that there were at present insufficient data on the stability of vitamin A during prolonged storage of flour and baking of bread.

Participants called for detailed specifications of ferrous sulfate used in fortification, such as particle size and colour and for better data on shelf-life and cooking properties of products fortified with ferrous sulfate.

The additional cost associated with an iron fortification programme was estimated to be about US$ 0.03 per person per year (US$ 2.00 per person per lifetime) but the economic benefits from improved productivity per lifetime in the Region were estimated to be at least US$ 15 000 per person per lifetime.

**Country action**

Jordan, Morocco, Syrian Arab Republic and Tunisia agreed that national committees would be established to examine the issue of iron fortification and draw up plans of action.

Egypt reported that wheat flour (82% extraction) had already been fortified with ferrous sulfate (30 ppm) on a trial basis, and that fortification did not change the appearance or taste of bread and was totally acceptable to consumers. Fortification of all 82% extraction wheat flour in Egypt was now planned, starting with Fayoum Governorate in early 1997.

The Islamic Republic of Iran stated that a pilot programme to fortify wheat flour with iron had started in Isfahan in August 1996. Based on the results of this study, the Government said it would consider fortifying all wheat flour. It wished to obtain more data on the possible interaction between iron and zinc in the diet, as there was evidence of low zinc intake in the population. In addition, the Government wished to obtain more information on the effectiveness of fortification of high phytate, high extraction wheat flour. It was also interested in examining the potential of adding EDTA (ethylenediaminetetraacetate) to enhance mineral absorption in high extraction flour.

Lebanon plans to carry out an analysis of the situation of iron deficiency anaemia and to set up a national committee to advise on the steps needed to introduce fortification. There were concerns in the country about possible negative effects of iron fortification, and it was stated that an international consensus on safety of iron fortification would be useful.

In Bahrain, Kuwait and Saudi Arabia, about 80% of the population consumes white flour (76% extraction). All these countries will establish a multisectoral fortification task force to draw up plans, establish standards and oversee the introduction of appropriate fortification programmes.

In Oman, the standard relating to wheat flour will be updated to include a requirement that it should contain a minimum additional quantity of 30 ppm iron and 1.5 ppm folic acid. Legislation requiring fortification will be passed.
Quality control measures, advocacy and social mobilization will be undertaken. The programme will be evaluated after 3 years. The possibility of adding vitamin A and other micronutrients to other food vehicles will be actively pursued and a plan of action developed.

General recommendations

- In the context of bilateral or multilateral food aid, Governments should insist on receiving only enriched food commodities which meet their national standards.
- Governments should regulate both the manufacture and importation of food products which have been identified to require fortification.
- Mechanisms for assuring the quality of fortification and enforcing regulations should be developed at the start of the programme.
- Comprehensive programmes to reduce iron deficiency anaemia are required, which include dietary improvement and education, public health measures and supplementation for vulnerable groups in addition to fortification.
- WHO, UNICEF, MI and other organizations should collaborate to develop simple fact sheets providing scientific information on iron deficiency, the importance of folic acid, the potential of fortification and the mechanisms of iron absorption, which could be used for advocacy and increasing political awareness.
- A rapid test kit (spot test) which can be used to identify the presence of iron in wheat flour or bread will be developed by the MI in collaboration with others.
- Further development work is needed on ways that small wheat mills (those producing less than 100 tonnes per day) can fortify their flour.
- WHO and UNICEF should bring the importance of fortification to the attention of the WHO and UNICEF regional forums. Food fortification should be the subject of a technical paper in the next WHO Regional Committee.
- A regional follow-up meeting on food fortification to review progress should be held.
1. Introduction

A joint WHO/UNICEF/MI Strategy Development Workshop on Food Fortification with Special Reference to Iron Fortification of Flour was held in Muscat, Oman from 26 to 31 October 1996. Representatives from ministries of health, the milling industry, bureaus of standards and ministries of commerce from 11 countries in the Region participated in the workshop. The programme of the workshop and the list of participants are given in Annexes 3 and 4.

The general objective of the workshop was:

- to achieve effective food fortification with essential micronutrients, especially iron, by the year 2000 in countries in the Region.

The specific objectives were:

- to develop the capacity for effective food fortification at the national level, including technical know-how, legislation, monitoring and evaluation mechanisms

- to develop a regional support mechanism for follow-up of food fortification in terms of technical expertise, exchange of experiences, standards and legislation and quality control

- to establish a working relationship between the public and private sectors and the consumers in the area of food fortification.

2. Regional situation

2.1 Introduction

A list of the countries in the Eastern Mediterranean Region of WHO and the countries in the Middle East and North Africa Region of UNICEF is given in Annex 5. They can be roughly grouped into three categories according to their gross national product (GNP) per capita. Over the years, the Region has experienced an economic slow-down whereby the average GNP per capita in 1991 was only 73% of that in 1983. The slow-down has been aggravated by global recession, population growth and the difficult situation and instability in some countries in the Region.

Nutrition problems in the Region can be divided into deficiency diseases and diet-related noncommunicable diseases. Both exist side by side in many countries.

Protein energy malnutrition (PEM) affects from 12% to 60% of children under the age of 5 years in different countries. Most of this is seen as growth failure, but acute malnutrition is found in countries facing emergencies. Iodine deficiency is a major problem in 14 countries in the Region. The prevalence of goitre ranges from moderate to as high as 80%, illustrating the need for urgent
action. In recent years, salt iodization has become the strategy of choice in the
countries affected, many of which have reached universal salt iodization. Iron
deficiency anaemia affects between 30% and 60% of women of childbearing age
and young children in all countries in the Region. Vitamin A deficiency is a
problem in some of the poorer countries, while Vitamin C deficiency is seen
among displaced populations. Vitamin D deficiency is still prevalent but often
unrecognized as a problem.

Diet-related noncommunicable diseases are on the increase in many
countries. A high prevalence of obesity, affecting up to half of the adult female
population, increased incidence of type II diabetes and increased morbidity
and mortality from cardiovascular diseases have been reported, especially in
high income countries but increasingly also in the middle and lower income
group.

2.2 Regional status of iron deficiency anaemia control

The regional goal for iron deficiency anaemia control is to reduce the
prevalence of iron deficiency anaemia in the Region from 1990 levels by one-
third. At present, in all countries in the Region, anaemia prevalence is
moderate to severe by WHO criteria (see Figures 2.1 and 2.2 for prevalences
among preschool children and women of childbearing age and/or pregnant;
Annex 1 has details by country).

Current control activities are aimed mainly at pregnant women, while
infants and young children, schoolchildren and adolescents are important
target groups not reached by present programmes.

The main causes of iron deficiency in the Region are:

- low total iron intake
- low bioavailability of the iron consumed
- high intake of inhibitors
- low intake of enhancers
- high birth rates/short birth intervals
- parasitic infestations.

There is a need for action based on a combination of strategies appropriate
to the Region, i.e.:

- effective supplementation programmes
- effective public education to achieve appropriate dietary modifications
- promotion of breast-feeding and adequate complementary feeding
- control of parasitic infections
- family planning for health
- fortification of suitable foods.
Figure 2.1 Reported prevalences of anaemia in preschool children in selected countries of the WHO Eastern Mediterranean Region

Figure 2.2 Reported prevalences of anaemia in women of childbearing age and/or pregnant in selected countries of the WHO Eastern Mediterranean Region
3. Iron deficiency and anaemia: an overview\(^1\)

3.1 Anaemia epidemiology

Nutritional anaemia refers to a condition in which the haemoglobin content of the blood is lower than normal as a result of a deficiency of one or more essential nutrients (usually iron, less frequently folate or vitamin B12), regardless of the cause of such deficiency. There are no sharp cut-off points below which anaemia can be stated as present. However, standards below which anaemia is likely to be present at sea level have been set out by WHO and are presented in Table 3.1. Anaemia is diagnosed by haemoglobin concentration. This is however a relatively insensitive index of milder degrees of nutrient depletion. By the time anaemia is diagnosed, the person in question is already suffering from a marked degree of nutrient deficiency. Since there are multiple causes of anaemia, and since iron deficiency can exist without haemoglobin levels being lowered, there are potentially four different situations or populations:

1. those iron anaemic and iron deficient
2. those iron deficient but not (yet) anaemic
3. those anaemic but not due to iron deficiency
4. those iron replete with normal haemoglobin.

Causes of anaemia other than nutrient deficiency include malaria, intestinal parasites and genetically determined haemoglobinopathies such as thalassaemia. It is generally held that at least half of the anaemia worldwide is due to nutritional iron deficiency, and that subclinical iron deficiency, also related to functional disadvantages, is as widespread as iron deficiency with anaemia. Therefore, anaemia prevalence can generally be taken as an indicator of the extent and trends of iron deficiency.

Subjects affected by anaemia are, in approximate descending order of severity, pregnant women, preschool children, low-birth-weight infants, other women, the elderly, school-age children and men.

On a population level, anaemia prevalence can be distinguished as mild, moderate or severe. Appropriate epidemiological criteria are presented in Table 3.2.

\(^1\) This section is extracted from Guidelines for the control of iron deficiency in countries of the Eastern Mediterranean, Middle East and North Africa (WHO/UNICEF, 1997).
Table 3.1 Haemoglobin levels indicative of anaemia in populations living at sea level

<table>
<thead>
<tr>
<th>Age/sex group</th>
<th>Haemoglobin level (g/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 6 months-5 years</td>
<td>&lt; 11</td>
</tr>
<tr>
<td>Children 6-14 years</td>
<td>&lt; 12</td>
</tr>
<tr>
<td>Adult males</td>
<td>&lt; 13</td>
</tr>
<tr>
<td>Adult females (non-pregnant)</td>
<td>&lt; 12</td>
</tr>
<tr>
<td>Adult females (pregnant)</td>
<td>&lt; 11</td>
</tr>
</tbody>
</table>

Table 3.2 Epidemiological criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Prevalence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severe</td>
</tr>
<tr>
<td>Mild/moderate anaemia or 25% &lt; haematocrit &lt;33%</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Severe anaemia (Haemoglobin &lt; 7 g/dl) or haematocrit &lt; 24.9%</td>
<td>&gt;10</td>
</tr>
</tbody>
</table>

According to WHO criteria; see Table 3.1

### 3.2 Etiology

Body iron can be considered as having two main components, functional iron and storage iron. The functional component is found largely in the circulating haemoglobin (and a smaller quantity in body tissue, myoglobin and enzymes). A deficiency of iron in the functional component does not ordinarily occur until stores are completely exhausted. The storage component, found as ferritin and haemosiderin in liver, spleen and bone marrow, serves as a reserve source for the functional component.

The diminishing of iron stores results from an imbalance between iron absorption and the body’s needs. Such an imbalance can generally arise from low dietary iron intake, poor absorption/utilization of ingested iron or increased demand. Demand is increased in case of growth, blood loss related to menstruation, childbirth and chronic parasitic infections such as malaria, hookworm infestation and schistosomiasis. Figure 3.1 gives a schematic overview of causality of iron deficiency and anaemia.
3.3 Dietary iron requirements

A dietary intake of iron is needed to replace iron lost in the stools and urine and through the skin. These basal losses represent approximately 0.9 mg of iron per day for an adult male and 0.8 mg per day for an adult female. For
women of reproductive age, the extra iron losses in menstrual blood must be taken into consideration. When basal losses are added, the total iron loss for menstruating women is about 1.25 mg per day.

Although menstruation-related losses are reduced to nil during pregnancy, additional iron is nevertheless required for the fetus, the placenta and the increased maternal blood volume. This amounts to approximately 1000 mg of iron over the entire pregnancy. Requirements per day during pregnancy rise from 0.8 mg per day in the first trimester to a high of 6.3 mg per day in the third trimester.

Infants, children and adolescents require iron for their expanding red cell mass and growing body tissue. Overall, the requirements for infants and children are substantially lower than in adults. But since they have lower total energy requirements than adults, they eat less and are thus at greater risk of developing iron deficiency, especially if their dietary iron is of low bioavailability.

### 3.4 Iron sources, bioavailability, enhancers and inhibitors

Dietary iron may be considered as being composed of two distinct pools, haem iron and non-haem iron. Haem iron is highly available (20% to 30% absorbed) and is found in meat. Non-haem iron is found in cereals, pulses, fruits, vegetables and dairy products and comprises the major source of dietary iron. Absorption of non-haem iron is highly variable, depending on enhancing and inhibiting factors. Figures of 1%-20% absorption have been found in various studies of mixed diets, although figures of over 50% have been quoted where the iron was mainly from animal sources.

Factors known to stimulate absorption (bioavailability) of non-haem iron are the presence of meat, poultry, seafood and various organic acids, particularly ascorbic acid (vitamin C). Important iron absorption inhibitors are polyphenols, including tannins, phytate, certain forms of protein and some forms of dietary fibre. Foods that contain these factors and therefore have a strong inhibiting effect on iron absorption include tea, coffee, egg yolk and bran (Figure 3.2).

In addition to the nutritional interactions, non-haem iron absorption is significantly affected by an individual’s iron status. Absorption decreases when iron stores increase and conversely a decrease in body iron stores is associated with an increase in absorption.
3.5 Consequences of iron deficiency and anaemia

Iron deficiency and anaemia have repercussions on working capacity, intellectual performance and pregnancy. Studies have shown the direct relationship between haemoglobin levels and the ability to perform physical exercise. The productivity of iron-deficient individuals is significantly less than that of workers with normal haemoglobin levels. After supplementation with iron, the performance of iron-deficient subjects improved most in those with the lowest initial haemoglobin levels. Studies indicate that even mild anaemia can decrease performance in exercise. Impaired work capacity results in adverse effects on productivity, earnings and the ability to care for children in the home.

Maternal anaemia results in intrauterine growth retardation, low birth weight, increased perinatal mortality and increased maternal morbidity and mortality. In developing countries, severe anaemia is the main causal factor in up to 20% of maternal deaths. Morbidity from infectious diseases is increased in iron-deficient populations because the immune system is adversely affected. Iron supplementation of deficient children and fortification of their milk or cereal reduces morbidity from infectious diseases. In addition, iron-deficient children are particularly vulnerable to lead poisoning, as lead has a high affinity for haemoglobin.

Anaemia is associated with less than optimal behaviour in infants and children. Iron-deficient children scored lower on tests of development, cognition, learning and school achievement. The impairment of performance
has been put at 5–10 points deficiency in IQ. Studies of infants have shown conclusively that iron deficiency anaemia delays psychomotor development and impairs cognitive development. This negative impact in children is not likely to be reversed by subsequent iron therapy. The effects of iron deficiency anaemia in early childhood were observed in Egyptian children; children who suffered anaemia in childhood had lower IQ scores at school-entry than children who were formerly non-anaemic. A study among Canadian children suggests that there is a negative impact on psychomotor development even when comparing non-anaemic iron-deficient children and controls.

Since the technological advancement and economic development of a nation depend heavily on its trained human resources, the behavioural effects of anaemia are highly relevant. Consequently, if anaemia is highly prevalent in a country's children, it can substantially affect its intellectual and economic potential.

4. Strategies for the prevention and control of iron deficiency and anaemia

The four basic approaches to the prevention and control of iron deficiency and its anaemia are:

- dietary change and diversification to increase iron intake
- supplementation with medical iron, most often iron tablets
- fortification of a suitable staple food with iron
- public health activities, such as the control of infection including parasitic infestations and family planning.

Table 4.1 shows the role of each strategy in improving dietary iron intake, increasing the bioavailability of the iron ingested and reducing iron losses.

National programmes should consider these approaches within the context of their health and development policies in an integrated and dynamic fashion. None of these strategies is exclusive of the others, rather they are complementary. The different strategies have been extensively described in Guidelines for the control of iron deficiency in countries of the Eastern Mediterranean, Middle East and North Africa (WHO/UNICEF, 1997), which was the outcome of a consultation on iron deficiency held in 1995 and which proposed the exploration of the modalities of flour fortification in selected countries in the Region. The strategies are also discussed in Major issues in controlling iron deficiency (MI/UNICEF, 1998).

In the present document, therefore, the emphasis will be on the fortification of foods with iron, with particular reference to flour fortification.
Table 4.1 Role of the four main strategies for control of iron deficiency in improving iron intake and increasing bioavailability of the iron ingested

<table>
<thead>
<tr>
<th>Aim</th>
<th>Supplementation</th>
<th>Fortification</th>
<th>Dietary diversification</th>
<th>Public health measures</th>
</tr>
</thead>
</table>
| Increased iron intake            | Iron to be given to select target groups:  
- pregnant women  
- preschool children  
- women of childbearing age  
- others, such as school-age children | Highly effective provided food(s) selected is widely consumed especially by women, children and adolescents | Education to increase intake of iron-rich foods is important. Major problems are expense and the difficulty of providing enough dietary iron to infants/children | Measures to improve appetite may be of use |
| Increased bioavailability of iron ingested | Not useful | Not useful | Need for:  
- increased consumption of foods rich in vitamin C together with iron-containing foods  
- food processing methodologies that reduce the effect of inhibitors of iron absorption, e.g. fermentation, germination, use of yeast  
- education  
- food pricing policies | Not useful |
| Reduction of iron losses         | Not useful | Not useful | Not useful | Measures that will reduce iron losses are:  
- improved water supply and sanitation  
- improved personal hygiene  
- regular deworming of (school-aged) children  
- family planning for health  
- disease control |
5. Food fortification

5.1 Introduction

Recognizing that food fortification is a cost-effective strategy for addressing micronutrient deficiencies, fortification of flour with iron is recommended as the primary strategy for most countries in the Region for reducing iron deficiency anaemia. Fortification is just one of four strategies, however, and must be used in conjunction with the others, supplementation, dietary diversification and public health measures such as promoting breast-feeding and controlling parasitic infestations.

In addition to the general fortification criteria, with iron fortification the following specific considerations must be taken into account:

- The vehicle should be a component of all meals because absorption varies inversely with the iron content of the meal.
- Food vehicles that are dark in colour or have a strong taste or odour permit the use of more reactive iron compounds.
- It should be ensured that iron does not separate out during mixing or storage.
- Ideally the vehicle should not require prolonged storage particularly under hot and humid climatic conditions since this could cause organoleptic problems.

5.2 Choosing the food vehicle(s): wheat flour as the vehicle of choice in the Region

Common food vehicles used around the world for iron fortification include processed cereals (such as wheat and corn), salt, sugar, condiments and other processed foods. Wheat flour represents perhaps the most appropriate vehicle for fortification in the Region because it meets the classical considerations for food vehicle choice. In this Region, wheat flour is:

- widely consumed in the form of bread and is affordable to groups vulnerable to iron deficiency anaemia;
- generally processed in a few large mills in most countries, with a few exceptions where there are numerous small flour producers;
- distributed through widespread networks that reach all regions of any given country;
- not subject to colour, taste or appearance change when fortified with the appropriate fortificant;
- not subject to nutrient loss on further processing into bread or cooking;
consumed in fairly constant amounts so that fortification levels can be calculated accurately (250-280 g per day, 80% white flour and 20% brown flour).

In its natural state, wheat is a good source of vitamin B1 (thiamin), vitamin B2 (riboflavin), niacin, vitamin B6 (pyridoxine), vitamin E, as well as iron and zinc. However, since most of these nutrients are concentrated in the outer layers of the wheat grain, a significant proportion is lost during the milling process. The lower the extraction rate of the flour (i.e. the more the refining), the greater the loss of vitamins and minerals.

In industrialized countries, wheat flour is generally fortified with vitamin B1, vitamin B2, niacin and iron. In some countries, calcium and folate are also added. Vitamin A and vitamin D can also be added to flour.

The technology of flour fortification is simple. A premix of the micronutrients to be added is prepared or procured. The premix is then added to the flour at a uniform rate through a volumetric screw feeder located towards the end of the milling process. The premix can be fed directly on to the flour by gravity or by air convection using a pneumatic system.

5.3 Choosing the fortificant: ferrous sulfate/elemental iron as the fortificants of choice in the Region

Numerous fortificants are available for iron fortification. The biggest challenge is to identify a form of iron that is adequately absorbed, i.e. bioavailable, yet stable and does not alter the appearance or taste of the food vehicle. The two principal groups of iron fortificant compounds are the haem iron compounds and non-haem compounds. Haem iron is not affected by inhibitory compounds in vegetable foods and, thus, is bioavailable; however, it causes colour and taste changes. As a result, it is not a suitable fortificant for many products, including flour.

The non-haem sources that have had widespread use in fortification include iron-EDTA, ferrous sulfate, elemental iron (reduced iron), ferric orthophosphate, ferrous fumarate, sodium ferric pyrophosphate and other compounds. Each has various advantages and disadvantages. Ferric orthophosphate is the most stable iron form but it is largely unavailable. Ferrous fumarate is also very stable but it affects the colour of flour and as a result is suitable for use only in maize flour. Ferric phosphate enhances iron absorption but it is both costly and unstable. Thus, the most practical options for the Region are iron-EDTA, ferrous sulfate and elemental iron.

Sodium iron EDTA (NaFeEDTA) is the only non-haem source that has good bioavailability as it is relatively independent of meal composition and withstands the inhibitory effects of phytates. It has been given provisional approval as safe when used in supervised fortification programmes in iron
deficient populations by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, NaFeEDTA is not widely produced, is very expensive and thus has limited application.

Ferrous sulfate has excellent bioavailability, and relative biological value (RBV) is 100%, but it is unstable. Nonetheless, it is the fortificant of choice when used in baked goods because of the relatively short storage time associated with these products, eliminating the concern about instability. However, the level of ferrous sulfate should be below 40 ppm and storage time should not exceed 3 months or be at a temperature above 30 °C. Ferrous sulfate is not recommended for flour intended for household use if this is stored for a long time.

Elemental iron is only half as bioavailable as ferrous sulfate and. On the other hand, it is more stable and half as expensive as ferrous sulfate. If elemental iron is used as the fortificant, higher levels (two or three times more) than those required for ferrous sulfate will be needed to compensate for the lower iron level and lower bioavailability. This makes the cost of fortification with elemental iron, in the end, more expensive than with ferrous sulfate.

Although ferrous sulfate is probably the fortificant of choice in the Region providing proper usage, elemental iron is a viable alternative, especially where the flour will have a relatively long shelf-life. Table 5.1 shows a comparison of ferrous sulfate and elemental iron as forticants.

| Table 5.1 Comparison of ferrous sulfate and elemental iron as forticants in flour |
|---------------------------------|---------------------------------|
| Ferrous sulfate                 | Elemental iron                  |
| Light tan colour, no colour effect if pH < 6 | Black colour, will darken flour slightly |
| Non-magnetic                    | Magnetic                        |
| Excellent bioavailability, RBV: 100% | Fair bioavailability, RBV: 40%-60% |
| 32% iron                        | 97% iron                        |
| Need desiccated form            | Need 325 mesh particle size     |
| Higher cost: two times that of elemental iron | Lower cost (but two to three times more needed than ferrous sulfate) |
| Unstable: use only in flour with < 1 month shelf-life | Excellent stability in flour |

Notes: 30 ppm iron = 30 ppm elemental iron = 90 ppm ferrous sulfate (not accounting for bioavailability)

There is no difference chemically between the iron naturally occurring in bread and iron in the form of ferrous sulfate or elemental iron.
5.4 Fortification of flour: biotechnical issues

Understanding technical and scientific issues will help with such decisions as choosing the appropriate food vehicle and fortificant, fortification levels and similar critical matters.

Bioavailability is affected by particle size where elemental iron is used as a fortificant.

Iron-absorption inhibitors include tannins (contained in tea and coffee), when taken within approximately 20 minutes of iron-rich food, phytates (contained in the fibre of high extraction flour itself) and soya. Infection in the individual or population and high iron stores in the individual or population (typically in men) can also depress iron absorption. While inhibitor issues need to be addressed, it is important to recognize the role they play on the other side of the equation: in populations with high iron stores, there is little danger of iron overload from consuming fortified flour since iron absorption in healthy populations with high stores will be only about 1%-2%, depending on food composition.

Iron absorption enhancers include ascorbic acid (vitamin C), meat, yeast fermentation (which counterbalances the effects of the phytates)\(^1\), EDTA and low iron stores. Although vitamin C doubles the amount of iron absorbed, and is usually added as an improver during the baking process, unfortunately, baking destroys it. However, people can be encouraged through IEC (information, education and communication) campaigns to eat fruit with their bread to enhance iron absorption. Consuming 70-100 mg of vitamin C can triple or quadruple iron absorption rates.

Stability of the iron added to flour is affected by both fortificant type and flour type. Instability in this case does not mean that iron levels will diminish; rather, oxidation of the iron causes fats contained in the flour to go rancid. Factors influencing rancidity include: 1) type of flour, 2) level of iron, 3) temperature during storage, 4) fat content of the flour and 5) moisture level of the flour. The higher the iron level (e.g. above 30 ppm) and temperature (e.g. above 30 °C), the sooner rancidity of the flour will occur. Also, since wheat germ has high levels of fat, flour with high levels of wheat germ (e.g. atta flour) will go rancid sooner when unstable iron compounds are used for fortification. In Bahrain, the turnover of flour is around 4 weeks, in Kuwait, about 2 weeks, in Lebanon, about 2 weeks. Therefore, turnover is not a problem for most countries in the Region.

\(^1\) It is not realistic to think that bakers will be willing to increase fermentation time as this will reduce turnover and thus profits.
5.5 Determining iron fortification levels

5.5.1 General principles

Numerous factors influence the recommended level of fortification. The amounts to be used should be decided by the appropriate nutrition authorities, based on sound nutritional surveys. In considering the level of fortification, the main determinants are:

- the recommended dietary intake (RDI) of the micronutrient
- prevalence of the deficiency
- per capita consumption of the food vehicle to be fortified
- extent of processing, transit, storage and food preparation losses of the micronutrient, if any
- current dietary habits of the population
- other dietary ingredients affecting absorption and bioavailability (including ingredients in the flour itself).

5.5.2 Extraction rates of flour

The rate of extraction will affect the level of iron that should be added during fortification. In milling wheat, the skin of the wheat is extracted (scratched off). The skin is the part of the grain that contains the vitamins and iron. Thus, the rate of extraction (the amount of flour recovered from the grain) will determine how much iron is left in the flour at the end of the milling process. The amount of iron left in the flour, in turn, will affect the amount of iron to add to flour during the fortification process.

The lower the rate of extraction, the lower the amount of iron (and vitamins) left. Extraction rates in the Region vary greatly, between 70% and 98%. Low extraction (white) flour has an extraction rate in the range 70%-78%. Flours with extraction rates above 82% are termed high extraction flours. Whole wheat flour (or atta flour) has extraction rates as high as 95%-98%. Extraction removes zinc as well as iron. Thus, fortifying wheat flour with both iron and zinc could be of interest to many countries in the Region. Flour extraction rates in various countries are presented in Table 5.2. Table 5.3 gives further details on extraction rates and the impact on nutrient value.
Table 5.2 Flour extraction rates in various countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Rate (%)</th>
<th>Country</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>76</td>
<td>Italy</td>
<td>74</td>
</tr>
<tr>
<td>Belgium</td>
<td>74</td>
<td>Iran, Islamic</td>
<td>70,80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Republic of</td>
<td>100</td>
</tr>
<tr>
<td>Canada</td>
<td>75</td>
<td>Netherlands</td>
<td>77</td>
</tr>
<tr>
<td>China</td>
<td>70 and 80</td>
<td>New Zealand</td>
<td>78</td>
</tr>
<tr>
<td>Egypt</td>
<td>74 and 82</td>
<td>Pakistan</td>
<td>74 and 97</td>
</tr>
<tr>
<td>France</td>
<td>74</td>
<td>Russia</td>
<td>80</td>
</tr>
<tr>
<td>Germany</td>
<td>79</td>
<td>Switzerland</td>
<td>72 and 80</td>
</tr>
<tr>
<td>Greece</td>
<td>83</td>
<td>Turkey</td>
<td>80</td>
</tr>
<tr>
<td>Hungary</td>
<td>77</td>
<td>UK</td>
<td>74</td>
</tr>
<tr>
<td>India</td>
<td>74 and 97</td>
<td>USA</td>
<td>75</td>
</tr>
</tbody>
</table>

Table 5.3 Micronutrient concentrations in whole wheat flour and in flours of different extraction rates (values per 100 g)

<table>
<thead>
<tr>
<th>Percentage extraction</th>
<th>Thiamin (mg)</th>
<th>Riboflavin (mg)</th>
<th>Niacin (mg)</th>
<th>Pyridoxine (mg)</th>
<th>Total folate (µg)</th>
<th>Vitamin E (mg)</th>
<th>Iron (mg)</th>
<th>Zinc (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.46</td>
<td>0.08</td>
<td>5.6</td>
<td>0.50</td>
<td>57</td>
<td>1.0</td>
<td>4.0</td>
<td>3.0</td>
</tr>
<tr>
<td>85</td>
<td>0.30*</td>
<td>0.06</td>
<td>1.7*</td>
<td>0.30</td>
<td>51</td>
<td>trace</td>
<td>2.5</td>
<td>2.4</td>
</tr>
<tr>
<td>72</td>
<td>0.10*</td>
<td>0.03</td>
<td>0.7*</td>
<td>0.15</td>
<td>31</td>
<td>trace</td>
<td>1.5</td>
<td>0.9</td>
</tr>
<tr>
<td>40</td>
<td>0.10*</td>
<td>0.02</td>
<td>0.7*</td>
<td>0.10</td>
<td>10</td>
<td>trace</td>
<td>1.5</td>
<td>0.7</td>
</tr>
</tbody>
</table>


* Before fortification

5.5.3 Levels of ferrous sulfate and elemental iron

It will be necessary to consider the type of flour being fortified and the characteristics of the fortificant used in setting fortificant levels.

Absorption of iron from bread is 1%-2%. At the beginning of the milling process, flour contains 30-40 ppm iron. As the flour is extracted at higher degrees to make white flour, approximately two-thirds of the iron is lost. Even at high extraction rates with atta flour, approximately 50% of the iron is lost. In fortifying the flour, the goal is to restore the levels lost through milling and to compensate where there is low bioavailability.
The typical levels of ferrous sulfate (as iron) used for fortification are 25 ppm to 35 ppm in flour\(^1\), 1000 mg/kg in salt, 1.3% in sugar, and 1–2 mg/100 Cal edible portion in infant cereal.

### 5.6 Iron fortification costs

In calculating the cost of iron fortification, it is necessary to consider the costs not only of production, marketing and distribution of the fortified product, but also costs related to programme management.

With regard to production of fortified flour, mills in the Region are very modern and equipment tends to be "state of the art". The only additional piece of equipment likely to be needed for fortification during milling is a mixer (feeder), which is relatively inexpensive (about US$ 5000), including shipping and delivery costs. Some companies that sell fortificants will even provide free mixers to mills that purchase their premixes. Since typical packaging currently used by millers and bakers is adequate for fortified flour, no additional packaging costs should be incurred, other than labelling to provide additional information (such as the manufacture/expiry date, fortificant type and level, and manufacturer's name). Producers must engage in routine quality assurance to be sure that the flour produced meets the standards set by the government. Additional laboratory equipment for quality assurance of fortified flour is relatively inexpensive. Materials for semi-quantitative rapid spot tests consist of three different reagents and a simple plastic or metal spatula and strip for analysis. For precise quantitative analysis, a spectrophotometer is required. Progressively, the incremental costs of fortification borne by producers could be passed on to the consumer, as is the case with iodized salt.

Programme costs include the cost of developing an information and communications strategy to inform the public and create a demand for fortified flour, regulation and enforcement, monitoring and evaluation. Regulation and enforcement costs include additional expenses for sample taking and analysis, as well as additional costs associated with inspection and enforcement. Since these mechanisms should already have been set up during the country's salt iodization programme, the incremental costs for iron fortified flour should be minimal. In any event, a country's food control system should have these mechanisms in place in order to assure food safety and other measures of consumer and industry protection, regardless of whether the foods are fortified are not. The dosages and costs of iron fortification with and without addition of folic acid are presented in Table 5.4.

---

\(^1\) A level of 30 ppm when using ferrous sulfate and 60 ppm when using elemental iron was agreed by the participants of the workshop to be the most appropriate for the Region.
Table 5.4 Application, dosages and costs of iron fortification of flour

<table>
<thead>
<tr>
<th>Property</th>
<th>Reduced iron</th>
<th>Ferrous sulfate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Black</td>
<td>Light tan</td>
</tr>
<tr>
<td>Magnetic</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Relative bioavailability (%)</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Iron content (%)</td>
<td>97</td>
<td>32</td>
</tr>
<tr>
<td>Type of flour in which iron source can be used at this level without problems of flour shelf-life (see note 1)</td>
<td>All flours</td>
<td>Bakery flour</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pasta flour/semolina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>White flour used within 6 weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutrient addition levels</th>
<th>+ folic acid</th>
<th>+ folic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron (ppm)</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Folic acid (ppm)</td>
<td>0</td>
<td>1.5</td>
</tr>
</tbody>
</table>

| Addition rate (g/t)                                           | 30           | 100          |
| Dilution required                                             | Yes          | No           |
| Cost (US FOB, US$/kg)                                        | 4.25 $       | 2.88 $       |
| Cost (US$/t flour)                                            | 0.15         | 0.36         |

Notes:
1. The shelf-life figures given for flour fortified with ferrous sulfate are very conservative and could be considerably longer with lower extraction rates and low storage temperatures.
2. Equipment (feeder and associated equipment) will be around US$ 5000 per mill unit. Costs based on "f" figures include the base price of a feeder (about $3000 per mill unit).
3. Base iron source cost for adding iron corrected for bioavailability:
   - 20 ppm iron as ferrous sulfate or 40 ppm iron as reduced iron: US$ 0.20/t flour
   - 30 ppm iron as ferrous sulfate or 60 ppm iron as reduced iron: US$ 0.30/t flour
4. "f" indicates firm price quotation, "e" indicates estimated cost, t = tonne or 1000 kg

5.7 Summary

Summary information on food vehicles, fortificants, dosages and costs is presented in Table 5.5.
<table>
<thead>
<tr>
<th>Vehicle</th>
<th>Fortificant</th>
<th>Dosage</th>
<th>Cost (range) per person per year (US$)</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt</td>
<td>Potassium iodate</td>
<td>50–80 ppm iodine</td>
<td>0.02–0.06 (1995)</td>
<td>Several</td>
</tr>
<tr>
<td>Salt</td>
<td>Ferrous sulfate</td>
<td>1000 ppm iron</td>
<td>0.12–0.18 (1994)</td>
<td>India</td>
</tr>
<tr>
<td>Sugar</td>
<td>Vitamin A (250 CWS)</td>
<td>15 000 IU/kg</td>
<td>0.29 (1994)</td>
<td>Guatemala</td>
</tr>
<tr>
<td>Corn flour/wheat flour</td>
<td>Iron</td>
<td>20–25 mg/kg</td>
<td>0.07–0.08 (1994)</td>
<td>Venezuela</td>
</tr>
<tr>
<td></td>
<td>Vitamin A (plus niacin, thiamin, riboflavin)</td>
<td>39 000 IU/kg</td>
<td>0.07–0.08 (1994)</td>
<td>Venezuela</td>
</tr>
<tr>
<td>Biscuits</td>
<td>Haem iron concentrate</td>
<td>1.8 g Hb/30 g</td>
<td>1.08 (1981)</td>
<td>Chile</td>
</tr>
<tr>
<td>Cooking fat</td>
<td>Vitamin A</td>
<td>50 000 IU/kg</td>
<td>0.30–0.40 (1988)</td>
<td>India</td>
</tr>
<tr>
<td>Edible oils</td>
<td>Vitamin A</td>
<td>20 IU/g</td>
<td>Not available</td>
<td>Pakistan</td>
</tr>
<tr>
<td>Margarine</td>
<td>Vitamin A</td>
<td>375 RE/15g</td>
<td>0.20 (1994)</td>
<td>Philippines</td>
</tr>
</tbody>
</table>

Hb = haemoglobin, RE = retinol equivalent
6. Planning and implementing an iron fortification programme

6.1 Summary

Box 6.1 summarizes key planning and implementation steps for flour fortification programmes.

Box 6.1 Key planning and implementation steps for iron fortification programmes

- Establish the need for correcting iron deficiency and the need for universal fortification of an appropriate food vehicle (or permissive (voluntary) fortification of multiple vehicles)
- Link fortification with other intervention strategies, such as supplementation and nutrition education
- Involve all relevant sectors actively in the planning and implementation of the programme at an early stage
- Identify the most appropriate food vehicle(s)
- Assess the feasibility of fortification and large-scale industrial production
- Where required, conduct community trials to demonstrate impact and consumer acceptability
- Advocate for political support and commitment, including financial support and commitment
- Open a dialogue with those involved with the production and processing of these foods and gain their support and commitment
- Identify and develop, if necessary, the technology required for fortification that will provide a stable and quality-assured product at a reasonable cost
- Prepare a strategic plan covering the proposed mix of interventions and targeted coverage
- Ensure installation of machinery and accessories for fortification and for quality assurance and quality control
- Ensure the initial supply of the fortificant and other material inputs
- Establish standards for the vehicle and fortificant and develop or improve, as applicable and necessary, the regulatory system for ensuring compliance with regulatory requirements
6.2 Food fortification as a multisectoral activity

Food fortification is an activity that extends beyond the health sector. Effective and sustainable fortification will be possible only if the public sector (which has the mandate and responsibility to improve the health of population), the private sector (which has the experience and expertise in food production and marketing) and the social sector (which has the grass-roots contact with the consumer) collaborate to develop, produce and promote micronutrient-fortified foods. The role of the various sectors is outlined below.

- **The scientific community** has identified the problems of micronutrient malnutrition and possible solutions through enrichment of a variety of foods. Over the past decade, considerable expertise has also been built up in the development of programmes with in-built support measures, such as advocacy and social communication, legislation and enforcement, monitoring and evaluation and training.

- **National governments** must provide the administrative support and prescribe the framework within which solutions can be implemented and regulated. In addition to overall supervision by the ministry of health, regulation of the production and sale of food typically involves the ministries of commerce and finance.

- **The food industry**, which is privately controlled in most countries, actually produces and markets fortified food products. It often has the technology, the capacity to mobilize resources and the marketing capability to translate these needs into economically viable products that will be affordable and nutritious. Industry should be involved in feasibility studies, technology development and transfer, production, quality assurance and quality control, and determining consumer acceptability and pricing of the product. Industry’s expertise in market development should be tapped by the government in creating IEC campaigns.

- **The consumer** needs to be educated regarding the benefits and low cost of food fortification in order to create a demand to which industry would have to respond.

- **International and bilateral aid agencies** can provide the link and the coordination between the different sectors and make them self-supporting and sustainable.

Social marketing and communication are critical for raising awareness of the problem and solutions for controlling iron deficiency anaemia and for creating demand for iron-rich foods. Therefore, all available media should be used to create consumer awareness of the problem, create demand for iron-rich foods, including fortified products, even at a slightly higher price, and...
modify behaviour to reduce the consumption of iron inhibitors and increase
the consumption of iron enhancers.

Involving all interested sectors from the outset will ensure appropriate
input in the planning process and in implementation, as well as early support
for the programme. Without the proper involvement of these sectors early on,
opposition, including unfounded fears about safety or costs, may arise and
jeopardize the programme.

The Ottawa Forum on Food Fortification, held from 6 to 8 December 1995\(^1\),
set the stage for public–private sector partnerships to operate collaboratively at
the national level toward the common goal of micronutrient malnutrition
elimination, primarily through fortification. The benefits of intersectoral
collaboration to promote food fortification initiatives that were identified at the
forum are summarized in Box 6.2. A summary of some of the recommenda-
tions of the forum are presented in Box 6.3.

6.3 Capacity building

Specialized training of both industry and government staff is called for,
especially with regard to assessment, fortification, quality assurance and
control, and monitoring and evaluation procedures. Since effective monitoring
of process and outcome variables is critical, measurement of food quality and
fortificant levels is an essential step both for industry quality assurance and for
governmental monitoring and inspection. Monitoring must be combined with
periodic assessment of biochemical and clinical indicators to evaluate the
impact of the iron control interventions.

6.4 Complementary programme strategies

It is important to link fortification with other strategies and ensure that they
are complementary. For example, if fortification of flour will not reach all
populations at risk or is not adequate to fully cater for the iron needs of those
populations, it should be complemented with targeted supplementation that
will reach those not likely to benefit from fortification. Special targeting of
those populations outside the central distribution system and those with
additional iron needs, such as women of reproductive age, might be indicated.
Dietary diversification and other nutrition education messages can also be
targeted to reach vulnerable groups.

\(^1\) The Ottawa Forum was sponsored by MI, the World Bank, UNICEF, USAID through OMNI
(Opportunities for Micronutrient Intervention) Project, UNDP (United Nations Development
Programme) and ILSI (International Life Sciences Institute) and was convened by MI, PAMM
(Program Against Micronutrient Malnutrition) and Keystone Center.
Box 6.2 Public-private partnerships: the benefits of intersectoral collaboration

- Sharing public health and scientific research with private industry saves time in the development of products and technologies.
- Public consultation with industry means legislation, standards and regulations will be more realistic, achievable and successful in stimulating the production of more fortified products.
- Social marketing can create new customers. One company reported that collaborating with a government campaign resulted in a new market created overnight.
- Government can shoulder some liability and protect private companies from sceptics and opponents of fortification.
- The private sector can communicate consumer benefits of specific products, but the public sector can more credibly communicate the health and national development benefits.
- For the private companies, collaboration often leads to additional opportunities for business with the public sector.
- Employees' perceptions that their company is socially responsible can lead to improved morale and ultimately higher productivity.
- Association with government and a socially responsible cause improves a company's image with consumers.
- A healthier, more productive workforce creates consumers with more disposable income, which benefits both those who sell products and those who collect taxes.

Source: *Sharing risk and reward, Report of the Ottawa Forum on Food Fortification, 1995*
Box 6.3 Recommendations from the Ottawa Forum on Food Fortification

<table>
<thead>
<tr>
<th>Roles of the partners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Government</strong></td>
</tr>
<tr>
<td>• generate political commitment for fortification at the highest levels</td>
</tr>
<tr>
<td>• organize education and awareness campaigns</td>
</tr>
<tr>
<td>• enact enabling legislation and regulations</td>
</tr>
<tr>
<td>• provide fiscal incentives where necessary (tax/tariff exemptions)</td>
</tr>
<tr>
<td>• facilitate technology transfer</td>
</tr>
<tr>
<td>• offer preferred access for fortified foods to the public infrastructure</td>
</tr>
<tr>
<td>• provide marketing support through seal of approval endorsements/health claims</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Private food industry</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• assist in assessing national needs</td>
</tr>
<tr>
<td>• communicate and advocate industry needs to the government</td>
</tr>
<tr>
<td>• assist in market research and development of promotional material</td>
</tr>
<tr>
<td>• create products and technologies</td>
</tr>
<tr>
<td>• develop marketing and distribution mechanisms</td>
</tr>
<tr>
<td>• compete on quality and excellence</td>
</tr>
<tr>
<td>• create best practices codes for production and marketing of fortified foods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>International agencies and nongovernmental organizations</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• provide experiential information for application elsewhere</td>
</tr>
<tr>
<td>• document lessons learned</td>
</tr>
<tr>
<td>• provide technical support for planning and monitoring</td>
</tr>
<tr>
<td>• provide support to governments and national groups to plan and implement programmes</td>
</tr>
</tbody>
</table>
7. Standards and regulations

7.1 Implementing regulations

Of primary concern when considering fortification will be a country's food regulatory system. A stringent commitment and follow-up by the authorities, achieved through a coordinated collaboration between governments, public and private sectors, and the scientific community will be needed along with an appropriate legislative mandate, objective laboratory testing capability and system of rewards and penalties.

Source: Controlling iron deficiency (United Nations Administrative Committee on Coordination/Subcommittee on Nutrition, 1991)

Regulation is a fundamental part of fortification planning and implementation and serves as the legal foundation for any food fortification programme. The purposes of regulation are to create and maintain an enabling environment for those engaged in the production and sale of fortified foods and to protect the consumers who will eat the foods. The first step in laying the legal foundation is to draft and enact general enabling legislation (or some other form of legal enactment) that provides legal authority for the government to require or allow, as the case may be, fortification of any particular food vehicle(s). This step is usually followed by the establishment of detailed implementing regulations by the ministry charged with administering the fortification law. Regular inspections, including examining production processes and testing samples of the end product at the factories where fortified foods are produced, as well as testing at the production sites, at the sites of import (if applicable) and at the retail stores where the food is sold, is a critical regulatory function that ensures a level playing field and guarantees the universal availability of a fortified product that meets government standards.

The processes for establishing and implementing a regulatory system for iron fortification are similar to those for salt iodization, which can be followed and adapted. However, there are some unique considerations when it comes to iron fortification, which include the following.

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1 It is possible either to create new legislation for fortification of flour with iron or to amend the general food control law or the salt iodization law to provide for flour fortification. Engaging in piecemeal legislation for each food vehicle and fortificant should be discouraged where it is politically feasible to enact one piece of legislation that covers all fortification activities. See Food fortification legislation and regulations manual (Nathan, 1995).
• **Protecting breast-feeding.** Since breast-milk is an excellent source of iron, fortification should in no way undermine breast-feeding. This may require special regulatory provisions with respect to marketing.

• **Mandatory or permissive (voluntary) fortification.** Since multiple food vehicles may be appropriate for iron fortification, and since other dietary sources of iron exist (unlike the case with iodine), all potential food vehicles and other sources of iron must be considered carefully. If only flour is to be fortified, mandatory fortification is advised.

• **Establishing upper limits for the fortificant.** Since iron overload can be a concern, a range of the fortificant with clear upper limits must be established in the regulations.

• **Requiring quality assurance.** The law and regulations should require producers fortifying their products with iron to engage in routine quality assurance. Even though such practices will not be complex or very expensive, quality assurance is not widely practised. Therefore, there will be a need to train for and encourage quality assurance so that the legal mandate can be met.

• **Monitoring and evaluating the programme and its impact.** As with salt iodization, it is critical to monitor both the programme and the product in order to ensure targets are being met and that the programme is operating successfully. Plans for both monitoring and evaluating the programme, including biological assessments, should be made from the beginning. Because iron fortification is not as well established or accepted as salt iodization, the ability to measure success is even more critical in order to continue political and food industry support for the programme.

### 7.2 Monitoring and quality assurance of iron fortification programmes

#### 7.2.1 Monitoring

Iron fortification programmes must be monitored:

• to improve programme effectiveness

• to test and ensure compliance with government regulations and standards

• to focus on coverage of those at highest risk of iron deficiency and anaemia

• to identify the problematic points in the fortification process

• to ensure safety of the fortified product.
Fortification with iron in order to reduce anaemia and improve iron status cannot be effective if the fortified products are not of good quality with regard to iron content and its bioavailability, stability and consumer acceptability, or if they do not reach those at highest risk of iron deficiency and anaemia. Monitoring fortification programmes can help ensure wide coverage of a high-quality product in a sustainable manner. In monitoring an iron fortification programme one needs to ensure that:

- the iron content of the fortified food is adequate and remains stable under storage conditions, and that there is no change in colour, appearance or organoleptic properties of the iron fortified product;
- the fortified food is available and accessible to the intended population;
- the fortified food is purchased and regularly consumed in adequate amounts by the intended population;
- there are relevant regulations and standards in place with which all manufacturers and retailers of the fortified product comply;
- there are routine quality checks of the product to ensure that it meets government and industry standards, and services are available to take corrective actions if standards are not met.

Monitoring is therefore concerned with the collection of relevant information on production, distribution, consumption, coverage and enforcement. It is, therefore, important to design and implement monitoring systems concerning the quality and availability of iron fortified products of a food processing company as the products move to the consumer. This should be part of the firm’s overall quality assurance plan for all products produced. While the private sector is engaged in production of a uniformly fortified product of high quality for distribution, the government’s responsibility is to ensure compliance with the standards set in collaboration with various health and industry authorities, and to facilitate distribution and access to the product, particularly by the intended beneficiaries. The government, through the food control authorities, must ensure that the public receives high-quality products fortified with sufficient iron to improve iron status but that at the same time the products are safe and the iron content does not exceed the limits set by the standards.

Monitoring is usually performed at various levels, such as production/importation, wholesale and retail, and household, with the production/importation levels being the most important stages of monitoring the fortification activity. Monitoring at wholesale/retail levels will mostly be restricted to ensuring the appropriateness of packaging and labelling of the product, whereas monitoring at the household level will ensure that the product is actually reaching the target population (i.e. is accessible and affordable), and is regularly consumed in adequate amounts.
The most important and crucial level of monitoring is at production. Both
the process and the product of any fortification programme need to be
monitored. Indicators for monitoring an iron fortification programme should
include both the fortification process at the industry end, to ensure constant
and appropriate levels of iron in the food, and also the actual consumption of
the fortified food by the population.

At the food processing plant, the fortification process must be validated.
There must be monitoring of iron content during production and samples
must be taken periodically at the end of the processing line to monitor iron
levels in the final product. The steps that specifically require quality assurance
(adapted from Monitoring universal salt iodization programmes, PAMM/MI
/ICCIDD/UNICEF, 1995) are:

• purchase of quality equipment and supplies
• routine inspection of processing equipment
• validation of the fortification process to ensure consistency
• monitoring of micronutrient levels during production
• monitoring of food ready for distribution
• keeping of adequate monitoring records.

7.2.2 Legal provisions on monitoring: two forms of monitoring

Internal, or self-monitoring, by the industry referred to as quality
assurance. With internal monitoring, the industry routinely
examines its own processes and procedures to identify and correct
any problem areas found.

External monitoring by the government pursuant to its inspection
and investigation powers. External monitoring provides the
government with the information necessary to enforce the law
whenever noncompliance with legal requirements is found.

Source: Monitoring universal salt iodization programmes (PAMM/MI/ICCIDD/UNICEF,
1995:19)

The responsibility for routine monitoring at the production plant rests with
the factory itself (internal monitoring). However, external monitoring by
independent agencies at periodic regular checks should be promoted. The
producer (millers in the case of flour fortification with iron) is responsible for
internal monitoring of the product as part of the overall quality
assurance/quality control plan of the company. To do so, the producers
should have a quality assurance plan and a continuous process of monitoring
their system for reproducibility and reliability of all products produced which
includes routine and periodic sample collection, and analysis of the samples to
ensure compatibility with the government and industry standards.
7.2.3 Quality assurance

A quality assurance plan should specify:

- production and mixing methods
- sampling procedures (frequency of sample taking, analytical methods, acceptability criteria)
- schedule for equipment maintenance
- individuals responsible for various activities, such as food sampling, equipment checking, packaging and labelling checks, handling and storage checks
- corrective actions to be taken when problems are identified
- reporting (routine reporting and keeping of log books and control charts)

In quality assurance of food fortification, as indeed in food control as a whole, hazard analysis critical control point (HACCP) is an essential methodology. HACCP is cost-effective and applicable to everyone. It helps to set priorities, and is a most effective method for maximizing product safety. The main steps in this process are conducting a hazard analysis, identifying critical control points, establishing critical limits for preventive measures, establishing critical control point monitoring requirements and corrective actions to be taken, and establishing effective record-keeping and verification procedures.

Steps for implementing a quality assurance programme may involve the following:

- providing specifications for both forticants and food vehicles (particle size, colour, potency, acceptable ranges of forticant, fortification level);
- sampling and testing forticants, food vehicles and fortified foods for potency, particle size, colour, net weight, adulteration, packaging and storage conditions;
- routinely undertaking hazard analysis of forticants and fortified foods for chemical, microbiological and physical contaminants;
- identifying and regulating the critical control points that might adversely affect fortified foods;
- establishing a recall system to trace or identify the product in case of consumer complaints;
- auditing and evaluating the quality assurance system on a regular basis to determine whether various elements within a quality management system are effective in achieving stated quality objectives;
- implementing corrective actions (detection of quality or safety problems and measures to eliminate the recurrence of these problems);
- documenting all aspects of the quality assurance system and making the documentation available to those responsible for the fortified foods.
The basic concept is establishing the routine limits of the system, i.e. through a control chart with calculated upper and lower control limits, and then using this chart to demonstrate that the process is "in control". The industry should organize itself in such a way that the technical, administrative and human factors affecting the quality of its products are maintained under control. All such controls should be designed to reduce, eliminate and prevent quality deficiencies. The process is in control if:

- the specific product/process parameter complies with the formulated standard at the critical control points at regular intervals;
- corrective action is immediately taken if an observation deviates from the specification.

When the process is not in control, there would be specific procedures to follow to determine the cause and to stop production until the problem is resolved. Everyone in the company, from the directors to the junior labourers, has a responsibility for quality. The benefits of meeting these responsibilities are often not fully realized. This results in failure to organize effective quality control cycles. To be effective, the cycle must be complete.

**Quality management system.** For all products made by the company, a quality management system should be developed and implemented, appropriate to the type of activity and product being offered, in order to achieve maximum effectiveness and to satisfy customer expectations. The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product. It involves all phases from initial identification to final satisfaction of requirements and customer expectations.

The impact of quality upon the profit-and-loss statement of a company can be highly significant. A company might survive if individual products fail to meet requirements, but if the most senior management fails to appreciate that cost must be identified and measured in relation to quality as part of a company-wide policy, then the company will cease to trade competitively and will eventually cease to trade at all. It is well known that the reported costs of quality are frequently markedly lower than the actual costs of quality. It is not uncommon for the cost of quality to be as high as 25% of sales (Lock, 1991). For fortified foods to be selected over unfortified ones by the intended target group, they should be made available at competitive prices compared with non-fortified foods.

**Monitoring by government and by consumers.** For external quality assurance, the authorized government agency should develop a plan for periodic checks of all producers of fortified products. The frequency of these checks should be adapted to ensure that the food reaching the market meets government standards. External monitoring should increase in frequency
when household- or retail-level monitoring indicates that some products fail to meet standards. The steps involved are:

- development of standards for fortified foods and the legislation required to ensure this
- development of a monitoring plan
- establishment of a list of producers of fortified products to monitor
- monitoring of producers
- recording of data
- implementation of enforcing procedures.

The overall responsibility for quality control inside the country often rests with the public health department, but consumer organizations can and should be involved in monitoring the micronutrient levels of the factory. The objective of this monitoring activity is to ensure that the specific content of the micronutrient is maintained at the required consumer level.

Determination of the level of iron fortification. Iron content can be determined by a variety of techniques, such as a simple colorimetric method or by using an atomic absorption spectrophotometer. Simple field kits are being developed which can give a qualitative (not quantitative) indication of the presence or absence of iron (American Association of Cereal Chemists, 1983; see also Annex 2). Regular monitoring of iron levels in the product is needed in order to avoid excess iron addition in case of poor iron distribution during production.

8. Regional options and guidelines for flour fortification

8.1 Introduction

Based upon the technical information provided and the specific situation in countries in the Region, a number of issues were reviewed by working groups and recommendations made for the situation in the Region.

8.2 Flour fortification as part of a national iron deficiency anaemia strategy

Micronutrient fortification of food is an effective strategy to improve nutrition. The fortification of wheat flour with iron in particular has the potential to make an important contribution to reducing the problem of anaemia in women and children throughout the Region.
8.3 Choice of fortificant

It was decided by the working group that the level of iron to add would be:

- 30 ppm iron if ferrous sulfate is used
- 60 ppm if elemental iron is used.

In the case of atta (high extraction) flour, several options were examined.

- One possibility is to use NaFeEDTA. However, this is still very expensive. The workshop recommended that studies be done to examine the feasibility of using ferrous sulfate together with EDTA, rather than NaFeEDTA.
- Longer fermentation should be promoted. This may however prove difficult as bakers may not be willing to change.
- Fortify with 30 ppm iron as ferrous sulfate. Although this is not the ideal solution, it is the least unattractive of possible alternatives.

8.4 Costs and benefits of iron fortification

Based on the recommended regional level of iron to add (30 ppm iron if ferrous sulfate is used or 60 ppm iron if elemental iron is used), the cost of iron fortification is estimated as follows:

- iron source: US$ 0.30 per tonne
- equipment: US$ 6000 per mill unit
- regulation and other: unknown

In Lebanon, for example, which has 11 mills, the cost of fortification of flour with iron in the first year would be US$ 312 000 with US$ 90 000 per year continuing costs.

The cost of 1 kg of bread in some countries in the Region in US dollars is:

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Islamic Republic of Iran</td>
<td>0.10</td>
</tr>
<tr>
<td>Jordan</td>
<td>0.40</td>
</tr>
<tr>
<td>Kuwait</td>
<td>0.35</td>
</tr>
<tr>
<td>Lebanon</td>
<td>0.70</td>
</tr>
<tr>
<td>Syrian Arab Republic</td>
<td>0.16</td>
</tr>
</tbody>
</table>

It was calculated that every kilogram of bread will cost an extra US$ 0.00025 when fortified so the cost increase of fortification will be insignificant.

For the purposes of the following calculations, it is assumed that a person’s bread consumption is about 10 kg per year (300 g per day), which equates to 7000 kg for life. Thus, the cost of fortification per person for life will be:

\[7000 \text{ kg} \times \text{US$ 0.00025} = \text{US$ 1.75}\]
Fortification of flour with iron

Per day, 300 g of bread, 80% white + 20% brown, provides 3.3 mg iron (of which 0.17 mg is available iron), around 875 calories, 26 g protein and 550 mg phytic acid. The recommended daily allowance (RDA) for iron is 1.8 mg, so 0.17 mg provides 10% of the daily needs. If the fortification level is 30 ppm ferrous sulfate, this gives 9 mg of iron in the 300 g of bread. Assuming 10% absorption, 0.9 mg iron will be provided from bread. Therefore, the total iron contributed by the bread is:

\[ 0.17 \text{ mg} + 0.9 \text{ mg} = 1.07 \text{ mg} \]

Thus, the fortified bread will supply 60% of the needed iron. This is assuming that ferrous sulfate is used as the fortificant. If elemental iron is used, 60 ppm need to be added because it has lower bioavailability (50% as available).

The calculation of cost in US dollars (taking Lebanon as an example) shows that:

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortificant 300 000 t at US$ 0.3/t</td>
<td>90 000</td>
</tr>
<tr>
<td>Cost of set of feeders + installation</td>
<td>132 000</td>
</tr>
<tr>
<td>[(US$ 5000 + US$ 1000) × 11] × 2</td>
<td></td>
</tr>
<tr>
<td>Cost of inspection (estimated) borne by the Ministry of Health</td>
<td>90 000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>312 000</strong></td>
</tr>
</tbody>
</table>

These are the start-up costs. Continued running costs at the mills is US$ 90 000. When dividing this over the total population, the cost per person for a lifetime is calculated at US$ 2.00.

The benefits of fortification are calculated based on a salary of US$ 5000 per year. If it is assumed that someone works for 30 years this will yield: \( 30 \times US$ 5000 = US$ 150 000 \) for a lifetime. If the worker is anaemic, one can assume that the productivity will be 20% less, which will result in a loss of US$ 30 000. Assuming 50% prevalence of anaemia in the Region, the loss to society caused by anaemia is US$ 15 000 per person.

In the Region, therefore, the cost and benefit of flour fortification are:

- Flour fortification cost per person per lifetime: US$ 2
- Anaemia cost per person per lifetime: US$ 15 000
8.5 IEC/advocacy/social marketing

The goal is to create a need and demand for fortified food among the entire population and especially among the target groups, and the objective is to achieve a specified coverage of the population with fortified food within a specified time period.

The following strategies and activities could be pursued.

Strategy 1: identify target groups and key messages

Activities:
- conduct rapid qualitative assessment, or a knowledge attitude and practices study
- assess dietary patterns
- assess food production and consumption patterns
- define coverage and market segment
- prepare document to include plan of action.

Strategy 2: obtain political commitment and support

Activities:
- present plan to policy-makers for acceptance and support
- prepare programme justification, with the assistance of the scientific community.

Strategy 3: build partnerships with industry, consumer organizations and the private health sector

Activities:
- conduct industry assessment
- arrange meetings with concerned partners to discuss plan and mobilize support
- collaborate with partners to develop themes and messages
- create awareness of fortified flour among bakers and flour processors.

Strategy 4: create public awareness through interpersonal communication and the mass media

Activities:
- develop appropriate health education material based on the messages identified for different target groups
- conduct training activities and information sessions for the users of the material
- implement IEC plan of action and dissemination of material.
8.6 Standards and regulations

8.6.1 Evaluating the present legal authority

Representatives from all countries believe that their laws provide adequate authority to allow their ministries to mandate or permit fortification of flour with iron. However, many feel the need to add or improve provisions related to quality assurance, packaging and labelling, and inspection and enforcement. Specific provisions for iron fortification covering standards for vehicles, fortificants, packaging, labelling and quality assurance procedures are needed in all countries.

Recommendations. Present laws should be reviewed and assessed and a strategy for making amendments, if necessary, should be established. While looking at provisions related to flour fortification, the opportunity to address weaknesses in the regulatory provisions related to iodized salt and other foods, as well as weaknesses in enforcement provisions, should be taken.

8.6.2 Setting standards

Programme officials will need to determine who will be involved in setting standards from among all relevant sectors, specifically the ministries of health, commerce and finance, the food industry, academic and scientific communities, agencies and NGOs, and consumer/women's groups. All groups should have an input into the establishment of the standards so that technical information can be exchanged, "buy in" established from the beginning, and potential barriers or resistance can be foreseen and strategies for overcoming them planned. It will also be necessary to choose the appropriate fortificant by consulting international and regional guidelines. Where there is a lack of consistency between the individual country food standards, this will need to be addressed.

Recommendations. In choosing the fortificant, the following factors should be considered: cost, availability and potential interactions with other ingredients or fortificants. National governments should adopt the standards of the Gulf Cooperation Council where possible. Suggested standards, representing minimal requirements for the protection of health and safety are shown in Table 8.1.

8.6.3 Process for making regulatory changes and setting standards

Not all countries in the Region have an iron deficiency anaemia working group.

Recommendations. Countries that do not have an iron deficiency anaemia working group should establish one that includes the sectors previously
Table 8.1 Suggested standards for flour fortification with iron

<table>
<thead>
<tr>
<th>Subject</th>
<th>Suggested standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food vehicles</td>
<td>Flour fortification mandatory (fortification of other vehicles may be optional)</td>
</tr>
<tr>
<td>Fortificant(s)</td>
<td>Ferrous sulfate for flour with a shelf-life of &lt; 1 month</td>
</tr>
<tr>
<td></td>
<td>Elemental iron for flour with a shelf-life of &gt; 1 month</td>
</tr>
<tr>
<td>Fortificant levels</td>
<td>Ferrous sulfate: 30 ppm</td>
</tr>
<tr>
<td></td>
<td>Elemental iron: 60 ppm</td>
</tr>
<tr>
<td>Fortificant specifications</td>
<td>Particle size, colour, quality</td>
</tr>
<tr>
<td>Labelling requirements</td>
<td>Fortificant and fortification level, expiry date/shelf-life, manufacturer identification</td>
</tr>
</tbody>
</table>

mentioned, including representatives from consumer/women's groups that are not always included in policy and planning. The iron deficiency anaemia working group should have a special regulatory task force that includes legislative/regulatory drafters. The task force should collect and review regulatory information and draft needed regulatory provisions. It should also anticipate barriers to fortification regulation and develop strategies for overcoming them. Finally, it should develop an advocacy plan to gain political support for legislative/regulatory changes.

8.6.4 Inspections and enforcement

Some countries need more frequent retail inspections and better coordination among ministries, between inspectors and sample analysts, and between national and municipal level staff, for example. Many countries have found a decentralized system of inspections successful. Most countries do not have adequate resources for inspections and government laboratories need strengthening.

Recommendations. Training in quality assurance methods and procedures should be given to inspectors and industry. Quality assurance should be added to the curricula of food safety courses in schools. Government laboratory technicians should be trained how to analyse samples. To maximize limited resources, consumer groups should be used for informal monitoring, industry made to pay for inspection and sample courses where non-compliance is found. To alleviate corruption, inspectors should be given
higher salaries. The regulatory system needs to be monitored and evaluated periodically.

8.6.5 Programme monitoring versus regulation

Recommendations. The government must monitor the fortification programme periodically, including testing the fortified product, assessing coverage (household access to fortified flour), assessing the population’s iron status and similar matters. When thinking of governmental monitoring, one thinks of reviewing programme components to be sure they are working, rather than inspecting in order to take enforcement action when non-compliance is found. While there is some overlap, and while information gained during the monitoring process should be shared with regulators, and vice versa, monitoring and inspecting/enforcing serve somewhat different purposes.

8.7 Evaluation and monitoring

The aim of flour fortification is to improve the health status of the population. The process objective is to have fortified food available, and to reach the people in need of the benefit of fortified food. The impact objective is to have increased levels of haemoglobin.

To ensure that all the objectives are achieved, both process and impact monitoring are essential. Internal process monitoring will be carried out by the mill management, the delegated quality control department, external public laboratories, as well as every employee through the HACCP system. The external process monitoring will be carried out by the bureau of standards, consumer organizations and NGOs, while international organizations also have a role, especially in the area of setting benchmarks.

Internal impact monitoring should be carried out by ministries of health, other (health) professionals, educators and social workers as applicable, with external impact monitoring being the responsibility of universities, research institutes and international organizations.

In process monitoring at the factory level, materials used and processes and products should be monitored and careful product analysis carried out, using approved sampling frequency. Full documentation should be available for all these procedures. At the retail level, monitoring should take into account labelling, storage and quality control. The public, i.e. the consumer, has a clear role to play in this.

Impact monitoring should examine a representative sample of the target group, such as preschool children and pregnant women, and measure changes in haemoglobin levels over time to monitor the prevalence of anaemia. A
survey to measure programme impact will include biochemical analysis of haemoglobin levels and dietary intake of the whole population and the target group, with careful documentation of every step and laboratory analysis verification.

It is important to ensure that the monitoring process is validated and evaluated as necessary.

9. Conclusions and action for the future

Micronutrient fortification of food is an effective strategy to improve nutrition. The fortification of wheat flour with iron in particular has the potential to make an important contribution to reducing the problem of anaemia in women and children throughout the Eastern Mediterranean, Middle East and North Africa. Wheat flour has been fortified with iron in many industrialized countries, including the USA, Canada and the UK, for over 40 years and has contributed to a reduction in anaemia in these countries.

Wheat is the main staple food consumed in all countries in the Region. Wheat is milled into flour and consumed in the form of bread. In most countries in the Region, there are large wheat mills, although in Egypt, Islamic Republic of Iran and Morocco there are also many relatively small mills.

Fortification of wheat flour in most countries in the Region will be simple and cheap and will be a major strategy for preventing anaemia. Salt iodization has already been proven to be feasible throughout the Region and provides a model for flour fortification. Successful iron fortification programmes will be best developed through close cooperation between the milling industry and government, with the involvement of community organizations and consumers, including women’s associations. The scientific community also needs to be involved in the programme from the very start.

Ferrous sulfate is the compound of choice for the fortification of wheat flour with iron in the Region, added at the rate of 30 ppm of iron. In most countries, the technology for adding iron to wheat flour already exists in the flour mills. Where flour is required to be stored for long periods, millers could alternatively use elemental iron at the rate of 60 ppm. In view of the growing recognition of the importance of folic acid in preventing birth defects, the addition of folic acid to wheat flour in addition to iron needs consideration and could be done at little extra cost. Edible oils would be a better vehicle for vitamin A than wheat flour in the Region, in view of the insufficient data on the stability of vitamin A during prolonged storage of flour and baking of bread.

The additional cost associated with an iron fortification programme was estimated to be about US$0.03 per person per year, or US$2 per person per
lifetime, but the economic benefits from improved productivity per lifetime in the Region were estimated to be at least US$ 15,000 per person per lifetime.

Even in countries where food fortification is not yet an option, governments should insist on receiving only enriched food commodities which meet their national standards, with regard to bilateral or multilateral food aid.

Governments should regulate both the manufacture and the importation of food products which have been identified to require fortification, which requires that mechanisms for assuring the quality of fortification and enforcing regulations should be developed or strengthened at an early stage.

Comprehensive programmes to reduce iron deficiency anaemia are required, which include dietary diversification and education, public health measures, and supplementation for vulnerable groups, in addition to fortification.

A simple fact sheet, providing scientific facts on iron deficiency, the importance of folic acid, the potential of fortification and the mechanisms of iron absorption should be developed, which could be used for advocacy and increasing political awareness. WHO, UNICEF, MI and other organizations should collaborate to continue the development of this and other necessary materials. A rapid test kit (spot test) which can be used to identify the presence of iron in wheat flour or bread is currently being developed by the MI in collaboration with others.

Further development work is needed on ways that small wheat mills (those producing less than 100 tonnes per day) can fortify their flour.

**References and further reading**


Annex 1

Country studies

Bahrain

A national survey that aimed at detecting the prevalence of iron deficiency anaemia and dietary intakes among pregnant women in Bahrain, showed that 19.1% of Bahraini pregnant women had iron deficiency anaemia as indicated by their haemoglobin and serum ferritin levels. In addition, 20.9% of the women screened had normal haemoglobin levels but indicated depleted iron stores (serum ferritin < 17 µg/l), and 14.3% of them had haemoglobin levels below 11 g/dl but showed normal serum ferritin levels. Infants and preschool children were studied in 1996, and 47% of those between 6 months and 5 years of age had haemoglobin levels below 11 g/dl. On the other hand, anaemia in Bahraini schoolchildren declined from 32% in 1980 to 24% in 1985. The studies have shown significant gender variations; the prevalence in females in 1980 was 42.8%, twice that of males.

Dietary intake data indicated that 37% of the women had low folate intake in the first trimester, but only 10% consumed less than the recommended daily allowance (RDA) in the third trimester. At the same time 10% of the women in the third trimester had low vitamin C intake. All the women screened had adequate iron intake in the first trimester, but 50% of them had intakes lower than the RDA in the second trimester and 27.5% of them had low dietary intakes in the third trimester.

Bahrain Flour Mills Company (BSC) was established in 1972. The capacity of the mill increased from 100 tonnes per 24 hours in 1972 to 420 tonnes per 24 hours in 1996. BSC is the only milling company in Bahrain, and the Government of Bahrain covers the operating costs. The company produces the following types of flour:

- 75% extraction 26 200 tonnes
- 78% extraction 14 900 tonnes
- 86% extraction 9 000 tonnes.

In 1993, the 75% extraction flour and 78% extraction flour were fortified with iron and vitamins, using a Rovifarin 955 premix supplied by Hoffmann Laroche. However, the process was discontinued after one year, primarily because of financial constraints. The cost of purchasing the equipment and one year fortification was 17 500.00 Bahraini dinars (US$ 1.00 = 0.376 Bahraini dinars) and this was covered by the Bahraini Government. Adding the premix was found to cost US$ 1.00 per tonne.
Egypt

The prevalence of anaemia among Egyptian preschool children has been found to be 38%, and 22% and 25% of pregnant and lactating women respectively are anaemic. In addition, anaemia prevalence among non-pregnant, non-lactating adult women has been found to be 17%. Dietary intake data show that 76% of preschool children have dietary intakes lower than those recommended, and 14% of mothers have a low intake of iron.


Interventions to combat micronutrient deficiencies in Egypt are targeted at different sectors of the population. Based on the findings of studies on iodine deficiency disorders (IDD), which showed IDD to be a problem, an IDD committee was formed in 1994, chaired by the undersecretary for primary health care and including members of the Government, academia and private industry. Steps have been taken to start universal salt iodization.

School children are provided with biscuits fortified with iron and zinc. To combat anaemia in pregnancy, iron supplements are given to pregnant women through primary health care facilities. Nutrition education programmes aimed at increasing the consumption of dietary iron and enhancing its absorption are carried out. In addition, programmes for the eradication of parasitic infestations, and pilot studies for a national nutritional surveillance programme are under way.

A flour fortification project is being discussed by the Ministries of Health and Population, Agriculture and Supply, and the National Research Centre and the Food Research Institute. Technical issues are being discussed, including the fortification level, quality control and method of fortification. The fortification of flour is expected to start shortly.

Islamic Republic of Iran

A multicentre study showed that 33.4% of adult Iranian women were anaemic as assessed by their haemoglobin levels, while 34.5% of them were iron deficient according to their serum ferritin levels. In addition, 40.5% of pregnant women were anaemic and 51.4% of them were iron deficient; 32.2% of pregnant women were reported to take iron supplements.

In some regions of the country, IDD are considered endemic; these are mainly in the middle and north-west parts of the country. Measures for salt iodization have therefore been taken. In order to achieve universal salt iodization, an intersectoral inspection group has been promoting iodized salt, monitoring the programme and measuring its impact and also educating the public on the importance of salt iodization.
Strategies to combat iron deficiency anaemia include establishing national and provincial iron deficiency anaemia committees, strengthening iron supplementation programmes and improving de-worming and malaria control programmes. In the Islamic Republic of Iran, cereals provide 63% of the total energy intake, and the rational per capita consumption of wheat was estimated to be 178 kg per year in 1993. The consumption of bread ranged from 230 to 505 g per person per day. The Iranian Cereal Organization, a government body, is responsible for wheat purchase, storage, distribution to mills and delivery to bakeries. A trial flour fortification programme is presently under way.

**Jordan**

Iron deficiency anaemia is a major public health problem in Jordan. The highest prevalence is seen among pregnant and lactating women, where 35% of them have been found to be anaemic. It has also been shown that 8.8% and 15.3% of infants and schoolchildren respectively have low haemoglobin levels. The causes of anaemia are thought to be low dietary intake; 25%-58% of the population consumes less than the RDA for iron, while 25% of schoolchildren are infected with intestinal parasites. There are no programmes to combat iron deficiency anaemia at the moment. However, the Government of Jordan is planning strategies to combat anaemia, including health education, supplementation and flour fortification.

A national iodine deficiency study was conducted in 1993, which showed that 37.7% of Jordanian schoolchildren had goitre. In addition, urinary iodate tests indicated moderate to severe iodine deficiency in some geographical areas. The median urinary iodine was found to be 40 μg/l. In 1995, import of all salt was prohibited, and a programme was initiated to iodize all the salt produced in Jordan.

**Kuwait**

The prevalence of anaemia among pregnant women was found to be 36.8% in 1990. Dietary intake data showed that 61% of pregnant women consumed less than 75% of the RDA in 1984. In 1995, it was found that 38% of preschool children consumed less than 70% of their RDA for iron.

Iron and folate supplements are distributed routinely to pregnant women through maternal and child health care systems.

In 1985, the average bread consumption was 277 g per capita per day, which contributed 33% of the total energy intake for Kuwaitis. Per capita flour consumption in Kuwait is estimated to be 75 kg per capita per year, some of which is produced locally by one large mill.

Imported and locally produced iodized salt is available in Kuwait; however, there is no legislation for iodized salt. Authorities in Kuwait are considering fortification of flour with iron, and margarine with vitamin A, as well as salt iodization.
Lebanon

Iron deficiency is recognized as a public health problem in Lebanon, in spite of a lack of recent documented studies. Iron/folate supplements are distributed to pregnant women through the health care system.

The average daily consumption of bread in Lebanon is estimated to be 350 g per capita per day, and the iron content of flour has been found to be 1.3 mg per 100 g and that of bread to be 0.8 mg per 100 g. Each of the 11 flour mills in Lebanon produces more than 100 tonnes of flour (75% extraction). The flour produced covers the country’s requirements and the import of flour is banned. However, 90%—95% of the wheat milled is imported.

Salt iodization is mandated by law in Lebanon. All salt produced in the country or imported must contain adequate amounts of iodine. In addition, the authorities are considering flour fortification with iron.

Morocco

In 1994, the Ministry of Public Health in Morocco found that 45.4% of pregnant women were anaemic according to WHO criteria. The prevalence of anaemia among children and adult females was found to be 35.4% and 30.8% respectively. As expected, only 9.9% of adult males were anaemic.

As a result of these findings, the Ministry of Public Health has started a supplementation programme for pregnant women. For 30 weeks, each pregnant woman is given an oral dose 120 mg iron and 0.5 mg folic acid per week in tablet form.

Iodization of salt has started but universal salt iodization has not been achieved to date. Fortification of sugar with iron has been considered; however, it was found that sugar fortified with iron changes colour, which reduces consumer acceptance. In addition, sugar is usually consumed in tea in Morocco and therefore the iron absorption would be inhibited by the tannins. This has led to the search for other vehicles and studies are being conducted on the feasibility and acceptability of flour fortification with iron. The private sector and the Ministry of Public Health are coordinating to advocate for flour fortification through these studies.

Oman

According to several studies carried out in Oman in 1986, 1991 and 1992, about 50% of pregnant women are anaemic, indicating that no significant improvement has been made in reducing anaemia. Among pre-adolescent schoolchildren, the prevalence of iron deficiency was found to be 33%.

The Ministry of Health of Oman has adopted a variety of strategies to combat micronutrient malnutrition. Health education programmes are being carried out; however, these programmes require a strong health infrastructure and high technical capability. Therefore several years are needed for the impact of these programmes to be seen.
Iodization of salt has been mandated to control iodine deficiency. The legislation bans importing or selling any non-iodized salt.

Another strategy carried out in combination with health education is the supplementation programme, where pregnant women are given iron/folate tablets through the primary health care system. The supplementation programme is targeted at one sector of the population and is highly dependent on the compliance of the target group.

Food fortification has been considered in order to reach the segments of the population which are not targeted in the other programmes. Iron fortification of flour has been considered in order to prevent iron deficiency anaemia. About 80% of the flour in Oman is produced by one mill with a production capacity of 800 tonnes per 24 hours and the average consumption of flour was estimated to be 286 g per capita per day in 1995. Thus, flour fortification is seen as a potentially cost-effective programme. A proposal is being made to start fortification of white flour with ferrous sulfate at 30 ppm, starting in January 1997, and to introduce legislation requiring flour to have the minimum iron content of 30 ppm. In addition, feasibility and applicability studies of vitamin A fortification are under way.

Saudi Arabia

Over the past two decades or so, virtually all socioeconomic indicators in Saudi Arabia demonstrate the development which has been made. The expansion of the educational and health systems, the rapid and intensive urbanization of the country, the electrification of urban and rural areas and the rapid increase in the production of different animal and agricultural food products have resulted in dramatic declines in mortality and morbidity.

In the second Saudi Symposium on Food and Nutrition held in King Saud University in Riyadh in November 1994, the nutritional anaemia eradication programme was presented. It was found that anaemia affects all vulnerable groups of the population, while the prevalence among all groups varies from 4.5% to 66.7%.

The programme aims at reducing the cases of anaemia by 25% every year, by increasing awareness among the population and medical staff, including doctors, nurses, social workers and nutritionist. In addition to improving the surveillance of anaemia in primary health care centres and hospitals, the programme will support research and field studies. Treatment of severe cases will also be achieved during this phase.

A national committee and a Ministry of Health committee are to be formed to continue research, conduct surveys and mass-education and collaborate with other agencies and flour fortification programmes.

The Public Organization of Grain Silos and Flour Mills is responsible for buying all wheat that is produced locally by Saudi farmers at a fair price. It is also responsible for storing enough wheat for any emergency, producing flour
of all kinds covering the market needs and exporting any excess wheat and wheat products.

The vitamin and iron mixture used for flour fortification in the country is Rovifarín 955 premix produced by Hoffmann Laroche. It has been estimated that the cost of flour fortification is about 1.00 Saudi riyals per person per year (US$ 1.00 = 3.75 Saudi riyals).

Measures taken for the prevention and cure of micronutrient deficiencies in Saudi Arabia include:

- educating the public about nutrition and raising awareness of nutritional disorders;
- conducting surveys, studies and applied research in order to monitor continually the nutritional situation in order to promote a realistic approach towards problem prevention and cure;
- adopting a food fortification strategy in which micronutrients are added to foods to overcome any deficiencies encountered; steps taken in this regard by the Saudi authorities include:
  - iron and vitamin fortification of wheat
  - vitamin A and D fortification of milk
  - iron fortification of milk
  - iodization of table salt.

**Syrian Arab Republic**

The Syrian Arab Republic has achieved self-sufficiency in most agricultural products, including beans, vegetables, fruit, eggs and chicken. However, it still imports half of its needs in sugar and more than half of its needs in red meat and vegetable oil. It also imports all its needs in tea, coffee and rice. The Syrian Arab Republic produces an excess of carbohydrates (wheat, potatoes), except sugar, and we also have an insufficiency of fat (energy food). Oil importation was 40,000 tonnes in 1993 despite the fact that olive cultivation and oil production in 1994 was more than half a million tonnes. In 1993, the country imported about half of its needs (nearly 53,000 tonnes) but its production increased from 126,000 tonnes in 1993 to 161,000 tonnes in 1994. In addition, chicken, with a production of between 75,000 and 76,000 tonnes per year, is not imported at all. Milk production is about 1.2 million tonnes annually and has not changed much over the past 5 years. In addition, 35,000 tonnes of fresh milk are imported.

A national survey was carried out in 1990 to estimate the prevalence of IDD which showed that the prevalence in school-age children was 73%. Universal salt iodization coverage is 100%; iodized salt is the only kind of salt allowed to be sold. The average iodine content is between 25 ppm and 50 ppm.

A national survey was carried out in 1995 to estimate iron deficiency among children under 5 years of age and women of childbearing age; it showed that iron deficiency and anaemia were common. Now there is a health education
programme for iron deficiency anaemia and health centres distribute iron tablets (60 mg) to pregnant women.

There are 23 mills with a flour production capacity above 100 tonnes per day and also smaller mills with production capacities below 100 tonnes per day; all of them are roller mills. About 4% of the flour consumed is made by the small mills. There are no stone mills in the country. The per capita flour consumption is 5000 tonnes per month. All flour has an extraction rate above 85%. Average bread consumption per person per day is 500 g (500 g of bread is eaten per day by young children and 300 g per day is eaten by women). The bread is usually fermented with yeast. The price of flour and bread is controlled by the Government and is subsidized.

**Tunisia**

The Tunisian citizen consumes about 200 g of bread per day. The bread is fermented with yeast. The prices of flour and bread are controlled and subsidized by the Government. About 380 g of meat are eaten per person per week and it is usually eaten with bread. Tea and citrus fruit are usually consumed after meals and without bread.

About 51% of the wheat for consumption is imported. There are 17 flour mills with a production above 100 tonnes per day. Small mills operate in some towns and in the villages, while stone mills are still used by some rural families. A decree issued in September 1995 permits only iodized salt to be marketed in the country (35–45 μg of potassium iodide per kg of salt).

Studies carried out in 1988 and 1989 showed that the national prevalence of anaemia was 38% and that the prevalence of anaemia among children aged between 6 months and 72 months was 41.7%. A national survey on household consumption revealed that the daily consumption of iron was insufficient among low-income groups. A regional survey (Tunis) on iron supplementation among pregnant women revealed that only 20% regularly took iron supplements, and that the rate of women with iron deficiency increased with the trimester of the pregnancy (with the increase in iron needs). This situation is thought to be caused by the lack of prenatal care for some women, the absence of continuity of prenatal visits during pregnancy and the lack of awareness of women of the advantages of iron consumption.

A national strategy for iron fortification for pregnant women started in 1990, which includes the provision of iron/folate tablets (100 mg iron + 0.50 mg folate) from the fifth month of pregnancy until the fourth month after delivery and health education to encourage the consumption of foods rich in iron. However, the strategy requires extended and regular prenatal care coverage of pregnant women, continuous availability of medicines and sufficient awareness among women of the need for regular consumption of iron.
Annex 2

**Spot test for iron in milled cereal flours**  
**AACC method 40-40, iron-qualitative**

**Scope**

This procedure can be used to determine if a flour was properly enriched or fortified with iron and vitamins if included in a premix with iron.

**Reagents**

- Iron reagent: dissolve 10 g potassium thiocyanate (KSCN) in 100 ml water. Mix with an equal volume of 2N or about 10% hydrochloric acid (HCl) just prior to use.
- 3% hydrogen peroxide (H₂O₂) solution.

**Procedure**

- Make a small pile or slick of the test flour (about 100 g) on a bench or flat plate.
- Press a spoon or beaker into the pile to make a smooth indented surface.
- Using an eye-dropper, wet the surface with the iron reagent.
- Let stand for 2 minutes and then wet with the 3% hydrogen peroxide.
- The appearance of red spots indicates iron has been added. The number of spots per unit area will be roughly proportional to the amount of iron added.

**Notes**

For a better estimate of how much iron was added, run the unknown sample along with flour standards containing known levels of iron or enrichment.

The type of iron used can be determined from the nature of the spots. Ferrous sulfate and ferrous fumarate show large spots that develop quickly. Elemental iron shows many small spots that take about five minutes to appear.
Annex 3

Programme

Saturday, 26 October 1996

08:30–09:30  Registration of the participants
09:30–10:30  Opening session
11:00–11:30  Introduction of participants
             Election of officers
             Workshop objectives and mechanics
11:30–12:00  Iron deficiency—extent and magnitude of consequences
             Dr A. Verster
12:00–12:30  Strategies for control
             Mr V. Manna and Dr A. Verster
14:00–17:00  Country specific issues/needs, etc.
             Country presentations (11 countries)
             Bahrain, Egypt, Islamic Republic of Iran, Jordan, Kuwait,
             Lebanon, Morocco, Syrian Arab Republic, Saudi Arabia,
             Tunisia and Oman

Sunday, 27 October 1996

08:00–09:00  Fortification—principles
             Mr V. Manna and Ms Rose Nathan
09:00–10:00  Multiple fortification
             Mr V. Manna, Dr R. Merx and Dr P. Ranum
10:30–11:30  Discussion on fortification/multiple fortification
11:30–12:30  Technologies and methods
             Dr P. Ranum
             Discussion
14:00–15:00  Fortification dosages and quality control
             Dr R. Merx
15:00–16:00  Experiences in fortification, including the report
             of a six-country visit
             Dr P. Ranum
16:00–17:00  Discussions
Monday, 28 October 1996
08:00–13:30  Visit to Omani flour mills
             Demonstration
             Dr P. Ranum
14:30–15:30  Discussion on visit to mills
15:30–16:30  Economics and cost: marketing issues
             Dr R. Ranum
16:30–17:00  Discussions

Tuesday, 29 October 1996
08:00–09:00  IEC/advocacy
             Mr V. Mannar and Dr R. Merx
09:00–10:00  Standards and legislation
             Ms Rose Nathan
10:30–11:30  Monitoring and evaluation, including quality control
             Dr R. Merx
11:30–12:30  Introduction to Group Work
             Dr A. Verster
14:00–17:00  Group Work (four groups, one on each issue)

Wednesday, 30 October 1996
08:00–10:00  Working group reports
10:30–11:30  Discussion
11:30 - 12:30 Panel session: multisectoral partnership and coordination
             Moderator: Mr David Alnwick and members: Dr Peter Ranum,
             Ms Rose Nathan and Mr V. Mannar
14:00–17:00  Country teams develop plans for follow-up

Thursday, 31 October 1996
08:00–10:00  Presentation of country follow-up plans
10:30–11:30  Presentation of follow-up plans continued
             Discussion
11:30–12:30  Conclusions and recommendations
             Dr A. Verster
             Proposals for follow-up
12:30–13:00  Closing session
Annex 4

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# Annex 5

## List of countries

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<th>Countries in the Eastern Mediterranean Region of WHO</th>
<th>Countries in the Middle East and North Africa Region of UNICEF</th>
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