



MANUAL FOR WHEAT FLOUR FORTIFICATION WITH IRON

GUIDELINES FOR THE DEVELOPMENT,
IMPLEMENTATION, MONITORING, AND
EVALUATION OF A PROGRAM FOR WHEAT
FLOUR FORTIFICATION WITH IRON

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Part 1
**Guidelines for the development, implementation,
monitoring, and evaluation of a program
for wheat flour fortification with iron**

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Table of Contents

Acknowledgments	v
Foreword.....	vii
Abbreviations.....	ix
Glossary	xi
I. Introduction	1
II. Controlling and Preventing Iron Deficiency and Anemia	3
A. Characterization and diagnosis of ID and IDA	3
B. Types of interventions	3
C. Cost-effectiveness of iron fortification.....	4
D. Goal and objective of an iron fortification program	6
III. Developing and Operating the Program	11
A. Assessing the milling industry.....	11
B. Forms of iron	12
C. Fortification level	13
D. Technology and inputs.....	13
E. Steps to be followed in an iron fortification program	14
F. Pilot studies.....	14
G. Program development process.....	15
IV. Quality Assurance	21
A. Quality control of the iron fortificant at the mill.....	21
B. Quality control of premix and fortified wheat flour.....	22
C. Monitoring fortified wheat flour	23
D. Resources required for an iron fortification program.....	24
V. Evaluating the Effectiveness of Iron Fortification of Wheat Flour.....	25
A. Design and frequency of the effectiveness evaluation	25
B. Evaluating the intermediate effect.....	26
C. Evaluating the biological effect.....	26
D. Sample selection	27
E. Resources required for evaluation	28
VI. Program Costs	29
A. Overall program costs.....	30
B. Costs for millers.....	33
C. Framing costs for retailers and consumers	33
VII. Report Preparation	35
Appendix 1.1: Iron deficiency and anemia.....	37
Appendix 1.2: Simplified flowchart of the wheat milling process.....	39
Appendix 1.3: Types and grades of wheat flours	41
Appendix 1.4: Lima Declaration	43
Endnotes.....	45

Tables

1.1. Cutoff points for hemoglobin (g/L) concentration to define anemia	27
1.2. Iron status indicators	27
1.3. Costs and relative costs of iron fortificants	29
1.4. Characteristics of country X	30
1.5. Estimated hypothetical costs of wheat flour fortification.....	31

Figures

1.1 Schematic diagram of the wheat grain.....	7
1.2 Loss of iron during milling	8
1.3 Legal framework for a wheat flour fortification program	20

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Foreword

Anemia is the most widespread micronutrient deficiency in the world; it affects all age groups in both developed and developing countries. The lower levels of anemia found in developed countries are attributed to higher levels of heme-iron intake and the fortification of staple cereals and other foods such as breakfast cereals. In developing countries, the regular consumption of high phytate meals precipitates anemia because much of the iron ingested is unavailable for absorption. Other micronutrient deficiencies, such as inadequate intake of folic acid and vitamin A, and parasites also cause anemia. Much of the anemia found in developing countries is not due solely to iron deficiency; thus, multiple interventions are needed.

Iron deficiency anemia can be controlled through iron supplementation and food fortification. Wheat-based foods are consumed in many countries, and their consumption is increasing. Fortification of wheat flour with iron (and other micronutrients) is a practical intervention because target populations do not need to alter their eating habits and programmers do not need to adapt a new or costly distribution system; wheat fortification only requires the existence of a well-established milling and marketing system that allows for the uniform addition of iron and monitoring the iron content in flour. Fortification of wheat flour with iron is safe and can be used to prevent, but not cure, iron deficiency anemia.

In this three-part manual, technical guidelines are presented to systematize and facilitate the establishment and implementation of a program for iron fortification of wheat flour. Part 1 describes why it is important to prevent and reduce both iron deficiency and iron deficiency anemia and how to go about establishing such a program. Existing strategies are discussed and the basic elements to be considered in establishing an appropriate program for iron fortification of wheat flour are described in detail. In addition, Part 1 offers an overview of the entire program so that public and private sector officials who manage and coordinate flour milling activities have information on the essential components to ensure adequate operation. Technical areas described in this document will also be helpful to specialists for specific components of the fortification process. These include the operations involved in wheat flour fortification, determinants of both the efficiency and efficacy of intervention, and guidelines for determining program costs.

Part 2, Technical and Operational Guidelines, is written specifically for technical personnel responsible for implementing wheat flour fortification with iron. It covers the different forms of iron compounds, composition and preparation of premixes, procedures for adding iron to wheat flour, and a description of quality control procedures.

Part 3, Analytical Methods for Monitoring Wheat Flour Fortification with Iron, presents laboratory methods to determine the content of iron in the premix and in fortified wheat flour. Part 3 is written primarily for laboratory personnel who will be responsible for laboratory analyses.

Each part of the manual is relatively self-sufficient in the essential areas of program design and implementation. Ideally, however, it is recommended that the three parts be considered as theoretical and practical units to be used together.

A sustainable program for iron fortification of wheat flour reflects collaborative efforts of millers, producers, the public sector, researchers, and donors. The purpose of this document is to share the experiences of those involved in wheat flour fortification so that other countries can plan and implement this important intervention to eliminate and prevent iron deficiency and iron deficiency anemia.

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Abbreviations

DALYs	Disability-Adjusted Life-Years
FAO	Food and Agriculture Organization of the United Nations
GDP	gross domestic product
ID	iodine deficiency
IDA	iodine deficiency anemia
IEC	information, education, and communication
INACG	International Nutritional Anemia Consultant Group
MT	metric ton
NGO	nongovernmental organization
RDI	recommended daily intake
UNICEF	United Nations Children's Fund
WHO	World Health Organization

GLOSSARY

Atta: hard or durum wheat flour commonly used to make unleavened bread in the Indian subcontinent. It has a 97% extraction rate.

Ash content: the incombustible material in flour that comprises mainly minerals. It is determined as a percentage of wheat flour after ignition of flour at 525–550°C. Flours with higher extraction rates have a higher ash content.

Bioavailability of iron: the degree to which iron is absorbed in the gastrointestinal tract and utilized for normal metabolic functions, for example, incorporated into hemoglobin. It is expressed as a percentage of the total amount of the nutrient.

Bridging: the material compaction of caking or cohesive premixes that contribute to the formation of a bridge or a stable arch inside the feeder resulting in poor or no flow of the premix. This is a commonly occurring problem with premix feeders, especially when the premix has a high bulk density and is compact.

Bulk density or specific weight: the weight of the raw material in grams per liter.

Carrier or filler: a substance used to dilute or add bulk to a premix. Starch is most commonly used as a carrier in commercial micronutrient premixes.

Certificate of analysis: the guarantee provided by the premix supplier/manufacturer to the customer (flour mill) that the premix meets the concentration specifications set by the customer.

Clears or clear flour: flour with greater amounts of bran and germ than patent or straight grade flours. Being less refined, these flours are off-white in color and have a higher ash content than patent flour.

Durum wheat: a hard wheat characterized by its high protein content. Durum wheat can be milled into semolina for pasta products such as macaroni and spaghetti or into durum wheat flour for noodles.

Enrichment: the process of adding micronutrients which are naturally present in the food to levels higher than naturally occurring, for example, adding iron at 66 ppm to wheat flour.

Extraction rate: the weight of flour produced or extracted from the grain compared to the weight of the original wheat grain, expressed as a percent.

Farina: a granular, free-flowing product milled from the endosperm of hard wheats. It is used in the manufacture of breakfast cereals and inexpensive pasta products.

Feeder or dosifier: the equipment used to add fortificant to flour.

Flour improvers: substances such as bleaching agents, enzymes, oxidants, and reducing agents that can be added to flour at the mill to enhance the color and baking performance of the flour.

Fortificant: the micronutrient(s) added to flour during fortification or enrichment.

Fortification: the process of adding micronutrients to food that are either not naturally present or to levels that are much higher than naturally found in the food, for example, adding vitamin A to sugar or adding iron at 66 ppm to wheat flour.

Mill capacity: the amount of flour that a mill can produce in a 24-hour period.

Overage: the amount of a micronutrient, over and above that required, that is added to a food to compensate for losses during processing, storage, distribution, and food preparation.

Patent-grade flour: flour containing the least bran and germ particles, thereby the whitest and lowest in ash. These highly refined flours are used for special cakes and pastries.

Premix: a blend of micronutrient(s) with or without a filler to be added to flour. It can also be a diluted iron-flour blend that is made at the fortification site.

Pro-oxidant: a substance such as iron that catalyzes oxidative reactions.

Qualitative test: a test that provides information on the presence or absence of a specific substance or compound without reference to the amount of that compound in the food, for example, the qualitative spot test for iron in flour.

Quality assurance: a systematic process that monitors and evaluates all aspects of fortified flour production to ensure that standards of quality are being met.

Quality control: a set of activities (for example, inspection of premix or regular feeder checks) designed to ensure that the quality of fortified flour produced meets a certain standard.

Quantitative test: a test that determines the exact amount of a specific substance or compound in foods, for example, the spectrophotometric method of measuring iron in flour.

Restoration: the replacement of nutrients lost during food processing, for example, adding to wheat flour the amount of iron lost during milling.

Rotation period: the period between flour production and retail sale.

Semi-quantitative test: a test that provides an estimate of a specific substance or compound in food within a predefined range, for example between 5 and 10 μg iron/g flour.

Semolina: a granular, free-flowing product milled from the endosperm of durum wheat. It is used to make macaroni, spaghetti, and other pasta products.

Straight-grade flour: flour that is obtained by blending together all the flour streams, which represent different grades of flour. It often has a 75% extraction rate and is used to make breads and other baked goods.

Tramp iron: extraneous fine remnant or contaminant iron particles that are inadvertently introduced during the milling process.

Tempering or conditioning: the addition of water to wheat grains to soften the grain, making it easier to mill.

Tunneling: the material compaction of caking or cohesive premixes that contribute to their sticking to the walls of the feeder, forming a “tunnel” that results in little or no flow of the premix into the flour. Tunneling is a common problem with premix feeders, especially when the premix has a high bulk density and is compact.

I. Introduction

The World Health Organization (WHO)¹ estimates that two billion people or one-third of the world's population are anemic based on hemoglobin levels; half of these cases are due to iron deficiency (ID). No other micronutrient deficiency is as widespread. The most commonly affected populations in developing countries are pregnant women (56%), school-age children (42%), non-pregnant women (44%) and preschool children (44%); as many as 50% of the elderly and adult males can be anemic as well. Regional differences exist, with much greater prevalence rates in sub-Saharan Africa and Southeast Asia. For further information on the physiologic role of iron in the body, the causes of iron deficiency and anemia, and food sources of iron, please refer to Appendix 1.1.

The other factors besides ID that cause anemia² include deficiencies of nutrients such as riboflavin, folic acid, vitamins A, B₆, B₁₂, and general infections and chronic diseases such as HIV/AIDS. The risk of ID and anemia is also increased in situations where individuals are exposed to infections and parasites, such as malaria and helminths. A failure to meet iron needs can, therefore, be due to either dietary or nondietary causes. The bulk of the cases of iron deficiency are diet related, however. The distinction between anemia caused by ID and that which is not is important and needs to be considered for evaluation purposes.

Anemia has important health and economic consequences. Anemia in early pregnancy can be harmful to the development of the unborn baby. It can also increase the risk of a mother having a miscarriage or stillbirth, or delivering a low-birth-weight baby, which, in turn, is linked to increased risk of perinatal and infant mortality. Anemic mothers may also be at increased risk of maternal mortality, especially those that have complications at birth that result in hemorrhaging.

Infants born to anemic mothers are more likely to be moderately or severely anemic than those born to nonanemic mothers. In young children, ID and anemia can have adverse effects on cognitive performance, motor development, coordination, language development, and scholastic achievement that are not always reversible. WHO³ estimates that anemia in infants and young children results in a permanent deficit of at least 5 IQ points below nonanemic counterparts and a 10% reduction in learning capacity during school years. Iron deficiency anemia (IDA) also affects children's growth. In adolescents both ID and anemia have been associated with poor concentration and cognitive performance, reduced appetite, and reduced growth. In adults, IDA has been associated with reduced capacity for heavy physical work as well as for sedentary industrial occupations.

Clearly the physical and mental performance deficits identified above have profound implications for national economic development. A recent study⁴ of 15 countries showed that the median value of productivity losses due to ID was about US\$4/person/year or 0.9% gross domestic product (GDP), and this excluded the lowered effectiveness of money spent on education. For almost all of the countries studied the cognitive losses in children accounted for more than one-half of the annual total loss per person. As a percentage of GDP, total losses were highest in the poorest countries where both anemia rates and the percentage of the labor force in heavy manual work were highest. While treating ID and anemia are clearly important and essential, like other illnesses their prevention is more cost-effective than their cure.

The consequences of ID and anemia can be prevented through both food-based and pharmaceutical interventions. In the next section, pharmaceutical and other options are described briefly, followed by the main topic, food fortification and specifically wheat flour fortification with iron.

II. Controlling and Preventing Iron Deficiency and Anemia

A. Characterization and diagnosis of ID and IDA

In deciding on the most appropriate intervention or interventions to combat ID and anemia, it is first necessary to document the characteristics of the deficiency at the national or subnational level. The following information must be gathered:

1. The extent of the problem, i.e., the prevalence and number of people affected.
2. The severity of the deficiency, i.e., the degree of the deficiency: marginal, moderate, or severe.
3. The distribution of the deficiency among different sectors of the population by ecological or administrative regions, age and sex groups, urban or rural location, and socioeconomic status.
4. The major causes of anemia, i.e., iron deficiency, malaria, hookworm, folic acid, and vitamin A deficiency.
5. The major causes of ID, i.e., low intake of bioavailable iron and blood loss.

To obtain the information, a population-based survey is needed with representative samples from the different population groups. Ideally, such a survey would include dietary data for the consumption of different food sources of iron and biological data to show that minimally anemia is prevalent. A standardized method should be used for data collection, as should indicators that have been established by recognized authorities such as WHO and the International Nutritional Anemia Consultant Group (INACG). The indicators will be discussed later in Section V of this document.

B. Types of interventions

ID and anemia can be corrected and prevented by increasing the dietary intake of iron and by reducing the underlying factors that prevent adequate iron absorption or increased iron losses. The strategies for achieving the latter include controlling the pathological factors that cause deficiency. These actions, however, will succeed only if the dietary intake of absorbable iron is sufficient to satisfy normal requirements. Interventions to prevent the loss of iron and to increase the supply of iron in populations whose diets have low amounts of readily absorbable iron include the following:

1. Public health measures

A variety of public health measures can be adopted to address nondietary causes of anemia, such as deworming, malaria control, and improvements in water and sanitation. However, the deficit in iron will have to be made good with iron supplementation, after which iron fortification can be used as a preventive measure.

2. Dietary modification

Educating families to consume flesh foods, to eat more vitamin C-rich fruits and vegetable with their staple food, or to refrain from drinking tea or coffee two hours before or after a meal is efficacious but has not been demonstrated to be achievable at the population level. Promoting modifica-

tions in food preparation practices that result in the breakdown of phytates in food that bind to iron can be efficacious. Programs to change eating behavior, however, have proven very difficult to implement and sustain on a large or national scale because eating patterns are often traditional and deeply rooted in social culture and are not always easy to change. Also, behavior change programs do not deal with the underlying problem of poverty that largely determines what people can afford to and do eat.

3. Supplementation

Increasing iron intake through the use of pharmaceutical supplements is an efficacious way to increase iron intake in order to correct IDA, to prevent ID from becoming IDA, and to prevent ID in the first place. Such programs have generally focused on pregnant women, playing a dual role of being both preventive and therapeutic with the emphasis on therapeutic action. To date, no large-scale iron supplementation program in any developing country has been implemented well enough to show a positive effect on lowering ID or anemia significantly. To succeed, programs require a reliable distribution system for delivering good-quality supplements when and where they are needed, as well as appropriate activities to sensitize both health care professionals and the public at large about the need for and appropriate use of iron supplements; these requirements have not been met. Moreover, unlike vitamin A or iodine supplementation, which require one or two large doses of the nutrient annually or biannually, respectively, preventive iron supplements must be taken at a low dose on a regular basis—daily or weekly, depending on the age group—for at least three to six months.

4. Food fortification

The term “food fortification” refers to the addition of one or more essential nutrients to a food, regardless of whether they occur naturally in the food. The purpose of fortification is to correct a recognized population-wide micronutrient deficiency or to add micronutrients lost in processing back to their original levels (restoration) or even higher. Government may mandate or encourage collaboration between the public or private sector and the health or agricultural sector through food fortification legislation, regulation, or a variety of incentives. Food fortification is also often used as a marketing tool by the food sector to increase sales. Thus, the types and levels of nutrients that are added are greatly influenced by which of the above purposes takes precedence.

Because ID and IDA affect all age groups and all strata of society, including many not served by the public health or welfare systems, iron fortification of food has distinct advantages over the other interventions. Fortifying a widely consumed, centrally processed food with iron also capitalizes on the production and distribution system of the food market to deliver an efficacious low dose of iron to a great number of people on a daily basis. Iron fortification is considered safe⁵ because individuals who are not at risk of ID can consume additional iron safely since the body is an efficient regulator of iron absorption. Experience has shown, however, that an iron fortification program will be successful only if the correct form of iron is used, the iron is protected from substances in the food to be fortified that can bind to the iron rendering it insoluble, and the underlying causes of the anemia cases are understood.

C. Cost-effectiveness of iron fortification⁶

In iron fortification, the cost for personnel, facilities, materials, and iron is minute compared with the value of the food being fortified. In fact the incremental cost of iron fortification of wheat flour is generally insignificant—usually less than 1% of the wholesale cost of flour. The added cost of fortifying wheat flour with iron has been calculated to be typically less than US\$1.00 per metric ton (MT).

The World Bank measures the cost-effectiveness of health interventions in a unit known as Disability-Adjusted Life-Years (DALYs) gained, which is essentially the monetary value of life-years free of illness. Globally, anemia is ranked as the third leading cause of loss of DALYs for women between 15 and 44 years. Among men of the same age range, IDA is ranked among the top ten disease burdens. The benefits that accrue from controlling ID and IDA include savings in health care costs; reduced worker absenteeism and increased worker productivity; and improved educability of children including a reduction in the costs of special education services and the need to reschool children who have to repeat a school year. Because of the low cost of iron fortification of flour and the large potential health gains in populations where ID and IDA are prevalent, it is one of the most cost-effective health interventions: US\$ 4.40/DALY⁷ compared with US\$ 12.80/DALY for iron supplementation to pregnant women, US\$ 7.50/DALY for salt iodization, US\$ 29.00/DALY for vitamin A fortification, and at least US\$ 100.00/DALY for certain other health interventions, such as TB treatment, that result in health improvements.

Poverty resulting in an inadequate intake of food, lack of knowledge, and disease are the main causes of undernutrition. Regarding ID and IDA, poverty is probably the most significant cause because readily absorbable iron-rich foods, i.e., flesh foods, are relatively expensive. General unawareness about ID and anemia can result in inadequate supplies of iron supplements being available in the public health system as well as low demand for them by both health care providers and recipients. Even where iron supplements are issued, lack of understanding can result in poor compliance. Diseases such as malaria and intestinal helminthes as well as diarrheal diseases can cause anemia, even when the diet contains sufficient iron.

Where disease is a major cause of iron deficiency, fortification of food is less effective than iron supplements because fortification does not ensure repletion, and the low regular doses of iron in the food are too small to be therapeutic. This means that iron supplementation is required for short-term larger doses, e.g., as part of parasite treatment and also during pregnancy and early childhood. Nevertheless, iron fortification of food is more cost-effective in total DALYs gained when the prevalence of anemia is also high among children and men, as is the case in many developing countries.

Where poverty and lack of nutritional knowledge are the main causes of ID and IDA, rather than malaria or hookworm, iron fortification of food is an important intervention. Poverty prevents people from eating more expensive foods that are good sources of iron, e.g. flesh foods, or foods that increase the absorption of iron from plant foods, e.g., vitamin C-rich fruits. Controlling ID by fortifying a cheaper food, such as wheat flour, with an iron that has good bioavailability can be considered similar to a price reduction in flesh foods. Where there is no widely consumed iron-fortified food and consumers have no choice but to buy more expensive foods that are good sources of bioavailable iron or promote the absorption of iron, this effective price reduction would be potentially very important because the lower a consumer's income the greater the response to price changes. The availability of a food such as iron-fortified wheat flour at a fixed price would also lower the cost of iron at those times when meat and vitamin C-rich food prices are high, and this too could offset the effect of seasonal price changes and resulting fluctuations in the intake of bioavailable iron.

D. Goal and objective of an iron fortification program

The goal of iron fortification is to eliminate ID and IDA. The objective is to increase the intake of this essential nutrient, to improve iron status in situations where daily requirements are not being met because of an inadequate intake of readily absorbable iron or excessive losses occur due to parasitic infestation.

1. When fortification with iron is appropriate

In each country, policymakers and program managers must make a decision as to when iron fortification is appropriate. This manual suggests that planners consider fortification an appropriate intervention when the prevalence of IDA in any age group other than pregnant women is greater than 10%. Determining that point requires knowledge of IDA prevalence and evidence that a large proportion of the IDA is due to iron deficiency, not parasite infestation. It is not appropriate to consider a fortification program on the basis of anemia alone since it could be caused by other factors such as malaria, which breaks down red blood cells while the iron remains in the body, or hookworm, which can cause blood loss, and/or other micronutrient deficiencies.

In addition to the health information needed, establishing an iron fortification program requires the existence of a technically developed food industry and a system of quality control and monitoring, to guarantee that iron is added correctly to the selected food(s).

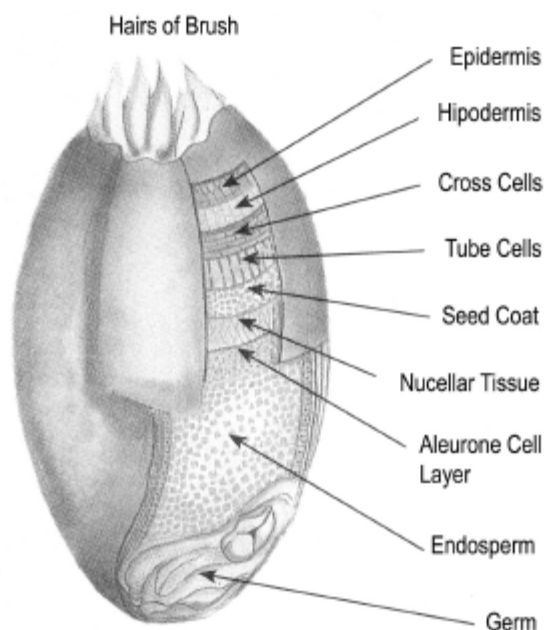
2. Wheat flour as a suitable food vehicle for fortification with iron

Before discussing wheat as a suitable vehicle for food fortification, some basic principles related to flour milling must be discussed. A wheat grain comprises an inner layer known as the endosperm, which is covered and protected by the outer layer known as the bran (Figure 1.1).

To make wheat more easily transformed into appealing edible foodstuffs, wheat grains must first be milled into flour using a process similar to that shown in Appendix 1.2. Wheat milling comprises the following basic steps:

- a. *Cleaning*—removing foreign materials and dust from the grain.
- b. *Tempering*—adding water to bring the moisture content to an optimum level (12–14%).
- c. *Grinding and refining*—breaking up the grain, separating the inner endosperm from the bran and germ, and grinding to a suitable degree of fineness.
- d. *Treatment*—aging the flour and adding improvers including micronutrients.

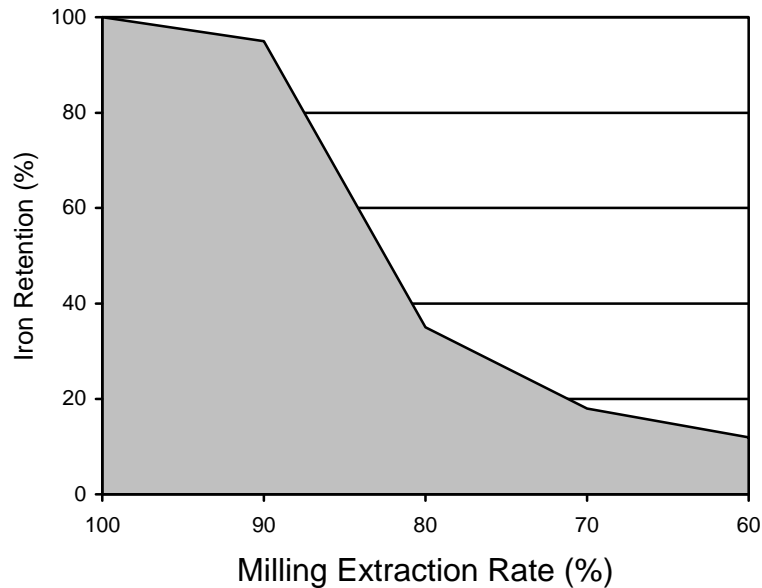
Figure 1.1
Schematic Diagram of the Wheat Grain



The type of milling used will depend on both the quality of refinement required and the technology available. The latter can vary from simple stone grain crushing, to small hammer mills, to large modern roller mills. Whatever the method, wheat flour is separated into few or many flour streams according to particle size, grade, and other quality parameters. At the end of milling, the different streams can be blended together to make different grades of flour. (These are described briefly in Appendix 1.3)

Whole wheat grains are good sources of some of the B-complex vitamins as well as iron and other minerals, which are concentrated in bran. During milling the bran is separated from the endosperm; at the end of the milling process, about 75% of the original wheat grain is ground endosperm or flour, and 25% is bran and other byproducts. The extent to which the bran is separated or extracted from the endosperm, or the weight of the flour relative to the original weight of the wheat grain, is known as the extraction rate⁸. Flours are typically extracted 72 to 78%. Flours with a high extraction rate, i.e., less refined, are those where less bran has been removed; thus, they tend to be browner flours. About two-thirds of the iron naturally found in flour is lost in milling; the amount varies depending on the extraction rate (Figure 1.2⁹).

Figure 1.2
Loss of Iron during Milling



Besides micronutrients, bran contains phytates that bind to iron in the gut making it unavailable for absorption. Flour with a high extraction rate, therefore, has more iron and more phytate, but because of the phytate less of the iron will be available for absorption. For this reason, the extraction rate of the flour is important in iron fortification because it determines which iron compound to use.

Deciding whether wheat flour is an appropriate vehicle for iron fortification requires reliable information on several crucial factors:

- a. Wheat consumption patterns and sources (subsistence or purchased).
- b. Marketing patterns for foods made with commercially available wheat flour, e.g., bread, noodles, and pasta.
- c. The capacity of wheat millers to adopt the fortification process.

Once the above information is gathered, wheat flour can be considered a good vehicle for iron fortification where it fits the following criteria:

- d. More than 50% of the population served consume wheat-based products, especially those at greatest risk of ID and IDA.
- e. Fortified flour would be a fair source of iron (providing 15 to 25% of the US RDA) or a good source (providing more than 25% of the US RDA). If for example the fortified flour contained 66 ppm iron that was fully bioavailable and provided 25% of the US RDA for iron of 14 and 48 g/day for children 2–6 years old and adult women, respectively, to meet their daily iron needs children 2–6 years old would have to consume on average 50 g/d

wheat flour (equivalent to two and one-half 1-cm thick slices of bread and one small-sized roti), while women would have to consume on average 160 g/d wheat flour (about eight 1-cm slices of bread or two medium-sized rotis).

- f. Little day-to-day intra- and inter-individual variation occurs in the amount of wheat-based products consumed.
- g. The wheat flour is centrally processed in relatively few mills where iron can be added under controlled conditions and at minimum cost.
- h. The marketing and distribution channels for iron-fortified wheat flour and wheat-based foods to consumers can be tracked.

The basic premise of a wheat flour fortification program is that wheat-based foods must be an integral component in the diet of the general population. That is not always the case in developing countries, especially among the lower socioeconomic groups. In many countries, especially those in which maize, rice, sorghum, millet, roots, and tubers are staple foods, wheat-based foods are consumed primarily by the upper and upper-middle socioeconomic groups who are less vulnerable to ID and IDA because they can also afford flesh foods. In some countries, an obstacle to wheat flour fortification is the fact that flour is produced by thousands of small-scale millers, which makes it difficult to distribute the iron and control the fortification process.

3. Additional benefits of an iron fortification program

Besides the health benefits of iron fortification of wheat flour, there are a number of other advantages to using wheat flour as the vehicle. These are:

- a. Iron is very stable in wheat flour during production and storage. Iron losses are negligible in the baking and processing of wheat-based foods.
- b. Other micronutrients can be easily added at the same time as iron¹⁰. Indeed, folate should be added to flour with iron wherever possible to prevent pregnant women delivering babies with neural tube defects and, for the purpose of these guidelines, it is assumed that this will be done.
- c. Government and industry can share the initial investment, but ultimately the cost of the intervention can be passed on to the consumer. Another economic benefit is that by protecting the population who regularly consume wheat flour against ID, public efforts and resources to deliver preventive iron supplements, dietary education, and other public health measures to control ID can be redirected to the more remote and disadvantaged populations who have limited access to commercial wheat flour.
- d. Wheat consumption is increasing in developing countries and, because wheat-based meals—especially those using breads and pastas—are often quicker to prepare than foods made from other staples, consumption is unlikely to fall. Thus, the benefits of fortification will expand.
- e. Iron fortification of wheat flour does not require significant change in purchasing and consumption habits because flour is already in the market and part of the diet. If consumers buy as much iron-fortified wheat flour as unfortified wheat flour, they inadvertently eat more iron. Consumers, however, may say they prefer unfortified wheat flour because they perceive it to taste better or they may believe there is some risk associated with eating forti-

fied flour. Educating the population about the benefits of fortification is important in itself to make the population at large aware of the problems of ID and IDA and the need to take corrective action at the individual, community, and national level.

- f. Fortification can be a market-based strategy that builds on private investment and consumer demand. For manufacturers it can become a more attractive, or even profitable, way of doing business. Among consumers, it can become a habitual purchasing preference. These market forces will sustain fortification long after the initial goals for the reduction of iron deficiency have been achieved.

In establishing a wheat flour fortification program, five components need to be considered. These include program planning and operation, quality control and monitoring, evaluation, cost analysis, and reporting. Each of these is discussed in detail in the following chapters.

III. Developing and Operating the Program

Gathering the background information needed to develop a program for iron fortification of wheat flour involves opening communication channels with a range of organizations in both the public and private sectors. Organizations include ministries of health, agriculture, trade, and commerce; flour millers and related trade organizations; bakers and other industries that process flour; consumer groups and civic organizations; and public health and development NGOs. Gathering information provides an opportunity to inform the key players about the effect of ID and anemia as well as to assess the opportunities for and barriers against supporting an iron fortification program.

A. Assessing the milling industry

Determining the number and distribution of flour millers, wheat-based food manufacturers, and flour wholesalers is key. The number of mills and the extent to which flour milling is centralized will determine how difficult it will be to communicate and advocate for iron fortification of wheat flour to millers. Those factors will also have a bearing on implementation of a quality assurance system. Similarly, knowing the number of wheat-based food manufacturers (and the products they make) and the number of flour wholesalers will help to identify and design an appropriate advocacy plan to both groups.

1. Number and size of mills

The amount of flour that a mill can potentially produce in a 24-hour day is known as the mill capacity, which is a measure of mill size. Mills range in capacity from 1 to 500 MT/day and a mill's capacity is the critical factor in determining the ease and method of fortification. This manual focuses on wheat flour fortification at medium (25–150 MT/day) and large sized mills (>150 MT/day), because the feasibility and effectiveness of fortification at smaller stone or hammer mills (<25 MT/day) has not been established.

Information on the total number of mills, the number that produce more than 25, 50, 100, and 150 MT flour/day, and the proportion of mills that account for 50% and 75% of total flour production will show the distribution of mills by size. This information will also make it possible to estimate what proportion of total flour can be fortified immediately at large mills, should a fortification program be implemented.

2. Extraction rate of wheat flour

The extraction rate of flour is critical for selecting the type of iron that can be used and, therefore, the potential effect of the fortification program. Information must be gathered on the percentage of flour with an extraction rate above and below 75%.

3. Use of wheat flour improvers

Wheat flour is often treated at the mill with non-nutritional flour improvers to enhance the color of the flour and baking performance. Frequently used dry powder improvers include bleaching agents, enzymes, oxidants, or reducing agents. Mills that add flour improvers may already have feeders or dosifiers for adding small amounts of ingredients. They may also have quality control or even assurance procedures in place. Getting information on the non-nutritional improvers that each mill routinely adds to flour, the equipment used to add the improvers, and the quality control procedures in place are important for determining how much investment would be needed to implement an iron fortification program.

Medium-sized mills use either a continuous or a batch type process¹¹ for adding improvers, whereas large mills with multiple roller mills generally use a continuous addition process. Mills that already add improvers are more likely to be able to fortify with iron fairly easily as the equipment and technology needed to add iron is the same as that used for improvers. The physical setup of a mill will determine the relative ease of incorporating equipment for iron fortification. The technical assessment should, therefore, determine whether there is scope for the feeders or dosifiers to be located in an appropriate place on the relevant flour production streams.

4. Wheat flour marketing and distribution

Information on flour¹² storage and warehousing facilities and conditions, as well as the amount of time that flour is in the distribution chain and stored in homes, is important for selecting the appropriate form of iron. Flour sent to bakers or industrial processors tends to be used quickly, while flour purchased at the retail level by consumers may be stored in homes over extended periods of time.

B. Forms of iron

Due to the relatively dry and free-flowing nature of wheat flour, a form of iron with the following characteristics is needed:

1. Disperses in the flour and does not segregate or separate from it.
2. Remains undetected by color, taste, odor, or other sensory characteristic once incorporated into wheat flour at the proposed concentration.
3. Does not interact chemically with wheat flour in such a way that could result in the formation of undesirable by-products or alter the functional properties (color, taste, smell, and texture) of wheat flour or products made with it.
4. Is sufficiently stable in the wheat-based processed food (e.g., pasta, noodles, bread) at all times to ensure that it will not spoil the processed food during its life span or shelf life.
5. Does not significantly increase the cost of the fortified wheat flour or wheat-based food to the consumer.
6. Has been evaluated for safety and is on the approved list of food additives.

In addition, the concentration of iron in wheat flour that can be absorbed (i.e., is bioavailable) should provide 25 to 50% of the WHO-recommended daily intake (RDI). That range has been chosen because dietary iron intakes are often only 50% of the RDI without fortification.

The major technical challenge in iron fortification is using a fortificant (i.e., a form of iron to add) that is absorbable in the gut and that does not alter the sensory properties of either the fortified flour or foods made with it. Appropriate iron fortificants are those that are both stable and do not deteriorate during production, storage, or processing. Added iron can result in color changes, particularly if other ingredients such as fruit are mixed with the flour, or interact with the fat¹³ in flour and cause rancidity. This interaction between the iron and fat tends to increase with humidity and length of storage; the interaction also depends on the type and amount of iron added. The less refined the flour, i.e., the greater the extraction rate, the more fat in the flour. Therefore, particular attention must be paid to the extraction rate of the flour when selecting the iron fortificant.

Iron fortificants that are more stable in food, i.e., cause no sensory (smell, taste, color, texture) changes in the flour and flour products, are less readily absorbed by the body. For example, ferrous sulfate is well absorbed, but in flour stored for more than three months it tends to react with the fat and cause rancidity or an off-flavor. For this reason ferrous sulfate is only appropriate for flour with a high turnover, i.e., flour used within one month of production, such as that destined for the bread and baking industries. Elemental iron, i.e., reduced or electrolytic iron, does not interact with the fat in flour, but it is not as well absorbed as ferrous sulfate. Flour containing elemental iron can be stored for up to two years under a variety of conditions with no negative effects on flour quality. Sodium iron ethylenediaminetetraacetic acid (EDTA) does not promote fat oxidation in flour and is water soluble, but it can cause color changes. Details of the different iron fortificants available for fortification are described in Part 2 of this manual.

Iron quality is another important issue to be considered in deciding on the form to use. On the one hand there is ferrous sulfate whose bioavailability is constant, and on the other hand, there are the elemental irons that come in many grades. Depending on the grade, some of the elemental irons may be absorbed at a modest but useful level, while others may not be absorbed at all. The source of the elemental iron is therefore crucial and important to control in any fortification program.

C. Fortification level

The amount of iron to add will depend on the amount consumed each day by the different age groups, the bioavailability of the iron in the diet, the deficit in intake, and the amount of wheat flour consumed each day by the different age groups. At the same time, the amount of iron to add will be limited by the maximum amount that can be added without affecting the sensory properties of the flour itself or foods made with it. Details of how to use this information to determine the fortification level are described in Part 2 of this manual.

D. Technology and inputs

Iron fortification of wheat flour requires very little modification of the usual milling process and is relatively simple. Iron or an iron-containing multiple micronutrient premix is purchased by the miller, who may add the iron directly to the flour or make an iron-flour premix containing a high iron content that can be added to flour at the end of milling.

The purpose of making an iron-flour premix is to dilute the iron. The production of homogeneous fortified wheat flour would be more difficult if a very small amount of undiluted iron were added to a large quantity of flour. For the premix, iron should be diluted at least once (50% iron and 50% flour). The manufacturing steps of both the iron-flour premix and fortified flour are described in Part 2 of this manual.

Although the preparation of the premix is a simple procedure, it requires strict adherence to procedures to guarantee quality, including mixing the iron, wheat flour, and any other flour improvers and packaging the resulting premix in gunny sacks. A good iron-flour premix will have a bulk density close to that of wheat flour, be relatively free flowing, and not cake in storage.

Preparation of the iron-flour premix should be synchronized with the production of fortified wheat flour so that it is used soon after it is manufactured, thus, reducing storage time. However, if a premix is not made immediately before being added to bulk flour, it must be stored in the mill warehouse. The warehouse should be well ventilated, dry, and at low or moderate temperatures.

Actual fortification occurs when the iron-flour premix is added to wheat flour during milling, using automatic micro-feeders or dosifiers. It is essential that the procedure be followed carefully to ensure that the correct level of iron is added to the flour and distributed homogeneously and uniformly.

Once produced, the fortified wheat flour should be packaged according to the regulations, after which it is ready for distribution, sale, and consumption. The entire production process should be subject to a rigorous quality control and monitoring system.

E. Steps to be followed in an iron fortification program

Although wheat production is seasonal, countries import wheat throughout the year to ensure a constant supply of flour in the marketplace. To ensure that fortified flour is available at all times, it is important to plan the different stages in the fortification process.

1. Procuring the iron

The shelf-life of food-grade iron is generally two years. The timing for ordering iron will depend on the quantity and use rate at the mill. Bulk quantities are generally less expensive on a per unit basis than smaller quantities.

2. Preparing the iron-flour premix

Preparation of the premix should be done so that there is a one-month stock at all times. As mentioned before, the premix should be packaged in bags made of appropriate materials to protect against moisture. The premix bags must be clearly labeled. Labeling requirements should be mandated by law or through appropriate regulations.

3. Adding the iron-flour premix to wheat flour

The iron-flour premix should be added to the flour according to approved procedures. Appropriately fortified wheat flour should be packaged in suitable sacks, e.g., gunny sacks or burlap bags, for distribution and retail sale. Labeling for these sacks, as with the premix, should be set by national law or regulation.

4. Quality control

The fortification process is complete once the correct level of iron in the flour is verified. Specific forms should be developed and available to register laboratory results. When deviations from the norms are observed, corrective actions should be documented.

F. Pilot studies

Wheat flour fortification with iron has been carried out at the national level in several countries¹⁴, and its technological and operational feasibility is well established. Nevertheless, directors of new programs are advised to carry out a pilot study at participating mills before implementing a national-level program to ensure that all the system components are operating properly, i.e., that both the iron-flour premix and fortified flour are produced with the correct level of iron.

Fortified wheat flour has been tested to confirm its chemical and physical stability under various environmental and handling conditions. The acceptance of fortified wheat flour by consumers is evident from the widespread use of foods made with iron-fortified flour; however, because the acceptability of foods differs among cultures, program managers may want to confirm that any sensory changes in foods made with fortified flour are acceptable to the populace.

G. Program development process¹⁵

Once the technical parameters have been assessed and fortification of wheat flour is deemed a viable option to control ID and IFA, a formal national iron fortification plan for wheat flour should be developed. A negotiated document synthesized from an intersectoral discussion that reflects a balance of public and private sector interests is more likely to attract support from the highest levels in business and government than a document developed by a single ministry.

1. Understanding the wheat flour industry environment and competitive trends

In some countries the milling industry is consolidating into larger production and/or business units. Larger mills invariably have more state-of-the-art equipment and technical capacity and can more readily integrate fortification technology. These mills can also take advantage of various efficiencies of scale, amortize start-up costs, and negotiate better prices and support from the iron suppliers. With expansion, the more aggressive or technically sophisticated companies may perceive there is an advantage to flour fortification and may assume a leadership position. This has been the case for millers in Latin America who believe that there are commercial and trade advantages to their governments' mandating iron-fortification of wheat and other flours.

The flour industry also extends beyond milling. A variety of food companies, bakers, and distributors purchase flour from millers either for retail distribution or for processing into breads, noodles, pastas, and other foods. These producers and distributors may be concerned that iron in flour could affect their production processes or consumer acceptance of their products. Because these companies are major customers of the milling industry, it is important to make available the necessary information to show that iron fortification of wheat flour at the level proposed will not alter the sensory or physical characteristics of commercially processed wheat-based foods.

2. Preparing a fortification plan

The objective of a wheat flour fortification plan is to clearly describe the purpose, characteristics, and components of the intervention. A public sector, often health, usually takes the lead, but preparing a fortification plan requires the active participation of other government institutions, including finance, commerce, trade, customs and excise, agriculture, and education, as well as the private sector, notably wheat millers and wheat flour users. Alternatively, another entity may be given official responsibility for drawing up the plan, depending on the political and administrative structure of the country. Even in that case, the sectors listed above should actively participate in the process. If possible, research institutes as well as consumer organizations should also be included. Likewise, it may be advisable to seek support from international agencies such as WHO, UNICEF, FAO, and bilateral donors, as well as financial institutions such as the World Bank and other development banks, to ensure support for the program.

The fortification plan should include details on:

- a. Program background, including a description of the problem the intervention intends to solve and the government's official declaration of support and commitment to establishing the program. This backing will ensure the availability of technical, material, and financial resources.
- b. Proposed and/or modified legislation and regulations that will facilitate program implementation.
- c. The goals and objectives with clearly defined target population(s).

- d. The characteristics and components of the program, including development of activities and necessary resources (human, material, financial, and technical assistance).
- e. Quality control, inspection, and monitoring systems.
- f. An evaluation plan.
- g. The reports to be produced and the dates they are due.

3. Generating the political commitment

The health sector is responsible for identifying that ID and anemia exist and publicizing their effect on physical and cognitive development, morbidity, and worker productivity. In this regard, the health sector should emphasize to the government, private sector, and consumers the need to control and prevent ID and anemia. Professional health organizations, medical and pediatric associations, universities, and international organizations (WHO, FAO, and UNICEF) play an important role in promoting and supporting advocacy efforts for flour fortification. Unless the scientists at these institutions are aware that ID is a problem and that fortification can help, they can be vocal in resisting program development and implementation.

During the promotion phase, it is very important that the mass media (newspapers, radio, and television) be well informed about the problem, the objectives of the fortification program, and their role in supporting a successful intervention. Through their messages, the media can generate and maintain a high level of awareness and acceptance among the other sectors involved and the general public.

4. Involving the millers and private sector

A national wheat flour fortification program is a collaborative effort involving milling enterprises and the agriculture and public health sectors. Nevertheless, millers—be they public or private companies—may initially resist a change in the way they do business. At the same time, private sector managers are sensitive to the potential to improve both their relations with government agencies and their public image. Because the establishment, implementation, and sustainability of a wheat flour fortification program require the active participation of millers and commercial flour users, these groups must be aware of and committed to the benefits of the program for the population. While government sets the regulations for quality control of fortified wheat flour, millers are responsible for their application. Millers and commercial flour users must also be aware of and understand the social and humanitarian implications of their full commitment and compliance, which are critical to achieving the program's objectives. Without the assurance of the flour sector, the intervention will not be effective.

To get the full support of millers for wheat flour fortification, clear information on technical and cost issues are needed. This information should emphasize technical feasibility, low costs, and proven consumer and commercial acceptance. Mill managers will be concerned about the total investment they will be required to make—either as an incremental cost to production or as a proportion of profit, and how their investment will be recouped. They will be less interested in the cost per person at risk of ID and IDA. Often millers will look for an indication of government's willingness to share in the investment by lowering or eliminating tariffs on fortificants, providing tax breaks for capital investment, or a partial and temporary subsidy for the start-up costs. Examples for how to calculate these costs are given in Section VI.

Once convinced, the milling sector can become a powerful ally in opening up communications channels and advocating to other public and private sector entities about the importance of wheat flour fortification. The Lima Declaration (Appendix 1.4), signed by 20 Latin American countries, is an example of public commitment by millers to promote fortification of wheat flour.

5. Consumer participation

The population at large must be informed of the importance of iron for good health and nutrition and the risks associated with iron deficiency. Political and business leaders as well as the general public look to research institutions and the medical community to validate new information about health. The latter may express a clinical concern that an untargeted intervention such as flour fortification could cause iron overload. As mentioned before, because the body regulates iron absorption based on iron status, iron overload from consumption of iron fortified wheat flour products is unlikely, even for individuals with clinical conditions that predispose them to iron overload.

Educating and increasing consumer awareness about ID and IDA and the role that wheat flour fortification can play in controlling these conditions is the best way to create and sustain demand for fortified flour. The flour should be clearly labeled to show that it is fortified, following national labeling regulations. Even with mandatory legislation, consumers may still be able to purchase non-fortified wheat flour at a lower price. Nevertheless, consumers who demand fortified wheat flour will be a powerful influence on society, because pressure from consumers and consumer organizations is often more effective than government regulations to assure compliance with fortification regulations.

6. Legislation

Wheat-based foods are often important food staples, and the government may be closely involved with the milling industry. The public sector may be involved in wheat purchasing, flour milling, bread baking, distribution, or a range of subsidies. Some government laws, regulations, programs, and policies associated with the above may present either opportunities or barriers to a national flour fortification program and should be reviewed.

The strongest expression of political commitment is legislative action to make the program official. Such legislation will define the basic norms for implementing fortification, including the responsibilities of each sector involved. At the same time, the legal consequences of failing to comply with the norms must be defined. The law must be complemented by specific regulations and standards that describe in detail the guidelines for correct implementation of activities¹⁶.

Existing food-control laws regarding flour fortification may be permissive, i.e., allowing voluntary fortification, or mandatory. When consumer demand and market competition for a product are high, companies may perceive that there will be an advantage in voluntarily fortifying food. This, however, may not be the case for wheat flour because its price margin is usually very small. Also, consumers are unlikely to notice or attribute any improvement in health to fortified wheat flour. Consequently, there is little business advantage to investing in the start-up expenses and taking the risk of developing a market for a “new” flour. With no consumer demand driving the market, companies may take a “wait and see” attitude. Mandatory fortification, in contrast, creates a level playing field and is recommended where the consumption of wheat-based foods is sufficiently high and fortification is likely to have a positive effect on ID and IDA. With mandatory fortification, all companies are treated equally and are obligated to make investments to fortify flour to specific standards. Although millers will continue to compete based on type of flour and price in the market place, the level of fortification would be standardized.

Where an institution is already authorized to establish food standards and regulations, or is authorized to amend regulations to compel or allow flour fortification, additional legislation may not be necessary. However, amending an existing law to strengthen provisions on enforcement powers may be needed. That process has to be balanced against political and time constraints, competing priorities, and other practical considerations. The commitment of the different sectors, especially the milling industry, is potentially more important and more decisive in terms of program success than the imposition of laws. Thus, the different sectors that will be affected by the law and its specific regulations should be involved in developing fortification legislation. The legal instruments should not overemphasize restrictive and punitive aspects but rather provide a clear definition of program objectives, basic activities, and the role of each of the sectors involved. This positive approach will promote cooperation between the milling sector and the different government bodies. If the different sectors involved are not willing to make a political commitment to controlling and preventing ID and IFA through wheat flour fortification, debating the importance of legislation becomes an academic exercise.

The legislation must clearly state that it is not appropriate to promote high consumption of the wheat flour by ascribing healing properties to the fortified wheat flour. The fortification program must be seen to have nutritional rather than medicinal or commercial objectives.

A general law for food fortification should include the following:

- a. Consideration of the health implications resulting from the addition of nutrients to selected, widely consumed foods.
- b. Formation of a National Food Fortification Committee (see below).
- c. Identification of the entities responsible for production, quality control, and monitoring of fortification programs.
- d. Consideration of the financial and tax exemption agreements relevant to the importation of materials and equipment necessary for fortification.
- e. Description of the sanctions to be applied to guarantee adequate program operation.

The technical specifications for mandatory or voluntary fortification that regulate iron fortification of wheat flour must state the type of iron fortificant to be used, the level of fortification, and the permitted range of iron in fortified wheat flour at the mill. The regulations must define the precautions and food-safety conditions to be observed during production, transportation, storage, and sale of wheat flour. They must also specify the information to be included on the label for fortified wheat flour and stipulate that misleading advertising ascribing healing properties to the consumption of iron-fortified wheat flour is not permitted. The regulation must also indicate the procedures and corrective actions for noncompliance with the specified regulations, as well as the procedures to be followed for the release of any imported wheat flour for sale or distribution in the country.

7. National Food Fortification Committee

In implementing a fortification program, collaborative participation of various government sectors, food producers, private organizations, and international agencies is needed. The official creation of a specific committee with representatives from the different sectors is recommended. When consumer organizations exist, they should also be included. The National Food Fortification Committee should be under the National Food and Nutrition Committee or its equivalent. In countries in which a Committee for the Control and Prevention of Micronutrient Deficiencies exists separately,

the link between the National Food Fortification Committee and the National Food and Nutrition Committee should be through the Committee for the Control and Prevention of Micronutrient Deficiencies. In some countries, the latter is responsible for overseeing food fortification, in which case there is no need for a National Food Fortification Committee.

The National Food Fortification Committee could be organized and directed by the ministry of health or another entity officially responsible for food and nutrition within the political and administrative structure of each country. Its functions would include the following:

- a. Monitoring program implementation and analyzing the information coming from the different operating units, that is, production, quality control, inspection, and monitoring. The committee and any subcommittees should ensure that operating units comply with their responsibilities.
- b. Directing problems that might arise to the relevant institutions to ensure prompt resolution.
- c. Updating regulations, such as the level of iron in flour or the characteristics required for the fortificant, depending on the prevailing situation.
- d. Coordinating the activities of the various sectors and the operating units involved.
- e. Working as a pressure front at the political and administrative decision-making levels.

8. Legal framework

While the Ministry of Health may take the lead as the initial advocate for iron fortification of wheat flour, the personnel and resources for regulating food standards may be situated in an agency that comes under another ministry, such as trade, industry, or agriculture. The food regulatory agency would be responsible for monitoring the adequacy and safety of the iron levels in flour—as it would for the fortification of any other food—while the ministry of health’s role would be to monitor the effectiveness of the program, i.e., the extent to which fortification is controlling or contributing to the control of the deficiency in question—in this case, ID and IDA.

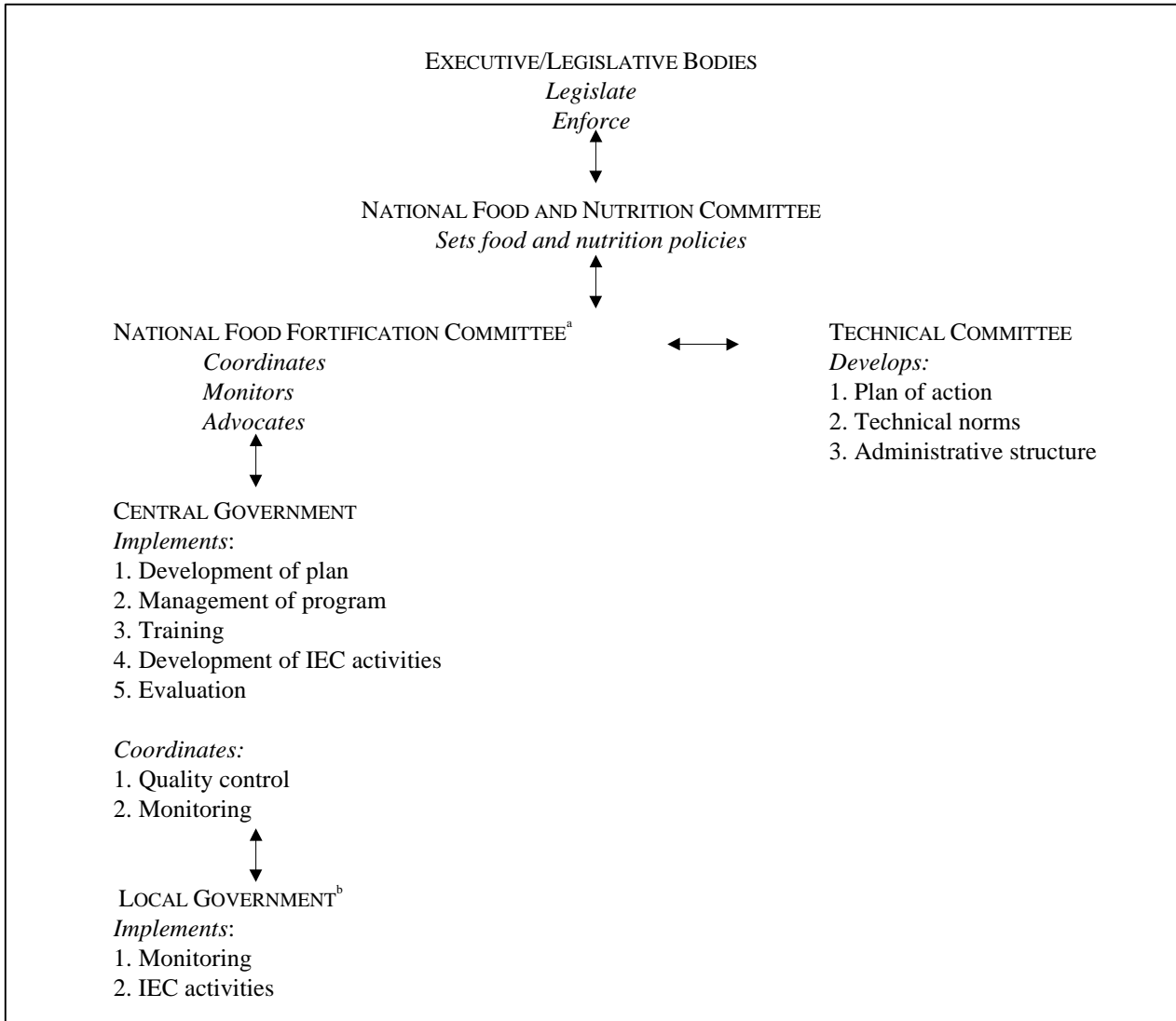
Irrespective of the players, an iron fortification of wheat flour program should be embedded institutionally within a legal framework that defines the authority and responsibilities of the agencies and other entities involved. The details of this framework must be set by each country; a general model is presented in Figure 1.3.

The legislation for food fortification should have identified the organization(s) responsible for coordinating and monitoring wheat flour fortification activities, for example, the National Food Fortification Committee. The latter also has an important role in advocating for wheat flour fortification to ensure that sufficient resources are available for the program.

The National Food Fortification Committee can be advised by a technical committee whose role includes developing the plan of action, the technical norms, and the administrative structure of the program. Actual program implementation is the responsibility of the government. At the central level, the government will implement a number of activities, including development of the wheat flour fortification plan; management of the program; training of personnel; development and implementation of information, education, and communication activities (IEC); and conducting the evaluations. In addition, it will coordinate quality control and monitoring activities.

Subnational or local government will be responsible for implementing inspection, monitoring, and IEC activities and report directly to the central level, which in turn will report to the National Food Fortification Committee. The feedback received by the National Food Fortification Committee will be provided to the National Food and Nutrition Committee, through the Committee for the Control and Prevention of Micronutrient Deficiencies, if it exists. The National Food and Nutrition Committee should only have to interact with the executive/legislative body when regulations need to be modified or enforced.

Figure 1.3
Legal Framework for a Fortification Program



^a Includes representatives from the ministries of health, agriculture, education, finance, commerce and customs; universities and research institutions; consumer associations; and the food industry, e.g., wheat flour sector.

^b Local representatives from the food control department and customs, as well as the ministry of health, agriculture, trade, and education.

IV. Quality Assurance

This section describes the quality assurance system that must be put in place to ensure that fortified wheat flour contains sufficient iron to provide the desired increase in iron intake. By setting up a quality assurance system, various aspects of the fortification process are systematically monitored and evaluated to ensure that the standards of quality and specifications laid down in the regulations are maintained at critical points in the milling sequence. Quality control procedures, e.g., design analysis and inspection of defects, must therefore be put in place.

The first step in any quality assurance system for food fortification programs is to confirm the quality, handling, and storage of the fortificant. Problems with quality are rare when the fortificant is purchased from a reliable company that issues a certificate of compliance with the shipment, stating that the shipment meets the relevant standards and specifications. The purchasing department at the mill should obtain or develop a list of iron suppliers¹⁷ whose products meet established requirements.

A. Quality control of the iron fortificant at the mill

Taking the following actions during the receipt and storage of the iron fortificant will help the mill to assure the quality of the iron in the final product:

1. Request that suppliers include a certificate of compliance with each shipment. A copy of the certificate of compliance should be kept with the permanent records.
2. Maintain a “first in, first out” policy. Number lots consecutively in the order that they are received. For each lot, write the lot number and the date of receipt on the sticker.
3. Arrange storage areas to facilitate the “first in, first out” policy. Store bags or boxes of the iron fortificant in consecutive order so that the oldest can be withdrawn first.
4. Store the iron fortificant in conditions that maintain its quality and prevent contamination or deterioration.
5. Record and monitor the movement of the iron fortificant in and out of the warehouse, and control the amounts used in manufacturing.
6. Maintain records of returned materials and their use and control.
7. Maintain sufficient stocks of iron fortificant. Ask the purchasing department to order a new shipment in sufficient time to avoid running out of iron fortificant.
8. To confirm that the composition of the iron fortificant meets specifications, send samples for laboratory analysis within three months of arrival.

B. Quality control of premix and fortified wheat flour

In any iron fortification program, wheat millers are required to determine the iron content of fortified flour as part of their routine quality control practices, including flour sampling, laboratory analyses, registration forms, and reports. The purpose of quality control is to facilitate immediate corrective action during the manufacturing process. Some mills may decide to make and use an iron-flour premix rather than purchasing the iron-containing fortificant obtained directly from the supplier. In either case, the resulting product must be checked for quality.

1. Iron-flour premix

Where an iron-flour premix is used and the level of iron varies from what was expected, the wrong proportion of iron to flour may have been used or the mixing time may have been too short. The quality of the iron-flour premix, which reflects the manufacturing process, is determined through chemical analyses that are detailed in Part 3 of the manual.

The iron content of the iron-flour premix should take into account the extent to which it is diluted when added to wheat flour at the mill. A 10% overage is usually added to compensate for any variation in the natural level of iron in wheat flour, to make up for any processing losses, and to insure that the final level will be minimally achieved.

Ninety percent of the iron-flour premix samples analyzed must show an iron content within a range of 10% on either side of the stipulated mean. For example, if the norm stipulates that fortified wheat flour should have 77 ppm elemental iron (66 ppm as iron fortificant and 11 ppm iron naturally found in flour):

- a. Using an iron premix containing 10,000 ppm (10 g iron per Kg iron fortificant), an iron-flour premix made in a 1:1 ratio contains 5,000 ppm (5 g iron per Kg iron-flour fortificant).
- b. The acceptable range for the iron content of the iron-flour premix would be 4,500 to 5,500 ppm, i.e., mean of $5,000 \pm 500$ ppm.
- c. Adding this iron-flour premix to bulk flour in a ratio of 1:74.75 will provide fortified flour containing a total of 77 ppm elemental iron on average, within a range of 70–84 ppm.

2. Fortified wheat flour

Wheat is fortified by adding the iron or iron-flour premix to the mixing conveyor or to the flour collection conveyor at the very end of milling. Both operations require reliable mechanisms to ensure that iron is distributed equally throughout the flour, i.e., it is homogenous. For this reason, adding the iron or iron-flour premix to flour requires careful supervision by a trained worker to ensure that the system is operating properly.

The following processes are important for quality control purposes in wheat flour fortification:

- a. Calculating the ratio of the amount of fortified wheat flour produced to the amount of iron or iron-flour premix used during each shift or every 24 hours. For example, if the iron-flour premix contains 5,000 ppm elemental iron and the flour must have 77 ppm elemental iron, then 1 Kg bag of iron-flour premix is needed to fortify 74.75 Kg of flour.
- b. Determining by chemical analysis the level of iron in wheat flour samples at the end of milling, just before packaging. The available quantitative and semi-quantitative analytical methods that can be used are described in Part 3 of the manual. Having timely results is important for immediately correcting any failures in the fortification process. The fre-

quency of taking flour samples depends on the rate of flour production at each mill. Sampling for iron content can be done at the same time that samples are taken for tests to determine moisture and protein levels, which is usually about every two hours.

- c. Determining that the mean iron level is at the level stipulated in the norms, for example, 77 ppm elemental iron in flour. The level of iron in individual samples must fall within the norms. The extent of variability or range for the norm is determined by variation in the iron content of fortified wheat at the mill. This should be determined by pilot studies and will be closely related to the technical efficiency of the system in a particular mill. For example, if the accepted variation is 10%, the iron content in the individually analyzed flour samples should be between 70 and 84 ppm elemental iron.

C. Monitoring fortified wheat flour

Through the food control authorities, government must guarantee that the public gets fortified wheat flour with sufficient iron to fulfill the expected increase in meeting the RDI for iron. To ensure this government food control entities must oversee or monitor the iron content of the flour at both the production site and the retail level. They must also report to a specific body such as the National Food Fortification Committee on a regular basis, for example, every six months.

1. Fortified wheat flour production

Food inspectors must visit the mills regularly, for example, every month. Inspection guidelines and registration forms should be developed to expedite the inspections. The visits must be long enough, e.g., one to two hours, to allow for detailed observation of all the production activities. These visits must take place according to a schedule that is sufficiently flexible to take into account the need to assist the mill in improving its quality control system and verifying the efficiency of process. These inspections will also enable the inspectors to review the laboratory results, collect flour samples to be sent to a central reference laboratory, and discuss any obstacles or difficulties in the production process.

2. Imported wheat flour

Most countries import whole wheat rather than wheat flour. In rare situations where iron-fortified wheat flour is imported, iron content must meet the same requirements as locally produced wheat flour. To this end, customs authorities should collaborate with food control inspectors to prevent any imported iron-fortified wheat flour being released until its compliance with the norms is verified. A proper sampling plan should be in place to determine the iron content of all imported fortified wheat flour. When countries import unfortified wheat flour and the national mandate is for all flour to be fortified, the government must ensure that this imported flour is fortified before it goes into the market.

For groups of countries that share a specific geopolitical area, it is recommended that regional marketing agreements be promoted that govern the exchange of fortified foods, including wheat flour. Such arrangements will enable authorities to control smuggling across borders. Many countries already have regional legislation regarding other aspects of common concern.

3. Retail marketing

Food inspection activities include examining the quality of the fortified wheat flour being marketed. The local food control authorities play an important role and should be trained by central-level staff. The fortification program must include a system for regular and random sampling of wheat flour. It is recommended that iron assays be carried out at the inspection site using a semi-

quantitative assay¹⁸ and the results sent monthly to the central level. Alternatively, samples may be sent to a central laboratory where the analyses can be performed to monitor levels of fortification at the retail level.

D. Resources required for an iron fortification program

The essential information that must be gathered to determine resources required for an iron fortification program is as follows:

- a. Number and location of flour mills and the volume of flour produced at each mill.
- b. Quantity of iron needed to fortify the standard flour produced over a one year period.
- c. Type and number of workers that will need to be trained to carry out the fortification process.
- d. Type and number of field and laboratory technicians that will need to be trained to take and analyze the fortified flour samples.
- e. Type and number of workers that will need to be trained in the supervision and control of all stages of the fortification process and data registration.

V. Evaluating the Effectiveness of Iron Fortification of Wheat Flour

Evaluation is an essential and integral component of the fortification program. The design and implementation of an evaluation must be based on a clear definition of the program's objectives. For iron fortification of wheat flour, the objective is to increase iron intake to control iron deficiency and iron deficiency anemia in the population.

In this manual, evaluation refers to assessing the biological effectiveness of the fortification program. This entails determining and interpreting the changes in iron intake (an intermediate effect) and the prevalence of anemia or, preferably, iron status (a biological effect). This section describes the steps to be followed in carrying out an evaluation to this end.

A. Design and frequency of the effectiveness evaluation

Because iron fortification of wheat flour is usually a universal program, it is not possible to use an experimental design that compares a control group that does not receive fortified flour with a group that does. Consequently, the design must compare indicators before and after fortification is implemented. This design requires conducting a baseline survey before fortification begins and at least one survey after the intervention has been in place for some time. The time period between surveys will depend on the type of evaluation or impact measured, as described below.

Both household- and individual-level dietary data as well as an individual-level biochemical variable or variables need to be collected. The same representative sampling frames and survey methods must be used at both times, with the most vulnerable groups being adequately represented in the sample. The post intervention survey or surveys should be done at the same time of year as the baseline survey in order to minimize seasonal factors that may change iron status, such as malaria, which could complicate the interpretation of results.

The evaluation surveys must be programmed according to a predetermined schedule. Once the data from the baseline survey are available and fortification has begun, post-intervention evaluation surveys will determine trends in the intermediate indicator as well as the biological indicator or indicators. The following periodicity is suggested:

1. Initial evaluation

The first post-intervention dietary consumption survey should be done 6 to 12 months after confirmation that the production of iron fortified wheat flour is operating efficiently. This survey will provide information on an early increase in iron intake through consumption of fortified wheat flour. The first post intervention biochemical survey should be done 12 to 15 months after the consumption survey.

2. Subsequent evaluations

a. A survey of the consumption of wheat-based foods, other iron fortified foods, and flesh foods should be repeated at 5-year intervals. These subsequent surveys can be done using a less extensive sample than in the baseline survey to increase operational and economic feasibility, especially if resources are limited. The purpose of these additional surveys is to confirm that the program is operating well and that no important changes in the diet or flour intake have occurred that would require an adjustment in the fortification level.

- b. Biochemical surveys will confirm the nutritional effect of the intervention. These are generally more complex and costly and, therefore, should also be repeated every 5 years. As with dietary surveys, the sample can be smaller, as long as it is statistically representative of the target population.

B. Evaluating the intermediate effect

The intermediate effect is the change in iron intake resulting from the fortification program, which will result in a biological improvement in iron status and a reduction in the prevalence of IDA. The basic elements for this evaluation require data from a representative sample of the groups at highest risk of ID and IDA, e.g., preschool children, and will include:

- a. Baseline: (a) wheat flour consumption (these data are necessary to monitor any changes in wheat flour consumption patterns after fortification is initiated) and (b) iron intake from other food sources.
- b. Post implementation: (a) iron intake from wheat flour (these data are calculated from the quantity of fortified flour consumed and the mean concentration of iron per gram of fortified flour as determined by chemical analysis) and (b) iron intake from other food sources.

The purpose of the program is to ensure that after 12 months of program implementation, no more than 15% of the target population have *total* iron intakes below 100% of their RDI and no more than 5% have intakes below 75% of their RDI. The primary indicator is iron intake from fortified wheat flour, and the criterion is the increment in the intake of iron as a result of the consumption of wheat flour.

The information needed to determine the intermediate effect should be obtained using research methods that accurately reflect real iron intake and not general tendencies or consumption patterns. Semi-quantitative 24-hour dietary recalls, when carefully done, are satisfactory¹⁹.

C. Evaluating the biological effect²⁰

The biological effect, as defined in the goals and objectives of the program, is reduced ID and IDA among the population.

There is no single test to diagnose ID or IDA. As a primary indicator, blood hemoglobin²¹ (Hb) is not an adequate proxy indicator for iron status in developing countries where infections, including inflammation and malaria, are common. This means that a combination of various biochemical indicators of iron status such as Hb, serum ferritin, erythrocyte protoporphyrin, transferrin saturation (that requires measuring serum iron and total iron-binding capacity), and transferrin receptors must be used. Serum ferritin and sometimes erythrocyte protoporphyrin concentrations rise when infection is present while transferrin saturation falls; thus a result in the normal range does not necessarily mean iron sufficiency. Unlike the other iron status indicators, transferrin receptors do not alter with infection. Erythrocyte protoporphyrin also increase when there is increased red cell turnover, such as hemolytic anemia caused by malaria. To overcome the individual limitations of each test, WHO has indicated that ID exists where two out of three tests are abnormal. Ideally, erythrocyte protoporphyrin and transferrin receptors should be included in these tests. Serum ferritin is the best indicator of iron stores when infections or inflammation are absent. An acute phase marker such as C-reactive protein can be used to monitor infection and inflammation.

Because there are other factors besides infection and inflammation that affect iron status parameters, data on the prevalence of malaria and hookworms or schistosomes in endemic areas would benefit the evaluation. Similarly, prevalence data on vitamin A, folic acid, vitamin B-12, and vitamin B-2 status will facilitate showing whether the fortification program has been beneficial.

In evaluating a wheat flour fortification program, the criterion is the reduction in the prevalence of low Hb or hematocrit levels, plus an improvement in at least two iron status indicators, in a population consuming fortified flour. The cutoff points to define anemia are shown in Table 1.1 and those for other indicators of iron status in Table 1.2.

Age or sex group	Hemoglobin below ^a
Children 6–60 months	110
Children 5–11 years	115
Children 12–13 years	120
Nonpregnant women	120
Pregnant women	110
Men	130

^a For black populations the Hb level should be reduced by 1 g/L.

	Iron status			
	Anemia	Iron deficiency	Iron depletion	Normal iron
Serum ferritin ($\mu\text{g/L}$)	<12	<18	<24	100 \pm 60
Serum iron ($\mu\text{g/L}$)	<40	<60	<115	115 \pm 50
Erythrocyte protoporphyrin ($\mu\text{g/dL RBC}$)	>200	>80	>80	30
Transferrin saturation (%)	<10	<15	<30	35 \pm 15
Transferrin receptors (mg/L)		>8.5		

In addition to presenting results as the proportion of the sample having Hb or iron status levels below or within the ranges noted in Tables 1.1 and 1.2, it is recommended that the results be presented graphically as a frequency distribution or tabulated using 1 g/dL intervals for Hb, 6 $\mu\text{g/L}$ intervals for ferritin, 20 $\mu\text{g/L}$ for plasma iron, and 5% intervals for transferrin saturation. This will show the extent to which the distribution curve for the indicator levels has shifted.

D. Sample selection

To ensure the evaluation is valid, the baseline and evaluation surveys must be carried out with a statistically representative sample that includes the different sectors in the population covered by the fortification program. Adequate representation of the groups most susceptible to ID and IDA must be given priority. If possible, the sample should be stratified by rural and urban categories and by socioeconomic levels (for example, below the 25th, between the 25th and 75th, and above the 75th income percentiles) with particular emphasis on the lowest socioeconomic stratum.

Where there are insufficient resources to study a large sample, evaluators may choose a smaller sample, which represents the most vulnerable sector or sectors. That group might be pre-school children, for example, from the lowest socioeconomic stratum who are among those at greatest risk of ID and IDA and who eat the least amount of wheat flour. If fortification has an impact on that

group, then it is logical to assume that the rest of the population will also benefit; thus, this group of children can be used as a good indicator of the program's effectiveness.

For dietary surveys, households with at least one preschool child can be used as the sampling unit. The food consumed by a household can be obtained from a 24-hour recall, with particular attention being given to wheat-based foods, flesh foods, and foods that enhance (vitamin C-rich fruits and vegetables) or inhibit (tea, coffee, other cereals) the absorption of non-heme iron. In addition, detailed individual 24-hour recalls are needed for preschool children. For the biochemical surveys, priority should be given to getting blood samples from preschool children.

E. Resources required for evaluation

Carefully determining the resources needed for the evaluation or evaluations is important to ensure that they will be available at the right time and place. Ideally, the costs of the impact evaluation should be estimated separately from the cost of the program itself, because the evaluation will vary in extent and frequency, depending on decisions made by the program director or directors. The resources required for the evaluation include:

1. Dietary surveys

1. Statistical and computer expertise for sample design and data analyses.
2. Technical and auxiliary field and office personnel.
3. Salaries, transportation, and per diem expenses for field personnel trained for the dietary survey.
4. Funds for survey materials and printing reports.

2. Biochemical surveys

1. Statistical and computer expertise for sample design and data analysis.
2. Technical and auxiliary personnel for taking, handling/preserving, and transporting samples.
3. Transportation and per diem expenses for field personnel.
4. Laboratory facilities and supplies as well as professional and technical personnel for carrying out the biochemical analyses of biological samples.
5. Funds for preparing and printing reports.

VI. Program Costs

Estimating program costs is important in planning the fortification program to determine the economic feasibility of fortifying wheat flour and to justify the allocation of resources. Prior to making a political decision and commitment to fortifying wheat flour, the government and other sectors involved must understand the economic implications regarding the investment required, recurrent costs, and financial commitments. A careful estimation of the costs can also identify components that may eventually require donor support. Finally, information on costs is essential for deciding whether the expected improvement in iron status can be achieved through wheat flour fortification at a lower cost than through other kinds of interventions, i.e., the relative cost-effectiveness of the program.

The costs of establishing a national wheat flour fortification program will vary depending on factors such as the number and size of mills; existing quality assurance facilities; functional regulatory and food inspections; and the level of iron being added. Table 1.3 shows the current retail market price per kilogram of the iron fortificants that can be used to fortify wheat flour. Because the different forms of iron have different concentrations of iron, cost is adjusted to reflect the amount of pure or elemental iron in the fortificant. Also, because of the variation in the amount of each iron that can be absorbed, a further adjustment is made to show the relative cost of absorbable or bioavailable iron. For example, ferrous sulfate is absorbed twice as much as elemental iron (electrolytic or reduced irons); thus, the costs if using 30 mg/Kg ferrous sulfate can be compared with that for 60 mg/Kg electrolytic or reduced iron. Sodium-iron EDTA is three times more absorbable than ferrous sulfate in foods containing high levels of phytates, such as high extraction flours. Using ferrous sulfate as the reference, the figures for relative cost per absorbable iron are shown in the last column.

Table 1.3: Costs and relative costs of iron fortificants²⁴

Iron Source	Iron Concentration (% Fe)	Cost of Iron Fortificant (\$/Kg)	Cost of Pure Iron (\$/Kg Fe)	Relative Bioavailability (RBV)	Relative Cost/ Kg Bioavailable Iron
Ferrous sulfate	20	1.30	6.50	1.00	6.50
Reduced iron	97	1.75	1.80	0.5	3.60
Electrolytic iron	97	4.00	4.12	0.5	8.24
Ferrous fumarate	33	2.50	7.57	1.00	7.57
Ferric orthophosphate	29	6.60	22.76	0.29	78.48
Iron-EDTA	14	8.5	60.70	3.00	20.23
Ferrous bisglycinate ²⁵	20	20.26	101.30	1.00 ^a	101.30 ^a

^a The relative bioavailability of this compound has not been fully established. A few published studies indicate that it is similar to that of ferrous sulfate.

In estimating program costs, the retail cost per kilogram of iron must be converted into the cost per metric ton (MT) of flour at the specified rate of fortification (in ppm or mg/Kg), i.e., Cost per MT flour = (Cost per Kg iron ÷ 1000) * fortification rate in ppm. For example, the cost of fortifying 1 MT of flour with electrolytic iron at 66 ppm would be:

$$(4.12 \div 1000) * 66 = \text{US\$ } 0.27 \text{ per MT}$$

This cost, however, excludes shipping and transport costs as well as any import duties and tariffs that would also have to be factored in. The shipping and transport costs can be significant, i.e., between 33 and 50% of the iron costs since iron is very heavy.

Beside the cost of the iron, other recurrent costs include any additional labor that may be needed in the fortification process, be it in the mill itself or the mill laboratory, as well as the costs of the reagents, supplies, and field expenses for quality control. Capital equipment costs vary depending on the quality and size of the equipment. For example, dosifiers used to add the iron or iron-flour pre-mix vary from \$2,000 to \$20,000²⁶. Efficiencies of scale, however, will lower the unit costs of fortification for large mills compared to small ones.

A. Overall program costs

The economic costs of a program can be calculated in a number of ways. These are presented below, based on the hypothetical characteristics of a country shown in Table 1.4.

Flour production (MT/year)	100,000
Annual cost of fortification (US\$)	65,275
Retail price/ MT of unfortified flour (US\$)	400
Average expenditure on wheat-based foods (US\$)	17
Total population	9,200,000
Number of preschool children	1,290,000
Percent coverage with fortified wheat flour	80
Percent of population consuming <75% RDI for iron	50

1. Total annual cost

Table 1.5 is a guide for estimating the costs of establishing and operating a program for iron fortification of wheat flour. Total costs include capital investment and recurrent costs for fortifying 100,000 MT flour/year in a continuous fortification system. Evaluation costs have been apportioned over five years. The table shows that in this example the iron fortificant accounts for about one-half of the program costs.

2. Cost per metric ton (CMT)

$CMT = \text{Total annual cost} \div \text{MT flour produced}$

$CMT = 65,275 \div 100,000 = \0.65 MT

That is, \$0.00065/Kg.

Using this cost, the percentage increase in consumer price that the fortification process adds to the product can be estimated. For example, if a kilogram of flour costs \$0.40 before fortification, when iron is added the price would increase to \$0.40065, that is, 0.16% above the original price of wheat flour.

Table 1.5: Estimated hypothetical costs of wheat flour fortification²⁷ (100,000 MT tons at 1 mill using a continuous fortification system)

	Total (US\$)	Annual (US\$)
A INDUSTRY COSTS		
1 Capital investment ¹		
Electronic scales	1,000	100
Dosifier with agitator and installation	7,000	700
Laboratory and quality control ²	200	20
Total capital investment for flour mill	8,200	820
2 Recurrent costs		
10% annual depreciation on equipment		400
5% annual maintenance on equipment		200
Electrolytic iron fortificant (US\$ 0.27 MT fortified flour + 33% for shipping)		35,910
Salaries (negligible, additional simple task for the workers)		0
Quality control ³		7,920
Total annual operating costs		44,430
Total industry costs		45,250
Cost per metric ton of fortified wheat flour		0.45
B STATE COSTS (quality control, monitoring, and evaluation)		
1 Capital investment and maintenance		
Equipment (spectrophotometer, scales, lab glassware, computer, etc.), 20% use	7,500	1,500
10% depreciation on equipment		750
5% annual maintenance on equipment		375
2 Mill inspection and monitoring (quality control)		
Salaries and benefits (inspectors), 10% time		2,500
Transportation, per diem expenses, and collection of 1 sample/month		1,000
Laboratory analysis and reports (including salaries of technicians)		1,500
Quality assurance and monitoring training		1,000
3 Program monitoring (iron intake) ⁴		
Travel, per diem, and surveys	5,000	1,000
Analysis and reports	2,000	400
4 Evaluation ⁴		
Travel, per diems, and collection of biological samples	15,000	3,000
Laboratory analysis and reports (including technician salaries)	25,000	5,000
State Costs		18,025
TOTAL PROGRAM COSTS		63,275
Cost per metric ton of fortified wheat flour		0.63

¹Amortization over 10 years.²The semi-quantitative assay requires very simple glassware. Balances, muffle furnace, water bath, and other equipment needed are generally standard items in the quality control laboratories. Quantitative assays can be carried out for the mill laboratory if it has a spectrophotometer. Where this equipment is unavailable, the assay can be contracted out to an analytical laboratory because only 1 pooled flour assay/day is needed.³Includes 12 semi-quantitative assays/day @ US\$1.00/assay and one quantitative assay/d @ US\$10.00/assay 360 days a year.⁴Apportioned over 5 years.

3. Cost per person (CPP)

Because fortification is universal, the potential recipients of a national program are the entire population.

$$\text{CPP} = \text{Total annual cost} \div \text{Total population}$$

$$\text{CPP} = 63,275 \div 9,200,000 = \$ 0.007/\text{person per year}$$

4. Cost per person covered (CPC)

$$\text{CPC} = \text{Total annual cost} \div \text{Covered population}$$

$$\text{Where population covered} = [9,200,000 * (80 \div 100)] = 7,360,000$$

$$\text{CPC} = 63,275 \div 7,360,000 = \$0.009/\text{person covered per year}$$

5. Cost per potential beneficiary (CPB)

Potential beneficiaries are all the people covered who are not getting enough iron from their diet before wheat flour fortification. In this example, they are all the individuals whose iron intake is less than 75% of the RDI.

$$\text{CPB} = \text{Total annual cost} \div \text{Percent of population consuming} < 75\% \text{ RDI}$$

$$\text{Potential beneficiaries} = [7,360,000 * (50 \div 100)] = 3,680,000$$

$$\text{CPB} = 63,275 \div 3,680,000 = \$0.017/\text{potential beneficiary per year}$$

6. Cost-effectiveness

By combining the results of the program's effectiveness with the cost figures, the intervention can be characterized by its cost-effectiveness. Using this expression, a comparison can be made between the wheat flour fortification program and other iron or micronutrient interventions.

a. Cost per protected beneficiary (CPrB)

Protected beneficiaries are the potential beneficiaries whose iron intake meets the RDI due to wheat flour fortification. Intake is calculated as total absorbable iron intake from the diet plus iron from fortified wheat flour (grams of flour eaten multiplied by the mean absorbable iron concentration per gram of flour).

$$\text{CPrB} = \text{Total annual cost} \div \text{Protected beneficiaries}$$

For example, if 80% of the 3,680,000 {i.e. $[7,360,000 * (50 \div 100)]$ } potential beneficiaries reached an adequate intake due to the fortification, then:

$$\text{Protected beneficiaries} = 3,680,000 * (80 \div 100) = 2,944,400$$

$$\text{CPrB} = 63,275 \div 2,944,400 = \$0.021/\text{protected beneficiary/year}$$

b. Cost per recovered beneficiary (CRB)

The biochemical data from the evaluation, especially among the high-risk population, can be used to calculate the number of recovered individuals, i.e., those who moved from the IDA and ID category to the non-IDA category or who remained in the latter category because of fortification. The maintenance concept is very important because, in the absence of the fortified product, the population would return to a deficient state.

$$\text{CRB} = \text{Total annual cost} \div \text{Recovered beneficiaries}$$

The prevalence and number of children with a low iron status:

Baseline Survey: 50% prevalence or 645,000 children, i.e., $1,290,000 * (50 \div 100)$

Evaluation: 15% prevalence or 193,500 children, i.e., $1,290,000 * (15 \div 100)$

Then:

Number of recovered children = $645,000 - 193,500 = 451,500$

CRB = $63,275 \div 451,500 = \$0.14/\text{recovered child/year}$

This approach may be too conservative, because it assumes that the recovered children were the only ones in the country who benefited. In reality, many other children as well as pregnant and lactating women and other adults would have been prevented from becoming iron deficient and, therefore, also benefited from the program.

Despite its limited focus, the CRB is valid when comparing the cost-effectiveness of fortification with other interventions such as taking iron tablets.

B. Costs for millers

Millers will want information on costs that take into account the total investment they will have to make. This can be either as an incremental cost to production or as a proportion of profits. Ultimately their concern will be how to recoup their investment and how long it will take. Various methods for calculating costs are given below. Governments may be willing to co-share the initial investment by lowering the tariff on the iron, providing tax breaks for capital investment, or subsidizing the start-up costs.

1. Incremental cost of production (ICP)

$$\text{ICP} = (\text{Flour mill output}) * (\text{Premix cost per MT}) + \text{Capital costs amortized over 10 years}$$

2. Percentage of production costs (PPC)

$$\text{PPC} = \text{ICP} \div \text{Total cost of production}$$

3. Percentage increase in costs (PIC)

$$\text{PIC} = (\text{Fortified flour production cost} - \text{Unfortified flour production cost}) \div (\text{Unfortified flour production cost}) * 100$$

4. Costs as a proportion of profit or margin (CPP)

$$\text{CPP} = \text{ICP} \div \text{Profit per MT unfortified flour}$$

5. Incremental costs for bakers (ICB)

$$\text{ICB} = \text{Cost per MT fortified flour} - \text{Cost per MT unfortified flour}$$

C. Framing costs for retailers and consumers

The cost of wheat flour fortification for retailers and consumers are negligible. Prices of bread or noodles will be a fraction of the smallest unit of currency as shown below.

1. Incremental retail cost of 1 Kg flour (IRC)

$$\text{IRC} = \text{Increased cost of a MT of flour} \div 1000$$

$$\text{IRC} = 0.63 \div 1000 = 0.00063$$

2. Projected percentage increase in retail cost of flour per Kg (PIRC)

$$\text{PIRC} = \{[(\text{Average retail price} + \text{IRC}) - \text{Average retail price}] \div \text{Average retail price}\} * 100$$

$$\text{PIRC} = [(400.63 - 400) \div 400] * 100 = 0.16\%$$

VII. Report Preparation

Two types of reports, one more general for policy purposes and one technical, should be prepared on a routine basis and targeted to the following audiences:

A. Public health personnel and policy planners, who may not be technical experts, but who make policy and program decisions. Program decisions will be based on the conclusions and recommendations in the general report, which should focus on operational issues related to meeting the program objectives; thus it should be written in a format that is clearly understood by nontechnical people. This report should be submitted annually before the annual work plans and budgets are developed.

B. The scientific community, who will be interested in technical description of the intervention and details of all the activities carried out including monitoring. The technical report should be sufficiently detailed to allow the reader to evaluate the quality of the program and the reliability of the conclusions. The evaluations should also be included in the technical report.

Once the wheat fortification program is fully operational and working effectively, shorter annual reports that focus on the monitoring activities will suffice.

Appendix 1.1

Iron deficiency and anemia

1. Physiologic role of iron

The major role of iron in the body is in the transport of oxygen from the lungs to body tissues and its storage in muscle. In other words, iron is important for delivering the fuel that is needed for human survival. Oxygen is transported in the blood attached to an iron containing protein complex called *hemoglobin*. It is also transported and stored in muscle attached to another iron containing protein complex called *myoglobin*. The body's ability to store iron is self-regulating, and iron balance is maintained by altering the amount of iron that is absorbed from food or pharmaceutical supplements. When the body needs more iron, more iron is absorbed, but this can happen only if the iron is not bound to other substances and is in a form that can be readily absorbed. Conversely, when the body is replete, the amount of iron absorbed is limited.

1. Development of iron deficiency and anemia

If insufficient iron is absorbed due to either low intake or low bioavailability (i.e., the degree to which iron is available for absorption in the gastrointestinal tract and utilized for normal metabolic functions), or excessive losses occur, iron deficiency results and this takes place in three stages. First, stored iron is depleted or used up. Second, the amount of circulating iron in the blood falls. Third, insufficient iron is available to be incorporated into hemoglobin and hemoglobin levels fall. Individuals falling into either of the first two stages have iron deficiency (ID), while those in the third stage have iron deficiency anemia (IDA). Because overt IDA represents advanced iron deficiency, the number of people with ID is much greater than those with IDA.

3. Causes of iron deficiency and anemia

Dietary iron requirements depend on the amount needed for growth and development as well as normal losses; thus, they vary by age and gender. When the body's blood supply expands during periods of rapid growth as in early childhood, adolescence, or pregnancy, the need for iron increases. At the same time, blood loss due to menstruation and childbirth draws on iron reserves, and the requirement for iron increases in non-pregnant and pregnant women to compensate for these losses, respectively. Given these factors, the risk of ID and IDA is greatest during those stages of life when iron requirements are highest, i.e., pregnancy, early childhood, and adolescence. This situation is compounded in areas where malaria and hookworms are endemic. Malaria, especially *P. falciparum*, causes anemia but not ID as the iron stays in the body, while some helminths such as hookworm and schistosomes cause blood and iron loss, thus ID, which in severe cases becomes iron deficiency anemia (IDA). Thus, anemia may be caused by iron deficiency or other factors. The distinction between causes is important because using low blood hemoglobin level as the measure of anemia is neither very sensitive nor specific to iron deficiency. Although hemoglobin count remains the easiest and most common measure of iron deficiency, measuring iron deficiency requires at least three tests (see section V).

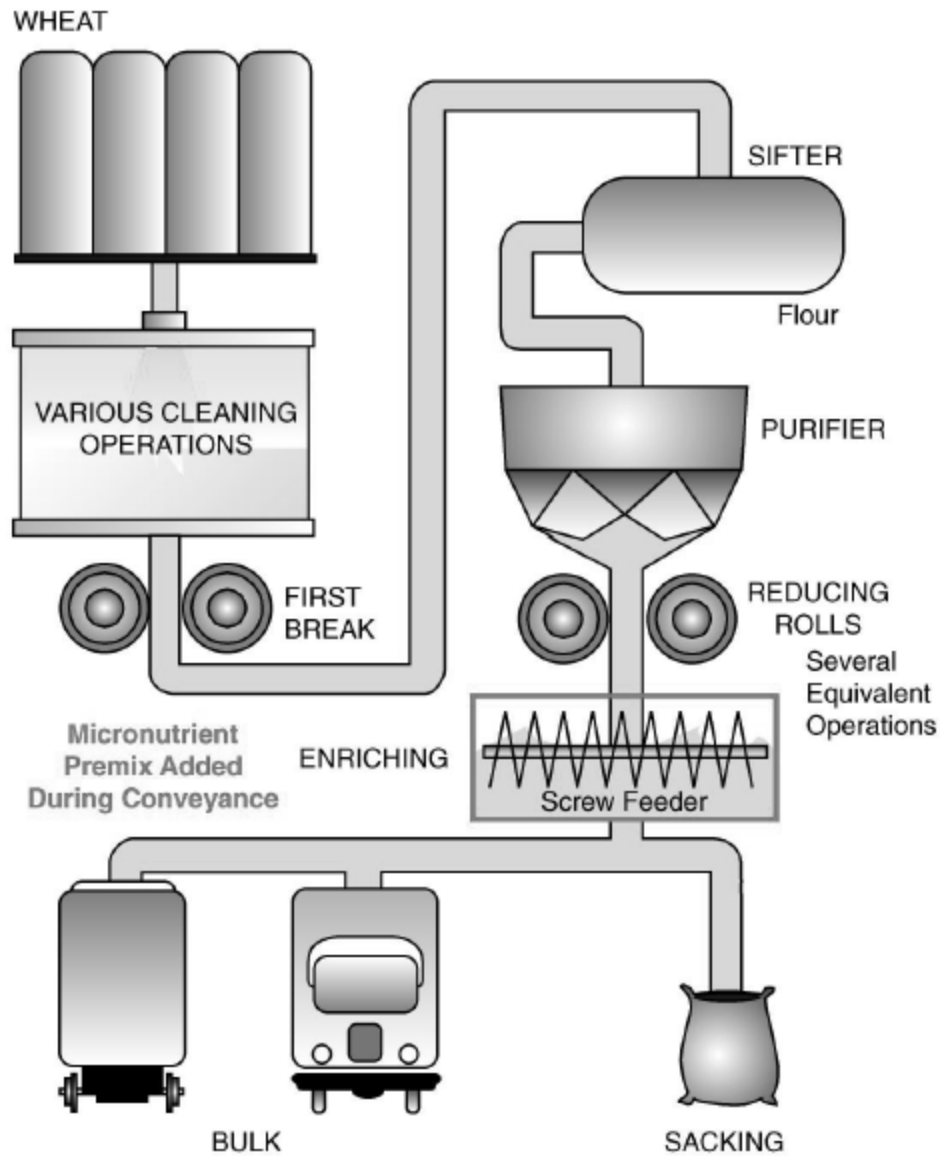
4. Food sources of iron

Iron is ubiquitous and that consumed comes from the iron naturally found in food as well as contamination iron in soil and water. Food such as meat, eggs, cereals, and some vegetables generally contain adequate iron. There are two types of food iron—heme and non-heme iron. Both types of iron are found in flesh food such as meat, fish, and poultry. Plant foods contain only non-heme iron. Heme iron is readily absorbed into the bloodstream, but other substances in food affect non-heme iron absorption by binding to the iron and preventing its absorption in the gut. These substances include phytates in cereal grains and legumes such as soya, phenolic compounds such as tannins in tea and coffee, and calcium in milk and milk products. Some of these iron-bound complexes are not soluble or are so tightly bound that the iron cannot be absorbed, while others are soluble or become soluble by combining with other food com-

ponents such as vitamin C in fruits and vegetables and partially digested protein from flesh foods. Once soluble, iron can be absorbed.

The majority of people in developing countries eat little flesh food either because they cannot afford it or from choice, as in the case of vegetarians; thus, their major source of iron is in the form of non-heme iron, which places them at increased risk of an inadequate iron intake.

APPENDIX 1.2 Simplified flowchart of the wheat milling process



Appendix 1.3

Types and grades of wheat flours

All-purpose flour: the finely ground endosperm of the wheat kernel separated from the bran and germ during the milling process. All-purpose flour is made from hard wheat or a combination of soft and hard wheat, from which the home baker can make a complete range of satisfactorily baked products such as yeast breads, cakes, cookies, pastries and noodles. All-purpose flour is a straight-grade flour made by combining several flour streams.

Bleached enriched all-purpose flour: enriched all-purpose flour that is treated with chlorine to mature the flour, condition the gluten, and improve the baking quality. The chlorine evaporates and does not destroy the nutrients but it reduces the risk of spoilage or contamination.

Bread flour: flour from the endosperm of the wheat kernel that is milled primarily for commercial bakers but is also available at retail outlets. Although similar to all-purpose flour in grade, it has a greater gluten strength and generally is used for yeast breads.

Cake flour: milled from soft wheat and especially suitable for cakes, cookies, crackers, and pastries. It is low in protein and gluten. Cake flour is from patent-grade flour streams with the lowest bran and germ content, thus it is the whitest in color

Clears: a grade of flour made from the streams with greater amounts of bran and germ compared with patent-grade flours. Clear flours have high ash and protein contents and are used for specialty breads.

Durum flour: a byproduct of semolina production. It is used in the U.S. to make commercial noodles.

Enriched all-purpose flour: all-purpose flour to which iron and B-vitamins are added in amounts equal to or exceeding that of whole wheat flour.

Farina: coarsely ground endosperm of hard wheats. It is the prime ingredient in many U.S. breakfast cereals. It is also used in the production of inexpensive pasta.

Gluten flour: used by bakers in combination with flours having a low protein content because it improves the baking quality and produces gluten bread of high protein content.

Pastry flour: milled from a soft, low-gluten wheat. It is comparable to cake flour in protein level but lower in starch content. Pastry flour is also from patent-grade flour streams with the lowest bran and germ content, thus it is the whitest in color.

Self-rising flour: an all-purpose flour with salt and leavening added. One cup of self-rising flour contains 1.5 teaspoons of baking powder and 0.5 teaspoon of salt.

Semolina: coarsely ground endosperm of durum wheat. It is high in protein and is used in high-quality pasta products.

Unbleached enriched all-purpose flour: enriched all-purpose flour that is bleached by oxygen in the air during an aging process and is off-white in color. Nutritionally, bleached and unbleached flour are the same.

Whole wheat flour: a course-textured flour ground from the entire wheat kernel, i.e., it contains the bran, germ, and endosperm. The presence of bran reduces gluten development. Baked products made from whole wheat flour tend to be heavier and denser than those made from white flour.

Appendix 1.4

LIMA DECLARATION

The representatives of trade associations of milling industries in Latin America and the Caribbean who sign this declaration acknowledge that:

- ▶ Wheat and Corn Flour fortification are proving to be an effective and sustainable contribution toward eliminating iron deficiency anemia and other diseases resulting from micronutrient deficiency. This has made it possible to raise survival rates by significantly improving the health and nutrition of children, mothers and women in general, as well as the population as a whole.
- ▶ The achievement of these goals will only be possible through the close collaboration of public and private sectors
- ▶ The high prevalence of iron deficiency anemia and diseases caused by malnutrition continues to exist seriously affecting the health, growth and development of children and a significant number of women.

We therefore declare that:

- ▶ The long and persistent existence of iron deficiency anemia and the typical diseases caused by micronutrient malnutrition in any country cannot be accepted; each country should therefore commit itself to ensuring that this problem is recognized at all levels of society.
- ▶ We will collaborate in our countries to determine whether existing conditions make iron and vitamin fortification a feasible and effective intervention
- ▶ Wherever wheat and corn fortification is feasible and effective, we urge the authorities, the milling industries, flour importers and distributors to work together to issue legislation that makes flour fortification with iron and micronutrients compulsory, based on international standards and control measures.

November 1997, Lima, Peru

Endnotes

¹ INACG Symposium 1999. Washington DC: ILSI Press, 2000.

² Some genetic abnormalities, such as thalassemia can also cause anemia, but these affect relatively few people and fortification interventions are highly unlikely to affect people with such conditions (see endnote 5).

³ WHO. WHO/UNICEF/UNU consultation on indicators and strategies for iron deficiency and anemia programs. Geneva: WHO, 1994.

⁴ Ross J, Horton S. Economic consequences of iron deficiency. Ottawa: The Micronutrient Initiative, 1998.

⁵ Gillespie S. Major issues in the control of iron deficiency. Ottawa: Micronutrient Initiative, 1998.

⁶ Musgrove P. Economic aspects of food fortification. Paper presented at the 9th world Congress of Food Science and Technology, 30 July-4 August, 1995, Budapest, Hungary.

⁷ Levin HM, Pollitt E, Galloway R, McGuire J. Micronutrient deficiency disorders. In Jamison DT, Mosley WH, Measham AR, JB Bobadilla (eds). Disease control priorities in developing countries. New York: Oxford University press. 1993.

⁸ The extraction rate may be calculated on the basis of weight of the wheat as received by the mill (sometimes referred to as *dirty-dry*) or on the basis of the wheat going into the first break rolls (sometimes referred to as *clean-tempered*). These provide different extraction rate values depending on how much non-wheat material is removed on cleaning and how much water is added during tempering.

⁹ Ranum P. Iron fortification of cereals. In: The Minerals Fortification of Foods, Hurrell R (ed). Leatherhead, UK: Leatherhead Publishing. 1999.

¹⁰ These include vitamins B1, B2, B6, and niacin. Vitamin A can also be added.

¹¹ Continuous-type process is where the ingredients are added at a constant rate through a feeder to a continuously flowing flour stream. Batch-type involves weighing and adding the ingredients to a batch of flour and mixing in a blender to achieve uniform distribution.

¹² Similar details for wheat products such as biscuits or pastas are less critical than that for flour as their moisture content is low and it is the interaction with iron in the flour that will cause any changes in the sensory properties of the product.

¹³ Specifically unsaturated fats.

¹⁴ Specifically, Bolivia, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nigeria, Panama, Peru, Saudi Arabia, United Kingdom, United States, and Venezuela.

¹⁵ Details provided here are similar to those for sugar fortification with vitamin A that are described in Arroyave G, Dary O. Sugar fortification with vitamin A: guidelines for the development, implementation, monitoring and evaluation of vitamin A sugar fortification program. Washington, DC: USAID/OMNI. 1996.

¹⁶ See, for example, Nathan R. Regulation of fortified foods to address micronutrient malnutrition: legislation, regulations, and enforcement. Ottawa: Micronutrient Initiative, 1999.

¹⁷ Two major suppliers of premixes are BASF, Inc. (6700 Ludwigshafen-Rhein, Ludwigshafen, Germany, Ph: 049 621 600, FAX: 049 622 525) or Hoffmann-La Roche (CH-4002, Basel, Switzerland, Ph: 061 688 1111, FAX: 061 691 9600). Premixes may also be obtained from local suppliers and readers are advised to explore these options. An inventory of global premix suppliers may be obtained by contacting the Micronutrient Initiative (PO Box 8500, Ottawa, Ontario, Canada, K1G 3H9, Ph: (613) 236-6163, FAX: (613) 236-9579, email: contact@micronutrient.org) or visiting their website at <http://www.micronutrient.org>.

¹⁸ See Part 3 of the manual.

¹⁹ Gibson R.S., Ferguson E.L. An Interactive 24-hour Recall for assessing the adequacy of iron and zinc intakes in developing countries. 1999. Washington DC: ILSI Press.

²⁰ Details of the procedures for using the various iron indicators as well as their relative costs will be available in a forthcoming INACG publication.

²¹ See: Anemia detection in health services: guidelines for program managers. PATH/USAID. 1996; Anemia detection methods in low-resource settings: a manual for health workers. PATH/USAID. 1997. Both are available at www.path.org.

²² WHO. Nutritional anemias: report of a WHO scientific group. Technical Report Series 405. Geneva: WHO, 1968.

²³ WHO. Indicators and strategies for iron deficiency anemia programs. Geneva: WHO, 1994.

²⁴ Hurrell, R. (ed). The mineral fortification of foods. Leatherhead, UK: Leatherhead Publishing, 1999.

²⁵ The iron concentration and cost of fortificant were obtained from Albion Laboratories, Inc.

²⁶ Part 2 Appendix 2.1b provides the cost of equipment needed in continuous and batch fortification systems.

²⁷ Adapted from data provided by Omar Dary for Central America.