



MANUAL FOR WHEAT FLOUR FORTIFICATION WITH IRON

TECHNICAL AND OPERATIONAL GUIDELINES

MANUAL FOR

WHEAT FLOUR FORTIFICATION WITH IRON

Part 2
Technical and operational guidelines

Ritu Nalubola and Penelope Nestel

This publication was made possible through support provided by the Center for Population, Health and Nutrition of the Bureau for Global Programs, Field Support and Research of the U.S. Agency for International Development (USAID).

MOST is managed by the International Science and Technology Institute, Inc. (ISTI) under the terms of Cooperative Agreement No. HRN-A-00-98-0047-00. Partners are the Academy for Educational Development (AED), Helen Keller International (HKI), the International Food Policy Research Institute (IFPRI), and Johns Hopkins University (JHU). Resource institutions are CARE, the International Executive Service Corps (IESC), Population Services International (PSI), Program for Appropriate Technology in Health (PATH), and Save the Children.

The opinions expressed in this document are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

October 2000

The MOST Project
1820 N. Fort Myer Drive, Suite 600
Arlington, VA 22209 USA
Telephone: (703) 807-0236 Fax: (703) 807-0278
Web site: <http://www.mostproject.org>
E-mail: most@istiinc.com

Table of Contents

Acknowledgments	v
Foreword	vii
Glossary	ix
I. Introduction	1
II. Iron Fortificants	3
A. Forms of iron	3
B. Specifications for iron fortificants.....	5
C. Level of iron to add.....	7
III. Iron/Micronutrient Premixes	13
A. Commercial premix versus iron-flour premix.....	13
B. Composition of the premix	14
C. Packaging, storage, and handling the premix	14
IV. The Fortification Process.....	15
A. Fortification of flour in continuous and batch systems	15
B. Equipment.....	15
C. Avoiding potential problems	17
D. Human resource requirements	18
V. Quality Control	19
A. Quality control of the iron fortificant or commercial premix	19
B. Quality control of iron-flour premix made at the mill.....	19
C. Quality control of the fortified flour.....	19
D. Sampling the flour for chemical analysis	20
Appendix 2.1: Commercial premix and iron fortificant suppliers	21
Appendix 2.2: Types and costs of batch mixers/blenders, feeders, and weighing scales	23
Appendix 2.3: Companies manufacturing batch mixers/blenders, feeders, and weighing scales	25
Appendix 2.4: An example of a quality control log for iron fortificant or commercial iron premix.....	27
Appendix 2.5: An example of a quality control log for iron-flour premix made at the mill	29
Appendix 2.6: An example of a quality control log for fortified flour	31
Endnotes.....	33

Tables

2.1	Cost and properties of different iron fortificants	4
2.2	Potential use of different iron forms in the fortification of wheat flour.....	4
2.3	WHO bioavailability classification and recommended daily intakes (RDI) for iron	8
2.4	Amount of ferrous sulfate or ferrous fumarate iron to add to wheat flour depending on wheat consumption level and deficit to be eliminated.....	8
2.5	Upper level sensory thresholds for iron fortificants added to wheat flour stored up to 3 months.....	9
2.6	Contribution (%) of elemental iron in restored and fortified wheat flour to daily iron requirements in different population groups based on selected flour consumption levels	10
2.7	Average wheat consumption, permitted iron fortification levels, and contri- bution of enriched and fortified flour to iron requirements by country	11
2.8	Bulk densities of different flours and iron compounds	18

Figure

Volumetric feeder for adding micronutrient premix	16
---	----

Acknowledgments

This three-part manual is the product of discussions with the Micronutrient Initiative that identified the need to make available to program managers in developing countries comprehensive programmatic and technical information related to iron fortification of wheat flour. The authors acknowledge the contributions of Jack Bagriansky and Venkatesh Mannar to the first draft of Part 1, and of Peter Ranum and Quentin Johnson to the first draft of Part 2.

Omar Dary reviewed an early draft of the report; Richard Hurrell, Jose Mora, and George Purvis reviewed a later draft. They all provided very helpful comments and suggestions.

The American Association of Cereal Chemists (AACC), the Association of Official Analytical Chemists (AOAC), and the Institute of Nutrition for Central America and Panama (INCAP) generously allowed us to cite and print their analytical methods for iron determination in flour.

We greatly appreciate the support and encouragement of Frances Davidson at the U.S. Agency for International Development (USAID) in Washington, D.C., and Roy Miller of the MOST project. We also thank Betsy Reddaway and Marianne Lown for their assistance in copyediting and finalizing this document.

Funding for preparation of this manual was provided through USAID projects: OMNI Research (contract no. HRN-5122-A-00-3046-00) and MOST (contract no. HRN-A-00-98-00047-00).

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.

Frances Davidson
Office of Health & Nutrition, USAID
Washington, D.C.

Roy Miller
MOST, The USAID Micronutrient Program
Washington, D.C.

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

Part 2 of the manual provides technical information for developing, implementing, and assuring quality in a wheat flour fortification program. This part is written specifically for wheat millers and other personnel directly involved in wheat flour fortification. Technical terms and concepts which appear in *italics* are explained as they arise; they can be also found in the glossary. The information presented is specific to wheat flour fortification with iron, but the principles and techniques described also apply to fortification of wheat flour with other micronutrients as well as to fortification of maize flour or maize meal¹.

II. Iron Fortificants²

Iron can be added to flour to replace what is lost in milling or to reach a level higher than is found naturally in whole wheat. The former is known as *restoration*, while the latter is known as *enrichment or fortification*. This manual deals with enrichment or fortification of wheat flour with iron, although the process for restoration is exactly the same.

A. Forms of iron

The criteria for selecting the form of iron to add, i.e., the *fortificant*, include its bioavailability, effect on the quality of flour, effect on the color of flour and flour products, and cost.

1. *Bioavailability* is the degree to which a particular iron compound is available for absorption in the gastrointestinal tract and utilized for normal metabolic functions. Ferrous sulfate has good bioavailability and is often used as the standard against which the bioavailability of other iron forms is measured. Ferrous fumarate also has good bioavailability—comparable to ferrous sulfate—and can be added at the same level as ferrous sulfate. Ferric orthophosphate has poor bioavailability—about 30% that of ferrous sulfate. Its bioavailability is less variable than some elemental iron forms; it should be added at three times the level of ferrous sulfate. The bioavailability of elemental iron, reduced and electrolytic, varies greatly depending on the particle size and shape and, as a result, ranges from 5% to 148% that of ferrous sulfate (Table 2.1). However, most commercially available reduced or electrolytic iron fortificants are believed have a bioavailability of less than 50% that of ferrous sulfate. Due to the inherent nature of the manufacturing process and the resulting physical properties of reduced and electrolytic iron, the bioavailability of the latter form is less variable, and thus it is preferred over reduced iron. Electrolytic iron should be added at twice the level of ferrous sulfate, and reduced iron at two to three times the level of ferrous sulfate³.

Sodium-iron-EDTA⁴ can be used as the fortificant to counteract the inhibitory effect on iron absorption of phytic acid present in wheat flour. The iron in this fortificant form is bound to EDTA making it unavailable for binding with phytic acid in the flour, and is then released in the gut for absorption. The reported bioavailability of sodium-iron-EDTA is 1.5 to 3 times that of ferrous sulfate and should be added at one-half the level of ferrous sulfate.

2. Flour quality and flavor: Adding iron to flour does not have any deleterious effects if the flour is stored under optimal conditions—at low temperature ($\leq 20\text{-}25^{\circ}\text{C}$) and low relative humidity ($\leq 50\%$)—and is used within one month of fortification. When stored for three months or more at higher temperatures and humidity, iron-catalyzed reactions may occur which adversely affect the quality of flour, i.e., result in caking and rancidity.

Iron in the ferrous form is a *pro-oxidant* (i.e., it catalyzes oxidative reactions) and can accelerate the rancidity of fat naturally present in flour and result in an off-flavor, thus reducing the shelf-life of flour. This is true for both ferrous sulfate and ferrous fumarate. Off-flavors do not develop if the flour is used within one month of fortification, for example, in bakeries, but they may develop if the flour is stored for longer periods in homes. Ferrous fumarate is similar to ferrous sulfate in its effects on flour, although it provokes far fewer off-flavors. In contrast, ferric orthophosphate, reduced iron, and electrolytic iron do not adversely affect the flavor of flour or flour products and may be used in any type of flour irrespective of storage time. Sodium-iron-EDTA may promote fat oxidation and produce off-flavors in stored flour or flour products; this compound has not been extensively studied and its effect on flour quality has not been clearly established.

3. Color: Ferrous sulfate is a white to off-white powder. Although it does not discolor flour, it can cause noticeable color changes in the dough and black spots on bread crust. Ferrous fumarate, a reddish-brown powder, produces a slight discoloration of flour that has not proven unacceptable and is used as the iron fortificant in some Latin American countries. It may produce off-colors, especially under acidic conditions such as inclusion of acid fruits for specialty breads or other baked products. Ferric orthophosphate is a yellow, buff-colored powder; reduced and electrolytic irons are black powders. None of these produce any noticeable change in the color of flour or dough, although the elemental irons may have a slight darkening effect on flour. Sodium-iron-EDTA may cause discoloration in certain cereal products; its effect on the color of flour and flour products has not been fully evaluated.

4. Cost: Table 2.1 shows the cost of different iron fortificants as the cost per kilogram material and cost per kilogram iron. The cheapest form of food-grade iron is reduced iron, followed by electrolytic iron, ferrous sulfate, ferrous fumarate, ferric orthophosphate, and finally iron-EDTA.

Recently, a new iron fortificant—aminoacid-chelated iron or ferrous bisglycinate—has been proposed. However, the bioavailability, absorption, and potential uses of this compound in different food products—especially wheat flour—have not been thoroughly investigated; thus no recommendations can be made about its use at this time.

Table 2.1: Cost and properties of different iron fortificants⁵

Iron Source	Concentration (% Fe)	Cost (\$/Kg)	Cost (\$/Kg Fe)	Color	Relative bioavailability in man
Ferrous sulfate	32	2.40	7.50	White	100%
Ferrous fumarate	33	3.00	9.09	Red	100%
Ferric orthophosphate	28	5.00	17.86	Yellow	25-32%
Reduced iron	97	2.00	2.06	Black	13-148% ^a
Electrolytic iron	98	6.70	6.84	Dark grey	5-100% ^a
Iron EDTA	13	8.70	66.92	Brown	150-300%
Ferrous bisglycinate	20	20.26	101.30	Grey-green	100% ^b

^a These results were based on tests done with experimental compounds that are not produced commercially. Most commercially available elemental iron fortificants have a bioavailability of less than 50% that of ferrous sulfate³.

^b 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.

The potential use and recommended forms of iron fortificants to fortify different wheat flours are shown in Table 2.2.

Table 2.2: Potential use of different iron forms in the fortification of wheat flour⁶

Product	Extraction rate (%)	Ferrous sulfate	Ferrous fumarate	Ferric orthophosphate	Reduced iron	Electrolytic iron	Iron EDTA
All-purpose flour	75	O	O	O	O	R	O
Bread flour	75	R	O	O	O	O	O
Whole wheat flour (atta)	97	N	N	O	O	O	R
Pastry flour	45	O	O	O	O	R	O
Cake flour	50-55	O	O	O	O	R	O
Semolina	60-65	R	O	O	O	O	O

R = Recommended; O = Optional; N = Not Recommended

B. Specifications for iron fortificants

Any iron compound used in food fortification must be of food-grade quality, comply with the quality standards outlined in the U.S. Pharmacopoeia or Food Chemical Codex (USP/FCC), and meet quality specifications such as those shown below to maximize bioavailability, ensure safety, and avoid any negative effects on flour quality. For the elemental irons—reduced and electrolytic—the particle size of the fortificant determines its bioavailability. Elemental iron powders with at least 80% of the fortificant of a particle size of less than 20 µm (or able to pass through a US Standard sieve 325 mesh) are recommended. Special attention is needed to ensure that the particle size and other specifications of the fortificant are met; this can be achieved by requesting a certificate of analysis from the manufacturer or supplier. A list of iron fortificant and premix suppliers is presented in Appendix 2.1⁷.

Ferrous sulfate for food enrichment or fortification should be a USP/FCC-grade, dried, white to greenish-white or off-white fine powder that is odorless or almost odorless.

Assay	86.0% Min to 89% Max
Iron content	31.6% Min - 32.7% Max
Acid insoluble substances	0.05% Max
Loss on drying	3.0% Max
Arsenic	30 ppm Max
Particle size	Min 90% through USP mesh No. 60 Min 60% through USP mesh No. 100
Aerobic bacteria	Max 1000/gram

Source: Hoffmann-La Roche, Chile

Ferrous fumarate for wheat flour enrichment or fortification should be a USP/FCC grade. It is an odorless, reddish-orange to red-brown powder and may contain soft lumps that produce a yellow streak when crushed.

Assay	97.0-101.0%
Iron content	31.9-33.2%
Loss on drying	1.5 % Max
Ferric iron	2.0% Max
Lead	10 ppm Max
Mercury	3 ppm Max
Sulfate	0.2% Max
Arsenic	3 ppm Max

Source: Jost Chemical, Inc., Missouri, USA

Ferric orthophosphate for wheat flour enrichment or fortification should be a yellowish powder and of USP/FCC grade.

Assay (as Fe)	26-32%
Loss on ignition (800°C/1h)	32.5% Max
Fluoride	0.005% Max
Arsenic	0.0003% Max
Lead	0.001% Max
Mercury	0.0003% Max

Source: Dr. Paul Lohmann Chemicals, Germany

Reduced iron for wheat flour enrichment or fortification should be a USP/FCC-grade, very fine particle size (80% <20µm), elemental iron produced by a hydrogen reduction process. It is grey-black in color, odorless, magnetic, and dissolves in dilute mineral acids.

Assay	96.0-100.5% Fe
Hydrogen loss	1.75 % Max
Acid-insoluble substances	1.25% Max
Arsenic	8 ppm Max
Lead	10 ppm Max
Mercury	5 ppm Max
Particle Size	
Sieve US Std 325 mesh	95% Min

Source: Mallinckrodt, Inc., Missouri, USA

Electrolytic iron for wheat flour enrichment or fortification should be a USP/FCC grade, very fine particle size (80% <20µm), elemental iron produced by an electrolytic process. It is dark grey in color, magnetic, and dissolves in dilute mineral acids.

Assay	97.0% Fe Min, 98.2% Fe typical
Hydrogen loss	1.5 % typical
Acid-insoluble substances	0.2 % Max, 0.05 typical
Arsenic	0.0004% Max, <0.0004 typical
Lead	0.002 Max, <0.001 typical
Mercury	0.0002 Max, <0.0002 typical
Total carbon	0.02% typical
Manganese	0.004% typical
Nitrogen	0.005% typical
Phosphorus	0.002% typical
Silicon	0.003% typical
Sulfur	0.008% typical
All other	0.07% typical
Average particle size (Fisher, µm)	8 Max, 4.4 typical
Nominally minus 325 mesh (less than 20 µm)	
Typically contain 70% by weight less than 20 µm	

Source: OMG SCM-Metals, Inc., Ohio, USA

Sodium-iron-EDTA for wheat flour enrichment or fortification should be a USP/FCC grade. It is a brownish-yellow powder.

Assay	
EDTA	66.0-71.0%
Fe (III)	12.5-14.0%
pH (1%)	3.5-5.5
Water-insoluble matter	0.1% Max.
Chloride	0.05% Max.
Sulfate	0.2% Max.
Arsenic	0.0003% Max.
Lead	0.001% Max.

Source: Dr. Paul Lohmann Chemicals, Germany

C. Level of iron to add

The concentration of iron to add to wheat flour is critical and should be based on the expert opinions of professional food scientists and nutritional epidemiologists. The underlying objective is to have effective fortification. The information required to determine the level of iron to add to wheat flour includes:

1. The amount of iron available for absorption from the typical diet that takes into account factors that influence its absorption such as the amount of iron from flesh foods, the presence of iron absorption enhancers including vitamin C-rich foods, and the intake of iron absorption inhibitors such as tea, coffee, or unrefined cereals. This is known as the bioavailability of dietary iron that is classified as low (relatively little iron absorbed), medium, or high (relatively high amount of iron absorbed) (Table 2.3). Individuals eating a diet that fits the description of being highly bioavailable will not require fortification. The diets of developing countries, however, typically fall into the low bioavailability category.
2. The recommended daily intake (RDI) for iron of the high-risk target groups (Table 2.3).
3. Wheat flour consumption in grams per person per day by age group. The best data would be those from national surveys that disaggregate the data by age group.

Where national wheat flour consumption data are not available and wheat is predominantly imported, national per person supply or availability statistics will be reasonably accurate because centralized records are often available from government offices, milling trade associations, and the large flour mills. National milling associations also often keep figures of the total amount of wheat milled by their member companies as well as the amount of imported flour. The formula below can be used to calculate the amount of wheat flour available for consumption per person per year that is “potentially” available for fortification. (“Potentially” is used here because the national production numbers may not be disaggregated by subsistence versus commercial use.)

$$\text{Kg wheat flour/person/yr} = \{[(P + M) - (A + X) * R] \div 1000\} \div Z$$

Where P=total (MT) wheat production per year

M=total (MT) wheat imports per year

A=total (MT) wheat destined for animal feed per year

X=total (MT) exports per year

R=usual extraction rate (%) of flour

Z=population of the country

When much of the wheat consumed is grown domestically, nationally generated data may be more difficult to obtain, particularly if the agricultural industry is decentralized. Where flour consumption data are not available in country, an overall estimate of per person supply or availability of wheat per year can be obtained from the FAO Food Balance Sheets⁸, but it is important to note that there is no differentiation between wheat for subsistence and wheat for sale. Nevertheless, multiplying this number by the usual extraction rate of flour will provide an estimate of the amount of flour that is “potentially” available for fortification.

4. Dietary iron intake in grams per person per day. Multiplying the amount of dietary iron consumed—from food intake surveys or calculated from the food balance sheets—by the appropriate WHO bioavailability category (usually 5% in developing countries) gives a value for the amount of iron that is absorbed and available for use in the body. Alternatively, total dietary iron

may be compared with the age-specific RDIs given in Table 2.3 that already factor in the bioavailability of the iron in the diet. Either way, the difference between iron intakes and the RDI is the intake-gap or dietary shortfall in iron that fortification can help close.

Table 2.3: WHO Bioavailability classification and recommended daily intakes (RDI) for iron⁹

Typical diet	Cereals, tubers, and legumes; negligible flesh foods or vitamin C-rich foods	Cereals, tubers, and legumes; some flesh foods or vitamin C-rich foods; large amounts of tea	Diversified diet containing flesh foods and vitamin C-rich foods
Bioavailability	Low: 5%	Medium: 10%	High: 15%
	RDI (mg/d)	RDI (mg/d)	RDI (mg/d)
Adult Men	23	11	8
Adult Women	48	24	16
Lactating Women	26	13	9
Boys (12-16)	36	18	12
Girls (12-16)	40	20	13
Children 1-2	12	6	4
Children 2-6	14	7	5
Children 6-12	23	12	8

5. The next step is to establish the level of fortification. This can be done in one of three ways, depending on the data available.

- a. If the iron deficit gap is known, then the amount of additional iron to be added can be determined. Table 2.4 shows the amount of an iron that is 100% bioavailable (ferrous sulfate or fumarate) that would have to be added to increase daily iron intake by 3, 5, 10, or 15 mg for average flour intakes of 50, 100, and 250 g/day. For example, if wheat flour intake is 50 g/day and an additional 5 mg of iron are needed, then the amount of ferrous sulfate, which has 100% relative bioavailability, to add to the flour is $(5 \div 50) \times 1000 = 100$ ppm or mg/Kg.

If a form of iron fortificant other than ferrous sulfate is used, the amount of fortificant to be added needs to be changed according to its bioavailability relative to ferrous sulfate. For example, the bioavailability of elemental iron is only 30% to 50% that of ferrous sulfate; thus the amount of iron to add would need to be at least doubled.

Table 2.4: Amount of ferrous sulfate or ferrous fumarate iron^a to add to wheat flour depending on wheat consumption level and deficit to be eliminated

Additional iron (mg/d)	Flour consumption (g/day)		
	50	100	250
	Iron to add (ppm) to reach additional iron level ^a		
3	60	30	12
5	100	50	20
10	200	100	40
15	300	150	60

^a Assuming 100% relative bioavailability.

The natural iron content of wheat flour is about 11 mg/Kg. The maximum amount of iron that can be added to wheat flour depends on the type of iron and ambient conditions (Table 2.5). Data from Sri Lanka¹⁰ showed that 6.6 mg, but not 8.8 mg, electrolytic or reduced

iron can be added to a kilogram of wheat flour (66 ppm) with a 75% extraction rate without affecting the sensory characteristics of either the flour stored for up to 3 months at ambient hot (35°C +) and humid (90%+) conditions or foods made from fortified wheat flour. Similarly, up to 40 ppm ferrous sulfate can be added to wheat flour with an extraction rate below 76% stored for up to 3 months below 30°C¹¹. Iron EDTA can be added at up to 15 ppm in hot humid climates without causing any adverse effects¹² on the flour or wheat-based foods.

Table 2.5: Upper-level sensory thresholds (ppm) for iron fortificants added to wheat flour stored up to 3 months

	High temperature (30-40°C), high relative humidity (70-80%)	Low-moderate temperature (20-30°C), low relative humidity (<50%)
Ferrous sulfate	30 ¹²	40 ¹¹
Ferrous fumarate	60 ¹²	NA
Ferric orthophosphate	NA	NA
Reduced iron	66 ¹⁰	88 ¹³
Electrolytic iron	66 ¹⁰	NA ^a
Sodium-iron-EDTA	15 ¹²	NA

NA = Published data or study results not available

^aExtrapolating published data for reduced iron a level of 88 ppm may be used.

Tables 2.4 and 2.5 show that if wheat flour intakes are equivalent to 50 g/day or less, it will not be possible to meet even an iron deficit of 3 mg iron/day from wheat flour fortified with 40 ppm ferrous sulfate or ferrous fumarate or 5 mg/day from wheat flour fortified with 66 ppm elemental iron without getting sensory changes in the flour. If the average flour intake is equivalent to 100 g/day, fortification with 40 ppm ferrous sulfate or fumarate would provide 4 mg/day additional iron while 66 ppm reduced or electrolytic iron would provide 6.6 mg/day additional iron with no adverse effects on the flour. At consumption levels equivalent to 250 g/day flour, fortification using 40 ppm ferrous sulfate or fumarate and 66 ppm elemental iron would meet an additional requirement for 10 mg/day and 16.5 mg/day, respectively.

- b. The second way to decide on the level of iron to add is based on meeting the RDI at an estimated absorption level. Fortifying flour with 66 ppm elemental iron would yield a flour containing 77 ppm iron (66 ppm as iron fortificant and 11 ppm naturally found in the flour). Table 2.6 shows the contribution such flour would make to daily iron requirements depending on the amount of flour consumed. For example, fortified flour that contained 77 ppm total iron would provide about 14% ($((3.85 \text{ mg iron} \div 14 \text{ mg/d for RDI}) * 100) * 0.5$ for bioavailability) of the RDI for iron for a 2-6 year old child consuming 50 g flour/d and whose diet provides iron of low bioavailability. For comparative purposes, the same child would get 7% of his RDI for flour in which the iron content was restored to its original pre-milling level of 41 ppm.

Because Table 2.6 assumes that the bioavailability of elemental iron is 50% that of ferrous sulfate or ferrous fumarate, the contribution to daily iron intake from flour fortified with the latter iron fortificants at the equivalent levels can be determined by doubling the numbers in Table 2.6. Similarly, the contribution to daily iron intake from flour fortified with iron-EDTA at the equivalent levels can be determined by tripling the numbers in Table 2.6. However, as Table 2.5 shows, there is a limit to the quantity of each iron fortificant that

can be added to flour without changing either its quality or that of wheat-based foods, and this is discussed further under the third option for determining how much iron to add.

Table 2.7 shows the percent of the RDI for iron for adult women and children 2-6 years old that can be met from iron enriched or fortified flour based on average wheat intakes and the permitted level of iron to be added to wheat flour in countries around the world.

Table 2.6: Contribution^a (%) of elemental iron^b in restored and fortified wheat flour to daily iron requirements in different population groups based on selected flour consumption levels

Recommended Daily Intake ^c	Flour Restoration (41 ppm total iron) ^d			Flour Fortification (77 ppm total iron) ^e		
	Consumption (g/day)					
	50 (2.05 mg iron)	100 (4.10 mg iron)	250 (10.25 mg iron)	50 (3.85 mg iron)	100 (7.70 mg iron)	250 (19.25 mg iron)
Women, menstruating						
Low—48 mg/d	2.1	4.3	10.7	4.0	8.0	20.0
Medium—24 mg/d	4.3	8.5	21.3	8.0	16.0	40.1
High—16 mg/d	6.4	12.8	32.0	12.0	24.1	60.1
Girls, 12-16 years						
Low—40 mg/d	2.6	5.1	12.8	4.8	9.6	24.1
Medium—20 mg/d	5.1	10.2	25.6	9.6	19.2	48.1
High—13 mg/d	7.9	15.8	39.4	14.8	29.6	74.0
Men, 16+ years						
Low—23 mg/d	4.5	8.9	22.3	8.4	16.7	41.8
Medium—11 mg/d	9.3	18.6	46.6	17.5	35.0	87.5
High—8 mg/d	12.8	25.6	64.0	24.1	48.1	120.3
Children, 2-6 years						
Low—14 mg/d	7.3	14.6	36.6	13.7	27.5	68.7
Medium—7 mg/d	14.6	29.3	73.2	27.5	55.0	137.5
High—5 mg/d	20.5	41.0	102.5	38.5	77.0	192.5

^a Also provided as mg/day in parentheses in the first row under the respective columns

^b Assumes 50% relative bioavailability

^c Based on iron bioavailability in diet (see Table 2.3)

^d 30 ppm added iron fortificant plus 11 ppm natural iron content of milled wheat flour

^e 66 ppm added iron fortificant plus 11 ppm natural iron content of milled wheat flour

- c. The third way to decide on the level of iron to add is based on meeting established upper-level sensory thresholds given ambient environmental conditions. Known upper-level thresholds that are relevant to developing countries, where flour extraction rates are above 75%, flour packaging is sub-optimum (jute sacks at the warehouse, paper bags at retail level), and rotation periods are greater than 3 months are given in Table 2.5.

As iron absorption is effectively controlled and eventually blocked when body iron stores are adequate, there is no risk of iron overload arising from iron fortification of foods¹⁴.

Besides the calculated amount of iron deemed necessary, an additional amount of iron should be included in the final fortification level 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. This additional amount is known as the *overage*.

A minimum overage of 10% is often used when fortifying dry cereals with iron. For example, to fortify wheat flour containing 11 ppm of iron to meet the U.S. standard of 44 ppm, 33 ppm plus 10%, i.e., 36.3 ppm iron should be added.

Table 2.7 Average wheat consumption, permitted iron fortification levels, and contribution of enriched and fortified wheat flour to iron requirements by country

	Wheat supply ^g (Kg/head/yr)	Wheat supply (g/head/d)	Iron permitted (ppm)	Added iron (mg/d)	% RDI for adult women ^a	% RDI for 2-6 years old ^a
Bolivia	38.2	105	60 ^b	6.3	6.6 ^c	2.3 ^c
Canada	87.8	240	44 ^b	10.6	33.1 ^d	106.0 ^d
Chile	110.3	302	30 ^e		37.5 ^f	128.6 ^f
Costa Rica	32.8	92	60 ^b	5.5	5.8 ^e	19.7 ^c
Dominican Republic	31.5	86	60 ^b	5.2	5.4 ^e	18.6 ^c
Ecuador	42.5	116	55 ^b	6.4	6.7 ^e	22.9 ^c
El Salvador	34.0	93	55 ^b	5.1	5.3 ^e	18.2 ^c
Guatemala	32.5	89	55-65 ^b	4.9-5.8	5.1-6.1 ^c	17.5-20.7 ^c
Honduras	28.0	77	60 ^b	4.6	4.8 ^e	16.5 ^c
Mexico	38.8	106	24-40 ^b	2.5-4.2	2.6-4.4 ^c	8.9-15.0 ^c
Nigeria	10.0	28	29-37 ^b	0.8-1.0	0.9-1.1 ^c	2.9-3.6 ^e
Panama	46.7	128	60 ^b	7.7	8.0 ^e	27.5 ^c
Saudi Arabia	113.8	311	36 ^b	11.2	11.7 ^c	40.0 ^c
United Kingdom	85.0	23	≥16.5 ^b	0.4	1.3 ^d	4.0 ^d
United States	88.5	242	44 ^b	10.6	33.1 ^d	106.0 ^d
Venezuela	42.6	116	20 ^g	2.3	9.6 ^f	32.9 ^f

^a Adjusting for relative bioavailability of iron fortificant, i.e., 100% for ferrous sulfate, 50% for reduced iron, and 100% for ferrous fumarate.

^b Reduced iron

^c 5% bioavailability (See Table 2.3 for RDIs)

^d 15% bioavailability (See Table 2.3 for RDIs)

^e Ferrous sulfate

^f 10% bioavailability (See Table 2.3 for RDIs)

^g Ferrous fumarate

III. Iron/Micronutrient Premixes

A *premix* is a blend of single or multiple micronutrients used in the enrichment or fortification of foods. The addition of iron to flour can be achieved through the use of a commercial iron-containing premix, which can be added directly to bulk flour, or the use of an iron fortificant that must be diluted at the mill to make an iron-flour premix before addition to bulk flour.

A. Commercial premix versus iron-flour premix

Large mills or a group of small- to medium-scale mills in a particular geographic region may choose to make their own iron-flour premix as it may be more cost-effective than using a commercial premix. However, for the addition of multiple micronutrients, it is preferable to obtain a commercial premix as the commercial suppliers have better access to raw materials and greater analytical capabilities to ensure an accurate micronutrient content. Appendix 2.1 provides a list of commercial premix suppliers.

1. Commercial iron-containing premix

Where flour is fortified with multiple micronutrients, the advantage of using a premix rather than adding micronutrients singly is that there is a greater likelihood of ensuring the correct concentration and even distribution. The process of adding micronutrients will also be simpler. Moreover, adding each nutrient separately is not possible in a continuous flour fortification operation used in most mills. However, issues of compatibility among the micronutrients will need to be considered in designing a multiple micronutrient premix.

Adding multiple micronutrients as a premix makes quality assurance more efficient. A properly designed, manufactured, and blended premix—that has a Certificate of Analysis—will have constant ratios of the different micronutrients present in the premix. Thus, testing the level of one micronutrient in the premix can verify the concentration of all other micronutrients at the time of delivery (assuming no degradation of the micronutrients). This single micronutrient can, therefore, be used as a reference for the other micronutrients during routine quality control checks of fortified flour at the point of production.

A commercial premix may also contain an inexpensive filler or *carrier*, such as starch, that serves to dilute the concentration of micronutrients and facilitates direct addition to bulk flour. It is easier to get a uniform distribution of iron in flour when a larger amount of diluted premix is added rather than a small amount of concentrated micronutrient. Adding a filler may also help adjust the bulk density of the premix to be similar to that of flour so it is easier to handle and add. On the other hand, concentrated premixes with a minimal amount of carrier may be preferred in order to limit shipping costs.

2. Iron-flour premix

When flour is fortified with iron alone, the purchase of an iron fortificant may be more economical than a commercial iron premix. (Appendix 2.1 provides a list of suppliers.) The iron fortificant can then be mixed with an equal amount of flour in a ribbon blender at the mill before addition to bulk flour. Mills usually make the iron-flour premix in amounts adequate for a single day's run to prevent problems of infestation and off-flavor developing during storage. Preparation of the iron-flour premix should be synchronized with production of fortified wheat flour so that the premix is used soon after it is manufactured. When storage is necessary, it must be properly labeled with the date of manufacture and stored at a low temperature ($\leq 20\text{-}25^{\circ}\text{C}$) and low relative humidity ($\leq 30\%$) for

no more than one week; where humidity cannot be controlled, vapor barrier packaging should be used.

Flour mills commonly add micro-quantities of color enhancers to flour. Such improvers include enzymes and oxidants, for example azodicarbonamide and ascorbic acid, and can be incorporated into the premix. The safety of including concentrated forms of oxidants in the premix should be checked prior to adding these ingredients to the iron-flour premix.

Although the preparation of the iron-flour premix is a simple procedure, it requires strict adherence to regulations to guarantee its quality. This includes steps for mixing the iron, wheat flour, and any other flour improvers and, if necessary, proper storage procedures. A good iron-flour premix will have a bulk density close to that of wheat flour, be relatively free flowing, and not cake on storage.

B. Composition of the premix

Whichever of the above premixes is used, a few factors need be considered in its formulation: the premix must meet the set levels for different micronutrients which when added at a set proportion to flour meet the fortification standard for those micronutrients; because the concentration of iron varies among the different iron fortificants, this variation must be accounted for in determining how much iron to add; the amount of a carrier or filler added will depend on the desired premix addition rate and the required premix bulk density that should be similar to that of flour; and in the case of commercial premixes, a small overage of micronutrients may be added to make sure the premix meets the level claimed in the certificate of analysis.

C. Packaging, storage, and handling the premix

Premixes are concentrated sources of iron or other micronutrients. Excessive intake of iron in a single dose is poisonous and can be fatal; lower concentrated doses over a prolonged period can also be harmful. For this reason, the boxes must be carefully labeled “Not suitable for direct consumption” and workers at the mill must understand and respect this warning. Operators at mill should take precautions such as wearing a dust mask, gloves, etc. to prevent inhalation of and exposure of skin to the premix or iron fortificant.

The premix and iron fortificant must be properly handled to minimize degradation of the compound. They must be stored in well-ventilated rooms at low or mild temperatures (preferably not higher than 25°C), and exposure to humidity must be avoided. The amount of commercial premix or iron fortificant needed should be estimated and obtained in quantities small enough so that it does not need to be stored for long periods of time. The production lot number(s) should be properly recorded and the premix used on a first-in/first-out basis. Once a commercial premix or iron fortificant box has been opened, it should be used within the period specified for its shelf life.

IV. The Fortification Process¹⁵

The type of fortification system to be used depends, to a large extent, on the mill's mechanical structure and existing operational capabilities. An assessment and decision on the type of fortification system to use, equipment needed, and any infrastructure changes should be made by an experienced flour fortification engineer. This section only briefly describes options for continuous and batch fortification systems, equipment needed, and how to avoid potential problems.

A. Fortification of flour in continuous and batch systems

In a continuous milling system, the iron fortificant or premix is continuously and gradually added as a free-flowing dry powder at a rate dependent on and compatible with the flow of flour along the conveyor belt (about 10 to 60 mg/100 g of flour). The homogeneity of micronutrients in the fortified flour is largely dependent on the location of the feeder, and it is very important that good mixing of the micronutrients in flour occurs. The two most common sites for adding micronutrients are 1) before packaging, which facilitates good mixing and 2) where flours from different streams converge, which facilitates excellent mixing.

Small- and medium-sized mills may choose to fortify flour using a batch system, where flour is fortified in individual batches rather than in a continuous process. In batch fortification, iron is measured out by weight or volume and added to a batch mixer that is partially or totally filled with flour. The well-mixed, fortified flour is then transferred to pack-out bins and another batch of flour is fortified.

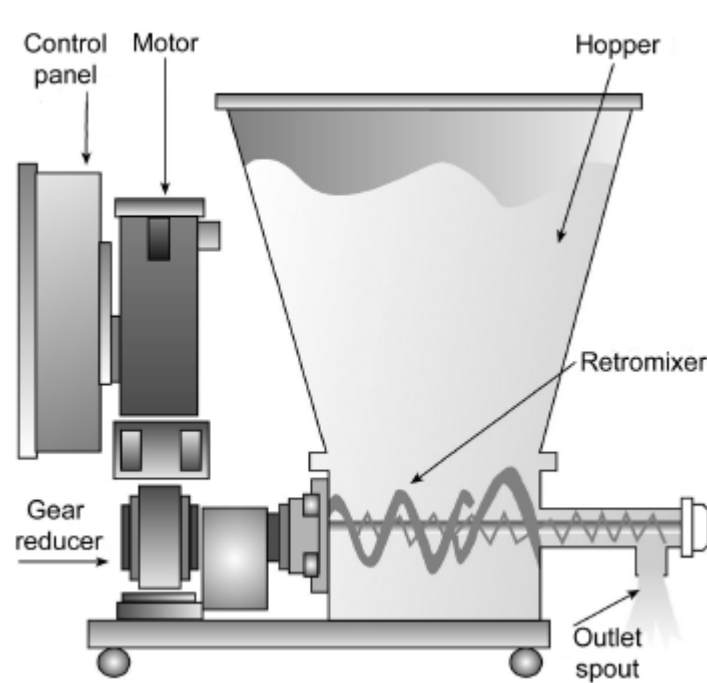
B. Equipment

The continuous system and batch system require different equipment, as described below.

1. Continuous system

- a. A blender to dilute the iron fortificant with flour.
If the iron-flour premix approach is used (as described in Section III), a blender is needed to dilute the iron fortificant in an equal aliquot of flour to make an iron-flour premix, before adding it to bulk flour. This step may not be needed when using commercial premixes as the supplier can customize the premix for direct addition to bulk flour. A ribbon blender is most commonly used for this purpose (Appendix 2.2). A list of manufacturers is provided in Appendix 2.3.
- b. A dry powder feeder or dosifier to meter out the premix.
Feeders measure out a specific amount of premix and add it to the flour. Flour is measured based on either volume (volumetric feeders), weight (gravimetric feeders), or loss of total weight of the feeder (loss-of-weight feeders). Once the material is measured, it is fed to the flour conveyor. For this, three types of powder feeder mechanisms are used: screw type, revolving disk, and drum or roll type (see Appendix 2.2). All three mechanisms are used in volumetric feeders, while the drum or roll mechanism is commonly used in gravimetric and loss-of-weight feeders. The most widely used feeder is the volumetric screw-type feeder shown in the figure below.

Volumetric Feeder for Adding Micronutrient Premix



Powder feeders range from complex to simple in their capacity, degree of sophistication, and amount of maintenance needed. The size and number of feeders needed is determined by the number of milling units and the number of flour streams in each unit to be fortified. A list of feeder manufacturers is provided in Appendix 2.3. These companies can also assist in determining the size and type of feeder needed for a particular flour mill operation. The premix addition rate is dependent on the flow rate of flour on the conveyor belt. Small volumetric feeders work well at rates less than 40 Kg/h, while gravimetric or loss-of-weight feeders are better for higher addition rates of 25 to 20,000 Kg/h.

Premix feeders use different techniques to agitate the premix continuously in the feeder hopper, preventing compaction and clumping and allowing a smooth and constant flow of the premix through the feeder. Material compaction or caking or cohesive premixes contributes to the formation of a stable arch inside the feeder (*bridging*) or to the premix sticking to the walls of the feeder (*tunneling*), resulting in poor or no flow of the premix. Some examples of agitation mechanisms include mechanical stirring of the fortificant with blades or paddles in the hopper, mechanical movement of the hopper walls, electrical vibration of the hopper walls, or pneumatic vibration of the hopper walls with a piston.

- c. A conveying system to deliver the premix from the feeder to the flour stream. The premix can be either fed directly into the flour by gravity or by air convection using a pneumatic system. In a gravity-driven system, experience has shown that the best site for adding micronutrients is before the midpoint along the mixing conveyor that collects flour from all the mill passages, just before bulk storage or sacking. If the feeder is placed towards the beginning of the conveyor, the amount of flour in the mixing conveyor will be too little. If, on the other hand, the feeder is located toward the end of the conveyor, the re-

quired homogenization will not be achieved. The advantage of using a pneumatic system is that feeders can be placed in a remote centralized location in the mill and the fortificant dropped through a chute onto the conveyor. Pneumatic systems are also easier to keep clean than gravity systems.

2. Batch system

- a. A blender to dilute the iron fortificant with flour.
If the iron-flour premix approach is used (as described earlier in Section III) a blender is needed to dilute the iron fortificant in an equal aliquot of flour to make an iron-flour premix, before adding it to bulk flour. This step may not be needed when using commercial premixes as the supplier can customize the premix for direct addition to bulk flour. A ribbon blender is most commonly used for this purpose (Appendix 2.2). A list of manufacturers is provided in Appendix 2.3.
- b. A weighing scale to weigh out the premix to be added to bulk flour.
Electronic digital scales accurate to one-tenth of a gram are now available (Appendix 2.2). A list of manufacturers is provided in Appendix 2.3.
- c. A batch mixer to blend the premix thoroughly into the flour.
Different types of batch mixers are available (Appendix 2.2). A list of manufacturers is provided in Appendix 2.3.

C. Avoiding potential problems

The potential problems that can arise in fortification include over-fortification and issues related to bulk density and compaction. Each of these is described below.

1. Over-fortification

Electrical interlocking systems can be used to avoid inadvertent over-fortification of flour in the event of a breakdown along the milling process. In gravity delivery systems, an interlock between the feeder and flour conveyor motors can be installed to stop the feeder when the flour conveyor (carrying the flour to which premix is added) stops. In pneumatic delivery systems, the interlock should be placed between the feeder and the blower to stop the feeder from functioning unless the blower is in operation. This will prevent accumulation of the premix in the delivery lines.

2. Bulk density and compaction problems

Bulk density is the weight per unit volume of a material. The difference between bulk densities of the material in a “loose” versus “compacted” state indicates the tendency of the material to settle or compact in feeders and hoppers. For example, wheat flour has a higher tendency to compact than semolina or farina (Table 2.8). Material compaction of premixes contributes to the formation of a stable arch inside the feeder (*bridging*) or sticking of the premix to the walls of the feeder (*tunneling*) resulting in poor or no flow of the premix. One solution to bridging and tunneling is to vibrate or agitate the premix in the feeder hopper as described in Section B.1.b. above. The feeder hopper must be regularly monitored through visual inspection to ensure a smooth flow of the premix without bridging or tunneling.

Compacted bulk densities should also be considered in determining the capacity of blender or batch mixer needed. An example is presented in Appendix 2.2.

Table 2.8: Bulk densities of different flours and iron compounds¹⁶

Product	Bulk density (g/cc)		Bulk density (lbs/cu. ft.)	
	Loose	Compacted	Loose	Compacted
Wheat flour	0.45	0.75	28	47
Semolina or Farina	0.63	0.73	40	46
Flour mixes	0.63	0.78	39	49
Ferrous sulfate	0.55	0.71	34	44
Ferrous fumarate	1.28	1.43	80	90
Ferric orthophosphate	0.94	0.97	58	60
Iron, reduced or electrolytic	2.55	3.05	160	190
Iron EDTA	0.75	0.97	47	61
Iron premix	0.70	0.90	45	58

D. Human resource requirements

The flour fortification process at the mill requires only a few additional responsibilities that existing trained employees may be able to take on. Personnel needs include a worker responsible for continuously observing and regulating the feeder(s) and a laboratory technician responsible for sampling the flour and conducting the iron assays. If additives are already being added to the flour, the former requires no additional labor. However, if an iron-flour premix must be made, workers will have to be designated for this task. In mills where flour is routinely tested for color, moisture, and protein, the laboratory personnel involved in those quality control exercises may be able to take on the additional task of conducting iron analysis; otherwise a laboratory technician will be needed for the quality control measures.

V. Quality Control¹⁷

A set of feasible and complementary quality control activities must be designed and implemented to provide indicators of operational efficiency of fortification. Supervision and control of all operations at the mill must include monitoring the level of iron in the iron fortificant and premix and the addition of the premix to flour.

A. Quality control of the iron fortificant or commercial premix

A recording and storage system must be in place to log the date the iron is received. The iron or premix must be stored under conditions specified by the manufacturer. Physical characteristics such as color, texture, and odor can be visually examined. The iron or premix should be free-flowing with no lumps or off-odor. The Certificate of Analysis provided by the manufacturer should be reviewed for the grade, particle size, and concentration of iron. The iron should be analyzed using semi-quantitative spot tests to ensure the iron level; the analytical methods are presented in Part 3 of this manual. All of these observations along with any corrective actions taken when the required specifications were not met must be properly recorded and filed for easy access. Appendix 2.4 gives an example of the type of recording form that can be used.

B. Quality control of iron-flour premix made at the mill

The iron-flour premix made at the mill should be analyzed using quantitative methods to verify the concentration of iron in the iron-flour premix. The amount of iron in the premix must be within 10% on either side of the specified mean. The analytical methods to determine the amount of iron in the iron-flour premix and fortified flour are presented in Part 3 of this manual. The mill manager should be responsible for monitoring the quality of the iron-flour premix, the date of manufacture, and the addition to bulk flour. The dates and results of all chemical analyses must be properly recorded. The mill manager also is responsible for any corrective actions. All records should be filed for easy access. Appendix 2.5 gives an example of the type of recording form that can be used.

C. Quality control of the fortified flour

Four methods can be used to supervise and control the addition of iron to flour. Proper recording of all the results of the quality control procedures is essential. An example for recording the quality control results of fortified flour is given in Appendix 2.6.

1. Premix inventory control

Comparing the amount of premix used against the flour production records provides a simple way of determining if the correct amount of premix is being used. Another way is to obtain the ratio of the amount of fortified flour produced to the amount of premix used in a predetermined period of time. These methods provide general information on whether the required amount of premix is being added. The mill manager may add this task to his routine quality control activities.

2. Regular weight checks

Here, a plate is put under the feeder to collect the fortificant for usually one to three minutes and the fortificant is weighed to determine if the feeder is dispensing the correct amount of fortificant at that setting; longer collection times are used for lower addition rates. Weight checks should be done every time flour samples are taken for routine quality analysis—approximately every two hours. The operator should record the time, weight, and feeder setting. Automated, loss-of-weight feeders are also available, wherein the disappearance of iron fortificant should correspond with calculated usage and any adjustments to the feeder can be made based on these results. The mill manager may add this task to his routine quality control activities.

3. Spot tests

Mills can use a simple qualitative spot test for iron to determine if the flour has been fortified or a semi-quantitative spot test that allows the determination of whether the flour is grossly under- or over-fortified. Spot tests are quick and simple, and can be used at various points in the production line – using them at the point of pack-out or in packed bags will ensure that the flour is fortified within a specified range of iron content. The results of qualitative or semi-quantitative tests, however, are not precise enough to make feeder adjustments. It is recommended that semi-quantitative spot tests be conducted every time the mill conducts routine quality control procedures (for example, for moisture or color), approximately every two hours in a continuous fortification process or for every batch of flour produced using the batch fortification process. The laboratory manager or a laboratory technician should be responsible for conducting these tests. Spot tests are described in detail in Part 3 of this manual.

4. Quantitative tests

Quantitative tests provide accurate data on the amount of iron in the flour and reflect the efficiency of the entire production process. Ideally, the same flour samples collected for semi-quantitative spot tests should be pooled for each production shift, mixed well, and analyzed. However, it is recommended that quantitative tests be conducted as often as routine tests for protein in flour. The tests may need to be performed more frequently when troubleshooting problems in the fortification process. The laboratory manager or a laboratory technician should be responsible for conducting these tests. The quantitative iron analysis methods are described in detail in Part 3 of this manual.

D. Sampling the flour for chemical analysis

The point at which the flour is sampled, the sampling procedure, and how the sample is collected and handled are critical in obtaining reliable and useful results. Samples should be collected at a point in the production line after the addition of the fortificant as well as the blending of fortified flour. Samples must be kept protected from high temperatures and humidity until analyzed. A good sample represents the entire production run averaging out any momentary variation in the fortification process. A composite sample can be obtained by taking a “grab” of flour at a specified point in the production line every two hours over a shift and mixing them together. This composite sample of fortified flour can then be analyzed for iron content.

Appendix 2.1

Commercial premix and iron fortificant suppliers⁷

The following companies sell iron fortificant, micronutrient premixes, or both for use in food fortification. Premixes and iron fortificants may also be obtained from local suppliers; readers are advised to explore those options.

BASF, Inc.
6700 Ludwigshafen-Rhein
Ludwigshafen
Germany
Ph: 049 621 600
FAX: 049 622 525

Feed Ad (Pty) Ltd
P.O. Box 11
Linbro Park 2065
South Africa
Ph: 27 11 608 2081
FAX: 27 11 608 1574

Fortitech, Inc.
2105 Technology Drive
Schenectady, NY 12308
USA
Ph: 518-372-5155
FAX: (518) 372-5599

Hexagon Chemie
H/3, Balkrishna
142/5 J.P. Rd., Andheri (West)
Mumbai 400 053
India
Ph: 91 22 634 1368
FAX: 91 22 634 1224

Hoffmann-La Roche
CH-4002, Basel
Switzerland
Ph: 061 688 1111
FAX: 061 691 9600

Mallinckrodt, Inc.
Specialty Chemicals Division
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134
Ph: 314-654-6065/800-554-5343
FAX: (314) 654-6527

Nutriblend Limited
Unit B7, Lakeside Park
Medway City Estate
Rochester, Kent ME2 4LT
United Kingdom
Ph: 44 1634 297 171
FAX: 44 1634 297 101

Dr. Paul Lohmann GmbH KG
Chemische Fabrik, Haupstr. 2
31860 Emmerthal
Germany
Ph: 049 5155 63140
FAX: 049 5155 63118

OM GROUP, INC.
OMG SCM-Metals
50 Public Square, Ste. 3500
Cleveland, OH 44113
Ph: 216-781-0083
Fax: (216) 781-1502

Takeda Vitamin & Food USA,
Inc.
101 Takeda Drive
Wilmington, NC 28401
USA
Ph: 910-762-8666
FAX: (910) 762-6846

Vifor International Inc.
Rechenstrasse 37 Allenspach
P.O. Box 9001
St. Gallen
Switzerland
Ph: 41 71 272 8484
FAX: 41 71 272 8485

Watson Nutritional Ingredients
301 Heffernan Drive
West Haven, CT 06516
USA
Ph: 203-932-3000
FAX: (203) 932-8266

Wright Enrichment, Inc.
6428 Airport Road
P.O. Box 821
Crowley, LA 70527
USA
Ph: 318-783-3096
FAX: (318) 783-3802

Appendix 2.2

Types and costs of batch mixers/blenders, feeders, and weighing scales

Batch mixers/blenders

Batch mixers and blenders are used for blending or mixing in batches small to large amounts of material. Depending on the size, they can be used in the preparation of an iron-flour premix and in batch fortification of wheat flour.

To calculate the size of blender required, information on the amount of flour milled per day, the fortification level, and iron-flour premix dilution rate is needed. For example, a mill produces 100,000 MT flour per year, (275 MT/d) with 66 ppm iron-flour premix. Assuming a 10 h work-shift/day, 45 lb/cu ft bulk density of premix-flour mix, and 4 blending batches/h, and using a batch ribbon blender:

1. Total mass production of 60,500 lbs/h ($275 \text{ MT/d} \div 10 \text{ h/d} * 1000 \text{ Kg/MT} * 2.2 \text{ lb/Kg}$).
2. Total volume production of 1,344 cu ft/h ($60,500 \div 45 \text{ lb/cu ft}$).
3. Volume of blending batch of 336 cu ft/batch ($1,344 \text{ cu ft/h} \div 4 \text{ batches/h}$).
4. A blender of 350 cu ft capacity will suffice assuming 15 minutes mixing per batch including time for loading (3-4 min), blending (6-7 min), and discharge (3-4 min). The loading and discharge times may vary depending on the conveying equipment and rates used at the mill. A minimum blending time of 5 minutes is recommended for a batch ribbon blender.

The different types of batch mixers/blenders include:

The *horizontal ribbon blender/mixer* works through the rotation of solid single (single-ribbon blender) or double (double-ribbon blender) tubular shafts inside a horizontal cylinder. The rotation speed of the shaft is set depending on the application and a vigorous mixing action provides a uniform blend in a short time. These blenders/mixers come in different sizes and are used extensively in food processing plants for mixing a variety of dry ingredients. Horizontal ribbon blenders cost between US\$9,000 and US\$130,000 depending on the size (2-375 cubic feet capacity) and features.

The *horizontal paddle blender* is another type of horizontal blender that uses paddles to create a vigorous mixing action and provide a uniform blend. Like other batch blenders, it comes in various sizes suitable for premix preparation. Horizontal paddle blenders cost between US\$ 9,000 and US\$130,000, depending on the size (2-375 cubic feet capacity) and features.

Unlike the horizontal blenders, a *rotary batch blender/mixer* uses a unique lifter and baffle design to create a gentle mixing action that provides a consistent blend in a short time. Rotary batch blenders and mixers are available in various sizes and are ideal for full-scale fortification as well as smaller-scale premix preparation. Rotary batch blenders range from 10 to 300 cubic feet capacity and cost US\$ 35,000 to US\$170,000.

Vertical batch mixers have a vertical construction in which the material is loaded at the top of the mixer or at the floor level (in which case an elevating screw and tube are used to take the material up into the mixing tube). A mixing tube equipped with baffles rotating at variable speeds ensures thorough mixing in a short mixing cycle followed by rapid discharge through the discharge gate. One advantage to using these mixers is the ability to produce maximum quantities on a small square foot area increasing plant efficiency. Vertical batch mixers vary from 12 to 1500 cubic feet capacity and cost from US\$ 15,000 to US\$200,000, depending on size and features of the mixer.

Feeder Mechanisms¹⁸

The *screw feeder* mechanism used in volumetric feeders operates by means of a rotating feed screw powered by a variable speed electric motor, which is used to control the feed rate of the powder. A wide range of material bulk densities can be dispensed at precise and reliable feed rates. This type of feeder uses fewer mechanical parts and is both easier to maintain and less expensive.

The *revolving disk feeder* mechanism used in volumetric feeders uses a revolving disk that is equipped with a slide mechanism to control the rate of powder discharge. The disk revolves at a constant speed providing reliable and uniform feed rates. The disadvantage of using this type of feeder is that it employs more mechanical parts than the screw-type feeder, and the hopper that holds the fortificant is smaller than in the other types of feeders.

Drum or roll feeder mechanism may be used in volumetric, gravimetric, or loss of weight feeders. It operates by allowing the fortificant to pass between two revolving cylinders and the speed is controlled by a pulley system. This type of feeder has more mechanical parts and thus is more difficult to maintain than the other two. In the newer drum feeders, the delivery system is controlled electronically rather than by mechanical adjustment of the addition rate.

Cost of feeders

The cost of feeders varies widely depending on the type of feeder (volumetric, gravimetric, or loss of weight), feeder mechanism, capacity of the feeder, and other features such as the accuracy and precision of feed rate, agitator design, and ability to neutralize material compaction and provide a uniform flow. Typical costs are US\$5,000 to US\$7,000 for volumetric feeders, US\$10,000 to US\$20,000 for gravimetric feeders, and US\$13,000 to US\$21,000 for loss-of-weight feeders.

Weighing scales

Electronic scales are easy to operate and provide precise measurements. Scales that are precise to one-tenth of a gram are now available at reasonably affordable prices. Although *mechanical load balance* type of weighing scales that require the use of weight loads to balance against a specific amount of material are also available, electronic scales are preferred because of the convenience and precision they offer. Electronic scales are available in different sizes ranging from analytical balances (20-400 g weighing capacity and 0.002-1.0 mg precision), precision balances (200-8,000 g weighing capacity and 0.001-1.0 g precision), high-capacity precision scales (8-16 Kg weighing capacity and 1-5 g precision), and bench scales (15-60 Kg weighing capacity and 5-10 g precision). Electronic scales may vary in cost from US\$100 to US\$2,000, depending on the type and features of the scale.

Appendix 2.3

Companies manufacturing batch mixers/blenders, feeders, and weighing scales

The following companies manufacture and supply feeders/dosifiers that can be used to fortify flour in mills. In addition, there are a number of manufacturers in other countries (e.g., India, Kenya); readers are advised to explore these and any local companies.

Batch mixers/blenders

Highland Equipment Ltd.
136 The East Mall
Toronto, Ontario
Canada M8Z 5V5
416-236-9610, 800-956-5630
FAX: (416) 236- 9611

JAYGO Inc.
675 Rahway Ave.
Union, NJ 07083
908-688-3600
FAX: (908) 688-6060

Marion Mixers
3575 Third Ave.
Box BB-286
Marion, Iowa 52302
319-377-6371
FAX: (319) 377-1204

Mueller Technologies Intl.
PO Box 1077
Westfield, IN 46074-1077
317-569-0541
FAX: (317) 569-0543

Munson Machinery Co., Inc.
PO Box 855
210 Seward Ave.
Utica, NY 13503-0855
800-944-6644
FAX: (315) 797-5582

Patterson Industries Ltd.
250 Danforth Road
Scarborough, Ontario
Canada M1L 3X4
416-694-3381, 800-336-1110
FAX: (416) 691-2768

Process-Innovations Canada,
Inc
120 Traders Blvd., Unit 108
Mississauga, Ontario
Canada L4Z 2H7
905-501-9145
FAX: (905) 501-9146

Tech Equipment Corp.
1902 Bayport, Ste. 200
Houston, TX 77586
281-474-1397
FAX: (281) 474-1415

Feeders

Acrison, Inc.
20 Empire Blvd.
Moonachie, NJ 07074
FAX: (201) 440-4939

Brabender Technologie Inc.
6500 Kestrel Road
Mississauga, Ontario
L5T 1Z6 Canada
905-670-2933
FAX: (905) 670-2557

Metalfab, Inc
PO Box 9
Prices Switch Road
Vernon, NJ 07462
973-764-2000
FAX: (973) 764-0272

Schenck AccuRate
746 E. Milwaukee St.
Whitewater, WI 53196
262-473-2441
FAX: (262) 473-2232

Tecnetics Industries, Inc.
1811 Buekle Road
St. Paul, MN 55110
612-777-4780
FAX: (612) 777-5582

Thayer Scale Co.
PO Box 669
Pembroke, MA 02369
781-826-8101
FAX: (781) 826-7944

Vibra Screw, Inc.
755 Union Boulevard
Totowa, NJ 07511
201-256-7567
FAX: (201)256-7410

Wallace & Tiernan Inc.
1901 West Gardner Road
Vineland, NJ 08360
609-507-9000
FAX: (609)507-4250

Weighing scales

A&D Weighing, Inc.
1555 McCandless Dr.
Milpitas, CA 95035
408-263-5333, 800-726-3364
FAX: (408) 263-0119

Marsden Weighing Machine
Group, Ltd.
Unit 16, Sutton's Business Park
Sutton's Park Ave., Earley
Reading, Berkshire RG6 1AZ
England
0118-935-1655
FAX: 0118-935-1657

Mettler-Toledo, Inc.
1900 Polaris Parkway
Columbus, OH 43240
800-METTLER, 800-786-0038
FAX: (614) 438-4900

Ohaus Corp.
29 Hanover Road
Florham Park, NJ 07932
973-377-9000
FAX: (973) 593-0359

Sartorius North America, Inc.
131 Heartland Blvd.
Edgewood, NY 11717
516-254-4249, 800-635-2906
FAX: (516) 254-4253

Scientech, Inc.
5649 Arapahoe Ave.
Boulder, Colorado 80303
303-444-1361, 800-525-0522
FAX: (303) 444-9229

Appendix 2.6

An example of a quality control log for fortified flour

Date _____

Shift and time	Premix inventory control				Regular weight checks			Semi-quantitative spot test (ppm) ¹	Quantitative test (ppm)	Observations/corrective actions
	Time (hours)	No. flour sacks produced (A)	No. fortificant bags used (B)	A ÷ B	Collection time (min and sec)	Weight (mg)	Feeder setting			

¹ ND = not detected

Mill manager _____
 Laboratory manager _____

Adapted from: Dary and Arroyave 1996

Endnotes

¹ For further information on single or multiple micronutrient fortification of other cereals, see Bauernfeind JC and DeRitter E. Cereal grain products. In: Nutrient additions to foods: nutritional, technological, and regulatory aspects. PA Lachance (ed). Trumbull, CN: Food & Nutrition Press 1991;142-210; Hurrell R (ed). The mineral fortification of food. Leatherhead UK: Leatherhead Publishers. 1999.

² In addition to iron, several other micronutrients may be simultaneously added to flour. Thiamin, riboflavin, niacin, and folic acid are commonly added to wheat flour in developed and, to a lesser extent, developing countries. The addition of calcium, zinc, and vitamin A is also possible but less commonly practiced.

³ Hurrell R, personal communication.

⁴ Ferric sodium ethylenediaminetetraacetic acid.

⁵ Adapted from a table in Guidelines for the Eradication of Iron Deficiency Anemia: A Report of the International Nutritional Anemia Consultative Group, Washington DC: ILSI Press, 1977. Costs, color, and concentration were provided by suppliers and relative bioavailability was provided by Hurrell R.

⁶ Based on information from Clydesdale FM and Wiemer KL. Iron fortification of foods, Orlando FL: Academic Press, 1985; stability trials in Sri Lanka (Gooneratne J, Mudalige R, Nestel P, Purvis G. Product evaluation using iron-fortified wheat flour. Ceylon J Med Sci 1996;39:23-34); and investigations in Central America by INCAP (Alvarado M, De Leon LF, Dary O. Technical and economical evaluation of wheat flour fortification with different iron compounds. Manuscript in preparation).

⁷ A more comprehensive list of premix and fortificant suppliers, the Global Directory of Commercial Manufacturers of Micronutrient Premixes and Supplements, can be obtained by visiting the Micronutrient Initiative's website, www.micronutrient.org or by contacting PO Box 8500, Ottawa, Ontario, Canada, K1G 3H9, Ph: (613) 236-6163, FAX: (613) 236-9579, Email: contact@micronutrient.org.

⁸ These data can be found on FAOSTAT <[www. apps.fao.org](http://www.apps.fao.org)> under nutrition.

⁹ FAO/WHO. Food and Nutrition Series No 32. Rome: FAO. 1988.

¹⁰ Gooneratne J, Mudalige R, Nestel P, Purvis G. Product evaluation using iron-fortified wheat flour. Ceylon J Med Sci 1996;39:23-34.

¹¹ Barrett F and Ranum P. Wheat and Blended Cereal Foods. In: Iron fortification of foods, Clydesdale FM, Wiemer KL (eds). Orlando FL: Academic Press. 1985.

¹² Investigations in Central America by INCAP (Alvarado M, De Leon LF, Dary O. Technical and economical evaluation of wheat flour fortification with different iron compounds. Manuscript in preparation).

¹³ Rubin SH, Emodi A, Scialpi L. Micronutrient additions to cereal grain products. Cereal Chem 1977; 54:895-904. Cort WM, Borenstein B, Harley JH, et al. Nutrient stability of fortified cereal products. Food Technol 1976; 30:52-62.

¹⁴ Gillespie, S. The practical significance of iron overload for iron deficiency control programs. In: Gillespie S. Major issues in the control of iron deficiency. MI/UNICEF, 1998.

¹⁵ For a more detailed discussion of this topic, see Ranum P. Iron fortification of cereals. In: The Mineral Fortification of Foods, Hurrell R (ed.) Leatherhead, UK: Leatherhead Publishing, 1999 and Barret F and Ranum P. Wheat and blended cereal foods. In: Clydesdale FM, Wiemer KL. Iron Fortification of Foods. New York: Academic Press, 1985.

¹⁶ Adapted from a table by Ranum P. Iron fortification of cereals. In: The Mineral Fortification of Foods, Hurrell R (ed.) Leatherhead, UK: Leatherhead Publishing, 1999.

¹⁷ This section derives material from Dary O and Arroyave G. Manual for sugar fortification with vitamin A. Part 2: Technical and operational guidelines for preparing vitamin A premix and fortified sugar, OMNI/USAID/INCAP. 1996.

¹⁸ For a more detailed discussion, see Ranum P. Iron fortification of cereals. In: The Mineral Fortification of Foods, Hurrell R (ed.) Leatherhead, UK: Leatherhead Publishing, 1999.